(19)日本国特許庁(JP)　(12)公表特許公報(A)　(11)特許出願公表番号
特表2004-532681
(P2004-532681A)
(43)公表日　平成16年10月28日(2004.10.28)

(51)Int.Cl.[7]	F I		テーマコード（参考）
A61H 31/00	A61H 31/00		2E185
A61B 5/00	A61B 5/00	101M	4C017
A61B 5/021	A61B 5/08		4C038
A61B 5/08	A61M 16/20	Z	4C074
A61B 5/145	A62B 7/04		4C117

審査請求 未請求　予備審査請求 有　（全 240 頁）　最終頁に続く

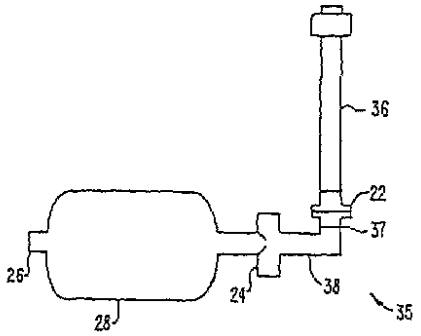
(21)出願番号　特願2002-589085(P2002-589085)
(86)(22)出願日　平成14年5月1日(2002.5.1)
(85)翻訳文提出日　平成15年11月11日(2003.11.11)
(86)国際出願番号　PCT/US2002/014039
(87)国際公開番号　WO2002/092169
(87)国際公開日　平成14年11月21日(2002.11.21)
(31)優先権主張番号　09/854,238
(32)優先日　平成13年5月11日(2001.5.11)
(33)優先権主張国　米国(US)
(31)優先権主張番号　10/119,203
(32)優先日　平成14年4月8日(2002.4.8)
(33)優先権主張国　米国(US)

(71)出願人　304013087
アドバンスド　サーキュレートリー　システムズ，　インコーポレイテッド
アメリカ合衆国　ミネソタ　５５３４４，　エデン　プレーリー，　テクノロジー　パーク　ナンバー５，　ゴールデン　トライ　アングル　ドライブ　７６１５，　スイート　エイ
(74)代理人　100078282
弁理士　山本　秀策
(74)代理人　100062409
弁理士　安村　高明
(74)代理人　100113413
弁理士　森下　夏樹

最終頁に続く

(54)【発明の名称】ショック治療システムおよび方法

(57)【要約】
本発明によれば、心肺蘇生を実行するときに胸の圧迫および除圧により誘発される心肺循環を高める方法および装置が提供されている。１方法によれば、患者の気道には、圧力応答性流入弁（２４）が連結される。胸の圧迫および胸の除圧が実行される。胸の除圧中にて、流入弁（２４）は、一定の負胸腔内圧レベルを超えるまで、呼吸気体が肺に入るのを防止し、超えた時点で、流入弁（２４）が開く。このようにして、流入弁（２４）は、除圧中での負胸腔内圧の規模および持続時間を高めるのを助け、心臓および肺に入る血流の量を多くする。さらに、流入弁（２４）が開いて患者を人工呼吸するとき、患者には、流入弁（２４）を通って加圧呼吸気体が供給される。



【特許請求の範囲】
【請求項１】
呼吸している患者の血圧上昇を促進する装置であって、該装置は、以下の部分を備える：
ハウジングであって、該ハウジングは、開口部を有し、該開口部は、患者の気道と連動するように適合されている；
流入弁であって、該流入弁は、患者の吸入が原因で該ハウジングを通る呼吸気体流れを増減するように作動可能であり、該流入弁は、該患者の胸への血液の還流を高めるために、胸腔内圧力を操縦するのを助ける；
該流入弁を操作して該ハウジングを通る該呼吸気体流れを変える機構；ならびに
センサであって、該センサは、該患者の少なくとも１つの生理学的パラメータを感知するように適合および構成されている、
装置。
【請求項２】
前記流入弁が、前記患者が１分あたり約０～約７０リットルの範囲の流速で呼吸するとき、約０ｃｍH_2O～約－５０ｃｍH_2Oの範囲内で、負胸腔内圧を達成するように作動可能である、請求項１に記載の装置。
【請求項３】
制御装置をさらに備え、該制御装置が、前記センサおよび前記機構に連結され、ここで、該制御装置が、該機構に信号を送信し、該センサが感知した生理学的パラメータに基づいて、前記流入弁を作動するように構成されている、請求項１に記載の装置。
【請求項４】
前記センサが、圧力センサ、フローセンサ、CO_2センサおよび酸素センサからなる群から選択される、請求項１に記載の装置。
【請求項５】
前記流入弁が、スロット付き開口部およびスロット付きプレートを含み、該スロット付きプレートが、該スロット付き開口部を横切って移動可能である、請求項１に記載の装置。
【請求項６】
前記流入弁が、気道および閉塞部材を含み、該閉塞部材が、該気道を横切って移動可能である、請求項１に記載の装置。
【請求項７】
前記流入弁が、気道および圧迫閉塞システムを含み、該圧迫閉塞システムが、該気道を圧迫する、請求項１に記載の装置。
【請求項８】
前記流入弁が、気道および虹彩閉塞システムを含む、請求項１に記載の装置。
【請求項９】
前記機構が、ステッピングモーターおよびシャフトを含み、該シャフトが、該ステッピングモーターから伸長している、請求項１に記載の装置。
【請求項１０】
前記ハウジングが、吸気ポートおよび呼気ポートを含み、フェースマスクをさらに含み、該フェースマスクが、該ハウジングに連結されている、請求項１に記載の装置。
【請求項１１】
前記患者に補足酸素または定期的補助人工呼吸を追加する手段をさらに備える、請求項１に記載の装置。
【請求項１２】
自発的に呼吸しているヒトの血圧を高める方法であって、該方法は、以下の工程を包含する：
該ヒトの少なくとも１つの生理学的パラメータを感知する工程；
該ヒトの気道に流入弁を連動させる工程であって、該気道は、該ヒトの肺への呼吸気体流れを増減するように作動可能である；
該ヒトが吸入している間に、該ヒトの肺への呼吸気体流れを増減する感知パラメータに基

づいて、該流入弁を操作して、胸郭内で真空を作り出し、そして該ヒトの右心への血液の還流を高めて、それにより、該ヒトの血圧を高める工程。

【請求項１３】

前記ヒトが、血液損失、薬剤投与、高重力状態、血液迷走神経失神、心臓タンポナーゼ、溺水、熱射病、心臓麻痺、右心不全、宇宙飛行後の地球への帰還、および敗血症からなる群から選択される状態が原因の低血圧である、請求項１２に記載の方法。

【請求項１４】

制御装置に、前記感知パラメータを表わす信号を送信する工程、および該制御装置からの信号を、該感知パラメータに基づいて、前記弁を操作する機構に送信する工程をさらに包含する、請求項１２に記載の方法。

【請求項１５】

前記感知パラメータが、負胸腔内圧、血圧、呼吸数、末端換気CO_2、呼吸終末陽圧および酸素飽和度からなる群から選択される、請求項１２に記載の方法。

【請求項１６】

前記流入弁が、前記ヒトが１分あたり約０～約７０リットルの範囲の流速で呼吸するとき、約０cmH_2O～約－５０cmH_2Oの範囲内で、負胸腔内圧を達成するように作動可能である、請求項１２に記載の方法。

【請求項１７】

前記流入弁が、気道および閉塞部材を含み、該閉塞部材が、該気道を横切って移動して、該流入弁を通る流速を変える、請求項１２に記載の方法。

【請求項１８】

前記生理学的パラメータが、繰り返し感知され、ここで、前記弁が、該感知パラメータに基づいて、繰り返し操作される、請求項１２に記載の方法。

【請求項１９】

前記ヒトに補助人工呼吸または酸素を供給する工程をさらに包含する、請求項１２に記載の方法。

【請求項２０】

前記流入弁の上流または下流で前記ヒトに薬剤または医薬を供給する工程をさらに包含する、請求項１２に記載の方法。

【請求項２１】

心肺蘇生を実行しているときに、負胸腔内圧を増大させることにより、胸の圧迫および除圧により誘発される心肺循環を高める方法であって、該方法は、以下の工程を包含する：

圧力応答性流入弁を患者の気道と連動させる工程；

胸の圧迫および胸の除圧を実行する工程であって、ここで、胸の除圧中にて、該流入弁は、約－３cmH_2O～－３０cmH_2Oの範囲の負胸腔内圧レベルを超えるまで、呼吸気体が肺に入るのを防止し、超えた時点で該流入弁は開き、該流入弁は、除圧中の負胸腔内圧の規模および持続時間を高めるのを助けて、それにより、心臓および肺に入る血流の量を増大させる；ならびに

該流入弁を開いて該患者を人工呼吸するとき、該流入弁を通る加圧呼吸気体を該患者に供給する工程。

【請求項２２】

前記患者の気道に呼気弁を連動させる工程をさらに包含し、ここで、該呼気弁が、正胸腔内圧閾値を超えるまで、空気が肺に残るのを防止し、超えた時点で該呼気弁は開き、該呼気弁が、胸郭からさらに多くの血液が出ていくのを助ける、請求項２１に記載の方法。

【請求項２３】

前記正胸腔内圧が、約２cmH_2O～２０cmH_2Oの範囲である、請求項２２に記載の方法。

【請求項２４】

加圧呼吸気体源を提供する工程をさらに包含し、該加圧呼吸気体源が、前記流入弁に作動可能に連結され、該呼吸気体が、該流入弁の開口圧力未満の圧力であり、ここで、該呼吸

気体が、該呼吸気体源から供給される、請求項２１に記載の方法。
【請求項２５】
前記除圧工程が、前記患者の胸を胸の弾性に応答して拡張させる工程を包含する、請求項２１に記載の方法。
【請求項２６】
前記除圧工程が、前記患者の胸を持ち上げるか能動的に拡張して、胸郭を広げる工程を包含する、請求項２１に記載の方法。
【請求項２７】
前記胸が、１回の圧迫あたり、約３．５ｃｍ～５ｃｍの範囲で圧迫され、ここで、該胸が、１分あたり、６０～１００回の割合で圧迫される、請求項２１に記載の方法。
【請求項２８】
心肺蘇生を実行しているときに、負胸腔内圧を増大させることにより、胸の圧迫および除圧により誘発される心肺循環を高める方法であって、該方法は、以下の工程を包含する：
弁システムを患者の気道と連動させる工程であって、該弁システムは、ハウジング、圧力応答性弁を備え、該ハウジングは、上流領域および下流領域を有し、そして該圧力応答弁は、該上流領域と該下流領域との間にあり、該下流領域の圧力が閾値レベルより低くなるまで、該上流領域から該下流領域へと流れる呼吸気体を加圧する；
胸の圧迫および胸の除圧を実行する工程であって、ここで、該圧力応答弁は、特定の負胸腔内圧を超えるまで、呼吸気体が肺に入るのを防止するために閉鎖され、超えた時点で、該圧力応答弁は開き、該圧力応答弁は、除圧中の負胸腔内圧の規模および持続時間を高めるのを助けて、それにより、心臓および肺に入る血流の量を増大させる；ならびに
該圧力応答弁を開いて該患者を人工呼吸するとき、該圧力応答弁を通る加圧呼吸気体を該患者に供給する工程。
【請求項２９】
胸圧迫中にて、正胸腔内圧閾値を超えて胸郭からさらに多くの血液が出ていくのを助けるまで、空気が肺に残るのを防止する工程をさらに包含する、請求項２８に記載の方法。
【請求項３０】
前記正胸腔内圧が、約２ｃｍH_2O～２０ｃｍH_2Oの範囲である、請求項２９に記載の方法。
【請求項３１】
加圧呼吸気体源を提供する工程をさらに包含し、該加圧呼吸気体源が、前記圧力応答弁に作動可能に連結され、該呼吸気体が、該弁の開口圧力未満の圧力であり、ここで、該呼吸気体が、該呼吸気体源から供給される、請求項２８に記載の方法。
【請求項３２】
前記除圧工程が、前記患者の胸を胸の弾性に応答して拡張させる工程を包含する、請求項２８に記載の方法。
【請求項３３】
前記除圧工程が、前記患者の胸を持ち上げるか能動的に拡張して、胸郭を広げる工程を包含する、請求項２８に記載の方法。
【請求項３４】
前記胸が、１回の圧迫あたり、約３．５ｃｍ～５ｃｍの範囲で圧迫され、ここで、該胸が、１分あたり、６０～１００回の割合で圧迫される、請求項２８に記載の方法。
【請求項３５】
心肺蘇生を実行しているときに、胸の圧迫および除圧により誘発される心肺循環を高める装置であって、該装置は、以下の部分を備える：
ハウジングであって、該ハウジングは、開口部を有し、該開口部は、患者の気道と連動するように適合されている；
圧力応答流入弁であって、該圧力応答流入弁は、該患者の胸の除圧中にて、閾値負胸腔内圧レベルを超えるまで、呼吸気体が該ハウジングを通って肺に入るのを防止し、超えた時点で該流入弁は開き、該流入弁は、除圧中の負胸腔内圧の規模および持続時間を高めるの

を助けて、それにより、心臓および肺に入る血流の量を増大させる；ならびに
加圧気体源であって、該加圧気体源は、該流入弁に作動可能に連結され、該流入弁を開いたとき、該ハウジングを通って該患者に加圧気体を供給する、
装置。
【請求項３６】
前記ハウジングに配置された一方向弁をさらに備え、該一方向弁が、前記患者の胸の圧迫中にて、該ハウジングを呼吸気体が出ていくのを可能にする、請求項３５に記載の装置。
【請求項３７】
調節器をさらに備え、該調節器が、前記気体源と前記流入弁との間に配置されて、前記気体の圧力が該流入弁の起動圧力未満であるように、該気体の圧力を調節する、請求項３５に記載の装置。
【請求項３８】
前記流入弁が、前記負胸腔内圧が約－３ｃｍH_2O～－３０ｃｍH_2Oの範囲であるときに開かれるように構成される、請求項３５に記載の装置。
【請求項３９】
心肺蘇生を実行しているときに、負胸腔内圧を増大させることにより、胸の圧迫および除圧により誘発される心肺循環を高める方法であって、該方法は、以下の工程を包含する：
圧力応答性流入弁を有するハウジングを患者の気道と連動させる工程；
胸の圧迫および胸の除圧を実行する工程であって、ここで、胸の除圧中にて、該流入弁は、閾値負胸腔内圧レベルを超えるまで、呼吸気体が肺に入るのを防止し、超えた時点で該流入弁は開き、該流入弁は、除圧中の負胸腔内圧の規模および持続時間を高めるのを助けて、それにより、心臓および肺に入る血流の量を増大させる；ならびに
該流入弁を開いて、該流入弁を通して該患者を人工呼吸するとき、該流入弁を通る加圧呼吸気体を該患者に供給する工程。
【請求項４０】
前記負胸腔内圧が－３ｃｍH_2O～－３０ｃｍH_2Oの範囲であるときに、前記流入弁が開き、ここで、前記加圧気体が、該流入弁の開口圧力未満である、請求項３９に記載の方法。
【請求項４１】
心肺蘇生を実行しているときに、胸の圧迫および除圧により誘発される心肺循環を高める装置であって、該装置は、以下の部分を備える：
ハウジングであって、該ハウジングは、開口部を有し、該開口部は、患者の気道と連動するように適合されている；
圧力応答流入弁であって、該圧力応答流入弁は、該患者の胸の除圧中にて、閾値負胸腔内圧レベルを超えるまで、呼吸気体が該ハウジングを通って肺に入るのを防止し、超えた時点で、該流入弁の起動活力を超え、そして該流入弁は開き、該流入弁は、除圧中の負胸腔内圧の規模および持続時間を高めるのを助けて、それにより、心臓および肺に入る血流の量を増大させる；ならびに
該流入弁の該起動圧力を変える機構。
【請求項４２】
前記機構が、約０ｃｍH_2O～約－３０ｃｍH_2Oの範囲内の圧力まで前記起動圧力を変えるように構成される、請求項４１に記載の装置。
【請求項４３】
前記流入弁が、ネジ付きシャフトおよびバネを含み、該ネジ付きシャフトが、シールを有し、該シールが、前記ハウジング内の開口部を遮断するように構成され、そして該バネが、該シールを該ハウジングに曲げ、ここで、前記機構が、ネジ付きノブを含み、該ネジ付きノブが、該シャフトの長手方向距離を増減することにより、該バネの偏向力を変えるように回転可能である、請求項４１に記載の装置。
【請求項４４】
前記ハウジング内の圧力ゲージをさらに備え、該圧力ゲージが、前記胸内の圧力量を感知

する、請求項４３に記載の装置。
【請求項４５】
心肺蘇生を実行しているときに、胸の圧迫および除圧により誘発される心肺循環を高める装置であって、該装置は、以下の部分を備える：
ハウジングであって、該ハウジングは、出口開口部を有し、該出口開口部は、患者の気道および安全換気通路と連動するように適合されている；
圧力応答流入弁であって、該圧力応答流入弁は、該患者の胸の除圧中にて、閾値負胸腔内圧レベルを超えるまで、呼吸気体が該ハウジングを通って肺に入るのを防止し、超えた時点で、該流入弁は開き、該流入弁は、除圧中の負胸腔内圧の規模および持続時間を高めるのを助けて、それにより、心臓および肺に入る血流の量を増大させる；ならびに
安全機構であって、該安全機構は、該安全換気通路を開いたまま維持して、救助者が該安全換気通路を閉じるように起動するまで、該患者の肺に呼吸気体を自由に流入させる、
装置。
【請求項４６】
前記安全換気通路が、前記流入弁が開放位置にあるとき、該流入弁を通って供給され、そして前記安全機構が、前記救助者が該流入弁を閉鎖位置に移動するように起動するまで、該流入弁を該開放位置で維持するように構成されている、請求項４５に記載の装置。
【請求項４７】
前記ハウジングが、換気ポートを含み、該換気ポートが、該ハウジング内に呼吸気体を注入させ、ここで、前記安全機構が、センサおよび制御システムを含み、該センサは、前記救助者が前記ハウジング内に呼吸気体を注入するときを感知し、そして該制御システムは、前記開放位置から前記閉鎖位置へと前記流入弁を移動させる、請求項４６に記載の装置。
【請求項４８】
前記センサが、前記ハウジング内に呼吸気体を注入すると移動可能であり、ここで、前記制御システムは、一組のギアおよびカムを含み、該ギアが、該センサに連結され、そして該カムは、前記流入弁を閉じるように、該ギアにより移動可能である、請求項４７に記載の装置。
【請求項４９】
前記センサが、可動フラップを含み、該可動フラップが、前記ハウジングに呼吸気体を注入すると移動し、ここで、前記制御システムは、一組の機械要素を含み、該機械要素は、該フラップを移動すると、前記安全機構に対してウェッジを移動して、前記流入弁を閉じる、請求項４７に記載の装置。
【請求項５０】
前記センサが、電子スイッチ、サーミスタ、機械フラップ、および曲げると抵抗変化に遭遇する材料からなるセンサ群から選択される、請求項４７に記載の装置。
【請求項５１】
前記流入弁が、シャフトおよびバネを含み、該シャフトが、シールを有し、該シールが、前記ハウジング内の開口部を遮断するように構成され、そして該バネが、該シールを該ハウジングに曲げる、請求項４６に記載の装置。
【請求項５２】
心肺蘇生を実行しているときに、胸の圧迫および除圧により誘発される心肺循環を高める装置であって、該装置は、以下の部分を備える：
ハウジングであって、該ハウジングは、開口部を有し、該開口部は、患者の気道と連動するように適合されている；
圧力応答流入弁であって、該圧力応答流入弁は、閉鎖位置および開放位置を有し、ここで、該流入弁は、該閉鎖位置にあるとき、呼吸気体が該ハウジングを通って肺に入るのを防止し、ここで、該流入弁は、該患者の胸の除圧中に閾値負胸腔内圧レベルを超えたとき、該開放位置に移動し、該流入弁は、該閉鎖位置にあるとき、除圧中の負胸腔内圧の規模および持続時間を高めるのを助けて、それにより、心臓および肺に入る血流の量を増大させ

る；ならびに
安全機構であって、該安全機構は、該流入弁を該開放位置で維持して、救助者が該流入弁を起動して該閉鎖位置にするまで、該肺に呼吸気体を自由に流入させる、
装置。
【請求項５３】
前記ハウジングが、換気ポートを含み、該換気ポートが、該ハウジング内に呼吸気体を注入させ、ここで、前記安全機構は、センサおよび制御システムを含み、該センサは、前記救助者が該ハウジング内に呼吸気体を注入するときを感知し、そして該制御システムは、前記開放位置から前記閉鎖位置へと前記流入弁を移動させる、請求項５２に記載の装置。
【請求項５４】
前記センサが、前記ハウジング内に呼吸気体を注入すると移動可能であり、ここで、前記制御システムは、一組のギアおよびカムを含み、該ギアは、該センサに連結され、そして該カムは、前記流入弁を閉じるように、該ギアにより移動可能である、請求項５３に記載の装置。
【請求項５５】
前記センサが、可動フラップを含み、該可動フラップが、前記ハウジングに呼吸気体を注入すると移動し、ここで、前記制御システムは、一組の機械要素を含み、該機械要素は、該フラップを移動すると、前記安全機構に対してウェッジを移動して、前記流入弁を閉じる、請求項５３に記載の装置。
【請求項５６】
前記センサが、電子スイッチ、サーミスタ、機械フラップ、および曲げると抵抗変化に遭遇する材料からなるセンサ群から選択される、請求項５３に記載の装置。
【請求項５７】
前記流入弁が、シャフトおよびバネを含み、該シャフトが、シールを有し、該シールが、前記ハウジング内の開口部を遮断するように構成され、そして該バネが、該シールを該ハウジングに曲げる、請求項５２に記載の装置。
【請求項５８】
心肺蘇生を実行しているときに、負胸腔内圧を増大させることにより、胸の圧迫および除圧により誘発される心肺循環を高める方法であって、該方法は、以下の工程を包含する：
弁システムを患者の気道に連動させる工程であって、該弁システムは、ハウジング、圧力応答性流入弁、安全気体流路および安全機構を含み、ここで、胸の除圧中にて、該流入弁は、約０ｃｍH_2O～３０ｃｍH_2Oの範囲の負胸腔内圧レベルを超えるまで、呼吸気体が肺に入るのを防止するように構成され、超えた時点で該流入弁は開くように構成され、該流入弁は、除圧中の負胸腔内圧の規模および持続時間を高めるのを助けて、それにより、心臓および肺に入る血流の量を増大させ、ここで、該安全機構は、起動するまで、該患者の肺に呼吸気体を自由に流入させるように構成されている；ならびに
該安全機構を起動して、該気体通路を閉じる工程。
【請求項５９】
前記安全機構を起動した後、胸の圧迫および除圧を実行する工程をさらに包含する、請求項５８に記載の方法。
【請求項６０】
前記起動工程が、前記ハウジングに呼吸気体を注入する工程を包含し、ここで、該注入は、前記安全機構が前記気体通路を閉じるようにセンサにより感知される、請求項５８に記載の方法。
【請求項６１】
前記気体通路が、前記流入弁を通り、ここで、前記起動工程が、該流入弁を閉じて該気体通路を閉じる工程を包含する、請求項５８に記載の方法。
【請求項６２】
自発的に呼吸しているヒトの血圧を高める方法であって、該方法は、以下の工程を包含する：

圧力応答性流入弁を該ヒトの気道と連動させる工程；
該流入弁が該ヒトの気道に連結している間に吸入し吐出する工程であって、ここで、該吸入中にて、該流入弁は、約０ｃｍＨ$_2$Ｏ～－３０ｃｍＨ$_2$Ｏの範囲の負胸腔内圧レベルを超えるまで、呼吸気体が肺に入るのを防止し、超えた時点で該流入弁が開き、該流入弁は、該ヒトの右心への血液の還流を高めるのを助けて、それにより、該ヒトの血圧を高める工程。
【請求項６３】
前記ヒトが、血液損失が原因の低血圧である、請求項６２に記載の方法。
【請求項６４】
前記ヒトが、薬剤の投与が原因の低血圧である、請求項６２に記載の方法。
【請求項６５】
前記ヒトが、高重力状態が原因の低血圧である、請求項６２に記載の方法。
【請求項６６】
前記ヒトが、血液迷走神経失神に付随した低血圧である、請求項６２に記載の方法。
【発明の詳細な説明】
【背景技術】
【０００１】
（関連出願の相互参照）
本願は、２００１年５月１１日に出願された米国特許出願第０９／８５４，２３８号の一部継続出願であり、その出願は、２０００年４月１０日に出願された米国特許出願第０９／５４６，２５２号の一部継続出願であり、その出願は、１９９７年１０月１５日に出願された米国特許出願第０８／９５０，７０２号（これは、現在、米国特許第６，０６２，２１９号である）の継続出願であり、その出願は、１９９５年３月１０日に出願された米国特許出願第０８／４０３，００９号の一部継続出願（これは、現在、米国特許第５，６９２，４９８号である）の一部継続出願であり、その出願は、１９９３年１１月９日に出願された米国特許出願第０８／１４９，２０４号（これは、現在、米国特許第５，５５１，４２０号である）の一部継続出願であり、これらの開示内容は、本明細書中で参考として援用されている。
【０００２】
（発明の背景）
本発明は、一般に、心肺蘇生処置と併用される装置および方法に関する。特に、本発明は、ひどい低血圧または心停止に罹った患者の心肺循環を高める装置および方法に関する。
【０００３】
世界的に、急激な心停止は、主な死因であり、これは、種々の状況（心臓病および著しい外傷を含めて）の結果である。心停止の場合には、患者が生存する可能性を高めるために、いくつかの手段が重要であると思われている。これらの手段は、患者の呼吸および血液循環を少なくとも部分的に回復するために、できるだけ早く施されなければならない。約４０年前に開発された最も一般的な技術には、外胸部圧迫術があり、これは、一般に、心肺蘇生（ＣＰＲ）と呼ばれている。ＣＰＲ術は、過去３０年間、殆ど変わっていない。
【０００４】
伝統的なＣＰＲでは、胸腔内圧を高めるために、患者の胸に圧力が加えられる。胸腔内圧が高まると、心臓および肺の領域から末梢動脈に向かう血液の移動が誘発される。このような圧力は、部分的には、患者の循環を回復させる。伝統的なＣＰＲは、胸に外圧を直接加えることによって胸を能動的に圧迫することにより、実行される。能動的な圧迫後、胸は、その自然な弾性により拡張されて、患者の胸壁の拡大を引き起こす。この拡大により、一定の血液が心臓の房室に入る。しかしながら、上記処置は、患者を人工呼吸するには不十分である。結果的に、通常のＣＰＲには、また、患者に定期的な人工呼吸を施す必要がある。これは、通例、口移し術または正圧装置（例えば、自然膨張バッグであって、これは、弾性バッグを絞って、マスク、気管内チューブまたは他の人工気道を経由して空気を送達することに頼っている）を使用することにより、達成される。

【０００５】
胸の圧迫により誘発される心肺循環を高めるために、能動圧迫－除圧（ＡＣＤ）と呼ばれる技術が開発されている。ＡＣＤ技術によれば、伝統的なＣＰＲの能動圧迫相は、患者の胸を圧迫するために、胸にアプリケータ体を押し付けることにより、高められる。このようなアプリケータ体は、患者の胸の一部にわたって実質的に均等に力を分散して加えることができる。しかしながら、さらに重要なことには、このアプリケータ体は、持ち上げられて除圧工程中に患者の胸を能動的に拡張し得るように、患者の胸を密封する。得られた負胸腔内圧は、患者の末梢静脈血管系から心臓および肺へと静脈血が流入するのを誘発する。

【０００６】
また、本発明には、患者を正しく人工呼吸するＣＰＲ技術に関連して使用される換気源が重要である。換気源の１型式には、ＡＭＢＵ Ｉｎｔｅｒｎａｔｉｏｎａｌ（Ｃｏｐｅｎｈａｇｅｎ，Ｄｅｎｍａｒｋ）から入手できるＡＭＢＵバッグがある。このＡＭＢＵバッグはまた、肺疾患および心臓疾患に罹った一部の患者を治療するために、ＡＭＢＵ Ｉｎｔｅｒｎａｔｉｏｎａｌから入手できる呼吸終末陽圧（ＰＥＥＰ）弁と関連して、使用できる。しかしながら、本発明まで、換気源と関連した呼吸終末陽圧弁は、いずれのＣＰＲ技術とも併用されていない。

【０００７】
伝統的なＣＰＲ技術およびＡＣＤ－ＣＰＲ技術を使うと、それに引き続いた圧迫段階中に胸郭に残っている含酸素血液の容量を高めるために、心臓および肺に流入する静脈血の量を増やすのが望ましい。従って、通常のＣＰＲ技術およびＡＣＤ－ＣＰＲ技術を行っている間、末梢静脈血管系から患者の心臓および肺に流入する静脈血を高める改良方法および装置を提供することが望ましい。特に、ＣＰＲおよびＡＣＤ－ＣＰＲ（さらに特定すると、ＡＣＤ－ＣＰＲ）の除圧工程中にて、酸素化を向上し胸に戻る全血液を増やす技術を提供することが望まれている。これは、負および正の両方の胸腔内圧を増大することにより達成でき、それにより、全胸腔内圧スイングが増幅する。この重要な改良をもたらす発明が記述されている。

【０００８】
重症の低血圧（すなわち、非常に低い血圧）は、気絶を引き起こし、また、ある状況では、心停止を引き起こし得る。心停止のように、低血圧の患者は、しばしば、各拍動後に心臓に戻る血液が不十分である。この結果、心臓から流出する前方血液流れの低下を生じ、最終的に、低血圧となる。従って、ヒトが低血圧に罹ったとき、心臓への静脈血流を高める技術または装置を提供することが望ましい。本発明によれば、このようなアプローチは、心臓に血流が戻るのを助け、生命の維持に重要な臓器への血液の流れを増大できる。

【０００９】
ＡＣＤ－ＣＰＲ技術は、Ｔｏｄｄ Ｊ．Ｃｏｈｅｎら、Ａｃｔｉｖｅ Ｃｏｍｐｒｅｓｓｉｏｎ－Ｄｅｃｏｍｐｒｅｓｓｉｏｎ Ｒｅｓｕｓｃｉｔａｔｉｏｎ：Ａ Ｎｏｖｅｌ Ｍｅｔｈｏｄ ｏｆ Ｃａｒｄｉｏｐｕｌｍｏｎａｒｙ Ｒｅｓｕｓｃｉｔａｔｉｏｎ，Ａｍｅｒｉｃａｎ Ｈｅａｒｔ Ｊｏｕｒｎａｌ，Ｖｏｌ．１２４，Ｎｏ．５，ｐｐ．１１４５～１１５０，１９９２年１１月；およびＴｏｄｄ Ｊ．Ｃｏｈｅｎら、Ａｃｔｉｖｅ Ｃｏｍｐｒｅｓｓｉｏｎ－Ｄｅｃｏｍｐｒｅｓｓｉｏｎ：Ａ Ｎｅｗ Ｍｅｔｈｏｄ ｏｆ Ｃａｒｄｉｏｐｕｌｍｏｎａｒｙ Ｒｅｓｕｓｃｉｔａｔｉｏｎ，Ｔｈｅ Ｊｏｕｒｎａｌ ｏｆ ｔｈｅ Ａｍｅｒｉｃａｎ Ｍｅｄｉｃａｌ Ａｓｓｏｃｉａｔｉｏｎ，Ｖｏｌ．２６７，Ｎｏ．２１，１９９２年６月３日に記載されている。これらの参考文献の内容は、本明細書中で参考として援用されている。

【００１０】
ＡＣＤ－ＣＰＲ中に患者の胸を能動的に圧迫し除圧する真空型カップの使用は、ＡＭＢＵ Ｉｎｔｅｒｎａｔｉｏｎａｌ Ａ／Ｓ，Ｃｏｐｅｎｈａｇｅｎ，Ｄｅｎｍａｒｋのパンフレット（これは、Ｄｉｒｅｃｔｉｏｎｓ ｆｏｒ Ｕｓｅ ｏｆ ＡＭＢＵ（登録商標）ＣａｒｄｉｏＰｕｍｐ（商標）と題され、１９９２年９月に出版された）に記載されて

いる。このＡＭＢＵ（登録商標）ＣａｒｄｉｏＰｕｍｐ（商標）はまた、ヨーロッパ特許第０５０９７７３Ａ１号で開示されている。これらの参考文献の内容は、本明細書中で参考として援用されている。

【発明の開示】

【課題を解決するための手段】

【００１１】

（発明の要旨）

本発明によれば、心肺循環を高める方法および装置が提供されている。これらの方法および装置は、一般に認められたいずれかのＣＰＲ方法または能動圧迫－除圧（ＡＣＤ）ＣＰＲ技術と関連して、使用され得る。好ましくは、これらの方法および装置は、ＡＣＤ－ＣＰＲと関連して、使用される。１局面では、それらは、重症の低血圧に罹っているが心停止がなく自発的に呼吸している患者で、使用され得る。

【００１２】

心肺循環は、本発明によれば、ＣＰＲ除圧段階中または自然吸入中にて、患者の肺に入る気流を妨害することにより、高められる。これは、患者の胸での負胸腔内圧の規模を高めその持続時間を延ばし、すなわち、末梢静脈血管系での圧力に関して、胸腔内圧がそれより低いか負になる持続時間および程度を高める。心臓および肺に入る静脈血流の量を高めることにより、患者の気道を経由して胸に入る気体の急速な流入よりもむしろ高い静脈還流量から、大きな程度まで、除圧中の胸腔内圧の平衡が起こるので、心肺循環が高められる。

【００１３】

特定の実施形態では、患者の肺に入る気流の妨害は、ＣＰＲの除圧段階中での換気を低下または防止することにより、達成される。この方法は、流れ制限または限定部材、例えば、流れ制限オリフィス（これは、換気チューブの管腔内に配置されているか、それと直列で連結されている）または圧力応答性弁（これは、このチューブの管腔内にあり、空気の流入を妨害する）を使用する。この圧力応答性弁は、胸腔内圧が閾値より低くなると、開いて空気を流入させるように、偏る。患者を正しく人工呼吸するために、この方法では、好ましくは、患者の胸を圧迫した後、人工呼吸チューブによって、患者を定期的に人工呼吸する。定期的な人工呼吸を実行するとき、気体は、その妨害工程により送達されるか、他の実施形態では、この妨害工程を迂回できるか、いずれかである。ある場合には、一旦、この弁が開くと、この圧力応答性弁によって、患者には、酸素に富んだ気体が供給され得る。

【００１４】

代表的な実施形態では、患者の口および鼻を顔面マスクで覆う。このマスクは、患者の胸の除圧中に患者の気道に入る気流を妨害する手段（例えば、すぐ上で述べたオリフィスまたは弁のいずれか）を含む。

【００１５】

特定の実施形態は、その圧迫段階中に正負胸腔内圧を高めることにより、患者の胸の圧迫中に肺に空気が残らないようにして心肺循環をさらに高める手段を提供する。

【００１６】

本発明により循環を高めるために心肺蘇生を実行するとき、オペレータは、患者の胸を圧迫して、患者の胸郭から血液を強制的に出す。次いで、患者の胸は、除圧されて、（ＡＣＤ－ＣＰＲにより）胸を能動的に持ち上げるか（通常のＣＰＲにより）胸をそれ自身の弾性まで拡張させるかいずれかにより、末梢静脈血管系から心臓および肺へと静脈血の流入が誘発される。この除圧工程中にて、気流は、患者の肺に入るのを妨害され、これは、負胸腔内圧を高め、そして胸郭が末梢静脈血管系よりも低い圧力である時間を長くする。それゆえ、末梢静脈血管系から心臓および肺への静脈血の流入が高められる。その理由は、除圧中の胸腔内圧の平衡が、気管を経由する空気の流入よりもむしろ静脈還流量の上昇の結果として起こるからである。特定の実施形態では、患者の胸の圧迫および除圧は、患者の胸にアプリケータ体を押し付けて胸を圧迫することにより、そしてアプリケータ体を持

ち上げて患者の胸を能動的に拡張することにより、達成され得る。

【００１７】

この方法により心肺循環を高める装置は、改良型気管内チューブを含み、これは、胸の除圧中に患者の肺からの気流を妨害する流れ制限要素を有する。本発明による第二装置は、改良型空気送達システムを提供し、これは、圧縮性構造体を含み、この構造体は、流れ制限要素を有し、この要素は、患者の肺への気体の流れを妨害するために、この圧縮性構造体に含まれているか、そこに装着されている。また、コネクタが設けられ、これは、好ましくは、その構造体に顔面マスクまたは気管内チューブを装着することにより、この圧縮性構造体を患者に連動する。

【００１８】

本発明の他の局面では、心肺蘇生を実行するとき、患者の肺への気流を調節する弁システムが設けられる。このシステムは、ハウジングを含み、このハウジングは、上流領域および下流領域を有する。この上流領域と下流領域との間には、下流領域での圧力が上流領域での圧力よりも低いとき、上流領域から下流領域に流れる気体を妨害する手段が設けられる。このようにして、空気は、患者の胸を除圧中にて、患者の肺に流入するのが阻止され、それにより、さらに多くの静脈血を胸に強制的に入れて、生命の維持に重要な臓器の灌流を高める。さらに、患者を人工呼吸するときに下流領域に空気を流入させる手段が提供される。このようにして、この処置中にて、患者に対して、十分な人工呼吸を行うことができる。

【００１９】

特定の１実施形態では、この阻止手段は、弁を含み、この弁は、その下流領域での圧力が上流領域での圧力より低いとき、上流領域から下流領域への気流を阻止する。この弁は、好ましくは、ダイアフラムを含み、これは、この下流領域での圧力が上流領域での圧力以下のとき、閉じられる。このような構成により、圧迫中に患者の胸から空気を排出しつつ、患者の胸の除圧中に患者の胸に空気が流入するのが防止される。好ましくは、このダイアフラムは、可撓性部材から作製される。あるいは、このダイアフラムは、ボールを使用して作製できる。

【００２０】

他の特定の局面では、このダイアフラムは、その下流領域での圧力が約２ｃｍH_2O以上、さらに好ましくは、約２ｃｍH_2O～１０ｃｍH_2Oになるとき、開くように偏る。このダイアフラムがこのように偏ることで、患者の胸の圧迫中の胸腔内圧が高まり、生命の維持に重要な臓器の灌流をさらに高める。

【００２１】

さらに別の局面では、空気を下流領域に入れる手段は、その上流領域に空気を注入して患者を人工呼吸するときにダイアフラムを開く手段を含む。このダイアフラムを開く手段は、大気圧領域を含み、これは、ダイアフラムと隣接している。この上流領域に空気を注入するとき、上流領域内の圧力が高まり、それにより、そのダイアフラムを大気圧領域に引き入れ、空気を患者の肺に流す。

【００２２】

さらに他の局面では、空気を下流領域に入れる手段は、その下流領域で手動操作弁を含み、これは、自然な循環に戻ると、手で開かれて、空気を下流領域に流入させる。このようにして、救助者は、患者が息をし始めたとき、この弁を手で開くことができる。

【００２３】

代替局面では、この下流領域に空気を入れる手段は、その下流領域に、圧力応答性弁を含む。この圧力応答性弁により、この下流領域での圧力が閾値レベル（通常、－３ｃｍH_2O～－３０ｃｍH_2Oの範囲）より低くなると、下流領域に空気が入る。この圧力応答性弁は、そのダイアフラムを使用して負胸腔内圧の程度および持続時間を高めつつ、患者に人工呼吸を施す際に、有利である。使用され得る圧力応答性弁の例には、例えば、バネ偏向弁、電磁駆動弁、または閾値圧力を超えると反る任意の偏向可能材料から作製された弁が挙げられる。特定の一例として、この弁は、ゲートに装着された狭い公差の材料の磁気

帯電断片から作製され得る。この弁は、その磁気帯電ゲート圧力を超えると、開く。このようにして、この負胸腔内圧を超えると、この弁は、このゲートから引き離されて、気体が肺に流れることができる。このような弁はまた、上述のダイアフラム弁の代わりに、使用され得る。

【００２４】

１つの選択肢では、この圧力応答性弁には、富酸素気体源が連結され得、その圧力応答性弁を開いたとき、患者に、富酸素気体を供給する。この気体の圧力および／または流速を調節するには、調節器が使用され得る。例えば、この圧力は、負胸腔内圧を超えたときに弁が開くまで、加圧した気体が患者の肺に流れないように、その弁の起動圧力未満になるように調節され得る。

【００２５】

他の局面での本発明のシステムは、このハウジングから気体を排出するために、その上流領域でハウジングにある空気排気開口部を備えている。この排気開口部には、弁が設けられ、これは、空気が排気開口部を通ってハウジングに流入するのを阻止する。このようにして、患者から排出された空気は、順に、このハウジングから、この排気開口部を通って、排出される。さらに別の局面では、患者を人工呼吸しているとき、このハウジングに空気を注入している間、この排気開口部を通って空気がハウジングを出ていくのを防止する手段が設けられる。好ましくは、このハウジングには、呼吸装置（例えば、呼吸バッグ、人工呼吸器など）から、またはポートまたはマウスピースを通る口移し呼吸により、空気が注入される。

【００２６】

本発明のさらなる局面では、気管内チューブ、密封顔面マスク、喉頭マスクまたは他の気道チューブなどが設けられ、これは、患者に装着するために、この下流領域にて、このハウジングに連結される。この気管内チューブなどの装置は、患者の気道に挿入するためにあり、それにより、その弁システムが患者に便利に装着される。

【００２７】

本発明は、さらに、心肺蘇生を実行するときに胸の圧迫および除圧により誘発される心肺循環を高める代表的な装置を提供する。この装置は、顔面マスクおよびハウジングを含み、このハウジングは、このマスクに作動可能に装着されている。このハウジングは、マウスピースおよび少なくとも１個の流入弁を含み、この流入弁は、閾値負胸腔内圧を超えるまで、呼吸気体が肺に入るのを防止し、超えた時点で、この流入弁は、開く。このハウジングは、さらに、空気チャンバ（これは、このマウスピースと連絡している）および弁部材（これは、マウスピースに空気を供給したとき、空気チャンバから顔面マスクへと空気を入れる）を含む。このようにして、救助者は、このマウスピースを吹き込んで、救助者の肺から呼吸気体を導入するのではなく、このチャンバに保存された空気または富酸素気体で患者を定期的に人工呼吸する。

【００２８】

類似の静脈では、本発明は、心肺蘇生を実行するときに胸の圧迫および除圧により誘発される心肺循環を高める方法を提供する。この方法によれば、少なくとも１個の流入弁および空気チャンバが患者の気道に連動される。次いで、胸の圧迫および胸の除圧が実行され、その流入弁は、閾値負胸腔内圧を超えるまで、除圧中に呼吸空気が肺に入るのを防止する。空気は、患者を空気で正しく人工呼吸するために、この空気チャンバから患者の肺に定期的に移動される。代表的な１局面では、空気は、この空気チャンバに手動で吹き込むことにより、そのチャンバから患者の肺に移動される。このようにして、救助者は、このチャンバに吹き入れて、救助者の肺から呼吸気体を導入することなく、患者の肺に空気を移動し得る。

【００２９】

１実施形態では、本発明は、その流入弁の起動圧力を変える機構を提供する。このようにして、救助者は、この機構を作動して、患者の状態に依存して、その抵抗を変えることができる。ある場合には、本発明の弁システムは、胸腔内圧を表示する圧力ゲージを含み得

る。この情報を容易に利用可能にすることにより、救助者は、この流入弁の所望の起動圧力を達成するのを助けるために、さらに多くの情報を有する。

【００３０】

１局面では、その起動圧力を約０ｃｍH_2O～約－３０ｃｍH_2Oの範囲内の圧力に変えるために、変化機構が構成される。別の局面では、この流入弁は、シャフトおよびバネを含み、シャフトは、シールを有し、シールは、そのハウジング内の開口部を遮断するように構成され、そしてバネは、シールをハウジングに曲げる。このような構成で、この機構は、ノブを含み得、これは、このバネの偏向力を変えるように移動可能である。例えば、このノブは、救助者が単にノブを回転して起動圧力を変え得るように、このシャフトに連結され得る。

【００３１】

別の実施形態では、本発明の弁システムは、安全換気通路を備え付け得る。もし、この弁システムが、自発的に呼吸している患者に不適切に適用されたなら、患者は、その弁システムを患者の気道に連結している間、この通路を通って、呼吸し得る。この安全換気通路を開いたまま維持して、救助者が安全換気通路を閉じるように起動するまで、患者の肺に呼吸気体を自由に流すために、安全機構が使用される。このような配置で、患者は、もし可能なら、自由に呼吸できるようになる。もし、患者が自発的に呼吸するのをやめたなら、救助者は、この換気通路が閉じられて流入弁がＣＰＲ中に所望の耐性を与えるまで、この弁システムを設定し得る。このようにして、呼吸気体は、一旦、その閾値のクラッキング圧力を超えた場合か患者が能動的に換気したときにのみ、許容される。他の実施形態と同様に、このクラッキング圧力は、ＣＰＲ中に患者の胸を除圧することにより、患者自身の吸入により、または他のものにより、超えられ得る。

【００３２】

１局面では、この安全換気通路は、その流入弁が開放位置にあるときに、流入弁を通って設けられる。この構成では、この安全機構は、救助者が流入弁を閉鎖位置に移動するまで、その流入弁を開放位置で維持するように構成される。この安全機構を起動するために、種々の様式が使用され得る。例えば、このハウジングは、呼吸気体がハウジングに注入されるように、換気ポートを含み得、また、この安全機構は、センサを含み得、救助者が呼吸気体をハウジングに注入したときを感知し得る。１実施形態では、制御システムにより、この流入弁を開放位置から閉鎖位置へと移動するために、このセンサからの信号が使用される。一例として、このセンサは、このハウジングに呼吸気体を注入すると、移動可能であり得、この制御システムは、一組のギアおよびカムを含み得、ギアは、センサに連結され、そしてカムは、この流入弁を閉じるように、ギアにより移動可能である。あるいは、この制御システムは、電子制御装置、ソレノイドおよびカムを含み得る。この機構は、このセンサからの電気信号を受け取ってソレノイドを操作しカムを移動して、それにより、この流入弁を閉じるように構成されている。他の例として、これらの気体を注入すると、フラップが移動され得る。このフラップは、この流入弁を閉鎖位置に物理的にリセットする種々の機械的要素の移動を引き起こし得る。

【００３３】

これらの呼吸気体の注入を感知するために、種々のセンサが使用され得る。例えば、使用され得るセンサには、電子スイッチ（これらは、気体流れで移動する）、サーミスタ（これは、温度変化を感知する）、CO_2検出器、曲げると抵抗変化に遭遇する材料、機械フラップ（これは、気体流れで移動する）などが挙げられる。

【００３４】

本発明はまた、自発的に呼吸しているヒトの血圧を高める方法を提供する。この方法によれば、ヒトの気道には、流入弁が連結され、ヒトは、吸入し吐出する。吸入中にて、この流入弁は、少なくとも一定時間にわたって、呼吸気体が肺から入るのを阻止するか完全に防止して、ヒトの負胸腔内圧を増大させ、それにより、ヒトの右心への血液の還流を高める。そうする際に、ヒトの血圧は、高められる。この流入弁の抵抗または起動圧力は、１つ以上の感知した生理学的パラメータに基づき得る。例えば、１つのパラメータは、負胸

腔内圧であり得る。例えば、この流入弁は、１分あたり約０～約７０リットルの範囲の流速に対して、約０ｃｍH_2O～－５０ｃｍH_2Oの範囲の負胸腔内圧を達成するのに、使用され得る。感知され得る他のパラメータには、呼吸数、末端換気CO_2、組織CO_2含量、呼吸終末陽圧、血圧および酸素飽和度が挙げられる。これらのパラメータは、この流入弁の抵抗を調整したとき、個々に使用されるか併用され得る。例えば、感知した負胸腔内圧が所望範囲内にあっても、末端換気CO_2は、所望範囲の外側であり得る。そういうものとして、この弁の抵抗は、末端換気CO_2が許容できるまで、調整され得る。逆に、この流入弁は、手動で操作され得るか、自動様式で操作され得る。例えば、感知したパラメータを受信するために、次いで、調整機構（これは、この弁を操作して、抵抗または起動圧力を変える）に信号を送信するために、制御装置が使用され得る。

【００３５】

このようなプロセスは、ヒトの血圧が低い場合の種々の病気を治療するのに、使用され得る。例えば、このような処置は、ヒトが、血液損失、薬剤投与、高重力状態、血液迷走神経失神、溺水、熱射病、心臓麻痺、右心不全、宇宙飛行後の地球への帰還、敗血症、心外膜液、心臓タンポナーゼなどが原因で低血圧の場合に、使用され得る。

【００３６】

本発明の性質および利点のそれ以上の理解は、本明細書の残りの部分および図面を参照して、明らかとなる。

【００３７】

（発明の詳細な説明）

本発明によれば、心肺蘇生を実行しているときに、胸の圧迫および除圧により誘発される心肺循環を高める方法および装置が提供される。このような方法および装置は、任意のＣＰＲ方法（この方法では、心肺循環を改善するために、胸腔内圧が意図的に操縦される）と関連して、使用され得る。例えば、本発明は、標準的な手動ＣＰＲ、「ベスト」ＣＰＲ（この場合、円周カラーが繰り返し圧迫されて、心臓からの血流を促進する）、新たに記述されたＨｉａｃｋ　Ｏｓｃｉｌｌａｔｏｒ換気系を備えたＣＰＲ（これは、事実上、鉄肺様の装置のように作動する）、横隔神経刺激装置（例えば、米国特許出願第０９／０９５，９１６号（０６／１１／９８に出願）；第０９／１９７，２８６号（１１／２０／９８に出願）；第０９／３１５，３９６号（０５／２０／９９に出願）；および第０９／５３３，８８０号（０３／２２／００に出願（これらの詳細な開示内容は、本明細書中で参考として援用されている）で記述されたものを含めて）、介在腹部圧迫－除圧ＣＰＲ技術、および能動圧迫－除圧（ＡＣＤ）ＣＰＲ技術を改良する。本発明は、このような技術の全てを改良し得るものの、以下の説明は、主に、論述を簡単にするために、ＡＣＤ－ＣＰＲ技術の改良に言及する。しかしながら、特許請求した方法および装置は、ＡＣＤ－ＣＰＲ技術にだけ限定されるものではない。

【００３８】

ＡＣＤ－ＣＰＲが心肺循環を高める正しい性能は、患者の胸をアプリケータ体で能動的に圧迫することにより、達成される。好ましくは、このアプリケータ体は、患者の胸に付着する吸引型装置（例えば、ＡＭＢＵ　Ｉｎｔｅｒｎａｔｉｏｎａｌ（Ｃｏｐｅｎｈａｇｅｎ，Ｄｅｎｍａｒｋ）から入手できるＡＭＢＵ（登録商標）ＣａｒｄｉｏＰｕｍｐ^{TM}）である。その圧迫工程の後、このアプリケータ体を患者の胸に付着すると、患者の胸を能動的に除圧するために、患者の胸を持ち上げることができる。このような能動的な圧迫－除圧の結果は、その圧迫工程中の胸腔内圧を高めることにあり、また、この除圧工程中の負胸腔内圧を高めることにあり、それにより、血液酸素化プロセスが高まり、そして心肺循環が高まる。ＡＣＤ－ＣＰＲ技術は、Ｔｏｄｄ　Ｊ．Ｃｏｈｅｎら、Ａｃｔｉｖｅ　Ｃｏｍｐｒｅｓｓｉｏｎ－Ｄｅｃｏｍｐｒｅｓｓｉｏｎ　Ｒｅｓｕｓｃｉｔａｔｉｏｎ：Ａ　Ｎｏｖｅｌ　Ｍｅｔｈｏｄ　ｏｆ　Ｃａｒｄｉｏｐｕｌｍｏｎａｒｙ　Ｒｅｓｕｓｃｉｔａｔｉｏｎ，Ａｍｅｒｉｃａｎ　Ｈｅａｒｔ　Ｊｏｕｒｎａｌ，Ｖｏｌ．１２４，Ｎｏ．５，ｐｐ．１１４５～１１５０，１９９２年１１月；Ｔｏｄｄ　Ｊ．Ｃｏｈｅｎら、Ａｃｔｉｖｅ　Ｃｏｍｐｒｅｓｓｉｏｎ－Ｄｅｃｏｍｐｒｅｓｓｉｏｎ：Ａ　Ｎｅｗ　Ｍｅ

thod of Cardiopulmonary Resuscitation, The Journal of the American Medical Association, Vol. 267, No. 21, 1992年6月3日；およびJ. Schultz, P. Coffeenら、Circulation, 89：684～693, 1994年で、詳細に記述されている。これらの参考文献の内容は、本明細書中で参考として援用されている。

【００３９】

本発明は、事実上、標準的な技術およびＡＣＤ－ＣＰＲ技術に関連して、有用である。特に、本発明は、患者の肺への気流を妨害して患者の胸の除圧中に負胸腔内圧を高めて、それにより、胸郭（心臓および肺を含めて）と末梢静脈血管系との間の圧力差の程度および持続時間を高める方法および装置を提供することにより、標準的な技術およびＡＣＤ－ＣＰＲ技術を改良する。それゆえ、気道への気体の移動を同時に妨害しつつ負胸腔内圧を高めると、心臓および肺への静脈血流が高まり、心肺循環が増大する。

【００４０】

広義には、本発明は、ＡＣＤ－ＣＰＲの能動除圧工程中にて、患者の気道を閉塞して外来空気（外気）が患者の肺に流入するのを防止し、負胸腔内圧の持続時間を高めてそれを維持し、また、能動除圧段階およびそれに続く圧迫段階の両方での血液酸素化および心肺循環を高める。患者の気道が閉塞され得るか、または気体の流入は、任意の適切な装置または機構（例えば、気管内チューブ、気管内チューブに装着された装置、顔面マスク、マウスピース（これは、口移し蘇生法で使用される）、またはオファリンギール気道、喉頭マスク気道など）により、妨害され得る。

【００４１】

本発明のさらに他の局面は、依然として、負胸腔内圧の程度および持続時間を高めて血液酸素化を高めつつ、患者に一定の人工呼吸を施すために、ＡＣＤ－ＣＰＲの能動除圧中にて、妨害された空気を患者の肺に流入させる。患者の肺への気流の妨害は、任意の流れ制限要素（例えば、オリフィス、一方向弁、バネ偏向弁または他の弁（これは、その負胸腔内圧が、約０ｃｍH_2O～－１００ｃｍH_2O、さらに好ましくは、約－３ｃｍH_2O～約－３０ｃｍH_2Oの範囲であるとき、開くように設定される））により、達成され得る。閾値圧力値で開くように設計された弁は、固定または可変のいずれかであり得、すなわち、その弁が開く圧力は、調整され得るか、永久的に固定され得る。さらに、使用され得る圧力応答性弁の例には、例えば、電磁駆動弁、または閾値圧力を超えると反る任意の偏向可能材料から作製された弁が挙げられる。特定の一例として、この弁は、ゲートに装着された狭い公差の材料の磁気帯電断片から作製され得る。この弁は、その磁気帯電ゲート圧力を超えると、開く。このようにして、この負胸腔内圧を超えると、この弁は、このゲートから引き離されて、気体が肺に流れることができる。

【００４２】

ある場合には、救助者が起動するまで患者の肺に呼吸気体を自由に流すために、安全機構が設けられ得る。このようにして、この弁システムは、患者に連結され得るが、これは、救助者が起動するまで、患者の吸気を妨害するにすぎない。

【００４３】

本発明の他の局面では、その圧迫段階中に胸腔内圧を高めることにより、心肺循環をさらに高めるために、患者の胸の除圧中にて、患者の肺に空気が残るのを妨害する。典型的には、空気は、正胸腔内圧が約２ｃｍH_2O～５０ｃｍH_2O、さらに好ましくは、約２ｃｍH_2O～約２０ｃｍH_2Oの範囲にあるとき、その圧迫段階中に肺に残るのが妨害される。このような機能を達成するのに使用され得る弁には、例えば、バネ弁、ダイアフラム弁が挙げられ、シリコーンから作製されたダイアフラム、および磁気帯電したプレート（これは、ゲートに連結されている）が含まれる。このようにして、この正圧が磁力を超えるとき、このプレートは、このゲートから強制的に離されて、これらの気体が肺から出ていくことができるようになる。

【００４４】

本発明の他の局面では、ＣＰＲ中に患者を人工呼吸する。患者の人工呼吸は、１実施形態では、約２回～２０回の圧迫ごと、好ましくは、１５回の圧迫ごとに２度実行され、それにより、患者の肺において血液との十分な気体交換のための十分な新鮮空気を供給する。患者の人工呼吸は、適切な任意の装置または方法（例えば、口移し蘇生法）により、圧縮性構造体または崩壊性構造体により、換気バッグ（例えば、ＡＭＢＵ（Ｃｏｐｅｎｈａｇｅｎ，Ｄｅｎｍａｒｋ）から入手できるＡＭＢＵ（登録商標）バッグ）などにより、達成され得る。さらに、定期的な人工呼吸は、その妨害工程により、または妨害工程を全く迂回することにより、いずれかにより、実行できる。

【００４５】

代替実施形態では、一旦、一定の閾値負胸腔内圧を超えると、人工呼吸は、この圧力応答性弁に富酸素呼吸気体を導入することにより行われ得、それにより、この除圧工程中にて、肺に規定が入ることができる。これは、圧力下または大気圧下にて、導入できる。このようにして、各除圧工程中にて、患者を人工呼吸するために、肺には、呼吸気体が供給され得る。加圧気体を使用することは、一旦、この圧力応答性弁を開けると、より多くの気体が肺に供給され得る点で、有利である。加圧気体は、一定長の配管を使用して、この圧力応答性弁の裏側に加圧気体源（例えば、O_2の加圧タンクまたはバッグ）を連結することにより、供給され得る。好都合なことに、この圧力源と弁との間には、圧力源から供給される気体の圧力および／または流速を調節するために、調節器が位置付けられ得る。その圧力は、例えば、約１～３ｃｍH_2Oだけ、その弁の起動圧力より低くなるように調節され得、その結果、この弁は、永久的に開く。例えば、もし、この負胸腔内圧が－１４ｃｍH_2Oを超えると、患者に呼吸気体が供給されるなら、この気体源からの気体の圧力は、１４ｃｍH_2O未満に設定されなければならない。

【００４６】

患者を人工呼吸するとき、本発明の弁は、肺に入る空気の流速を調節するように、改良され得る。これは、その弁に呼吸気体が注入されるにつれて、それらの流速が、患者の気道に気体が入る閾値量より低く制限されるように、その弁内のたはそれに付随して、例えば、流量調節器、弁、大きさを小さくした制限オリフィスなどを含めることにより、達成され得る。注入した呼吸気体の流速を調節することにより、食道にかかる圧力は、ガストロノミック（ｇａｓｔｒｏｎｏｍｉｃ）膨張を防止するために、一定限度内に保たれ得る。例えば、気体が患者の気道に入る前に、気体の流速を調節するために、その弁システムハウジングの出口開口部またはその近くには、大きさを小さくしたオリフィスが設けられ得る。このようにして、注入した呼吸気体の実質的に全てが患者の肺に入ることを保証する技術が提供される。

【００４７】

本発明の１つの著しい利点は、ヒトの血圧を高める性能にある。本発明の弁システムを自発的に呼吸している患者と連動することにより、これらの弁システムは、ヒトが吸入するときの負胸腔内圧を高めることができる。そうすることにより、右心には、より多くの血液が戻り、ヒトの血圧が高まる。ヒトの血圧を高めるのに使用される弁システムは、最初は、呼吸を試みている間の肺への気体流れを完全に防止し得るか、またはある程度の抵抗を与え得る。この完全な防止または初期の抵抗は、時には、その呼吸サイクルの少なくとも一部にわたって気体流れがヒトの肺に進行するように、呼吸操縦中に、調整され得る。例えば、もし、圧力応答性弁を使用するなら、この弁は、約０～約７０リットルの範囲の流速に対して、約０ｃｍH_2O～約－５０ｃｍH_2O、さらに好ましくは、約０ｃｍH_2O～約２０ｃｍH_2O、最も好ましくは、約－５ｃｍH_2O～約－１５ｃｍH_2Oの範囲の圧力に達したとき、開くように設定され得る。単に抵抗を与える弁については、その弁は、この呼吸を試みている間、類似の抵抗を与えるように設計され得る。さらに、１個以上のセンサは、種々の生理学的パラメータを感知するのに使用され得、また、その弁のクラッキング圧力または弁により発生する抵抗を手動または自動で変えるのに使用され得る。

【００４８】

本発明の弁システムが血圧を高めるのに使用され得る状況の例には、自発的に呼吸している患者が血液損失に遭遇する場合、または血圧の低下を引き起こす薬剤（麻酔薬を含めて）を受けた後が挙げられる。低血圧の患者は、しばしば、各拍動後に心臓に戻る血液が不十分である。この結果、心臓からの前方血流が低下し、最終的には、低血圧となる。この弁システムを起動に連動させることにより、右心への静脈還流量が高まり、血圧が高くなる。別の例には、自発的に呼吸をしている患者が著しい血液損失に伴うショック状態にあって右心への血流を高める必要がある場合である。他の例として、このような技術は、高重力状態にあるか宇宙飛行後に地球に帰還するときに右心に戻る血流を高めるために、パイロットまたは宇宙飛行士で使用され得、また、血液迷走神経または血管降圧薬の失神が原因の急速な血圧低下に罹った患者で使用され得る。さらなる例には、熱射病、溺水、心臓麻痺、右心不全、敗血症、心外膜液、タンポナーゼなどが原因の低血圧が挙げられる。

【００４９】

１つの選択肢では、これらの弁システムのいずれかは、その弁システムを使用していかにしてＣＰＲを実行するかに関して、ボイスプロンプトを発生するために、電子装置および付属したスピーカーを含み得る。このようなボイスプロンプトは、この弁システムを連動する指示、胸の圧迫を加える指示、人工呼吸を行う指示などを有し得る。また、適切な胸の圧迫を与える際に救助者を助けるために、メトロノームが設けられ得る。このような技術は、係属中の米国特許出願第０９／８５４，４０４号（５／１１／０１に出願（弁護事件番号１６３５４－００４３００））で記載されており、その内容は、本明細書中で参考として援用されている。

【００５０】

本発明の弁システムはまた、センサを組み込むか付属し得、これらは、胸腔内圧または他の生理学的なパラメータを検出するのに使用される。このようにして、患者が自発的に呼吸しているのが検出され得る。一旦、このセンサが特定胸腔内圧を１回以上加えることにより起動されると、これは、順に、患者が何らの抵抗なしで呼吸し得るように、この弁システムを制御するのに使用され得る。このようなセンサの例は、米国特許第６，１５５，２５７号で記載されており、その完全な開示内容は、本明細書中で参考として援用されている。

【００５１】

本明細書中で記述したセンサのいずれかは、測定した信号を制御装置と連絡したリモートレシーバに無線で伝達するように構成され得る。次に、この制御装置は、測定した信号を使用して、本明細書中で記述した弁システムの操作を変え得る。例えば、センサは、血圧、心臓内の圧力などを感知するように使用され得、また、この情報をレシーバに無線で伝達するように使用され得る。この情報は、次いで、制御装置を使用することにより、流入弁の起動圧力または抵抗を制御するために、呼気弁の起動圧力または抵抗を制御するために、酸素または他の気体の注入を制御するために、薬剤または医薬の投与を制御するためなどに使用され得る。

【００５２】

本発明の弁システムおよび／または顔面マスクはまた、患者の呼吸器系に薬剤または他の医薬を投与するための１個以上のポートを含み得る。例えば、注射器または加圧缶により医薬を注入するポートが設けられ得る。別の例として、このようなポートを通って、霧状にした液状医薬品が供給され得る。他の例として、このようなポートを通って、粉末医薬品が供給され得る。

【００５３】

本発明の別の特徴は、頭蓋内圧（これは、しばしば、頭部の外傷に起因する）を低下するのに使用され得ることにある。本発明の弁システムおよび技術を使用して胸腔内圧を低下させることにより、脳から心臓への静脈還流量の抵抗は、少なくなる。そういうものとして、脳から、さらに多くの静脈血が除去され、それにより、頭蓋内圧が低下する。例えば、本発明の弁システムのいずれかは、患者が息をするときに発生する負胸腔内圧が脳から静脈血を引き出すために増大されるように、患者の気道に連結され得る。

【００５４】
さて、図１を参照すると、患者の胸を圧迫または除圧するときに時間の経過に伴う胸腔圧力の変化を図示しているグラフが示されている。領域１０は、ＡＣＤ－ＣＰＲの圧迫段階での胸腔圧力の量を表わす。斜行平行線領域１２は、患者の肺への空気の流れを制限する流れ制限手段なしでのＡＣＤ－ＣＰＲの除圧工程中の負胸腔圧力を表わす。二重斜行平行線領域１４は、ＡＣＤ－ＣＰＲの除圧工程中に本発明に従って患者の気道を閉塞したときの負胸腔圧力の増加を表わす。この除圧工程中に負胸腔内圧が増加したことで重要なことには、末梢静脈血管系から胸へとさらに多くの血液が強制的に入ることにある。結果的に、さらに多くの血液が酸素化され、さらに多くの血液が、次の圧迫中にて、胸から強制的に出ていく。

【００５５】
代表的な実施形態では、気流は、患者の口および鼻に換気マスクを置くことにより、患者の胸の除圧中にて、患者の胸に入るのを妨害され得る。この換気マスクはまた、圧力応答性弁を有し得、これは、患者の負胸腔内圧が閾値量に達するまで、気流が患者の肺に入るのを防止するために、装着される。また、このマスクおよび圧力応答性弁には、換気源が装着され、これは、患者を人工呼吸される。この換気源は、患者を正しく人工呼吸するのに適切な任意の素子または装置であり得る。好ましくは、この換気源は、ＡＭＢＵバッグである。換気が必要なとき、このＡＭＢＵバッグは、患者の肺に空気を強制的に入れるために、絞られ得る。このＡＭＢＵバッグは、米国特許第５，１６３，４２４号で記載され、その内容は、本明細書中で参考として援用されている。

【００５６】
代替実施形態では、換気源（好ましくは、ＡＭＢＵバッグ）は、改良型気管内チューブと関連して、使用される。このＡＭＢｕバッグと気管内チューブとの間には、圧力応答性弁または他の流れ制限要素が設置される。好ましくは、この弁は、このＡＭＢＵバッグを気管内チューブに連結するチューブ内に位置付けられる。この気管内チューブとＡＭＢＵバッグとアダプタの組合せは、「換気チューブ」の定義に含むことができる。患者にＡＣＤ－ＣＰＲを実行する前に、この気管内チューブは、患者の気管に設置される。患者の胸の除圧中にて、この弁は、その胸腔内圧が閾値量に達するまで、気流が患者の肺に入るのを防止する。さらに、このＡＭＢＵバッグは、所望の時点で、患者を人工呼吸するのに使用され得る。また、この実施形態には、一方向呼気弁が含まれる。この弁により、この圧迫工程中にて、患者から空気を呼気することが可能となる。

【００５７】
最初の２つの実施形態のいずれかの改良では、圧力応答性弁はまた、このＡＭＢＵバッグ（または同程度の換気源）とマスクまたは気管内チューブとの間に挿入され得る。この弁は、患者の肺に入る気流を制限する圧力応答性弁に対して、類似の様式で作用する。しかしながら、この圧力応答性弁は、ＡＣＤ－ＣＰＲの圧迫工程中にて患者の肺からの気流を制限する。同じ弁には、呼吸終末陽圧（ＰＥＥＰ）弁があり、これは、ＡＭＢＵ　Ｉｎｔｅｒｎａｔｉｏｎａｌ（Ｃｏｐｅｎｈａｇｅｎ，Ｄｅｎｍａｒｋ）から入手できる。このような圧力応答性弁を圧迫中に使用すると、胸腔内圧がさらに高まり得、それにより、胸郭から、さらに多くの血液を強制的に出す。

【００５８】
他の代替実施形態では、この能動除圧工程中に患者の肺に入る気流を制限するために、改良型気管内チューブが使用される。この気管内チューブには、流れ制限要素が含まれ、これは、患者の肺に空気が流入するのを妨害するように作動する。この気管内チューブを患者の気管に挿入して患者の胸を能動的に除圧したとき、この流れ制限要素は、患者の肺に空気が流れるのを妨害して、胸腔内圧の上昇を遅らせ、それにより、血液酸素化を高める。

【００５９】
ＡＣＤ－ＣＰＲ中に改良型気管内チューブを使用するとき、患者の気体交換を高めるために、通常、依然として、患者の定期的な人工呼吸が実行される。改良型気管内チューブを

使うと、このような手動人工呼吸は、その気管内チューブの開口部に換気源を設置して気管内チューブに酸素を強制的に通して患者の肺に入れることにより、達成され得る。

【００６０】

さて、図２Ａを参照すると、本発明に従って患者の胸を圧迫するときに換気回路２０を通る気流を図示している概略図が示されている。ＡＣＤ－ＣＰＲ中にて、胸は、能動的に圧迫されて、空気は、肺から強制的に出される。この空気は、換気回路２０内で、一方向呼気弁２２を通って、吐き出される。

【００６１】

さて、図２Ｂを参照すると、同じ概略図が示され、これは、患者の胸を除圧するとき、換気回路２０を通る気流を図示している。患者の胸が能動的に除圧されるとき、負胸腔内圧が作り出される。この圧力が閾値量に達したとき、流入弁２４が開いて、空気は、換気回路２０を通り、患者の肺に入る。空気は、呼気弁２６を通って、換気回路２０に入り、そして換気バッグ２８に入る。換気バッグ２８から、この空気は、その負胸腔内圧が閾値量に達したとき、流入弁２４を通る。換気バッグ２８はまた、必要なＡＣＤ－ＣＰＲ中に患者を手動で人工呼吸するのに使用される。

【００６２】

図２Ａおよび２Ｂに関連して述べた方法では、胸は、成人に対して、１回の圧迫あたり、約３．５ｃｍ～５ｃｍの範囲で、また、１分間あたり、約６０～１００回の圧迫速度で、圧迫する必要がある。

【００６３】

さて、図３を参照すると、本発明に従って患者の肺に空気が入るのを妨害する装置３５の第一代替実施形態の概略図が示されている。装置３５は、気管内チューブ３６を含み、これは、患者の気管に設置され、そして換気通路を提供する。気管内チューブ３６には、移行チューブ３８が連結され、これは、気管内チューブ３６を換気バッグ２８に接続する。気管内チューブ３６は、換気バッグ２８と連結して示されているものの、気管内チューブ３６は、単独で、または換気バッグ２８と連結して、使用され得る。換気バッグ２８は、患者を人工呼吸できる任意の種類の換気源（例えば、圧縮性または崩壊性構造体）を含有できる。好ましくは、換気バッグ２８は、ＡＭＢＵバッグからなる。換気バッグ２８の末端には、一方向呼気弁２６が装着または連結される。呼気弁２６は、装置３５に空気を導入するように働く。移行チューブ３８には、流入圧力応答性弁２４が装着または連結される。流入弁２４は、患者の胸における負胸腔内圧が閾値に達したときに開くように、偏っている。図示しているように、装置３５には、１個の流入弁２４だけが含まれている。しかしながら、本発明は、１個だけの流入弁２４には限定されない。あるいは、換気チューブ３８に沿って、直列で、複数の流入弁２４が連結できる。流入弁２４もまた、移行チューブ３８の中心に連結されることには限定されず、移行チューブ３８に沿ったいずれの場所にも位置付けられ得る。流入弁２４は、換気バッグ２８または移行チューブ３８に永久的に装着できるか、取り外し可能であり得る。あるいは、流入弁２４は、換気バッグ２８それ自体または気管内チューブ３６に連結できる。

【００６４】

装置３５はまた、一方向呼気弁２２を含み、これにより、空気は、患者の肺から吐き出される。これは、一般に、ＡＣＤ－ＣＰＲの圧迫段階中に起こる。患者の肺から吐き出された空気が呼気弁を通って出ていくことを保証するために、流入弁２４と呼気弁２２との間には、一方向魚口弁３７（好ましい弁）または任意の他の種類の一方向弁が設置できる。あるいは、流入弁２４それ自体は、一方向弁として、構成され得る。いずれの場合でも、気管内チューブ３６から換気バッグ２８に向かって流れる空気は、呼気弁２２を通って、強制的に吐出する。

【００６５】

装置３５は、さらに、圧力応答性呼気弁３９（図示せず）を含むように改良され得、これは、気管内チューブ３６と移行チューブ３８との間に位置している。この圧力応答性呼気弁は、流入弁２４とは逆の様式で、作用する。具体的には、この圧力応答性呼気弁は、Ａ

ＣＤ－ＣＰＲの圧迫工程中にて、その胸腔内圧が閾値に達したときだけ空気が患者から吐出するように、偏らされる。圧迫中に圧力応答性弁３９により引き起こされる胸腔内圧の増加は、より多くの血液を胸郭から強制的に出して肺の無気肺を少なくするのを助け得る。

【００６６】

換気バッグ２８の目的は、ＡＣＤ－ＣＰＲ中に患者を人工呼吸することにある。換気バッグ２８がＡＭＢＵバッグ、または人工呼吸に使用される類似のバッグを含むとき、患者の人工呼吸は、単に、ＡＭＢＵバッグをヒトの手で絞ることにより、実行され得る。これにより、望ましいように、患者の肺に空気が強制的に入る。

【００６７】

図４Ａを参照すると、本発明に従って患者の肺に気流が入るのを妨害する装置の第二代替実施形態が示されている。この特定の実施形態は、改良型気管内チューブである。それゆえ、第二代替実施形態は、気管内チューブ３６を含み、これは、その近位末端に、２本の管腔を有する。第一管腔は、流出管腔４０であり、そして第二管腔は、流入管腔４２である。流出管腔４０内には、一方向圧力応答性呼気弁４４が位置しており、これは、呼気弁４４が一方向弁として特に設計されていること以外は、図３に関連して述べたものと類似して様式で、作動する。流入管腔４２内には、一方向圧力応答性流入弁４５が位置しており、これは、流入弁４５もまた一方向弁として特に設計されていること以外は、図３に関連して述べたように、肺への気流を妨害するように作動する。また、流入管腔４２および流出管腔４０内には、Ｏ－リング４６が示されており、これは、次に述べる。流入弁４５および呼気弁４４は、その圧迫段階中に、その胸腔内圧が閾値量に達したとき、気管内チューブ３６を通って患者から空気が吐出できるにすぎないように、一方向弁として、設計されている。その瞬間、呼気弁４４は、開き、空気は、流出管腔４０を通って、患者から吐出する。除圧中にて、空気は、負胸腔内圧が閾値量に達するまで、気管内チューブ３６を通って患者の肺に流入できない。その瞬間、流入弁４５が開いて、空気は、一方向呼気弁４４があるために、流出管腔４０を通って入ることができない。

【００６８】

もし、流入管腔４２が換気源（例えば、換気バッグ）に連結されるなら、図４Ａおよび４Ｂで開示された実施形態では、人工呼吸が可能である。この換気バッグを絞るとき、空気は、流入管腔４２を通り、気管内チューブ３６を通り、患者の肺へと流入できる。この実施形態では、呼気弁４４は、一時的に閉じたままになり、空気が管腔４２を通って流出管腔４０から逃げるのを防止する。

【００６９】

図５Ａは、本発明に従って気流を妨害する装置で使用される一方向流入弁４５の概略図である。流入弁４５は、空気を一方向にだけ流すように、作動する。図示しているように、バネ偏向流入弁４５は、完全に開いている。しかしながら、本発明はまた、バネ偏向流入弁４５またはバネ偏向呼気弁４４が完全に開いていないなら、正しく機能する。ＡＣＤ－ＣＰＲがうまく完結すると、流入弁４５の上に位置付けられたＯリング４６は、流入弁４５が図５Ｂで示すように開いたまま保持されるように、再配置される。Ｏリング４６のこのような配置により、一旦、自然な循環に戻り流入弁４５が必要なくなると、患者には、妨害されない気流を入れることができる。Ｏリング４６はまた、自然な循環が戻ると、一方向呼気弁４４を開放位置でロックするために、類似の様式で、使用される。図５Ｃは、閉鎖位置の一方向流入弁４５を図示している。閉じたとき、流入弁４５を通る空気の流入は、閉塞される。

【００７０】

図６Ａは、流入弁４７（これは、バネ偏向されている）および呼気弁４８（これもまた、バネ偏向されている）を図示している。流入弁４７および呼気弁４８は、直列に連結され、図３に関連して述べられている第一代替実施形態で使用されるか、または図９らに関連して以下で述べられている好ましい実施形態と併用され得る。図６Ｃで示すように、この能動除圧工程中にて、流入弁４７は、その負胸腔内圧が閾値に達するときに開くように、

偏らされる。ＡＣＤ－ＣＰＲの圧迫段階中にて、呼気弁４８は、図６Ｂで示すように、患者の胸内の胸腔内圧が閾値量に達するとき、患者の肺から空気を吐出させるように開く。流入弁４７または呼気弁４８のいずれも、一方向弁ではないので、図３に関連して述べたような一方向弁２２に関連して使用される魚口弁３７が使用されなければならない。この魚口弁と一方向弁との組合せと類似の原理で設計される他の弁もまた、使用できる。図６Ａ～６Ｃでは、１個の流入弁２４および１個の呼吸終末陽圧弁４４だけが示されている。しかしながら、空気の流入および流出を妨害するために、直列で、永久に固定した様式または取り外し可能に様式で、複数の流入弁４７および／または呼気弁４８が連結され得る。

【００７１】

図６Ａ～６Ｃの弁は、バネ偏向して示されているものの、類似の原理で設計した他の任意の弁もまた、同様に作用する。図６Ａ～６Ｃで開示されているような弁の使用は、１実施形態にすぎず、種々の他の方法および材料により作製した弁もまた、本発明の範囲内である。

【００７２】

図７で示すように、流入弁４７および呼気弁４８は、図示している１個の接合弁４９と組み合わされ得る。接合弁４９は、図６に関連して記述されているように、２個の弁４７および４８と類似の様式で、作動する。

【００７３】

図８は、この気流が患者の肺に入るか出ていくかいずれかを妨害するのに使用される流れ制限オリフィス５０を例示している。流れ制限オリフィス５０は、ＡＣＤ－ＣＰＲの除圧工程中にて、気流が患者の肺に入るのを妨害して負胸腔内圧を高めるように、作動する。その圧迫工程中には、流れ制限オリフィス５０は、患者の肺に空気が存在するのを制限することにより、患者の胸の胸腔圧力を高めるように、作動する。

【００７４】

図９は、本発明に従って患者の肺に気流が入るのを妨害する代表的な実施形態を例示している。図示しているように、装置５１は、換気バッグ２８を含み、これは、流入弁２４および呼気弁２２により、顔面マスク５２に連結されている。顔面マスク５２は、換気バッグ２８と連結して示されているものの、顔面マスク５２は、単独で、または換気バッグと連結して、使用できる。空気が患者の肺から出て換気バッグ２８に流れるのを防止するために、流入弁２４と呼気弁２２との間には、一方向魚口弁３７または任意の他の種類の一方向弁がある。換気バッグ２８はまた、装置５１に空気を流入させる一方向換気弁２６を含む。その代表的な実施形態は、図３に関連して述べたような第一代替実施形態の類似の様式で、作動する。しかしながら、気管内チューブ３６を患者の気道に挿入する代わりに、顔面マスク５２は、患者の口および鼻を覆って配置される。患者の顔に換気マスク５２を固定するために、患者の頭の周りはまた、顔面絆創膏５４（図示せず）で包まれ得る。

【００７５】

装置５１は、好ましくは、例えば、患者の舌により、患者の気道が閉塞されるのを防止するために、経口気道装置（図示せず）に関連して、使用される。この経口気道装置は、患者の舌が後方に滑って気道を閉塞しないように使用される任意の装置であり得る。好ましくは、この経口気道装置は、曲げられ、プラスチック材料から作製され、装置５１に装着され得るか装着され得ない。

【００７６】

ＡＣＤ－ＣＰＲの除圧工程中にて、空気は、閾値流入弁２４を通って患者の肺に入るのを阻止され、それにより、負胸腔内圧が高まる。その圧迫工程中にて、空気は、呼気弁２２を通って、患者の肺から吐出できる。また、患者は、ＡＣＤ－ＣＰＲ中にて、換気バッグ２８を手で絞ることにより、人工呼吸できる。結果的に、この好ましい実施形態は、負胸腔内圧を高めて、より多くの血液を末梢静脈血管系から胸に強制的に入れることにより、心肺循環を高めるように働く。

【００７７】

図１０Ａ～１０Ｃは、本発明の他の実施形態を示し、これは、その妨害工程を迂回することにより、患者を人工呼吸させる。この実施形態は、近位末端６２および遠位末端６４を備えた換気チューブ６０を含み、これは、患者に連結されている。換気チューブ６０は、一方向バイパス弁６６および一方向圧力応答性弁６８を有する。換気チューブ６０はまた、バイパス弁６６に装着した手動スイッチ７０を有し得、これは、換気チューブ６０の側面を通って伸長している。図１０Ａで示すように、スイッチ７０は、弁６８の閾値圧力を超えたときに一方向圧力応答性弁６８が開くように、閉鎖位置で設定され得る。この時点で、弁６８が開いて、患者を人工呼吸させる。図１０Ｂで示すように、一方向圧力応答性弁６８は、バイパス弁６６が開いて空気を患者に流すように、スイッチ７０を手で開放位置に置くことにより、完全に迂回され得る。図１０Ｃは、スイッチ７０を不活性モードにしたバイパス弁６６の操作を図示している。ここでは、換気を実行している救助者は、図１０Ａのような妨害工程による抵抗が加わることなしに、それを行い得る。その代わりに、バイパス弁６６は、チューブ６２の近位末端での圧力が大気圧（０ｍｍＨｇ）より高いとき、好ましくは、約０ｍｍＨｇ～５ｍｍＨｇの範囲にあるときにのみ、開く。患者の胸の除圧工程中にて、一方向弁６６は、大気圧を超えない限り、閉じたままになる。それゆえ、患者は、人工呼吸を実行している救助者がチューブ６２の近位末端での圧力を大気圧より高くするときにのみ、人工呼吸される。一方向バイパス弁６６の機能は、当該技術分野で公知の多くの異なる閾値弁設計により、果たされ得る。

【００７８】

本発明の他の局面では、代表的な弁システムは、患者を十分に人工呼吸しつつ、ＣＰＲの除圧段階中に負胸腔内圧の持続時間および程度を高める。この弁システムは、空気の流れが患者の胸に入るのを妨害または阻止することにより、除圧中での胸の胸腔内圧の急速な平衡を遅くするのに使用される。このようにして胸腔内圧を低くすると、大きな環状灌流圧が得られ、それゆえ、さらに多くの血液を胸郭に入れる。この弁システムは、心肺循環を改善するために胸腔内圧を意図的に操縦する種々のＣＰＲ方法で使用でき、これらには、「ベスト」ＣＰＲ、Ｈｅｉｍｌｉｃｈ換気システムを組み込んだＣＰＲ、イントラポーズド腹腔圧迫－除圧ＣＰＲ、標準手動ＣＰＲなどが挙げられ、ＡＣＤ－ＣＰＲと併用すると、最も有用となる。

【００７９】

図１１～１５を参照すると、弁システム１００の代表的な実施形態が概略的に示されている。弁システム１００は、ハウジング１０１を含み、これは、上流領域１０２および下流領域１０４を有する。上流領域１０２と下流領域１０４との間には、ダイアフラム１０６が保持されている。ダイアフラム１０６は、好ましくは、可撓性膜またはエラストマー膜であり、これは、下流領域１０４の上に保持され、患者を人工呼吸しているときに上流領域１０２で正圧（すなわち、大気圧より高い圧力）が発生したとき以外、下流領域１０４の圧力が上流領域１０２の圧力未満のとき、空気が上流領域１０２から下流領域１０４に流れるのを阻止する。弁システム１００は、さらに、弁１０８を含み、これは、プラグ１１０を有する。以下でさらに詳細に記述するように、弁１０８は、開いたときに患者を人工呼吸するように、含まれている。弁１０８は、軸方向並進運動により、手で開くことができるか、または下流領域１０４の圧力が閾値量に達するかそれを超えるとき、自動的に開くことができる。上流領域１０２には、吸気開口部１１２および排気開口部１１４が含まれる。空気は、ハウジング１０１から排気開口部１１４を通って排出されている間、吸気開口部１１２を通って、ハウジング１０１内に送達される。吸気開口部１１２と排気開口部１１４との間には、アコーディオン弁１１６、魚口弁などが設けられる。以下でさらに詳細に記述するように、アコーディオン弁１１６は、患者を人工呼吸しているとき、吸気開口部１１２に注入された空気が排気開口部１１４を出ていくのを防止するのに使用される。ハウジング１０１に注入された空気を濾過するために、フィルター１１７が設けられる。必要に応じて、過剰の体液および空気媒介病原体がシステム１００に入るのを防止するために、下流領域１０４には、フィルター１１９を設けることができる。

【００８０】

患者の胸を圧迫している間の弁システム１００の操作は、図１１で図示している。患者の胸を圧迫するとき、空気は、患者の肺から、下流領域１０４に強制的に入る。下流領域１０４に強制的に入った空気は、ダイアフラム１０６に向かい、そのダイアフラムを大気圧領域１１８に強制的に入れる。下流領域１０４にある空気は、次いで、逃されて上流領域１０２に入り、この場所で、排気開口部１１４を通って排気される。必要に応じて、ダイアフラム１０６は、下流領域１０４内の圧力が約２ｃｍH_2O以上、さらに好ましくは、約２ｃｍH_2O～４ｃｍH_2Oとなるまで、大気圧領域１１８に入らないように、曲げることができる。

【００８１】

患者の胸を除圧（または静止）している間の弁システム１００の操作は、図１２で図示している。患者の胸を能動的に持ち上げる（またはその自体に拡張させる）とき、空気は、下流領域１０４から、患者の肺に引き入れられ、それにより、下流領域１０４での圧力を低下させる。領域１０２、１０４間で得られる圧力差は、ダイアフラム１０６を下流領域１０４上に保持して、空気が上流領域１０２から下流領域１０４へと流れるのを防止する。このようにして、空気は、患者の胸の除圧中にて、患者の肺に流入するのが阻止され、それにより、胸腔内圧を低くして、環状灌流圧力を高め、さらに多くの静脈血を胸郭に入れる。

【００８２】

弁システム１００を使用して患者に人工呼吸を行う種々の方法は、図１３～１５で描写している。図１３は、閾値量の負胸腔内圧に達した後、患者の胸の除圧中に、下流領域１０４に入り患者の肺に向かう気流を図示している。この様式での人工呼吸は、弁システム１００が少なくとも閾値量の胸腔内圧を発生させて心臓および肺への血流を高めるのに使用できる点で、有利である。一旦、このような圧力に達すると、一部の空気は、患者の肺に流れて、患者を人工呼吸する。

【００８３】

弁１０８を閾値弁に構成することにより、閾値量の胸腔内圧に達したとき、空気は、下流領域１０４に入ることができる。弁１０８は、種々の様式で構成でき、主な機能は、閾値量の胸腔内圧に達したとき、弁１０８が空気に下流領域１０４に流入させることにある。これは、好ましくは、下流領域１０４の圧力が閾値量に達するかそれを超えたとき、プラグ１１０が曲がって上流領域１０２と下流領域１０４との間に開口部１２６を設けるように、プラグ１１０を一方向で可撓性に構成することにより、達成される。プラグ１１０が曲がると、空気は、低圧上流領域１０２から下流領域１０４および患者の肺へと流れる。従って、プラグ１１０は、一方向弁として作用し、閾値量に達したとき、上流領域１０２から下流領域１０４へと空気を流すが、下流領域１０４から上流領域１０２へは空気を流さない。好ましくは、プラグ１１０は、下流領域１０４内の圧力が約０ｃｍH_2O～５０ｃｍH_2O、さらに好ましくは、約１０ｃｍH_2O～４０ｃｍH_2O、さらに好ましくは、約１５ｃｍH_2O～２０ｃｍH_2Oの範囲のとき、曲がって開く。あるいは、弁１０８が開いたとき、弁１０８は、外気から直接的に下流領域１０４に空気が入るように、下流領域１０４に設置できる。それは、可撓性プラグとして示しているものの、他の種類の弁配置が使用され得ることが分かる。例えば、プラグ１１０は、図１６Ａに関連して記述した様式と類似の様式で、バネがこの弁を開く力に負胸腔内圧が打ち勝つまで、開口部１２６を閉じるバネ偏向弁で置き換えることができる。

【００８４】

上流領域１０２に空気を注入することにより患者を人工呼吸することは、図１４で図示されている。吸気開口部１１２を通って空気を注入するとき、空気は、アコーディオン弁１１６に入り、弁１１６を壁１２０に押し付け、壁１２０にある穴１２２を覆って、排気開口部１１４を通る気流を防止する。アコーディオン弁１１６を閉じるとき、空気は、弁１１６の壁１２４を貫流し、上流領域１０２に入る。あるいは、アコーディオン弁１１６に代えて、魚口弁が使用できる。この空気を上流領域１０２に注入すると、上流領域１０２内の圧力は、大気圧領域１１８の圧力より高くなり、ダイアフラム１０６を大気圧領域１

１８に入れる。上流領域１０２と下流領域１０４との間では、開口部が作り出され、空気を、上流領域１０４に流入させ、患者の肺に入れる。好ましくは、患者は、胸を５回圧迫するごとに１回、さらに好ましくは、２人の救助者を使って、胸を１５回圧迫するごとに約２回、吸気開口部１１２に空気を注入することにより、手動で人工呼吸される。同様に、患者の人工呼吸は、バネ偏向弁が位置している同じポート（例えば、図１６Ａの弁１６０）を通って、行うことができる。

【００８５】

自発的な循環に戻ったときの弁システム１００の構成は、図１５で図示されている。患者の循環が回復したとき、弁１０８は、弁１０８を並進運動することにより手で開かれ、アパーチャ１２６からプラグ１１０が除去される。次いで、上流領域１０２および下流領域１０４は、領域１０２、１０４の各々の間で自由に空気が交換できるように、連絡して設置される。弁１０８は、上流領域１０２を通って伸長して図示されているものの、その代わりに、下流領域１０４に沿ったいずれの場所でも設置できる。

【００８６】

弁１０８は、圧力応答性弁（図１３を参照）として、手動操作弁（図１５）として、またはその両方として、構成できる。さらに、弁システム１００には、あるいは、弁１０８と類似の２個以上の弁を備え付けることができる。例えば、１個の弁は、ハウジング１０１にて、並進運動不可能に保持でき、圧力応答性プラグ１１０を備え付け、他の弁は、並進運動可能に取り付けられる。このようにして、可撓性プラグを備えた弁は、圧力応答性弁として機能し、その閾値圧力に達したときに開くのに対して、並進運動可能弁は、自発的な循環に到達した後に手動操作と連絡して、領域１０２、１０４を設置するように機能する。

【００８７】

図１６Ａおよび１６Ｂを参照して、弁システム１３０の代表的に実施形態が描写されている。弁システム１３０は、ハウジング１３２から構成され、これは、吸気開口部１３４、排気開口部１３６および送達開口部１３８を有する。排気開口部１３６には、一方向弁１４０が含まれ、これにより、空気は、ハウジング１３２から、排気開口部１３６を流出する。吸気開口部１３４に注入された空気が排気開口部１３６から出ていくのを防止するために、吸気開口部１３４と排気開口部１３６との間には、アコーディオン弁１４０が設けられる。好ましくは、吸気開口部１３４は、呼吸装置（例えば、換気バッグ（ＡＭＢＵバッグを含めて）、換気装置、システム１３０による口移し呼吸用のマウスピースまたはポートなど）に装着可能に構成される。送達開口部１３８は、好ましくは、気管内チューブまたは他の気道チューブ、密封顔面マスク、喉頭マスクなどに連結するように構成される。

【００８８】

ハウジング１３２内には、上流領域１４２、下流領域１４４および大気圧領域１４６がある。ダイアフラム１４８は、下流領域１４４から上流領域１４２を分離している。ダイアフラム１４８は、好ましくは、エラストマー材料から作製される。ハウジング１３２は、好ましくは、下流領域１４４では、円筒形であり、ダイアフラム１４８は、周囲条件では、このシリンダーの上に載っている。患者の胸の除圧中にて、下流領域１４４の圧力が低下すると、ダイアフラム１４８は、このシリンダーの末端に引き付けられて、上流領域１４２と下流領域１４４との間の空気交換を防止する。患者の胸の圧迫中には、空気は、患者の胸から排出される空気が排気開口部１３６を通って排出できるように、下流領域１４４に強制的に入り、ダイアフラム１４８を大気圧領域１４６に押し付ける。

【００８９】

図１６Ｂで最もよく示されているように、弁システム１３０は、さらに、開窓マウント１５０を備え付けている。１局面では、開窓マウント１５０は、下流領域１４４の上でダイアフラム１４８を保持するマウントとして、働く。開窓マウント１５０は、さらに、大気圧領域１４６を提供する。マウント１５０には、マウント１５０を通って空気を交換させるために、開窓マウント１５２が設けられている。マウント１５０には、デフレクター１

５４が含まれ、これは、開窓マウント１５０の周りの空気をそらせる。ハウジング１３２は、気流を領域１４２と１４４の間に向けるために、種々の他のデフレクター１５６が設けられている。ハウジング１３２には、ハウジング１３２に注入された空気を濾過するために、フィルター１５８が設けられている。必要に応じて、過剰の体液がシステム１３０に入るのを防止するために、フィルター１５９を設けることができる。

【００９０】

弁システム１３０は、さらに、下流領域１４４にて、閾値弁１６０を含む。下流領域１４４内の圧力が閾値量より低いとき、閾値弁１６０が開いて、空気を下流領域１４４に流入させる。閾値弁１６０は、バネ１６２を含み、これは、閾値量に達したときに伸長するように構成されている。あるいは、閾値弁１６０は、弁１１０と同じように構成できる。所望の胸腔内圧に達したかそれを超えたときに空気を下流領域１４４にいれる他の構成もまた、提供できる。例えば、さらに別の例では、ダイアフラム１４８は、閾値量の胸腔内圧に達したときに空気を患者の肺に流入させる閾値弁として作用するように、構成できる。ダイアフラム１４８は、エラストマー材料からダイアフラム１４８を作製することにより、そしてその周囲の近くに少なくとも１個の穴を設けることにより、閾値弁として作ることができる。このダイアフラムが、下流領域１４４を形成するシリンダーに載っているとき、この穴は、このシリンダーの周囲を超えて、上流領域１４２に位置付けられる。下流領域１４４に真空が作られるにつれて、このダイアフラムは、穴がこのシリンダーに上を伸展されて、上流領域１４２および下流領域１４４の両方と重なり合うまで、下流領域に引っ張られる。このようにして、下流領域１４４で閾値圧力に達すると、領域１４２と１４４の間で、流体経路が設けられる。閾値弁１１１の他の代替物は、図１６Ｃで図示されている。弁１１１は、下流領域１４４内に取り付けられた旋回軸であり、バネ１１３により、偏って閉じられる。下流領域１４４内で閾値圧力に達したとき、バネ１１３が加圧され、空気は、下流領域１４４に引き入れられる。

【００９１】

図１６Ａに戻ると、閾値弁１６０は、必要に応じて、上流領域１４２にあるハウジング１３２内に設けることができる。閾値弁１６０には、さらに、必要に応じて、オン／オフスイッチを備え付けることができ、これは、自発的な循環が達成されたとき、弁１６０を開く。このようにして、救助者は、弁１６０を開いて、必要なときに、患者の肺に自由に空気交換を行うことができる。図１６Ｃで示した１代替例では、マウント１５０は、患者の蘇生が成功すると下流領域１４４からダイアフラム１４８を持ち上げるために垂直に上昇できるように、ハウジング１３２内に滑り可能に取り付けることができ、それにより、患者への自由な気流が得られる。マウント１５０は、伸長部材１３３（これは、ハウジング１３２内で滑り可能である）にマウント１５０を装着することにより、ハウジング１３２内に滑り可能に取り付けることができる。部材１３３は、好ましくは、吸気および排気開口部１３４および１３６を含む。このようにして、部材１３３を並進運動してダイアフラム１４８を開閉するとき、簡単な握り面が設けられる。もし、ダイアフラム１４８がまた、先に記述したような閾値弁として作られるなら、弁１０８または１１１は、必要ではなくなり得る。

【００９２】

ハウジング１３２は、好都合には、いくつかの部品で作製でき、これらは、種々の連結点で、共に連結される。このようにして、このハウジングは、他の装置への連結、修理、洗浄などのために、分解できる。例えば、このハウジングのうち、吸気開口部１３４、弁１４０および排気開口部１３６を有する部分を取り外し可能に連結するために、１つの連結点は、好都合には、フィルター１５８の近くに設けることができる。あるいは、洗浄のためにマウント１５０に簡単にアクセスするために、連結点は、マウント１５０の近くに設けることができる。

【００９３】

弁システム１３０は、好都合には、ＣＰＲ処置で有用な種々の装置と合体できる。例えば、弁システム１３０は、換気バッグ（例えば、ＡＭＢＵバッグ）内に合体できる。あるい

は、弁システム１３０は、呼吸バックおよび気管内チューブまたは他の気道チューブの両方を有する呼吸回路の一部として、このバッグとチューブとの間に位置付けられた弁システム１３０と共に、含めることができる。さらに他の代替例では、弁システム１３０は、気管内チューブだけに加えることができる。あるいは、この弁システムは、マスク、経口咽頭気道、喉頭マスクまたは他の換気装置に組み入れることができる。

【００９４】

ある場合には、患者の人工呼吸は、図１６Ｄで示すように、閾値弁１６０によって行われ得る。このような場合、全ての人工呼吸が閾値弁１６０によって起こり得るので、吸気開口部および弁１４０は、任意である。もちろん、人工呼吸は、両方の経路を通って、行うことができる。さらに、弁システム１３０の状況で示したように、本明細書中で記述した他の実施形態は、この閾値弁と接合される圧力源を含むように改良され得ることが分かる。

【００９５】

図１６Ｄで示すように、ハウジング１３２には、一定長の配管３０２により、加圧気体（例えば、O_2）のタンク３００が接合される。このようにして、閾値弁１６０の裏側には、加圧気体が供給され得る。閾値弁１６０に供給される圧力が弁１６０を開くのに必要な圧力未満であるように、その圧力を調節するために、タンク３００には、調節器３０４が接合される。例えば、負胸腔内圧が－１４ｃｍH_2Oを超えたとき、もし、患者に呼吸気体を供給するなら、その起動弁圧は、－１４ｃｍH_2Oに設定され得、タンク３００からの気体の圧力は、－１４ｃｍH_2O未満に設定され得る。このようにして、弁１６０があまりに早く開くことはない。ある場合には、調節器３０４はまた、弁１６０を通る気体の流速を調節するのに、使用され得る。

【００９６】

弁１６０にタンク３００を接合することにより、呼吸気体は、先に記述したように、弁１６０を開いたとき、負胸腔内圧の低下が原因で、下流領域１４４に引き入れられる。このようにして、患者の胸が除圧されるたびに、患者には、より多くの呼吸気体が供給される。このアプローチにより、各能動救助者人工呼吸で静脈が胸に戻るのを妨害する正圧人工呼吸とは異なり、負圧人工呼吸が可能となる。このアプローチを使う負圧人工呼吸により、ＣＰＲ中にて、十分な酸素化および最大の静脈血還流量が得られる。タンク３００はまた、一旦、誘発圧力に達すると、酸素を供給するように機能し得る。

【００９７】

図１７を参照すると、代替弁システム１６４が描写されている。弁システム１６４は、概略的に示されており、事実上、弁システム１００と同じように作動するが、その差は、弁システム１６４がダイアフラムとしてボールまたは球体部材１６６を含むことにある。患者の胸の除圧中にて、下流領域１６８での圧力は、上流領域１７０での圧力より低く、それにより、ボール１６６は、下流領域１６８の上で引っ張られる。弁システム１６４には、先に記述したように、下流領域１６８にて、閾値圧力に達するかそれを超えるまで、患者の胸の圧迫中にて、ボール１６６を下流領域１６８上で保持するために、必要に応じて、バネ１７２または他の付勢機構を備え付けることができる。

【００９８】

さて、図１８を参照すると、心肺蘇生を実行するときに有用な他の代表的な装置２００が描写されている。以下でさらに詳細に記述するように、装置２００の１つの重要な特徴は、心肺蘇生を実行するとき、患者の肺に定期的に空気を供給するために、その装置を患者の気道に連動させ得ることにある。このようにして、患者は、典型的には、口移し蘇生法を実行するときのように、救助者の肺からの呼吸気体ではなく、空気（または他の気体（例えば、O_2））で人工呼吸され得る。

【００９９】

装置２００は、顔面マスク２０２およびハウジング２０４（これは、界面２０６にて、顔面マスク２０２に操作可能に装着されている）を含む。ハウジング２０４は、上部領域２０８および下部領域２１０を含む。下部領域２１０は、圧力応答性弁システム２１２を含

み、これは、閾値負胸腔内圧を超えるまで、患者の肺に気体が流入するのを防止するために、本明細書中で先に記述した実施形態と類似の様式で、作動する。この時点で、圧力応答性弁システム２１２は、本明細書中で先に記述した様式と類似の様式で、患者の肺に気体を流入させる。下部領域２１０は、さらに、魚口弁２１４および一方向流出弁２１６を含む。弁２１４および２１６は、共に作動して、患者の肺から排出された気体を、矢印２１８で示すように、装置２００から出す。特に、患者の肺から気体を強制的に出すとき、魚口弁２１４が閉じられ、排出された気体は、装置２００から、弁２１６を通って、逃げる。

【０１００】

上部領域２０８は、マウスピース２１９を含み、これにより、救助者は、（通常のＣＰＲと類似して）患者を人工呼吸しようとするとき、装置２００に吹き込むことが可能となる。上部領域２０８は、空気チャンバ２２０を規定し、これは、室内空気を保持し、約２００ｍｌ～約８００ｍｌの容量を有する。チャンバ２００はまた、酸素源に連結され得る。上部領域２０８内には、ダイアフラム２２２およびバネ２２４が配置される。この構造を使って、救助者がマウスピース２１９に空気を吹き込むとき、バネ２２４は、ダイアフラム２２２が下方に移動するにつれて、圧縮される。次に、空気チャンバ２２０内に保持された空気または酸素は、圧縮されて、それにより、弁システム２１２を強制的に通って、顔面マスク２０２に入る。このようにして、救助者からの空気（呼吸気体ではなく）は、救助者がマウスピース２１９に吹き込むことにより口移し蘇生法を実行するとき、患者に供給される。

【０１０１】

上部領域２０８は、さらに、一方向流入弁２２６を含み、これにより、気体チャンバ２２０は、人工呼吸に続いて室内空気を補充できるようになる。特に、バネ２２４が拡大するにつれて、弁２２６は、開いて、バネ２２４により、チャンバ２３０で生じた負圧が原因で、室内空気がチャンバ２３０を満たす。流入弁２２６はまた、閾値負胸腔内圧を超えたときに開き、それにより、圧力応答性弁システム２１２が開く。このようにして、流入弁２２６はまた、通気機構としても働き、負胸腔内圧限界を超えたとき、空気をハウジング２０４に排出させる。

【０１０２】

それゆえ、装置２００により、救助者は、単に、マウスピース２１９に吹き込むことにより、室内空気で患者を人工呼吸できるようになる。もちろん、救助者がマウスピース２１９に吹き込んだとき、このような気体が患者に供給され得るように、空気チャンバ２２０内には、他の望ましい気体が入れられ得ることが分かる。例えば、チャンバ２２０内には、一定容量のO_2が入れられ得る。

【０１０３】

先に記述したように、本発明の１局面は、一定の負胸腔内圧に達するかそれを超えるまで、呼吸気体が肺に入るのを防止する性能にある。本発明の１局面は、呼吸気体が肺に流れる圧力を変える性能にある。ある場合には、これは、この圧力応答性流入弁の起動圧力またはクラッキング圧力を変えることにより、達成され得る。しかしながら、この圧力応答性流入弁のクラッキング圧力を変えることなく、呼吸気体を肺に流す圧力を変えるために、他の機構が設けられ得る。それゆえ、呼吸気体を肺に流す圧力を変える機構は、圧力応答性流入弁、この弁システムの他の弁に組み込まれ得るか、または弁システム全体の別の一部であり得る。

【０１０４】

このようなシステムは、起動圧力が約０ｃｍH_2O～約－３０ｃｍH_2Oの間で変え得るように、設計され得る。さらに、このような弁システムは、単独で自発的に呼吸している患者、または標準手動閉鎖－胸ＣＰＲを受けている患者で、使用され得る。このような弁システムはまた、他の蘇生技術および／または装置と併用され得、これには、例えば、ＡＣＤ、ＣＰＲ、Ｖｅｓｔ　ＣＰＲなどが挙げられる。ある場合には、このような弁システムは、心停止から蘇生させる目的のためだけでなく、静脈還流を促進することにより血圧

を高める目的のために、横隔膜刺激装置と併用され得る。蘇生の目的のための横隔膜刺激装置用の代表的なシステムおよび技術は、米国特許出願第０９／０９５，９１６号（０６／１１／９８に出願）；第０９／１９７，２８６号（１１／２０／９８に出願）；第０９／３１５，３９６号（０５／２０／９９に出願）；および第０９／５３３，８８０号（０３／２２／００に出願）で記述されており、それらの内容は、本明細書中で参考として援用されている。さらに別の例として、このような弁システムは、心停止状態の患者、低血圧の患者および右心不全やショック状態の患者の心臓への中枢血液還流を向上させるのに使用され得る。

【０１０５】

呼吸気体が肺に流れる程度を変えるために、種々の機構が使用され得る。例えば、このような機構は、機械的または電子的であり得るか、機械部品および電子部品の種々の組合せを含み得、また、例えば、蘇生に使用する装置と圧力応答性流入弁との間の電子連絡により、より大きいシステム内で調節され得る。このような機構はまた、気体のインライン測定（例えば、末端換気CO_2、平均分換気、ピーク負吸気圧力などの測定）に基づいて、調節可能であり得る。

【０１０６】

図１９を参照すると、調節可能圧力応答性流入弁４０２を有する弁システム４００の１実施形態が描写されている。弁システム４００は、概略的に示されており、本明細書中で記述した実施形態のいずれかと類似して、構成され得る。そういうものとして、弁システム４００が患者の気道と連動するとき、患者は、弁システム４００を通って、自由に吐出し得る。吸入しようとするとき、またはＣＰＲの除圧中にて、呼吸気体は、閾値起動圧力に達するまで、肺に入るのが妨げられる。このような時点では、呼吸気体は、他の実施形態で先に記述した様式と類似の様式で、流入弁４０２を通って、肺に流れることが可能となる。

【０１０７】

流入弁４０２は、張力調整ノブ４０４を含み、これは、救助者により、流入弁４０２の閾値起動圧力を調整するために回転され得、このことは、図２０～２２を参照して、さらに詳細に記述されている。図２０で最もよく示されているように、流入弁４０２は、外部ハウジング４０６を含み、これは、一組のトラッキングチャンネル４０８を有する（図２２を参照）。外部ハウジング４０６は、Ｏリングハウジング４１０を保持するように構成され、これは、上部セグメント４１２および下部セグメント４１４を有する。上部セグメント４１２と下部セグメント４１４との間には、Ｏリング４１６が配置されている。上部セグメント４１２は、さらに、一組のトラッキングレール４１８を含み、これらは、トラッキングチャンネル４０８内で、滑る。張力バネ４２０は、張力調整ノブ４０４と上部セグメント４１２との間にあり、Ｏリング４１６を外部ハウジング４０６に曲げる。Ｏリング４１６が外部ハウジング４０６に偏ると、この弁は、閉鎖位置にあり、この場所では、呼吸気体は、換気ポート４２２を通って患者の肺に入るのを妨げられる。負胸腔内圧が流入弁４０２の閾値起動圧力を満たすかそれを超えたとき、バネ４２０の張力が打ち勝って、Ｏリング４１６は、外部ハウジング４０６から分離される。この時点で、呼吸気体は、換気ポート４２２に自由に流れ込み、患者の肺に入る。

【０１０８】

流入弁４０２の起動圧力を変えるために、ノブ４０４は、回転されて、ネジ付きボルト４２６に沿って、ネジ付きナット４２４を前進または後退し、これは、順に、上部セグメント４１２に接合される。そうする際に、バネ４２０の張力が変えられ、流入弁４０２の起動圧力を変える。それゆえ、ノブ４０４は、救助者が単にノブ４０４を回転することにより起動圧力を調整する便利な方法を提供する。図示していないものの、弁システム４００内には、圧力ゲージが配置され得、また、この負胸腔内圧を表示するために、表示装置が設けられ得る。このようにして、救助者は、弁システム４００内で発生した圧力を容易に視覚化し得、ノブ４０４を調整して、呼吸気体が肺に流れる圧力を変え得る。

【０１０９】

本発明の他の特徴は、安全機構の使用にあり、これは、救助者が弁システムを操作モードにするまで、その弁システムを通って呼吸気体を患者に自由に流す。一旦、操作モードになると、この弁システムは、そのモードのまま永久にまたは限られた時間にわたってとどまり、それから、この安全機構は、その初期状態に戻り、この場合、呼吸気体は、肺に自由に流れ得る。ある実施形態では、これは、救助者が起動するまで、（吸気流れに対して何ら妨害なしで）、この安全機構が圧力応答性流入弁を開放位置で維持させることにより、達成され得る。起動は、種々の様式（例えば、その弁システムへの呼吸気体の注入（例えば、患者を人工呼吸するとき）、弁システムにあるボタンまたはスイッチの操作など）で、達成され得る。

【０１１０】

このような安全機構の１つの有利な点は、この圧力応答性流入弁からの抵抗が全くなしに、この弁システムを通って、患者が自由に呼吸できる（患者は、自発的に呼吸するか自発的に呼吸し始めていると仮定して）ことを保証することにある。一旦、救助者がＣＰＲの実行のような処置を開始する準備ができると、この弁システムは、操作モードにされ、この場合、呼吸気体流れは、その閾値負胸腔内圧が満たされるかそれを超えるまで、この圧力応答性流入弁を通って肺に入るのが妨げられる。本明細書中で記述した他の実施形態と同様に、呼吸気体はまた、この弁システムを通って、患者の肺に注入され得、それにより、この圧力応答性流入弁を迂回する。

【０１１１】

この安全機構は、純粋な機械装置、純粋な電子装置として作動し得るか、機械部品および電子部品の種々の組合せを含み得る。この弁システムを操作モードにする１つの方法は、センサを使用して、呼吸気体が換気ポートを通って弁システムに注入されたときを感知することによる。このセンサからの信号は、次いで、この弁システム内の換気通路を閉じるのに使用され得る。ある場合には、この換気通路は、この圧力応答性流入弁を通って伸長され得る。この通路を閉じるには、その流入弁が単に閉じられる。ある実施形態では、もし、一定時間内に救助者を手配できないなら、この安全機構が使用され得、患者の肺に呼吸気体が自由に流れ得るように、この弁システムをその操作モードから取り出し得る。

【０１１２】

さて、図２３および２４を参照すると、このような安全機能を備えた弁システム４３０の１実施形態が記述されている。この構成は、患者の肺への気流を妨害する手段を有するように、先に記述した弁システムのいずれかと直列で、使用され得る。それゆえ、弁システム４３０は、本明細書中で記述した他の弁システムと類似の部品を有するように作製され得るか、それらと併用され得ることが分かり、これらは、論述を簡単にするために、図示していない。弁システム４３０は、ハウジング４３２を含み、これは、ハウジング４３２が安全換気ポート４３４を含むこと以外は、本明細書中で記述した他の弁システムのハウジングと類似し得、このポートにより、図２３で点線で示すように、呼吸気体が患者の肺に流れ得るように、ハウジング４３２を通って呼吸気体を流入させる。それゆえ、図２３で示すように、弁システム４３０は、受動モードであり、この場合、患者は、ハウジング４３２を通って、自由に呼吸し得る。

【０１１３】

弁システム４３０は、さらに、安全機構４３６を含み、これは、救助者が起動するまで、換気ポート４３４を開いて維持するように作動可能である。起動したとき、安全機構４３６は、換気ポート４３４を閉じて、弁システム４３０を操作モードにし、この場合、呼吸気体は、他の実施形態で記述した様式と類似の様式で、閾値負胸腔内圧を満たすかそれを超えるまで、圧力応答性流入弁を通って肺に達するのが妨げられる。

【０１１４】

安全機構４３６は、電子空気フローセンサ４３８を含み、これは、制御回路網４４０に電気的に接続されている。次に、制御回路網４４０は、弁ストップ４４４を有するマイクロソレノイド４４２に電気的に接続される。これらの電子部品に電力を供給するために、電池４４５が使用される。救助者が弁システム４３０を操作モードにする準備ができると、

救助者は、（例えば、換気ポート（図示せず）に空気を吹き込むか加圧気体を注入することにより）、ハウジング４３２に呼吸気体を注入する。この呼吸気体が、ハウジング４３２を通って、患者の肺に流れるとき、センサ４３８が移動して、スイッチを引き、制御回路網４４０に電気信号を送る。制御回路網４４０は、次いで、ソレノイド４４２に信号を送り、ストップ４４４を移動して、それにより、この弁を閉じ、それゆえ、安全換気ポート４３４を通って患者に気流が入るのを防止する。このような状態は、図２４で図示しており、この場合、弁システム４３０は、操作モードにある。この時点で、自発的に呼吸している患者は、圧力応答性流入弁によって呼吸する必要がある。呼吸していない患者については、呼吸気体は、閾値負胸腔内圧を超えるまで、ＣＰＲの実行中にて、肺に達するのが妨げられ、それを超えた時点で、呼吸気体は、他の実施形態で記述した様式と類似の様式で、この流入弁を通って流れ、患者の肺に入り得る。もし、一定時間後、センサ４３８が救助者により起動されないなら、制御回路網４４０は、ソレノイド４４２を操作して弁システム４３０を操作モードから外すように構成され得、この場合、呼吸気体は、安全換気ポート４３４を貫流し得る。

【０１１５】

ある実施形態では、本発明の弁システムは、ほぼ全ての機械要素を有する安全機構を組み込み得る。弁システム４８０のこのような１つの実施形態は、図２５～３３および図３６～４０で図示されている。弁システム４８０は、ハウジング４８２を含み、これは、種々の部品を収容し、これらの部品は、本明細書中で技術した他の実施形態と類似し得る。そういうものとして、ハウジング４８２は、換気ポート４８４および出口開口部４８６を含む。弁システム４８０は、さらに、圧力応答性流入弁４８８を含み、これは、他の実施形態で記述した様式と類似の様式で、一定負胸腔内圧レベルを満たすかそれを超えるまで、呼吸気体が患者の肺に流れるのを防止する。弁システム４８０は、さらに、安全機構４９０を含み、これは、弁システム４８０を操作モードに作動させるまで、呼吸気体を患者の肺に自由に流し、この場合、圧力応答性流入弁４８８は、呼吸気体が肺に流されるときに制御する。以下でさらに詳細に記述するように、安全機構４９０はまた、流入弁４９２を含む。ある実施形態では、流入弁４９２は、圧力応答性流入弁として構成され得、それにより、流入弁４８８が必要ではなくなる。

【０１１６】

安全機構４９０は、さらに、フローセンサ４９４を含み、これは、フラップの形状である。フローセンサ４９４は、旋回軸４９６の周りで旋回して、カム機構４９８を移動し、それにより、車輪５００を回転させる。図２５および３０では、弁システム４８０は、非活動状態にあり、この場合、フローセンサ４９４は、いまだに起動されていない。呼吸気体をハウジング４８２に向けるとき、フローセンサ４９４は、先に記述したように、旋回軸４９６の周りで旋回して、図２７、２８および３０で図示されているように、車輪５００を回転させる。

【０１１７】

図２９で最もよく示されているように、車輪５００は、ギアシステム５０２に連結され、これは、反跳バネ５０４および弁カム５０６を有する。反跳バネ５０４は、図２５および３０で図示した位置にカム５０６を曲げるのに使用され、この場合、弁４９２は、開放位置にある。気体がハウジング４８２を通るとき、フローセンサ４９４は、移動して、車輪５００を回転させ、それにより、ギアシステム５０２を作動する。そうする際に、カム５０６は、図２７および３１で示す位置に回転され、その場合、弁４９２は、閉鎖位置に移動する。一定時間（例えば、約１０～２０秒）が経過した後、ギアシステム５０２および反跳バネ５０４が作動して、弁４９２を開く。

【０１１８】

図３０および３１で最もよく示されているように、弁４９２は、弁ハウジング５０８を含み、ここで、弁シャフト５１０が保持され、これは、Ｏリング５１２を保持する、弁４９２を図３１で図示したように閉鎖位置に曲げるために、ハウジング５０８とシャフト５１０上の突出部５１６との間には、張力バネ５１４が位置付けられる。この弁システムのハ

ウジングに救助者が気体を注入するとき、カム５０６は、図３０で示した位置に移動し、この場合、それは、シャフト５１０と噛み合い、ハウジング５０８からＯリング５１２を外して、弁４９２を開放位置に置く。この開放位置では、呼吸気体は、弁４９２を通って自由に流れ、ハウジング４８２に流入し、この場合、それらは、出口開口部４８６を通って、患者の肺に流れ得る。

【０１１９】

本発明は、さらに、安全機能を有するシステムを提供し、これにより、患者は、所定範囲まで吸入でき、呼吸気体が肺に流れるのを妨害または阻止するのに使用される機構を解除して、それにより、そのシステムをタイマーがリセットするまで、または救助者がシステムをリセットするまで、抵抗のない吸気が可能となる。このシステムと併用され得る安全弁６００の１実施形態は、図３２および３３で図示されている。安全弁６００は、本明細書中で記述した圧力応答性弁（例えば、弁１０８、１６０および１１１）の交換品として、使用され得る。弁６００は、ハウジング６０２を含み、これは、スリット膜６０４で覆われる。弁部材６０６は、図３２で示す閉鎖位置にバネ６０８で曲げられている。この閉鎖位置では、ウェッジ６１０（これは、好都合には、識別を簡単にするために、着色され得る）は、膜６０４のスリット上に伸長する。そういうものとして、ウェッジ６１０は、弁６００が閉鎖位置にあることを救助者に示す視覚表示器として働く。患者と連動して閉鎖位置にあるとき、呼吸気体は、他の実施形態で記述した様式と類似の様式で、その負胸腔内圧が閾値を満たすかそれを超えるまで、肺に流れるのが妨げられ得る。このような時点では、弁部材６０６にあるシール６１２は、ハウジング６０２にあるストップ６１４から離れて移動し、呼吸気体を肺に流す。次いで、バネ６０８は、弁部材６０６を閉鎖位置に押し戻す。

【０１２０】

もし、あえぎながら息をし始めるなら、患者が作り出した負圧の量は、図３３で示すように、膜６０４にあるスリットを通ってウェッジ６１０が引っ張られるのに十分に遠くに、バネ６０８を圧縮する。ウェッジ６１０は、次いで、弁６００を開放位置で保持し、この場合、気体は、肺に自由に流れ得る。救助者は、ウェッジ６１０がもはや見えないことを認めることにより、弁６００が開放位置にあることを容易に決定し得る。救助者は、単に、プルタブ６１６を引っ張ってウェッジ６１０を膜６０４に戻すことにより、任意の時点で、弁６００をリセットし得る。

【０１２１】

本明細書中で記述したシステムで使用され得る安全弁６２０の他の実施形態は、図３４および３５で図示されている。弁６２０は、ハウジング６２２を含み、これは、ストップ６２４を有する。ハウジング内には、マイクロソレノイド６２６が配置され、このソレノイドは、アーム６２８（これは、棒磁石６２９を有する）および視覚表示器６３０（反対端）を含む。棒磁石６２９から間隔を置いて、極が反対の他の棒磁石６３２が配置され、これは、シール６３６を有する弁部材６３４と接合されている。ハウジング６２２には、通常開放接触ストリップスイッチ６３８が接合され、弁部材６３４は、導電性ストリップ６４０を含む。ストリップ６４０とストップ６２４との間には、バネ６４２が配置されている。

【０１２２】

図３４は、閉鎖位置、すなわち、起動位置での弁６２０を図示している。ＣＰＲ中にて、シール６３６は、負胸腔内圧が閾値を超えたとき、ストップ６２４から離れ、呼吸気体を肺に流す。次いで、弁６２０は、閉鎖位置に戻る。もし、患者があえいでいるなら、弁部材６３４は、図３５で示した位置に移動し、この場合、導電性ストリップ６４０は、スイッチ６３８と接触する。（通常のＣＰＲ中では、弁部材６３４は、この接触が起こる程には十分に遠くに移動しない）。これは、この開放回路を閉じ、ソレノイド６２６を起動して、アーム６２８を伸長し、そして制御回路網および電池区画６４４内のタイミング回路を誘発する。磁石６２９および６３２は、極が反対であり、ソレノイド６２６が起動されている限り、弁を、図３５で示す開放非起動位置のままにする。このようにして、患者は

、弁６２０により、自由に呼吸し続け得る。極が反対の磁石で示されているものの、磁石は、ソレノイドアーム（これは、プランジャーとして作用して、弁部材６３４と物理的に接触し得る）で置き換えられ得、それにより、この弁を開放した非起動状態で保持することが分かる。救助者は、表示器６３０が後退してもはや見えないのを認めることにより、弁６２０が開放位置にあることに気づき得る。

【０１２３】

弁６２０は、自動／手動スイッチ６４６を含み得、これは、自動モードで設定され得る。このモードでは、このタイミング回路は、ソレノイド６２６を自動的に停止状態にし、予め設定したタイミング間隔が終了した後、弁６２０を、図３４で示した閉鎖起動位置に戻す。もし、スイッチ６４６が手動に設定されるなら、図３５で示すように、ソレノイド６２６は、起動したままになり、弁６２０は、開放した非起動状態のままとなり、この場合、呼吸気体は、肺に自由に流れ得る。弁６２０は、手動リセットスイッチ６４８を加圧することにより、救助者がソレノイド６２６を手動でリセットするまで、開いたままになる。救助者は、表示器６３０（これは、現在、開いている）を観察することにより、弁６２０が閉じて起動していることに気づき得る。

【０１２４】

図３６および３７は、安全弁６５０のさらに他の実施形態を図示しており、これは、本明細書中で記述したシステムと併用され得る。弁６５０は、ハウジング６５２を含み、これは、ストップ６５４を有する。ハウジング６５２内には、弁部材６５６が配置され、これは、シール６５８を有し、このシールは、図３６で示す閉鎖位置、すなわち、起動位置にあるとき、ストップ６５４と接触して、弁６５０に気体が流れるのを防止する。閉鎖位置では、バネ６６０は、負胸腔内圧が閾値を超えるまで、シール６５８をストップ６５４に曲げ、シール６５８は、ストップ６５４から離れて、呼吸気体を肺に流す。一旦、負胸腔内圧が閾値より低くなると、弁６５０は、閉鎖位置に戻る。

【０１２５】

患者があえいでいるとき、生じる力は、一対のバネ装填ピン６６２が、図３７で示すように、弁部材６５６上のロッキングピンレセプタクル６６６の溝部６６４内に引っ掛かるように、弁部材６５６を移動するのに十分に大きい。このようにして、弁６５０は、開放位置、すなわち、非起動位置に固定され、これは、患者のあえぎにより、生じる。ピン６６２が溝６６４内に移動するにつれて、ピン６６２の末端は、ハウジング６５２内に移動して、救助者に、この弁が非起動状態であることを指示する。好都合には、ピン６６２の末端は、救助者がよく見えるように、着色され得る。弁６５０を再起動するために、救助者は、弁部材６５６にあるプルタブ６６８を上方に引っ張り得る。これは、ピン６６２を溝６６４から解除し、その弁を図３６の閉鎖位置に跳ね返らせる。

【０１２６】

さて、図３８～４０を参照すると、改良型弁６５０が示されており、これは、弁システム６７０に組み込まれ、このシステムは、ＣＰＲ処置中での患者の肺への気流を調節するために、本明細書中で記述する他の弁システム実施形態と類似の様式で、患者の気道に接合され得る。説明し易くするために、弁６５０の同じ要素は、図３８～４０を記述する際に、同じ参照番号を使用する。弁６５０を使用すると、患者は、最初のあえぎが起こった後、気道抵抗なしで、あえぎつつ呼吸できるようになる。あるいは、弁６５０は、最初は、非起動位置に設定され得、弁システム６７０を通って人工呼吸すると、または、もし、患者があえいでいて弁６５０を開いて停止状態にロックするなら、引き続いて人工呼吸すると、起動状態になる。

【０１２７】

弁６５０は、システムハウジング６７２に組み込まれ、これは、入口末端６７４および出口末端６７６を有する。好都合なことに、患者の人工呼吸は、他の実施形態と類似の換気源を使用して、入口末端６７４を通って起こり得る。出口末端６７６は、界面と接合され得、これにより、システム６７０は、患者の気道と連動され得る。ハウジング６７２内には、一方向膜弁６７８が配置され、これは、ポート６８０から間隔を置いて配置されてい

る。図３８では、システム６７０は、静止状態にあり、この場合、あえぎまたは人工呼吸は、起こらない。ＣＰＲを実行すると、胸は、圧迫され、患者から強制的に出てくる空気は、ポート６８０を通って、弁６７８を貫流する。患者の胸を除圧している間、弁膜６７８は、ポート６８０に移動して、負胸腔内圧が高まるにつれて、この弁を閉じる。もし、閾値圧力を超えると、弁６５０は、開いて、呼吸気体は、弁６５０を通った後、開口部６７６を貫流する。弁６５０は、次いで、閉鎖位置に戻り、そのサイクルが繰り返される。もし、弁システム６７０が患者の気道に接合されて患者があえぎ自分で呼吸し始めるなら、弁システム６７０は、呼吸気体の交換が起こり得るように、患者が抵抗なしの気道経路を通って呼吸し得るように、図３９で示した構成に自動的に調整する。患者があえいで呼吸し始めたとき、弁６７８は、閉じて、負胸腔内圧により、弁６５０が開き、図３７に関連して先に記述した様式と類似の様式で、所定位置で固定される。このようにして、弁６５０は、救助者がプルタブ６６８を引っ張ってリセットするまで、開いた非起動状態のままになる。

【０１２８】

弁６５０を閉鎖位置、すなわち、起動位置に戻す他の様式は、図４０で示したように、入口６７４により患者を人工呼吸することによる。呼吸気体を入口６７４に注入すると、注入した気体は、弁６７８を通って、ポート６８０を貫流し、この場所で、出口６７６から出て、患者に入る。そうする際に、気体の流れは、換気フラップ６８２を移動させ、これは、順に、アーム６８４を移動させ、それは、ウェッジ６８２に接合される。ウェッジ６８６を移動すると、アーム６８８の側方移動が起こり、これは、リセットウェッジ６９０に連結される。ウェッジ６９０は、上方移動ランプ６９２の上部に載る。アーム６８８が側方に移動するにつれて、ウェッジ６９０は、ランプ６９２を持ち上げ、プルタブ６６８と接する。そうする際に、弁部材６５６は、ピン６６２が溝部６６４から引っ張られるまで引き上げられ、弁６５０は、バネ６６０の力により、閉鎖起動位置に戻る。次いで、リセットバネ６９４は、換気フラップ６８６をリセットして、その本来の位置に戻し、ウェッジ６９０は、もし引き続いて必要なら、弁６５０が閉鎖位置に戻ってリセットされ得るように、ランプ６９２を滑り落とす。弁６５０は、他のあえぎまたは自発呼吸が起こるまで、閉鎖起動位置の状態にとどまる。

【０１２９】

図４１は、弁システム７００の他の実施形態を図示しており、これは、ＣＰＲ中にて、患者の胸内の圧力を表示するように、構成されている。弁システム７００は、本明細書中で記述された弁システムのいずれかと類似して構成され得る。それゆえ、説明し易くするために、弁システム７００は、簡単にしか記述しない。弁システム７００は、ハウジング７０２を含み、これは、入口７０４および出口７０６を有する。他の実施形態で記述した様式と類似の様式で、患者の胸の除圧中にて、ハウジング７０２への気体の流入を制御するために、圧力応答性弁７０８が使用される。ハウジング７０２内の圧力（これは、患者の胸内の圧力に対応している）を測定し表示するために、圧力ゲージ７１０が設けられる。このようにして、圧力ゲージ７１０は、救助者に直ちにフィードバックするために使用され得、また、胸の圧迫および／または除圧が適切に実行されているかどうかを決定するためのガイドとして、使用され得る。

【０１３０】

圧力感知ポート７１２は、チューブ７１４に連結され、これは、圧力感知制御ユニット７１６に連結される。このようにして、圧力の変化は、胸の圧迫中または除圧中のいずれかで検出され得、一定数が検出された後、換気装置７２０を使用して患者を自動的に人工呼吸するために、換気制御回路網７１８を誘発する計数回路として、作用し得る。

【０１３１】

あるいは、デジタル制御ユニットが使用され得、これは、胸内の圧力だけでなく、人工呼吸間の圧迫数を表示する。このような構成を使って、感知ポート７１２は、圧力の情報を空気で伝達する。そういうものとして、ハウジング７０２の圧力ゲージは、必要ではない。

【０１３２】
本発明の弁システムはまた、ショックを処理するのに使用され得る。ショックは、好都合には、危険な低血圧として、定義され得、これは、治療しないと、死または障害を引き起こし得る。本発明の技術を使用して治療し得るショックの種類には、血液損失、熱射病、血液迷走神経失神（通例の気絶）、溺水、薬剤過剰服用、心臓麻痺、右心不全、宇宙飛行後の地球への帰還、敗血症、心外膜液、タンポナーゼなどが挙げられるが、これらに限定されない。さらに、本発明の弁システムは、頚動脈心肺反射感度（これは、（呼息で胸腔内圧を低下させることにより）、血圧を制御する）を変えるのに使用され得る。
【０１３３】
ショックを治療するのに使用される弁は、患者が呼吸している間、患者への呼吸気体の流入を完全に妨げるかそれに対する抵抗を与えるように、構成される。呼吸気体の流れを完全に妨げる弁システムについては、このような弁は、閾値負胸腔内圧に達した後に開く圧力応答性弁として、構成され得る。呼吸気体の流入に対して単に抵抗を与える弁システムもまた、一旦、所望の負胸腔内圧に達すると、流れに対する抵抗が少なくされ得るように、可変であり得る。さらに、本発明の弁は、手動または自動のいずれかで、可変でありように構成され得る。流れに対する抵抗が変わる範囲は、１個以上のセンサで測定される生理学的パラメータに基づき得、これらは、治療するヒトに関連している。そういうものとして、流れに対する抵抗は、ヒトの生理学的パラメータが許容できる範囲内に入るように、変えられ得る。測定され得る生理学的パラメータの例には、負胸腔内圧、呼吸数、末端換気CO_2、呼吸終末陽圧、血圧、酸素飽和、組織CO_2含量などが挙げられるが、これらに限定されない。もし、自動化システムを使用するなら、このようなセンサは、制御装置に接合され得、この制御装置は、その流入弁の抵抗または起動圧力を変える１個以上の機構を制御するのに、使用される。
【０１３４】
さて、図４２および４３を参照すると、ショック状態のヒトを治療するのに使用され得るシステム８００の１実施形態が記述されている。システム８００は、ハウジング８０２を含み、これは、顔面マスク８０４に接合されている。ハウジング８０２は、吸気開窓ポート８０６を含み、この場合、吸気された気体は、ハウジング８０２に入ることができる。ポート８０６の下には、スロット付き気道抵抗機構８０８が配置され、これは、ポート８０６を通ってハウジング８０２に流入する呼吸気体を完全に妨げるかそれに対して抵抗を与えるのに、使用され得る。図４６Ａおよび４６Ｂでは、抵抗機構８０８も図示されており、これは、スロット付き部材８１０およびスロット付きプレート８１２から作成され得る。スロット付き部材８１０は、図４６Ｂで図示しているように、プレート８１２に対して移動可能であり、プレート８１２内のスロットを部分的または完全に覆う。このようにして、吸気された気体の流れに対する抵抗は、単に、スロット付きプレート８１２をスロット付き部材８１０に移動することにより、高められ得る。図４２で最もよく示されているように、シャフト８１６を移動するモーター８１４は、流れ抵抗を変えるために、スロット付き部材８１０をスロット付き部材８１２の上に並進運動させるのに使用され得る。必要に応じて、抵抗機構８０８の下には、フィルター８１８が配置され得る。
【０１３５】
システム８００は、さらに、一方向弁８２０を含み、これは、吐出された気体が抵抗機構８０８を通って戻るのを妨げる。一方向弁８２０の上流には、酸素ポート８２２が配置され、吸気中にて、ヒトに酸素を供給する。システム８００は、さらに、他の一方向弁８２４を含み、これは、ヒトが息を吐き出して吐出気体が吐出ポート８２６を通ってハウジング８０２を出ていくとき、開く。
【０１３６】
システム８００はまた、１個以上のセンサ８２８を含み、これらは、種々の生理学的パラメータ（例えば、流速、患者の内圧、末端換気CO_2など）を測定する。これらのセンサは、回路板または制御装置８３０に接合され得、これは、感知したパラメータに基づいて、モーター８１４の操作を変えるように、プログラム化され得る。このようにして、測定

したパラメータは、単に、自動化様式で、抵抗機構８０８により得られる抵抗を制御することにより、所望範囲内で保たれ得る。図示していないものの、回路板８３０には、他のセンサもまた接合され得るが、必ずしも、ハウジング８０２またはマスク８０４に組み込まれ得ないことが分かる。システム８００はまた、電池８３２を含み得、これは、システム８００の種々の電気部品に電力を供給する。システム８００を起動するために、制御ボタン８３４もまた、使用され得る。

【０１３７】

必要に応じて、呼気管腔が気道抵抗機構により決して完全には閉塞されないことを保証するために、気道が常に呼気を起こす僅かな開口部を有し得る様式で、成形ストップが製作され得る。他の選択肢として、この弁および感知システムは、他の気道装置に装着され得、これには、気管内チューブ、喉頭マスクなどが挙げられる。

【０１３８】

図４４は、マスク８０４をヒトに接合してヒトが吸入するときのシステム８００を図示している。図示しているように、吸気された気体は、抵抗機構８０８を通り、これは、流れ抵抗を高めるように、作動されている。必要に応じて、酸素ポート８２２を通って、ヒトには、酸素もまた供給され得る。図４５は、ヒトが息を吐出するときを図示している。図示しているように、吐出された気体は、一方向弁８２４を通り、吐出ポート８２６を通る。

【０１３９】

システム８００は、特定の種類の弁と共に示されているものの、先に記述したもののいずれかを含めた種々の流入弁が使用され得ることが分かる。さらに、図４７～５３は、吸気を試みている間に流れを妨げるかそれに対する抵抗を高めるのに使用され得る他の種類の流入弁を図示している。さらに、これらの流入弁のいずれかは、その流れ抵抗を変えるように弁を作動するのに使用され得る他の機構と接合され得る。このようにして、制御装置は、その抵抗の量を自動的に制御するのに使用され得る。さらに、この制御装置は、ヒトの種々の生理学的パラメータを測定して抵抗量を変えるのにそれらのパラメータを使用することにより、これらのパラメータを所望範囲内に保ち得るように、１個以上のセンサに接合され得る。

【０１４０】

図４７Ａおよび４７Ｂは、流入弁８３６を図示しており、これは、気道８３８および可動ディスク８４０を含む。ディスク８４０は、流れ抵抗を高めるように示されているので、任意の種類の機械的機構により移動されて、気道８３８を閉塞し得る。

【０１４１】

図４８Ａおよび４８Ｂは、流入弁８４２の他の実施形態を図示しており、これは、気道８４４および回転可能ディスク８４６を含む。図４８Ｂで示すように、ディスク８４６は、気道８４４を通る流れ抵抗の量を高めるために、回転され得る。

【０１４２】

図４９Ａおよび４９Ｂは、流入弁８４８を図示しており、これは、気道８５０を含み、この気道は、一対のプレート８５２と８５４の間に位置付けられる。図４９Ｂで示すように、プレート８５４を移動して気道８５０を圧縮するのに、回転可能カム８５６が使用され得、それにより、流れ抵抗を高める。好都合なことに、カム８５６は、モーター８５８により回転され得、これは、順に、先に記述した様式と類似の様式で、制御装置により、制御され得る。

【０１４３】

図５０Ａおよび５０Ｂは、流入弁８６０のさらに他の実施形態を図示しており、これは、気道８６２を含み、この気道は、２枚のプレート８６４と８６６の間に位置付けられている。次に、プレート８６６は、ネジ付きシャフト８６８と接合され、これは、ステッピングモーター８７０により前後に移動可能であり、このモーターはまた、制御装置に接合され得る。作動中、ステッピングモーター８７０は、図５０Ｂで示すように、気道８６２に対してプレート８６６を移動するのに使用され、その流れ抵抗を高める。

【０１４４】
図５１Ａおよび５１Ｂは、流入弁８７２を図示しており、これは、気道８７４を含み、この気道は、一対のプレート８７６と８７８の間に位置付けられる。これらのプレートは、カリパス機構８８０に接合され、これは、順に、親ネジ８８２に接合され、この親ネジは、ステッピングモーター８８４によって可動である。このように、ステッピングモーター８８４は、順に、カリパス機構８８０を操作して図５１Ｂで示すような気道８７４を絞って流れ抵抗を増大させるために使用され得る。
【０１４５】
図５２Ａおよび５２Ｂは、流入弁８８６を図示しており、これは、虹彩閉塞機構８８８を含む。図５２Ｂで示すように、虹彩閉塞機構８８８は、気道の大きさを小さくするために作動され得、それにより、流れ抵抗を高める。
【０１４６】
図５３Ａおよび５３Ｂは、流入弁８９０の他の実施形態を図示しており、これは、気道８９２および回転可能アーム８９４を含み、このアームは、順に、ステッピングモーターに接合され得る。図５３Ｂで図示しているように、アーム８９４は、気道８９２の上を回転可能であり、流れ抵抗を高める。
【０１４７】
図５４Ａ～５４Ｃは、ショック状態のヒトを治療する代表的な１方法を図示している。そのプロセスは、工程９００で開始し、この場合、その治療システムは、患者の気道に接合され得る。例えば、図４２に関連して先に記述したシステムは、患者の顔に接合され得る。その出力は、工程９０２で示すようにオンにされ、気道抵抗機構は、工程９０４で示すように、開放位置に設定され得る。この治療機構は、予め設定した種々の生理学的パラメータを含み得、これらは、最初は、ヒトの状態を決定するのに使用され得る。工程９０８では、工程９０６で先に読み取った生理学的パラメータに基づいて、呼吸が感知されたかどうかに関する決定が行われる。もし、呼吸が感知されなかったら、そのプロセスは、工程９０４に戻されて、この気道抵抗機構が開放位置にあることを保証する。
【０１４８】
もし、呼吸が感知されたなら、そのプロセスは、工程９１０に進行し、この場合、その気道抵抗機構は、プリセット位置に設定される。この位置は、工程９０６で感知された初期生理学的パラメータに基づき得る。さらに、その気道抵抗は、手動で設定され得るか、制御装置（これは、測定した生理学的パラメータに基づいて、種々のプリセット位置でプログラム化される）を使用して、自動的に行われ得る。そのプロセスは、次いで、工程９１２に進行し、この場合、これらの生理学的パラメータは、その負胸腔内圧が患者の吸入として許容できるかどうかを決定するために、評価される。もし、この負胸腔内圧が低すぎるなら、そのプロセスは、工程９１４に進行し、この場合、その気道抵抗は、高められる。これは、制御装置（これは、この気道抵抗機構を操作して、その気道抵抗を高める）を使用して、自動化様式で、作動する。この抵抗が高まったとき、そのプロセスは、工程９１６に進行し、この場合、センサが使用されて、呼吸が感知されているかどうかを決定する。もし、感知されていないなら、このプロセスは、工程９０４に戻り、この場合、その気道抵抗は、その初期位置または完全に開いた位置に戻され、そのプロセスは、継続する。
【０１４９】
もし、この負胸腔内圧が高すぎるなら、そのプロセスは、工程９１８に進行し、この場合、気道抵抗が低下する。次いで、工程９２０にて、呼吸測定が行われ、呼吸が感知されているかどうかを決定する。もし、感知されていないなら、そのプロセスは、工程９０４に戻り、この場合、この気道抵抗機構は、開かれ得る。もし、工程９２０または工程９１６のいずれかで、呼吸が感知されたなら、そのプロセスは、工程９１２に戻り、この場合、その負胸腔内圧に関する他の検査が行われる。一旦、この負胸腔内圧が許容できるようになると、このプロセスは、工程９２２に進行し、この場合、その呼吸数が評価される。もし、この呼吸数が許容できなければ、そのプロセスは、工程９２４に進行し、この場合、

その気道抵抗が低下する。工程９２６にて、呼吸が感知されているかどうかの評価が行われる。呼吸が感知されていないなら、そのプロセスは、工程９０４に戻り、この場合、この気道抵抗機構が開かれ得る。もし、呼吸が感知されたなら、そのプロセスは、工程９２２に戻り、この場合、この呼吸数の他の評価が行われる。もし、この呼吸数が許容できるなら、そのプロセスは、工程９２８に進行し、末端換気CO_2に関する評価が行われる。もし、低すぎるなら、工程９３０で示すように、気道抵抗が高められ、患者が工程９３２で呼吸しているかどうかに関して、他の評価が行われる。もし、呼吸していないなら、そのプロセスは、工程９０４に戻り、この場合、この気道抵抗機構が開かれる。この末端換気CO_2が高すぎるなら、そのプロセスは、工程９３４に進行し、この場合、その気道抵抗は、低下し、患者の呼吸は、再度、工程９３６で感知される。もし、呼吸が感知されないなら、そのプロセスは、工程９０４に戻り、この場合、この気道抵抗機構が開かれる。もし、工程９３２または９３６のいずれかで、呼吸が感知されたなら、そのプロセスは、工程９２８に戻り、この場合、末端換気CO_2が再評価される。一旦、許容できるようになると、そのプロセスは、工程９３８に進行し、この場合、その酸素飽和が評価される。もし、低すぎるなら、工程９４０で示すように、その気道抵抗が低下され得、工程９４２で示すように、ヒトが呼吸をしているかどうかに関して、評価が行われる。もし、呼吸していないなら、そのプロセスは、工程９０４に戻り、この気道抵抗機構が開かれる。もし、その酸素飽和が許容できるなら、そのプロセスは、その負胸腔内圧、呼吸数、末端換気CO_2および酸素飽和が引き続いてモニターされ得るように、また、その気道抵抗がこれらのパラメータに基づいて変性され得るように、工程９１２に進行する。

【０１５０】

それゆえ、図５４Ａ～５４Ｃで示した方法により、種々の生理学的パラメータが継続的にモニターでき、ショックに罹った患者を治療するとき、これらのパラメータが許容範囲内にとどまるように、吸気流れに対する抵抗が変えられる。さらに、先に記述したように、負胸腔内圧の増大により、高まった血流が右心に戻り、患者の血圧を高める。これらの種々の生理学的パラメータを特定の順序でモニターして示されているものの、それらのパラメータは、他の順序でもモニターされ得ることが分かる。さらに、ショック状態の患者を治療するとき、その患者が安定な状態のままであることを保証するために、他の生理学的パラメータが測定され得る。必要に応じて、図５４Ａ～５４Ｃの方法はまた、患者の正末端呼気圧力を評価するのに使用され得る。さらに、その呼気ポートには、類似の気道抵抗機構が適用され得、この呼気ポートの気道抵抗は、感知したパラメータに基づいて、変えられ得る。例えば、この呼気圧力は、肺胞崩壊（無気肺）（これは、その負胸腔内圧が長時間にわたって低すぎるときに、起こり得る）の阻止を助けるように、変えられ得る。

【０１５１】

前述の発明は、理解し易くする目的で、図解および例によって、ある程度詳細に記述されているものの、添付の特許請求の範囲の範囲内で、ある種の変更および改良が実行され得ることは、明らかである。

【図面の簡単な説明】

【０１５２】

【図１】図１は、本発明に従って、患者の胸を圧迫し除圧するとき、時間の経過に伴う胸腔圧力の変化を図示しているグラフである。

【図２Ａ】図２Ａは、本発明に従って患者の胸を圧迫するとき、換気回路を通る気流を図示している概略図である。

【図２Ｂ】図２Ｂは、本発明に従って患者の胸を除圧するとき、換気回路を通る気流を図示している概略図である。

【図３】図３は、本発明に従って患者の肺に入る気流を妨害する装置の第一代替実施形態の概略図である。

【図４Ａ】図４Ａは、本発明に従って患者の肺に入る気流を妨害する装置の第二代替実施形態の概略図である。

【図４Ｂ】図４Ｂは、共通吸入／吐出ポートを備えた図４Ａの装置の概略図である。

【図５Ａ】図５Ａは、本発明に従って気流を妨害する装置で使用される一方向弁の概略図である。
【図５Ｂ】図５Ｂは、ＡＣＤ－ＣＰＲが終わった後に開いた状態で保持されている図５Ａの一方向弁の概略図である。
【図５Ｃ】図５Ｃは、本発明によるチューブで閾値圧力が存在するまで閉じている一方向弁の概略図である。
【図６Ａ】図６Ａは、本発明に従って使用されるバネ偏向流入弁およびバネ偏向呼気弁の概略図である。
【図６Ｂ】図６Ｂは、空気の流出中でのこれらの弁の操作を示す図６Ａの概略図である。
【図６Ｃ】図６Ｃは、空気の流入中でのこれらの弁の操作を示す図６Ａの概略図である。
【図７】図７は、本発明に従って流入弁および呼気弁として使用されるように両側で曲げたバネである単一弁の概略図である。
【図８】図８は、本発明に従って流れ制限装置と併用される流れ制限オリフィスの概略図である。
【図９】図９は、本発明に従って患者の肺に入る気流を妨害する装置の代表的な実施形態の概略図である。
【図１０Ａ】図１０Ａは、バイパス弁を通る定期的な患者の人工呼吸を可能にする本発明の他の実施形態を図示している概略図である。
【図１０Ｂ】図１０Ｂは、バイパス弁を通る定期的な患者の人工呼吸を可能にする本発明の他の実施形態を図示している概略図である。
【図１０Ｃ】図１０Ｃは、バイパス弁を通る定期的な患者の人工呼吸を可能にする本発明の他の実施形態を図示している概略図である。
【図１１】図１１は、本発明に従って患者の肺に入る気流を調節する代表的な弁システムの概略図である。この弁システムは、患者の胸の圧迫中にて患者の胸から排出される空気と共に、示されている。
【図１２】図１２は、図１１の弁システムを図示しており、これは、患者の胸の除圧または静止中である。
【図１３】図１３は、図１１の弁システムを図示しており、これは、圧力応答性弁を備え、この圧力応答性弁は、患者の胸における負胸腔内圧が患者の胸の除圧中に閾値量を超えたときに、開く。
【図１４】図１４は、図１１の弁システムを図示しており、これは、ダイアフラムを備え、このダイアフラムは、患者を人工呼吸するとき、ハウジングに空気を注入中に開く。
【図１５】図１５は、図１１の弁システムを図示しており、これは、手動で作動可能な弁を備え、この弁は、自然な循環に戻ると、患者の肺に空気を入れるように開く。
【図１６Ａ】図１６Ａは、本発明による代表的な弁システムの切取側面図である。
【図１６Ｂ】図１６Ｂは、図１６Ａの弁システムのデフレクターおよび開窓マウントの上面図である。
【図１６Ｃ】図１６Ｃは、図１６Ａの弁システムの代替実施形態である。
【図１６Ｄ】図１６Ｄは、図１６Ａの弁システムを図示しており、これは、加圧気体源を備え、この気体源は、本発明による圧力応答性弁に接合されている。
【図１７】図１７は、ダイアフラムとしてボールを有する弁システムの代替実施形態の概略図である。
【図１８】図１８は、患者の肺への気流を妨害し、人工呼吸が必要なとき、患者の肺に空気を供給する装置の概略図である。
【図１９】図１９は、本発明による調整可能圧力応答性弁を有する弁システムの１実施形態の側面図である。
【図２０】図２０は、図１９の調整可能圧力応答性弁の断面側面図である。
【図２１】図２１は、図２０の弁の上面図である。
【図２２】図２２は、図２１の弁を図示しており、これは、キャップが除去されている。
【図２３】図２３は、弁システム用の安全機構の概略側面図であり、これにより、呼吸気

体は、本発明の換気通路を通って、患者の肺に自由に流れることができる。
【図２４】図２４は、図２３の安全機構を図示しており、これは、呼吸気体がその換気通路を貫流するのを防止するように、起動されている。
【図２５】図２５は、安全機構を一体化した弁システムの概略図であり、これにより、呼吸気体は、本発明による流入弁を通って、患者の肺に自由に流れることができる。
【図２６】図２６は、救助者が起動する前の図２５の安全機構のフローセンサおよびレバーアームを図示している。
【図２７】図２７は、その安全機構が救助者により起動されて流入弁を閉じたときの図２５の弁システムを図示している。
【図２８】図２８は、救助者が起動したときの図２６のフローセンサおよびレバーアームを図示している。
【図２９】図２９は、図２５の弁システムの末端図である。
【図３０】図３０は、開放位置にあるときの図２５の流入弁のさらに詳細な図である。
【図３１】図３１は、閉鎖位置にあるときの図３０の流入弁を図示している。
【図３２】図３２は、本発明に従って閉鎖位置で示した安全弁の１実施形態の側面概略図である。
【図３３】図３３は、開放位置にあるときの図３２の流入弁を図示している。
【図３４】図３４は、本発明に従って閉鎖位置で示した安全弁の他の実施形態の側面概略図である。
【図３５】図３５は、開放位置にあるときの図３４の安全弁を図示している。
【図３６】図３６は、本発明に従って閉鎖位置で示した安全弁のさらに他の実施形態の側面概略図である。
【図３７】図３７は、開放位置にあるときの図３６の安全弁を図示している。
【図３８】図３８は、本発明に従って閉鎖位置にある安全弁を有する弁システムの１実施形態の概略側面図である。
【図３９】図３９は、図３８の弁システムを図示しており、これは、その安全弁が患者のあえぎ中に開放位置に移動している。
【図４０】図４０は、図３８の弁システムを図示しており、これは、その安全弁を閉鎖位置に戻す人工呼吸中である。
【図４１】図４１は、弁システムの概略図であり、これは、本発明に従って、その弁システム内の圧力を測定する圧力ゲージを有する。
【図４２】図４２は、本発明に従ってショック状態にあって呼吸しているヒトを治療するシステムの１実施形態の断面概略図である。
【図４３】図４３は、図４２のシステムの上部概略図である。
【図４４】図４４は、ヒトが吸気しているときの図４２のシステムを図示している。
【図４５】図４５は、ヒトが吐出しているときの図４２のシステムを図示している。
【図４６Ａ】図４６Ａは、本発明による流入弁の１実施形態を図示している。
【図４６Ｂ】図４６Ｂは、流れ抵抗を高めたときの図４６Ａの流入弁を図示している。
【図４７Ａ】図４７Ａは、本発明による流入弁の他の実施形態を図示している。
【図４７Ｂ】図４７Ｂは、本発明に従って流れ抵抗を高めるようにディスクを移動したときの図４７Ａの流入弁を図示している。
【図４８Ａ】図４８Ａは、本発明による流入弁のさらに他の実施形態を図示している。
【図４８Ｂ】図４８Ｂは、本発明に従って流れ抵抗を高めるようにディスクを回転したときの図４８Ａの流入弁を図示している。
【図４９Ａ】図４９Ａは、本発明による流入弁のさらに他の実施形態を図示している。
【図４９Ｂ】図４９Ｂは、流れ抵抗を高めるように圧迫したときの図４９Ａの流入弁を図示している。
【図５０Ａ】図５０Ａは、本発明による流入弁のさらに他の実施形態を図示している。
【図５０Ｂ】図５０Ｂは、流れ抵抗を高めるように圧迫したときの図５０Ａの流入弁を図示している。

【図５１Ａ】図５１Ａは、本発明による流入弁のさらに他の実施形態を図示している。
【図５１Ｂ】図５１Ｂは、流れ抵抗を高めるように圧迫したときの図５１Ａの流入弁を図示している。
【図５２Ａ】図５２Ａは、本発明による流入弁のさらに他の実施形態を図示している。
【図５２Ｂ】図５２Ｂは、虹彩機構を図示しており、これは、図５２Ａの流入弁の流れ抵抗を高めるように作動されている。
【図５３Ａ】図５３Ａは、本発明による流入弁のさらに他の実施形態を図示している。
【図５３Ｂ】図５３Ｂは、流れ抵抗を高めるように旋回したときの図５３Ａの流入弁を図示している。
【図５４Ａ】図５４Ａは、本発明に従ってショックを治療する方法の１実施形態を図示している。
【図５４Ｂ】図５４Ｂは、本発明に従ってショックを治療する方法の１実施形態を図示している。
【図５４Ｃ】図５４Ｃは、本発明に従ってショックを治療する方法の１実施形態を図示している。

【図１】

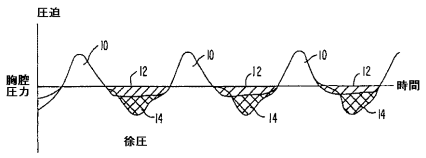


FIG. 1.

【図４Ｂ】

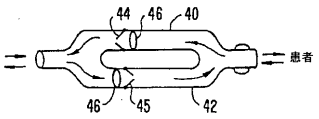


FIG. 4B.

【図６Ａ】

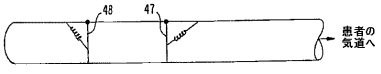


FIG. 6A.

【図６Ｂ】

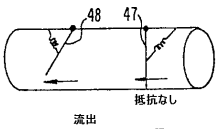


FIG. 6B.

【図６Ｃ】

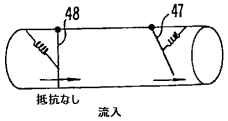


FIG. 6C.

【図１０Ａ】

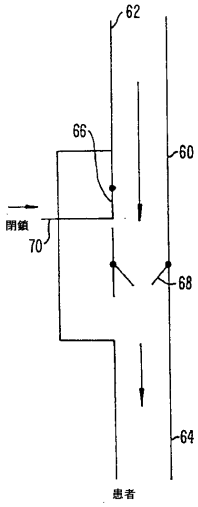


FIG. 10A.

【図１０Ｂ】

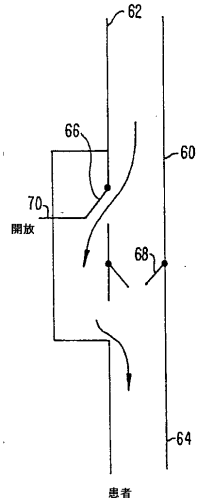


FIG. 10B.

【図１０Ｃ】

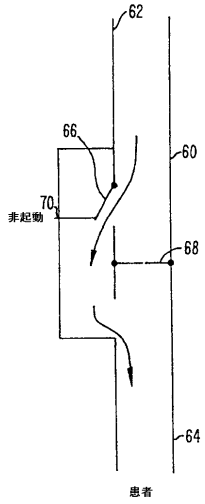


FIG. 10C.

【図１９】

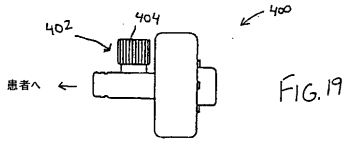


FIG.19

【図２３】

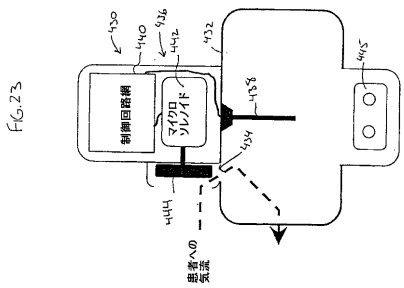


FIG.23

【図２４】

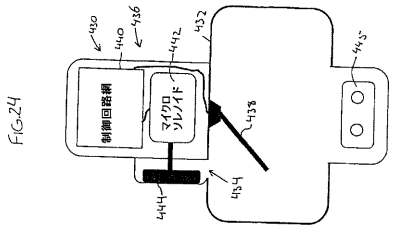


FIG.24

【図４１】

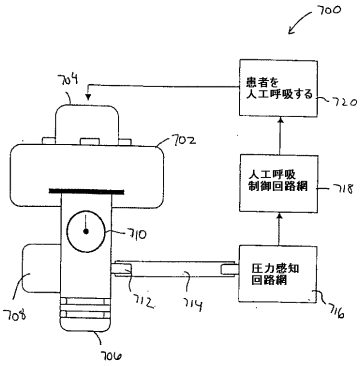


FIG.41

【図４４】

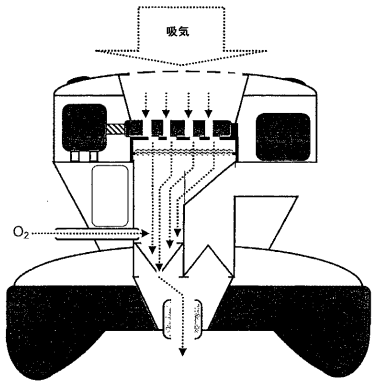


FIG.44

【図４５】

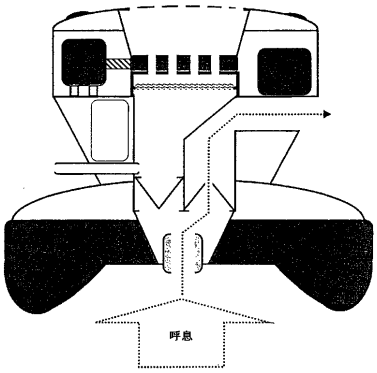
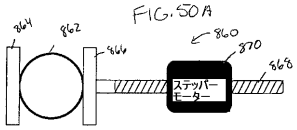


FIG.45

【図５０Ａ】

FIG.50A



【図５１Ａ】

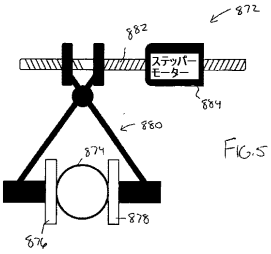
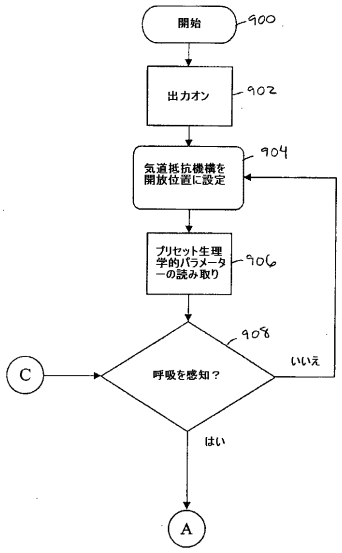


FIG.51A

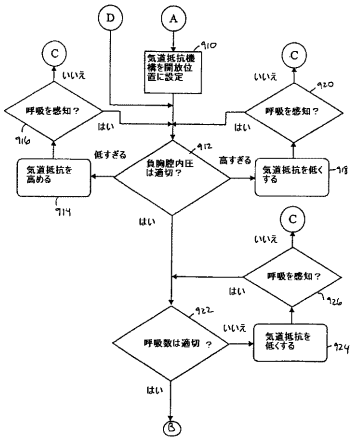
【図５４Ａ】

FIG.54A



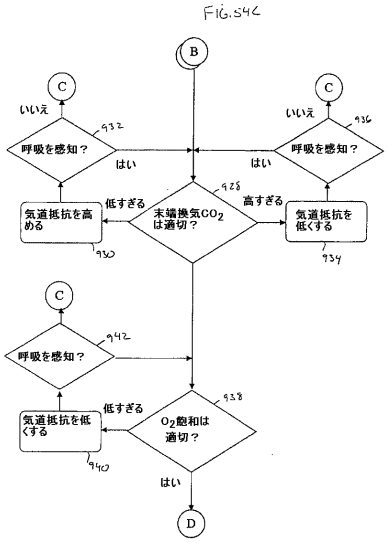
【図５４Ｂ】

FIG.54B



【図５４Ｃ】

FIG.54C



【国際公開パンフレット】

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 November 2002 (21.11.2002)

PCT

(10) International Publication Number
WO 02/092169 A1

(51) International Patent Classification⁷: A62B 9/02, 7/04, A61M 16/00, F16K 31/26

(21) International Application Number: PCT/US02/14039

(22) International Filing Date: 1 May 2002 (01.05.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/854,238 11 May 2001 (11.05.2001) US
10/ , 8 April 2002 (08.04.2002) US

(71) Applicant: CPRX LLC [US/US]; 4330 Upton Avenue South, Minneapolis, MN 55410 (US).

(72) Inventors: LURIE, Keith, G.; 4751 Girard Avenue South, Minneapolis, MN 55409 (US). ZIELINSKI, Todd, M.; 3549 43rd Ave. South, Minneapolis, MN 55406 (US).

(74) Agents: GIBBY, Darin, J. et al.; Townsend and Townsend and Crew LLP, Two Embarcadero Center, Eighth Floor, San Francisco, CA 94111-3834 (US).

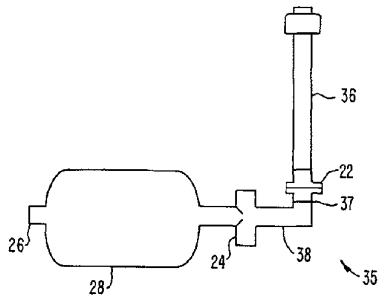
(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SHOCK TREATMENT SYSTEMS AND METHODS



(57) Abstract: According to the invention, methods and devices for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation are provided. According to one method, a pressure responsive inflow valve (24) is coupled to a patient's airway. Chest compressions and chest decompressions are performed. During chest decompression the inflow valve (24) prevents respiratory gases from entering the lungs until a certain negative intrathoracic pressure level is exceeded at which time the inflow valve (24) opens. In this way, the inflow valve (24) assists in increasing the magnitude and duration of negative intrathoracic pressure during decompression to enhance the amount of blood flow into the heart and lungs. Further, the patient is supplied with a pressurized respiratory gas through the inflow valve (24) when the inflow valve (24) opens to ventilate the patient.

WO 02/092169 A1

SHOCK TREATMENT SYSTEMS AND METHODS

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation in part application of U.S. Patent Application Serial No. 09/854,238, filed May 11, 2001, which is a continuation in part application of U.S. Patent Application Serial No. 09/546,252, filed April 10, 2000, which is a continuation of U.S. Patent Application No. 08/950,702, filed October 15, 1997 (now U.S. Patent No. 6,062,219), which is a continuation-in-part application of U.S. Patent Application Serial No. 08/403,009, filed March 10, 1995 (now U.S. Patent No. 5,692,498), which is a continuation-in-part application of U.S. Patent Application Serial No. 08/149,204, filed November 9, 1993 (now U.S. Patent No. 5,551,420), the disclosures of which are herein incorporated by reference.

BACKGROUND OF THE INVENTION

The present invention relates generally to devices and methods used in conjunction with cardiopulmonary resuscitation procedures. In particular, the present invention relates to devices and methods for increasing cardiopulmonary circulation in patients with severe low blood pressure or cardiac arrest.

Worldwide, sudden cardiac arrest is a major cause of death and is the result of a variety of circumstances, including heart disease and significant trauma. In the event of a cardiac arrest, several measures have been deemed to be essential in order to improve a patient's chance of survival. These measures must be taken as soon as possible to at least partially restore the patient's respiration and blood circulation. One common technique, developed approximately 40 years ago, is an external chest compression technique generally referred to as cardiopulmonary resuscitation (CPR). CPR techniques have remained largely unchanged over the past three decades.

With traditional CPR, pressure is applied to a patient's chest in order to increase intrathoracic pressure. An increase in intrathoracic pressure induces blood

movement from the region of the heart and lungs towards the peripheral arteries. Such pressure partially restores the patient's circulation. Traditional CPR is performed by actively compressing the chest by direct application of an external pressure to the chest. After active compression, the chest is allowed to expand by its natural elasticity which causes expansion of the patient's chest wall. This expansion allows some blood to enter the cardiac chambers of the heart. The procedure as described, however, is insufficient to ventilate the patient. Consequently, conventional CPR also requires periodic ventilation of the patient. This is commonly accomplished by mouth-to-mouth technique or by using positive-pressure devices, such as a self-inflating bag which relies on squeezing an elastic bag to deliver air via a mask, endotracheal tube or other artificial airway.

In order to increase cardiopulmonary circulation induced by chest compression, a technique referred to as active compression-decompression (ACD) has been developed. According to ACD techniques, the active compression phase of traditional CPR is enhanced by pressing an applicator body against the patient's chest to compress the chest. Such an applicator body is able to distribute and apply force substantially evenly over a portion of the patient's chest. More importantly, however, the applicator body is sealed against the patient's chest so that it may be lifted to actively expand the patient's chest during the decompression step. The resultant negative intrathoracic pressure induces venous blood to flow into the heart and lungs from the peripheral venous vasculature of the patient.

Also of importance to the invention are ventilation sources that are used in connection with CPR techniques to properly ventilate the patient. One type of ventilation source is the AMBU bag available from AMBU International, Copenhagen, Denmark. The AMBU bag can also be used in connection with a positive end-expiratory pressure (PEEP) valve, available from AMBU International, to treat some patients with pulmonary and cardiac diseases. However, until the present invention, a positive end-expiratory pressure valve in connection with a ventilation source has not been used with any CPR techniques.

With both traditional CPR and ACD-CPR techniques, an increase in the amount of venous blood flowing into the heart and lungs from the peripheral venous vasculature would be desirable to increase the volume of oxygenated blood leaving the thorax during the subsequent compression phase. It would therefore be desirable to provide improved methods and apparatus for enhancing venous blood flow into the heart and lungs of a patient from the peripheral venous vasculature during both conventional CPR and ACD-

CPR techniques. It would be particularly desirable to provide techniques which would enhance oxygenation and increase the total blood return to the chest during the decompression step of CPR and ACD-CPR, more particularly of ACD-CPR. This can be accomplished according to the present invention by augmentation of both negative and positive intrathoracic pressure, thereby amplifying the total intrathoracic pressure swing. An invention for providing this crucial improvement is described.

Severe hypotension or very low blood pressure can lead to passing out and in some circumstances cardiac arrest. Like cardiac arrest, patients with low blood pressure often suffer from insufficient blood returning to the heart after each beat. This results in a decrease in forward blood flow out of the heart and eventually to low blood pressure. It would therefore be desirable to provide techniques or devices that would increase venous blood flow to the heart when a person suffers from low blood pressure. According to the invention, such an approach could help return blood flow to the heart and result in an increase in blood flow to the vital organs.

ACD-CPR techniques are described in detail in Todd J. Cohen et al., *Active Compression-Decompression Resuscitation: A Novel Method of Cardiopulmonary Resuscitation*, American Heart Journal, Vol. 124, No. 5, pp. 1145-1150, November 1992; and Todd J. Cohen et al., *Active Compression-Decompression: A New Method of Cardiopulmonary Resuscitation*, The Journal of the American Medical Association, Vol. 267, No. 21, June 3, 1992. These references are hereby incorporated by reference.

The use of a vacuum-type cup for actively compressing and decompressing a patient's chest during ACD-CPR is described in a brochure of AMBU International A/S, Copenhagen, Denmark, entitled Directions for Use of AMBU® CardioPump™, published in September 1992. The AMBU® CardioPump™ is also disclosed in European Patent Application No. 0 509 773 A1. These references are hereby incorporated by reference.

BRIEF SUMMARY OF THE INVENTION

According to the invention, methods and devices for increasing cardiopulmonary circulation are provided. The methods and devices may be used in connection with any generally accepted CPR methods or with active compression-decompression (ACD) CPR techniques. Preferably, the methods and devices will be used in connection with ACD-CPR. In one

aspect, they may be used in patients with severe low blood pressure and who are not in cardiac arrest and breathe spontaneously.

Cardiopulmonary circulation is increased according to the invention by impeding airflow into a patient's lungs during the CPR decompression phase or during a spontaneous inhalation. This increases the magnitude and prolongs the duration of negative intrathoracic pressure during in the patient's chest, i.e., increases the duration and degree that the intrathoracic pressure is below or negative with respect to the pressure in the peripheral venous vasculature. By enhancing the amount of venous blood flow into the heart and lungs, since equilibration of intrathoracic pressure during decompression occurs to a greater extent from enhanced venous return rather than rapid inflow of gases into the chest via the patient's airway, cardiopulmonary circulation is increased.

In a specific embodiment, impeding the airflow into the patient's lungs is accomplished by decreasing or preventing ventilation during the decompression phase of CPR. The method employs the use of a flow restrictive or limiting member, such as a flow restrictive orifice disposed within or connected in series with a lumen of a ventilation tube, or a pressure-responsive valve within a lumen of the tube to impede the inflow of air. The pressure-responsive valve is biased to open to permit the inflow of air when the intrathoracic pressure falls below a threshold level. In order to properly ventilate the patient, the method preferably provides for periodically ventilating the patient through the ventilation tube after compression of the patient's chest. When periodic ventilation is performed, gases can be delivered either through the impeding step or in another embodiment they can bypass the impeding step. In some cases, an oxygen enriched gas may be supplied to the patient through the pressure-responsive valve once this valve opens.

An exemplary embodiment provides for covering the patient's mouth and nose with a facial mask. This mask contains means for impeding airflow into the patient's airway during decompression of the patient's chest, e.g. either an orifice or valve as just discussed.

A specific embodiment further provides means for impeding air from leaving the lungs during compression of the patient's chest to further enhance cardiopulmonary circulation by enhancing positive intrathoracic pressure during the compression phase.

When performing cardiopulmonary resuscitation to enhance circulation according to the invention, an operator compresses a patient's chest to force blood out of the patient's thorax. The patient's chest is then decompressed to induce venous blood to flow into

the heart and lungs from the peripheral venous vasculature either by actively lifting the chest (via ACD-CPR) or by permitting the chest to expand due to its own elasticity (via conventional CPR). During the decompression step, airflow is impeded from entering into the patient's lungs which enhances negative intrathoracic pressure and increases the time during which the thorax is at a lower pressure than the peripheral venous vasculature. Thus, venous blood flow into the heart and lungs from the peripheral venous vasculature is enhanced. This is because the intrathoracic pressure equilibrium during decompression occurs as a result of enhanced venous return rather than from inflow of air via the trachea. In a particular embodiment, compression and decompression of the patient's chest may be accomplished by pressing an applicator body against the patient's chest to compress the chest, and lifting the applicator to actively expand the patient's chest.

An apparatus for enhancing cardiopulmonary circulation according to the method comprises an improved endotracheal tube having a flow restrictive element for impeding airflow from the patient's lungs during chest decompression. A second apparatus according to the invention provides for an improved air-delivery system comprising a compressible structure having a flow restrictive element included in or attached to an opening of the compressible structure to impede the flow of gases to the patient's lungs. Also, a connector is provided for interfacing the compressible structure to the patient, preferably by attaching a facial mask or endotracheal tube to the structure.

In another aspect of the invention, a valving system is provided for regulating airflow into a patient's lungs when performing cardiopulmonary resuscitation. The system includes a housing having an upstream region and a downstream region. A means is provided between the upstream region and the downstream region for inhibiting air from flowing from the upstream region to the downstream region when the pressure in the downstream region is less than the pressure in the upstream region. In this manner, air is inhibited from flowing into the patient's lungs during decompression of the patient's chest thereby forcing more venous blood into the chest and enhancing vital organ perfusion. A means is further provided for allowing air to flow into the downstream region when ventilating the patient. In this way, adequate ventilation can be provided to the patient during the procedure.

In one particular aspect, the inhibiting means comprises a valve which inhibits airflow from the upstream region to the downstream region when the pressure in the

downstream region is less than the pressure in the upstream region. The valve preferably includes a diaphragm which is closed when the pressure in the downstream region is less than or equal to the pressure in the upstream region. Such a configuration prevents air from flowing into the patient's lungs during decompression of the patient's chest while allowing air to be exhausted from the patient's lungs during compression. Preferably, the diaphragm is constructed of a flexible membrane. Alternatively, the diaphragm can be constructed using a ball.

In another particular aspect, the diaphragm is biased to open when the pressure in the downstream region is about 2 cm H_2O or greater, and more preferably at about 2 cm H_2O to 10 cm H_2O. Biasing of the diaphragm in this manner increases intrathoracic pressure during compression of the patient's chest to further enhance vital organ perfusion.

In still a further aspect, the means for allowing air into the downstream region includes a means for opening the diaphragm when air is injected into the upstream region to ventilate the patient. The means for opening the diaphragm preferably includes an ambient pressure region that is adjacent the diaphragm. When air is injected into the upstream region, the pressure within the upstream region increases thereby drawing the diaphragm into the ambient pressure region and allowing the air to flow to the patient's lungs.

In yet another aspect, the means for allowing air into the downstream region includes a manually operable valve at the downstream region which is manually opened to allow air to flow into the downstream region upon return of spontaneous circulation. In this manner, a rescuer can manually open the valve when the patient begins breathing.

In an alternative aspect, the means for allowing air into the downstream region comprises a pressure-responsive valve at the downstream region. The pressure-responsive valve allows air into the downstream region when the pressure in the downstream region falls below a threshold level, usually in the range from –3 cm H_2O to -30 cm H_2O. The pressure-responsive valve is advantageous in allowing ventilation to be provided to the patient while still employing the diaphragm to enhance the extent and duration of negative intrathoracic pressure. Examples of pressure-responsive valves that may be used include, for example, a spring biased valve, an electromagnetically driven valve, or a valve constructed of any deflectable material that will deflect when the threshold pressure is exceeded. As one specific example, the valve may be constructed of a magnetically charged piece of material with a narrow tolerance that is attracted to a gate. This valve will open when the

magnetically charged gate pressure is exceeded. In this way, when the negative intrathoracic pressure is exceeded, the valve will be pulled away from the gate to permit gases to flow to the lungs. Such a valve could also be used in place of the diaphragm valve discussed above.

In one option, a source of oxygen-enriched gas may be coupled to the pressure-responsive valve to supply an oxygen-enriched gas to the patient when the pressure-responsive valve is opened. A regulator may be employed to regulate the pressure and/or flow rate of the gas. For example, the pressure may be regulated to be less than the actuating pressure of the valve so that the pressurized gas will not flow to the patient's lungs until the valve is opened when the negative intrathoracic pressure is exceeded.

The system of the invention in another aspect is provided with an air exhaust opening in the housing at the upstream region for exhausting air from the housing. A valve is provided in the exhaust opening which inhibits air from flowing into the housing through the exhaust opening. In this manner, air exhausted from the patient is in turn exhausted from the housing through the exhaust opening. In a further aspect, means are provided for preventing air from exiting the housing through the exhaust opening during injection of air into the housing when ventilating the patient. Preferably air is injected into the housing from a respiratory device, such as a respiratory bag, a ventilator, or the like, or by mouth-to-mouth breathing through a port or a mouthpiece.

In still a further aspect of the invention, an endotracheal tube, a sealed facial mask, a laryngeal mask, or other airway tube, or the like is provided and is connected to the housing at the downstream region for attachment to the patient. The endotracheal tube or like device is for insertion into the patient's airway and provides a convenient attachment for the valving system to the patient.

The invention further provides an exemplary device for increasing cardiopulmonary circulation that is induced by chest compression and decompression when performing cardiopulmonary resuscitation. The device comprises a facial mask and a housing that is operably attached to the mask. The housing includes a mouth piece and at least one inflow valve which prevents respiratory gases from entering the lungs until a threshold negative intrathoracic pressure level is exceeded at which time the inflow valve opens. The housing further includes an air chamber in communication with the mouth piece, and a valve member to force air from the air chamber and into the facial mask when air is supplied through the mouth piece. In this way, a rescuer may blow into the mouth piece to

periodically ventilate the patient with air or oxygen-enriched gas stored in the chamber, rather than introducing respiratory gases from the rescuer's lungs.

In a similar vein, the invention provides an exemplary method for increasing cardiopulmonary circulation that is induced by chest compression and decompression when performing cardiopulmonary resuscitation. According to the method, at least one inflow valve and an air chamber are interfaced to a patient's airway. Chest compression and chest decompression is then performed, with the inflow valve preventing respiratory gases from entering the lungs during decompression until a threshold negative intrathoracic pressure is exceeded. Air is periodically transferred from the air chamber into the patient's lungs so as to properly ventilate the patient with air. In one exemplary aspect, the air is transferred from the air chamber to the patient's lungs by manually blowing into the chamber. In this way, the rescuer may blow into the chamber to transfer air to the patient's lungs without introducing respiratory gases from the rescuer's lungs.

In one embodiment, the invention provides a mechanism to vary the actuating pressure of the inflow valve. In this way, the rescuer is able to operate the mechanism to vary the impedance depending upon the condition of the patient. In some cases, the valve systems of the invention may include a pressure gauge to display the intrathoracic pressures. By having this information readily available, the rescuer has more information to assist in setting the desired actuating pressure of the inflow valve.

In one aspect, the varying mechanism is configured to vary the actuating pressure to a pressure within the range from about 0 cm H_20 to about -30 cm H_20. In another aspect, the inflow valve comprises a shaft having a seal that is configured to block an opening in the housing, and a spring that biases the seal against the housing. With such a configuration, the mechanism may comprise a knob that is movable to vary the biasing force of the spring. For example, the knob may be rotatably coupled to the shaft so that the rescuer may simply turn the knob to vary the actuating pressure.

In another embodiment, the valve systems of the invention may be provided with a safety ventilation passage. If the valve system is inappropriately applied to a patient who is spontaneously breathing, the patient may breath through this passage while the valve system is coupled to the patient's airway. A safety mechanism is used to maintain the safety ventilation passageway open to permit respiratory gases to freely flow to the patient's lungs until actuated by a rescuer to close the safety ventilation passageway. With such an

arrangement, the patient is able to freely breathe if they are capable of so doing. If the patient stops breathing on their own, the rescuer may set the valve system so that the ventilation passage is closed and the inflow valve provides the desired resistance during CPR. In this way, respiratory gases are permitted only once the cracking pressure of the threshold valve is exceeded, or when the patient is actively ventilated. As with other embodiments, the cracking pressure may be exceeded by decompressing the patient's chest during CPR, by the patient's own inhalation, or the like.

In one aspect, the safety ventilation passageway is provided through the inflow valve when the inflow valve is in an open position. With this configuration, the safety mechanism is configured to maintain the inflow valve in the open position until actuated by the rescuer to move the inflow valve to a closed position. A variety of ways may be used to actuate the safety mechanism. For example, the housing may include a ventilation port to permit respiratory gases to be injected into the housing, and the safety mechanism may comprise a sensor to sense when the rescuer injects respiratory gases into the housing. In one embodiment, a signal from the sensor is used by a control system to move the inflow valve from the open position to the closed position. As an example, the sensor may be movable upon injection of respiratory gases into the housing, and the control system may comprise a set of gears that are coupled to the sensor and a cam that is movable by the gears to close the inflow valve. Alternatively, the control system may comprise an electronic controller, a solenoid and a cam. This mechanism may be configured to take electrical signals from the sensor and to operate the solenoid to move the cam and thereby close the inflow valve. As another example, a flap may be moved upon injection of the gases. The flap may cause the movement of a variety of mechanical components that physically reset the inflow valve to the closed position.

A variety of sensors may be used to sense injection of the respiratory gases. For example, sensors that may be used include electronic switches that move in a gas stream, thermistors to sense temperature changes, CO_2 detectors, materials that experience a change of resistance when flexed, mechanical flaps that move in a gas stream, and the like.

The invention also provides methods for increasing the blood pressure in a spontaneously breathing person. According to the method, an inflow valve is coupled to the person's airway and the person inhales and exhales. During inhalation, the inflow valve inhibits or completely prevents respiratory gases from entering the lungs for at least some

time to augment the person's negative intrathoracic pressure and thereby assist in increasing blood flow back to the right heart of the person. In so doing, the person's blood pressure is enhanced. The resistance or actuating pressure of the inflow valve may be based on one or more sensed physiological parameters. For example, one parameter may be the negative intrathoracic pressure. For instance, the inflow valve may be used to achieve a negative intrathoracic pressure in the range from about 0 cm H_20 to -50 cm H_20 for flow rates in the range from about zero flow to about 70 liters per minute. Other parameters that may be sensed include respiratory rate, end tidal CO_2, tissue CO_2 content, positive end expiratory pressure, blood pressure and oxygen saturation. These parameters may be used individually or in combination when adjusting the resistance of the inflow valve. For example, even if the sensed negative intrathoracic pressure is within a desired range, the end tidal CO_2 may be outside of a desired range. As such, the resistance of the valve may be adjusted until the end tidal CO_2 is acceptable. Conveniently, the inflow valve may be manually operated or operated in an automated fashion. For example, a controller may be used to receive the sensed parameters and then to send signals to an adjustment mechanism that operates the valve to vary the resistance or actuating pressure.

Such a process may be used to treat a variety of conditions where the person's blood pressure is low. For example, such a procedure may be used where the person has low blood pressure due to blood loss, due to the administration of a drug, due to a high gravitational state, due to vasodepressor syncope, due to drowning, due to heat stroke, due to heart attack, due to hypothermia, due to right heart failure, after a return to earth from space, due to sepsis, pericardial effusion, cardiac tamponade, or the like.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a graph illustrating thoracic pressure changes over time when compressing and decompressing a patient's chest according to the present invention.

Fig. 2A is a schematic view illustrating airflow through a ventilation circuit when compressing a patient's chest according to the present invention.

Fig. 2B is a schematic view illustrating airflow through a ventilation circuit when decompressing a patient's chest according to the present invention.

Fig. 3 is a schematic illustration of a first alternative embodiment of a device for impeding airflow into a patient's lungs according to the present invention.

Fig. 4A is a schematic illustration of a second alternative embodiment of the device for impeding airflow into a patient's lungs according to the present invention.

Fig. 4B is a schematic illustration of the device in Fig. 4A with a common inhalation/exhalation port.

Fig. 5A is a schematic view of a one-way valve used in the device for impeding airflow according to the present invention.

Fig. 5B is a schematic view of the one-way valve in Fig. 5A that is held open after ACD-CPR has ceased.

Fig. 5C is a schematic view of a one-way valve that is closed until a threshold pressure is present in the tube according to the present invention.

Fig. 6A is a schematic view of a spring biased inflow valve and a spring biased expiration valve to be used in accordance with the present invention.

Fig. 6B is a schematic view of Fig. 6A showing the operation of the valves during outflow of air.

Fig. 6C is a schematic view of Fig. 6A showing the operation of the valves during inflow of air.

Fig. 7 is a schematic view of a single valve that is spring biased from both sides to be used as an inflow valve and an expiration valve according to the present invention.

Fig. 8 is a schematic view of a flow restricting orifice to be used with a flow restrictive device according to the present invention.

Fig. 9 is a schematic view of an exemplary embodiment of the device for impeding airflow into a patient's lungs according to the present invention.

Figs. 10A-10C are schematic views illustrating another embodiment of the present invention allowing for periodic patient ventilation through a bypassing valve.

Fig. 11 is a schematic view of an exemplary valving system for regulating airflow into a patient's lungs according to the present invention. The valving system is shown with air being exhausted from a patient's lungs during compression of the patient's chest.

Fig. 12 illustrates the valving system of Fig. 11 during decompression or resting of the patient's chest.

Fig. 13 illustrates the valving system of Fig. 11 with a pressure-responsive valve being opened when the negative intrathoracic pressure in the patient's chest exceeds a threshold amount during decompression of the patient's chest.

Fig. 14 illustrates the valving system of Fig. 11 with a diaphragm being opened during injection of air into the housing when ventilating the patient.

Fig. 15 illustrates the valving system of Fig. 11 with a manually operable valve being opened to allow air into the patient's lungs upon return of spontaneous circulation.

Fig. 16A is a cutaway side view of exemplary valving system according to the present invention.

Fig. 16B is a top view of a deflector and a fenestrated mount of the valving system of Fig. 16A.

Fig. 16C is an alternative embodiment of the valving system of Fig. 16A.

Fig. 16D illustrates the valving system of Fig. 16A with a source of pressurized gas coupled to a pressure-responsive valve according to the invention.

Fig. 17 is a schematic view of an alternative embodiment of a valving system having a ball as a diaphragm.

Fig. 18 is a schematic view of a device for impeding air flow into the patient's lungs and for providing air to the patient's lungs when needed for ventilation.

Fig. 19 is a side view of one embodiment of a valving system having an adjustable pressure responsive valve according to the invention.

Fig. 20 is a cross sectional side view of the adjustable pressure responsive valve of Fig. 19.

Fig. 21 is a top view of the valve of Fig. 20.

Fig. 22 illustrates the valve of Fig. 21 with a cap being removed.

Fig. 23 is a schematic side view of a safety mechanism for a valving system that permits respiratory gases to freely flow to the patient's lungs through a ventilation passage according to the invention.

Fig. 24 illustrates the safety mechanism of Fig. 23 when actuated to prevent respiratory gases from flowing through the ventilation passage.

Fig. 25 is a schematic side view of a valving system having an integrated safety mechanism that permits respiratory gases to freely flow to the patient's lungs through an inflow valve according to the invention.

Fig. 26 illustrates a flow sensor and lever arm of the safety mechanism of Fig. 25 prior to actuation by the rescuer.

Fig. 27 illustrates the valving system of Fig. 25 when the safety mechanism is actuated by the rescuer to closed the inflow valve.

Fig. 28 illustrates the flow sensor and lever arm of Fig. 26 when actuated by the rescuer.

Fig. 29 is an end view of the valving system of Fig. 25.

Fig. 30 is a more detailed view of the inflow valve of Fig. 25 when in the open position.

Fig. 31 illustrates the inflow valve of Fig. 30 when in the closed position.

Fig. 32 is a side schematic view of one embodiment of a safety valve shown in a closed position according to the invention.

Fig. 33 illustrates the safety valve of Fig. 32 in an open position.

Fig. 34 is a side schematic view of another embodiment of a safety valve shown in a closed position according to the invention.

Fig. 35 illustrates the safety valve of Fig. 34 in an open position.

Fig. 36 is a side schematic view of yet another embodiment of a safety valve shown in a closed position according to the invention.

Fig. 37 illustrates the safety valve of Fig. 36 in an open position.

Fig. 38 is a schematic side view of an embodiment of a valving system having a safety valve that is in a closed position according to the invention.

Fig. 39 illustrates the valving system of Fig. 38 when the safety valve is moved to the open position during a gasp by a patient.

Fig. 40 illustrates the valving system of Fig. 38 during ventilation which causes the safety valve to move back to the closed position.

Fig. 41 is a schematic diagram of a valving system having a pressure gauge to measure pressures within the valving system according to the invention.

Fig. 42 is a cross-sectional schematic view of one embodiment of a system for treating a breathing person who is in shock according to the invention.

Fig. 43 is top schematic view of the system of Fig. 42.

Fig. 44 illustrates the system of Fig. 42 when the person is inspiring.

Fig. 45 illustrates the system of Fig. 42 when the person is exhaling.

Fig. 46A illustrates one embodiment of an inflow valve according to the invention.

Fig. 46B illustrates the inflow valve of Fig. 46A when the resistance to flow has been increased.

Fig. 47A illustrates another embodiment of an inflow valve according to the invention.

Fig. 47B illustrates the inflow valve of Fig. 47A when a disk has been moved to increase flow resistance according to the invention.

Fig. 48A illustrates yet another embodiment of an inflow valve according to the invention.

Fig. 48B illustrates the inflow valve of Fig. 48A when a disk has been rotated to increase resistance according to the invention.

Fig. 49A illustrates a further embodiment of an inflow valve according to the invention.

Fig. 49B illustrates the inflow valve of Fig. 49A when compressed to increase flow resistance.

Fig. 50A illustrates yet another embodiment of an inflow valve according to the invention.

Fig. 50B illustrates the inflow valve of Fig. 50A when compressed to increase flow resistance.

Fig. 51A illustrates a further embodiment of an inflow valve according to the invention.

Fig. 51B illustrates the inflow value of Fig. 51A when compressed to increase flow resistance.

Fig. 52A illustrates still a further embodiment of an inflow valve according to the invention.

Fig. 52B illustrates iris mechanisms that have been operated to increase the resistance to flow of the inflow valve of Fig. 52A.

Fig. 53A illustrates still a further embodiment of an inflow valve according to the invention.

Fig. 53B illustrates the inflow valve of Fig. 53A when a disk has been pivoted to increase flow resistance.

Figs. 54A through 54C illustrate one embodiment of a method for treating shock according to the invention.

DETAILED DESCRIPTION OF THE INVENTION

According to the present invention, methods and devices for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation are provided. Such methods and devices may be used in connection with any method of CPR in which intrathoracic pressures are intentionally manipulated to improve cardiopulmonary circulation. For instance, the present invention would improve standard manual CPR, "vest" CPR where a circumferential collar is compressed in a repetitive manner to promote blood flow from the heart, CPR with a newly described Hiack Oscillator ventilatory system which operates essentially like an iron-lung-like device, phrenic nerve stimulators, including those described in copending U.S. Application Nos. 09/095,916, filed 06/11/98; 09/197,286, filed 11/20/98; 09/315,396, filed 05/20/99; and 09/533,880, filed 03/22/00, the complete disclosures of which are herein incorporated by reference, interposed abdominal compression-decompression CPR, and active compression-decompression (ACD) CPR techniques. Although the present invention may improve all such techniques, the following description will refer primarily to improvements of ACD-CPR techniques in order to simplify discussion. However, the claimed methods and devices are not exclusively limited to ACD-CPR techniques.

The proper performance of ACD-CPR to increase cardiopulmonary circulation is accomplished by actively compressing a patient's chest with an applicator body. Preferably, this applicator body will be a suction-type device that will adhere to the patient's chest, such as the AMBU® CardioPump™, available from AMBU International, Copenhagen, Denmark. After the compression step, the adherence of the applicator body to the patient's chest allows the patient's chest to be lifted to actively decompress the patient's chest. The result of such active compression-decompression is to increase intrathoracic pressure during the compression step, and to increase the negative intrathoracic pressure

during the decompression step thus enhancing the blood-oxygenation process and enhancing cardiopulmonary circulation. ACD-CPR techniques are described in detail in Todd J. Cohen et al., *Active Compression-Decompression Resuscitation: A Novel Method of Cardiopulmonary Resuscitation*, American Heart Journal, Vol. 124, No. 5, pp. 1145-1150, November 1992; Todd J. Cohen et al., *Active Compression-Decompression: A New Method of Cardiopulmonary Resuscitation*, The Journal of the American Medical Association, Vol. 267, No. 21, June 3, 1992; and J. Schultz, P. Coffeen, et al., *Circulation*, 89:684-693, 1994. These references are hereby incorporated by reference.

The present invention is especially useful in connection with standard and ACD-CPR techniques. In particular, the invention improves standard and ACD-CPR by providing methods and devices which impede airflow into a patient's lungs to enhance negative intrathoracic pressure during the decompression of the patient's chest, thus increasing the degree and duration of a pressure differential between the thorax (including the heart and lungs) and the peripheral venous vasculature. Enhancing negative intrathoracic pressure with simultaneous impedance of movement of gases into the airway thus enhances venous blood flow into the heart and lungs and increases cardiopulmonary circulation.

In a broad sense, the present invention provides for occluding a patient's airway to prevent foreign (outside) air from flowing to a patient's lungs during the active decompression step of ACD-CPR to enhance and sustain the duration of negative intrathoracic pressure and enhance blood oxygenation and cardiopulmonary circulation during both active decompression and the subsequent compression phase. The patient's airway may be occluded or inflow of gases impeded by any suitable device or mechanism such as by an endotracheal tube, a device attached to an endotracheal tube, a facial mask, a mouth piece used in mouth-to-mouth resuscitation, oropharyngeal airway, laryngeal mask airway, and the like.

A further aspect of the present invention provides for allowing impeded air to flow into the patient's lungs during the active decompression step of ACD-CPR in order to provide some ventilation to the patient while still enhancing the extent and duration of negative intrathoracic pressure to enhance blood oxygenation. Impeding airflow to the patient's lungs may be accomplished by any flow restrictive element such as an orifice, a one-way valve, a spring biased or other valve which is set to open when the negative intrathoracic pressure is in the range from about 0 cm H_2O to -100 cm H_2O, and more preferably from

about -3 cm H_2O to about -30 cm H_2O. A valve designed to open at a threshold pressure value may be either fixed or variable, i.e., the pressure at which the valve opens may be adjusted or may be permanently fixed. Further, examples of pressure-responsive valves that may be used include, for example, an electromagnetically driven valve or a valve constructed of any deflectable material that will deflect when the threshold pressure is exceeded. As one specific example, the valve may be constructed of a magnetically charged piece of material with a narrow tolerance that is attracted to a gate. This valve will open, i.e. separate from the gate, when the magnetically charged gate pressure is exceeded. In this way, when the negative intrathoracic pressure is exceeded, the valve will be pulled away from the gate to permit gases to flow to the lungs.

In some cases, a safety mechanism may be provided to permit respiratory gases to freely flow to the patient's lungs until the safety mechanism is actuated by the rescuer. In this way, the valving system may be coupled to the patient but will only impede patient inspiration until actuated by the rescuer.

Another aspect of the invention provides for air to be impeded from leaving the patient's lungs during compression of the patient's chest to further enhance cardiopulmonary circulation by enhancing intrathoracic pressure during the compression phase. Typically, air is impeded from leaving the lungs during the compression phase when the positive intrathoracic pressure is in the range from about 2 cm H_2O to 50 cm H_2O, and more preferably from about 2 cm H_2O to about 20 cm H_2O. Valves that may be used to accomplish such a feature include, for example, a spring valve, a diaphragm valve, include diaphragms constructed of silicone, and a magnetically charged plate that is coupled to a gate. In this manner, when the positive pressure exceeds the magnetic force, the plate is forced away from the gate to permit the gases to exit the lungs.

Another aspect of the present invention provides for ventilating the patient during CPR. Ventilation of the patient in one embodiment is performed at about every two to 20 compressions, preferably twice every fifteen compressions, thus providing sufficient fresh air for adequate gas exchange with the blood in the lungs to the patient. Ventilating the patient may be accomplished by any device or method suitable such as by mouth-to-mouth resuscitation, by a compressible or collapsible structure, by a ventilatory bag such as the AMBU bag available from AMBU, Copenhagen, Denmark, or the like. Ventilation could also be superimposed on the compression phase to further augment positive intrathoracic

pressure. Furthermore, periodic ventilation could be performed either through the impeding step or by bypassing the impeding step altogether.

In an alternative embodiment, ventilation may be provided by introducing oxygen-enriched respiratory gases through the pressure-responsive valve that permits gases into the lungs during the decompression step once a certain threshold negative intrathoracic pressure is exceeded. This could be introduced under pressure or at atmospheric pressure In this way, during each decompression step, respiratory gases may be supplied to the lungs to ventilate the patient. Use of a pressurized gas is advantageous in that more respiratory gases may be supplied to the lungs once the pressure responsive valve opens. The pressurized gas may be supplied by connecting a pressurized gas source, such as a pressurized tank or bag of O_2, to the back side of the pressure-responsive valve using a length of tubing. Conveniently, a regulator may be positioned between the pressure source and the valve to regulate the pressure and/or flow rate of the gas supplied from the pressure source. The pressure may be regulated such that it is less than the actuating pressure of the valve, e.g. by about 1 to 3 cm H_2O, so that the valve will not prematurely open. For example, if respiratory gases are to be supplied to the patient when the negative intrathoracic pressure exceeds −14 cm H_20, the pressure of the gas from the gas source must be set to less than 14 cm H_2O.

When ventilating a patient, the valves of the invention may be modified to regulate the flow rate of air into the lungs. This may be accomplished for example, by including a flow regulator, valve, restriction, reduced size orifice or the like within or associated with the valve so that as respiratory gases are injected into the valve, their flow rate is limited below a threshold amount as the gases enter the patient's airway. By regulating the flow rate of injected respiratory gases, the pressure on the esophagus may be kept within certain limits to prevent gastronomic distention. For example, a reduced size orifice may be provided at or near the exit opening of the valve system housing to regulate the gas flow rate before the gases enter the patient's airway. In this way, a technique is provided to ensure that substantially all of the injected respiratory gases enter the patient's lungs.

One significant advantage of the invention is the ability to increase a person's blood pressure. By interfacing the valving systems of the invention with spontaneously breathing patients, the valving systems are able to increase the negative intrathoracic pressure when the person inhales. By so doing, more blood is returned to the right heart, thereby

increasing the person's blood pressure. The valving systems used to increase the person's blood pressure may initially completely prevent gas flow to the lungs during an inspiratory effort, or provide some measure of resistance. The complete prevention or initial resistance may be adjusted sometime during the breathing maneuver so that gas flow may proceed to the person's lungs for at least a portion of the inspiratory cycle. For example, if using a pressure responsive valve, the valve may be set to open when reaching a pressure in the range from about 0 cm H_2O to about -50 cm H_2O, more preferably from about 0 cm H_2O to about -20 cm H_2O, and most preferably from about -5 cm H_2O to about -15 cm H_2O for flow rates of about zero flow to about 70 liters per minute. For valves that simply provide resistance, the valve may be configured to provide similar resistances during the inspiratory effort. Further, one or more sensors may be used to sense various physiological parameters and may be used to manually or automatically vary the cracking pressure of the valve or the amount of resistance produced by the valve.

Examples of situations where the valving systems of the invention may be used to increase blood pressure include those where a spontaneously breathing patient has experienced blood loss, or after receiving a drug (including an anesthetic agent) that causes a decrease in blood pressure. Patients with low blood pressure often suffer from insufficient blood returning to the heart after each beat. This results in a decrease in forward blood flow out of the heart and eventually to low blood pressure. By interfacing the valving systems to the airway, the amount of venous return to the right heart is increased to increase blood pressure. Another example is where a spontaneously breathing patient is in shock secondary to profound blood loss and needs increased blood flow to the right heart. As a further example, such techniques may be used with pilots or astronauts to increase blood flow back to the right heart in high gravitational states or when returning to earth after space flight, and in patients who suffer from a rapid decrease in blood pressure due to vasovagal or vasodepressor syncope. Further examples include low blood pressure due to heat stroke, drowning, heart attack, right heart failure, sepsis, pericardial effusion, tamponade, or the like.

In one option, any of the valving systems may include an electronic device and an associated speaker to produce voice prompts on how to perform CPR using the valving systems. Such voice prompts may have instructions for interfacing the valving system, applying chest compressions, giving ventilations, and the like. Also, a metronome may be provided to assist the rescuer in providing appropriate chest compressions. Such techniques

are described in copending U.S. Application No. 09/854,404, filed 5/11/01 (attorney docket no. 16354-004300), the complete disclosure of which is herein incorporated by reference.

The valving systems of the invention may also incorporate or be associated with sensors that are used to detect changes in intrathoracic pressures or other physiological parameters. In this way, spontaneous patient breathing may be detected. This in turn may be used to control the valving system so that the patient may breathe without any resistance once the sensor is activated by achieving a certain intrathoracic pressure one or more times. Examples of such sensors are described in U.S. Patent No. 6.155,257, the complete disclosure of which is herein incorporated by reference.

Any of the sensors described herein may be configured to wirelessly transmit their measured signals to a remote receiver that is in communication with a controller. In turn the controller may use the measured signals to vary operation of the valve systems described herein. For example, sensors may be used to sense blood pressure, pressures within the heart, or the like and to wirelessly transmit this information to a receiver. This information may then be used by a controller to control the actuating pressure or the resistance of an inflow valve, to control the actuating pressure or resistance of an expiratory valve, to control the injection of oxygen or other gases, to control the administration of drugs or medications, or the like.

The valve systems and/or facial masks of the invention may also include one or more ports for the administration of drugs or other medicaments to the patient's respiratory system. For example, ports may be provided for injecting medicaments by a syringe or pressurized canister. As another example, a nebulized liquid medicament may be supplied through such a port. As a further example, a powdered medicament may be supplied through such a port.

Another feature of the invention is that it may be used to decrease intracranial pressures that often result from trauma to the head. By decreasing intrathoracic pressures using the valve systems and techniques of the invention, the resistance of venous return from the brain to the heart is decreased. As such, more venous blood may be removed from the brain, thereby decreasing intracranial pressures. For example, any of the valve systems of the invention may be coupled to the patient's airway so that as the patient breathes, the negative intrathoracic pressures generated by the patient are augmented to draw venous blood out of the brain.

Referring now to Fig. 1, a graph illustrating thoracic pressure changes over time when compressing and decompressing the patient's chest is shown. Area 10 represents the amount of thoracic pressure during the compression phase of ACD-CPR. Cross-hatched area 12 represents the negative thoracic pressure during the decompression step of ACD-CPR without a flow restrictive means to restrict the flow of air into the patient's lungs. Double cross-hatched area 14 represents the increase in negative thoracic pressure when the patient's airway is occluded according to the present invention during the decompression step of ACD-CPR. The significance of the increase in negative intrathoracic pressure during the decompression step is that more venous blood is forced into the chest from the peripheral venous vasculature. Consequently, more blood is allowed to be oxygenated and more blood is forced out of the chest during the next compression.

In an exemplary embodiment, airflow may be impeded to the patient's lungs during decompression of the patient's chest by placing a ventilatory mask over the patient's mouth and nose. The ventilatory mask also has a pressure-responsive valve attached to prevent airflow to the patient's lungs until the negative intrathoracic pressure of the patient reaches a threshold amount. Also attached to the mask and the pressure-responsive valve is a ventilatory source to provide ventilation to the patient. The ventilatory source may be any device or apparatus suitable for properly ventilating the patient. Preferably, the ventilation source will be an AMBU bag. When ventilation is needed, the AMBU bag may be squeezed to force air into the patient's lungs. The AMBU bag is described in U.S. Patent No. 5,163,424 which is incorporated herein by reference.

In an alternative embodiment, a ventilation source, preferably an AMBU bag, is used in connection with an improved endotracheal tube. A pressure-responsive valve or other flow restrictive element is placed between the AMBU bag and the endotracheal tube. Preferably, the valve will be positioned within a tube that connects the AMBU bag to the endotracheal tube. The combination of the endotracheal tube with the AMBU bag with adapter can be included in the definition of a "ventilation tube." Before ACD-CPR is performed on the patient, the endotracheal tube is placed in the patient's trachea. During decompression of the patient's chest, the valve prevents airflow to the patient's lungs until the intrathoracic pressure reaches a threshold amount. Additionally, the AMBU bag may be used to ventilate the patient at a desired time. Also included in this embodiment is a one-way

expiration valve. This valve allows for expiration of air from the patient during the compression step.

In a modification of either of the first two embodiments, a pressure-responsive expiration valve may also be inserted between the AMBU bag (or comparable ventilation source) and the mask or endotracheal tube. This valve works in a similar manner to the pressure-responsive valve which restricts airflow into the patient's lungs. However, the pressure-responsive expiration valve restricts airflow from the patient's lungs during the compression step of ACD-CPR. An equivalent valve is a positive end-expiratory pressure (PEEP) valve available from AMBU International, Copenhagen, Denmark. Use of such an pressure-responsive expiration valve during compression may further increase intrathoracic pressure and thereby force more blood out of the thorax.

In another alternative embodiment, an improved endotracheal tube is used to restrict airflow into the patient's lungs during the active decompression step. Included in the endotracheal tube is a flow restrictive element which operates to impede air from flowing into the patient's lungs. When the endotracheal tube is inserted into the patient's trachea and the patient's chest is actively decompressed, the flow restrictive element impedes air from flowing to the patient's lungs slowing the rise in intrathoracic pressure and thus enhancing blood oxygenation.

When using the improved endotracheal tube during ACD-CPR, periodic ventilation of the patient will usually still be performed to enhance gas exchange to the patient. With the improved endotracheal tube, such manual ventilation may be accomplished by placing a ventilation source at the opening of the endotracheal tube to force oxygen through the endotracheal tube and into the patient's lungs.

Referring now to Fig. 2A, a schematic view illustrating airflow through a ventilation circuit 20 when compressing a patient's chest according to the present invention is shown. During ACD-CPR, the chest is actively compressed forcing air out of the lungs. This air is allowed to expire through a one-way expiration valve 22 within a ventilation circuit 20.

Referring now to Fig. 2B, the same schematic is shown illustrating airflow through the ventilation circuit 20 when decompressing the patient's chest. When the patient's chest is actively decompressed, a negative intrathoracic pressure is created. When this pressure reaches a threshold amount, the inflow valve 24 will open causing air to flow through the ventilation circuit 20 into the patient's lungs. Air is allowed into the ventilation

circuit 20 through a ventilation valve 26 and into a ventilation bag 28. From the ventilation bag 28, the air passes through the inflow valve 24 when the negative intrathoracic pressure reaches the threshold amount. The ventilation bag 28 is also used to manually ventilate the patient during ACD-CPR as required.

The method as discussed in connection with Figs. 2A and 2B requires the chest to be compressed in the range from about 3.5 cm to 5 cm per compression and at a rate from about 60 to 100 compressions per minute for adults.

Referring now to Fig. 3, a schematic illustration of a first alternative embodiment of a device 35 for impeding airflow into a patient's lungs according to the present invention is shown. The device 35 comprises an endotracheal tube 36 which is placed into the patient's trachea and provides a ventilation passageway. Connected to the endotracheal tube 36 is a transition tube 38 which connects the endotracheal tube 36 to the ventilation bag 28. Although the endotracheal tube 36 is shown connected to the ventilation bag 28, the endotracheal tube 36 can be used alone or in connection with the ventilation bag 28. The ventilation bag 28 can comprise any type of ventilation source capable of ventilating the patient such as a compressible or collapsible structure. Preferably, the ventilation bag 28 consists of an AMBU bag. Attached or connected to the end of the ventilation bag 28 is a one-way ventilation valve 26. The ventilation valve 26 serves to introduce air into the device 35. Attached or connected to the transition tube 38 is an inflow pressure-responsive valve 24. The inflow valve 24 is biased so that it opens when the negative intrathoracic pressure in the patient's chest reaches a threshold amount. As shown, only one inflow valve 24 is included in the device 35. However, the invention is not limited to only one inflow valve 24. Alternatively, a plurality of inflow valves 24 could be connected in series along the ventilation tube 38. The inflow valve 24 is also not limited to being connected in the center of the transition tube 38, but may be positioned anywhere along the transition tube 38. The inflow valve 24 could be permanently attached to the ventilation bag 28 or transition tube 38 or could be detachable. Alternatively, the inflow valve 24 could be connected to the ventilation bag 28 itself or to the endotracheal tube 36.

The device 35 also contains a one-way expiration valve 22 which allows for air to be expired from the patient's lungs. This generally occurs during the compression phase of ACD-CPR. To insure that the air expired from the patient's lungs will exit through the expiration valve 22, a one-way fish mouth valve 37 (the preferred valve) or any other type

of one-way valve can be placed between the inflow valve 24 and the expiration valve 22. Alternatively, the inflow valve 24 itself may be configured as a one-way valve. In either case, air flowing from the endotracheal tube 36 toward the ventilation bag 28 will be forced to expire through the expiration valve 22.

The device 35 may be further modified to include a pressure-responsive expiration valve 39 (not shown) located between the endotracheal tube 36 and the transition tube 38. The pressure-responsive expiration valve works in a reverse manner to that of the inflow valve 24. Specifically, the pressure-responsive expiration valve is biased so that during the compression step of ACD-CPR, air will be allowed to expire from the patient's lungs only when the intrathoracic pressure reaches a threshold amount. The increase in intrathoracic pressure caused by the pressure-responsive expiration valve 39 during compression may assist in forcing more blood out of the thorax and reduce atelectasis of the lungs.

The purpose of the ventilation bag 28 is to provide ventilation to the patient during ACD-CPR. When the ventilation bag 28 comprises an AMBU bag or similar bag used for ventilation, ventilation of the patient may be performed by merely squeezing the AMBU bag with a human hand. This forces air to the patient's lungs as desired.

Referring to Fig. 4A, a second alternative embodiment of the device for impeding airflow into a patient's lungs according to the present invention is shown. This particular embodiment is a modified and improved endotracheal tube. Hence, the second alternative embodiment comprises an endotracheal tube 36 having two lumens at its proximal end. The first lumen is an outflow lumen 40, and the second lumen is an inflow lumen 42. Located within outflow lumen 40 is a one-way pressure-responsive expiration valve 44 which operates in a manner similar to that discussed in connection with Fig. 3, except that the expiration valve 44 is specifically designed as a one-way valve. Located within inflow lumen 42 is a one-way pressure-responsive inflow valve 45 which operates to impede airflow to the lungs as discussed in connection with Fig. 3, except that the inflow valve 45 is also specifically designed as a one-way valve. Also shown in inflow lumen 42 and outflow lumen 40 is an O-ring 46 which will be discussed subsequently. Inflow valve 45 and expiration valve 44 are designed as one-way valves so that during the compression phase, air can only be expired from the patient through the endotracheal tube 36 when the intrathoracic pressure reaches a threshold amount. At that moment, expiration valve 44 opens and air expires from

the patient through the outflow lumen 40. During decompression, air cannot flow through the endotracheal tube 36 to the patient's lungs until the negative intrathoracic pressure reaches a threshold amount. At that moment, inflow valve 45 opens allowing air to flow through inflow lumen 42 to the patient's lungs. Air is prevented from entering through the outflow lumen 40 because of the one-way expiration valve 44.

Ventilation is possible with the embodiment disclosed in Figs. 4A and 4B if the inflow lumen 42 is connected to a ventilation source such as a ventilation bag. When the ventilation bag is squeezed, air is allowed to flow through the inflow lumen 42, through the endotracheal tube 36, and to the patient's lungs. In this embodiment, expiration valve 44 is designed so that during ventilation, expiration valve 44 will remain temporarily closed preventing air flowing through inflow lumen 42 escape through outflow lumen 40.

Fig. 5A is a schematic view of a one-way inflow valve 45 used in a device for impeding airflow according to the present invention. The inflow valve 45 operates so as to allow air only to flow in one direction. As shown, the spring biased inflow valve 45 is completely open. However, the invention also functions properly if the spring biased inflow valve 45 or the spring biased expiration valve 44 are not fully open. Upon successful completion of ACD-CPR, the O-ring 46 that is positioned above the inflow valve 45 is repositioned so that inflow valve 45 is held open as shown in Fig. 5B. Such a positioning of O-ring 46 allows for unimpeded airflow to the patient once there is a return of spontaneous circulation and the inflow valve 45 is no longer needed. An O-ring 46 is also used in a similar manner to lock the one-way expiration valve 44 in an open position upon return of spontaneous circulation. Fig. 5C illustrates the one-way inflow valve 45 in a closed position. When closed, the inflow of air through the inflow valve 45 is occluded.

Fig. 6A illustrates an inflow valve 47 that is spring biased and an expiration valve 48 that is also spring biased. The inflow valve 47 and the expiration valve 48 are connected in series and may be used in the first alternative embodiment as discussed in connection with Fig. 3, or with the preferred embodiment discussed following in connection with Fig. 9. As shown in Fig. 6C, during the active decompression step, the inflow valve 47 is biased such that it will open when the negative intrathoracic pressure reaches a threshold amount. During the compression phase of ACD-CPR the expiration valve 48 will open to allow air to expire from the patient's lungs when the intrathoracic pressure within the patient's chest reaches a threshold amount as shown in Fig. 6B. Since neither inflow valve 47 nor

expiration valve 48 are one-way valves, a fish mouth valve 37 used in connection with a one-way expiration valve 22 as discussed in connection with Fig. 3 must be used. Other valves designed upon a similar principle as the fish mouth valve combination with a one-way expiration valve could also be used. Only one inflow valve 24 and one positive end pressure valve 44 are shown in Figs. 6A-6C. However, a plurality of inflow valves 47 and/or expiration valves 48 may be connected in a permanent or detachable manner in series to impede the inflow and outflow of air.

Although the valves in Figs. 6A-6C are shown as being spring-biased, any other valves designed upon a similar principle would work equally as well. The use of such valves as disclosed in Figs. 6A-6C is only one embodiment and valves constructed according to various other methods and materials is also within the scope of the invention.

As shown in Fig. 7, the inflow valve 47 and the expiration valve 48 may be combined into one joint valve 49 as shown. The joint valve 49 will operate in a manner similar to the two valves 47 and 48 as described in connection with Fig. 6.

Fig. 8 illustrates a flow restricting orifice 50 to be used to either impede the airflow into or out of a patient's lungs. The flow restricting orifice 50 operates so that during the decompression step of ACD-CPR airflow is impeded from entering into the patient's lungs, thus increasing the negative intrathoracic pressure. During the compression step, the flow restricting orifice 50 operates to increase the thoracic pressure in the patient's chest by restricting air from existing from the patient's lungs.

Fig. 9 illustrates an exemplary embodiment for impeding airflow into a patient's lungs according to the present invention. As shown, the device 51 comprises a ventilation bag 28 that is connected to a facial mask 52 by an inflow valve 24 and an expiration valve 22. Although the facial mask 52 is shown connected to the ventilation bag 28, the facial mask 52 can be used alone or in connection with the ventilation bag. Between the inflow valve 24 and the expiration valve 22 is a one-way fish mouth valve 37 or any other type of one-way valve to prevent air from exiting the patient's lungs and flowing to the ventilation bag 28. The ventilation bag 28 also contains a one-way ventilation valve 26 for allowing air to inflow into the device 51. The exemplary embodiment operates in a manner similar to that of the first alternative embodiment as discussed in connection with Fig. 3. However, instead of inserting an endotracheal tube 36 into the patient's airway, the facial mask 52 is placed over the patient's mouth and nose. A facial strap 54 (not shown) may also

be wrapped around the head of the patient to secure the ventilation mask 52 to the patient's face.

Device 51 is preferably used in connection with an oral airway device (not shown) to prevent the patient's airway from becoming occluded, e.g. by the patient's tongue. The oral airway device can be any device that is used to keep the patient's tongue from slipping backward and occluding the airway. Preferably, the oral airway device will be curved and constructed of a plastic material and may or may not be attached to the device 51.

During the decompression phase of ACD-CPR, air is prevented from entering into the patient's lungs through the threshold inflow valve 24 thus increasing the negative intrathoracic pressure. During the compression phase, air is allowed to expire from the patient's lungs through the expiration valve 22. Also, the patient can be ventilated during ACD-CPR by manually squeezing the ventilation bag 28. Consequently, the preferred embodiment serves to enhance cardiopulmonary circulation by increasing the negative intrathoracic pressure to force more blood into the chest from the peripheral venous vasculature.

Figs. 10A - 10C show another embodiment of the present invention which allows the patient to be ventilated by bypassing the impeding step. The embodiment comprises a ventilation tube 60 with a proximal end 62 and a distal end 64 that is connected to the patient. The ventilation tube 60 has a one-way bypass valve 66 and a one-way pressure responsive valve 68. The ventilation tube 60 may also have a manual switch 70 attached to the bypass valve 66 and extending through a side of the ventilation tube 60. As shown in Fig. 10A, the switch 70 may be set in a closed position so that the one-way pressure responsive valve 68 opens when the threshold pressure of the valve 68 has been exceeded. At this point, the valve 68 opens allowing for ventilation of the patient. As shown in Fig. 10B, the one-way pressure responsive valve 68 may be bypassed altogether by manually placing the switch 70 in the open position so that the bypass valve 66 is opened allowing air to flow to the patient. Fig. 10C illustrates the operation of the bypass valve 66 with the switch 70 in an inactive mode. Here, the rescuer performing ventilation may do so without added resistance from the impedance step as in Fig. 10A. Instead, bypass valve 66 opens only when the pressure at the proximal end of the tube 62 is greater than atmospheric pressure (0 mmHg), preferably in a range from about 0 mmHg to 5 mmHg. During decompression of the patient's chest, the one-way bypass valve 66 remains closed unless atmospheric pressure is exceeded. Thus, the

patient is ventilated only when the rescuer performing ventilation causes the pressure at the proximal end of the tube 62 to exceed atmospheric pressure. The function of the one-way bypass valve 66 may be performed by many different threshold valve designs which are known in the art.

In another aspect of the invention, an exemplary valving system is provided for enhancing the duration and extent of negative intrathoracic pressure during the decompression phase of CPR while still providing adequate ventilation to the patient. The valving system is employed to slow the rapid equilibrium of intrathoracic pressure in the chest during decompression by impeding or inhibiting the flow of air into the patient's chest. Lowering of the intrathoracic pressure in this manner provides a greater coronary perfusion pressure and hence forces more venous blood into the thorax. The valving system can be employed in a variety of CPR methods where intrathoracic pressures are intentionally manipulated to improve cardiopulmonary circulation, including "vest" CPR, CPR incorporating a Heimlich ventilatory system, intraposed abdominal compression-decompression CPR, standard manual CPR, and the like, and will find its greatest use with ACD-CPR.

Referring to Figs. 11-15, an exemplary embodiment of a valving system 100 is shown schematically. The valving system 100 includes a housing 101 having an upstream region 102 and a downstream region 104. Held between the upstream region 102 and downstream region 104 is a diaphragm 106. The diaphragm 106 is preferably a flexible or elastomeric membrane that is held over the downstream region 104 to inhibit air from flowing from the upstream region 102 to the downstream region 104 when the pressure in the downstream region 104 is less than the pressure in the upstream region 102, except when positive pressure, i.e. greater than atmospheric, is developed in the upstream region 102 when ventilating the patient. The valving system 100 further includes a valve 108 having a plug 110. As described in greater detail hereinafter, the valve 108 is included to provide ventilation to the patient when opened. The valve 108 can be manually opened by axial translation or it can be automatically opened when the pressure in the downstream region 104 reaches or exceeds a threshold amount, or both. Included at the upstream region 102 is an air intake opening 112 and an air exhaust opening 114. Air is delivered into the housing 101 through the air intake opening 112, while air is exhausted from the housing 101 through the air exhaust opening 114. An accordion valve 116, fish mouth valve, or the like is provided

between the air intake opening 112 and the air exhaust opening 114. As described in greater detail hereinafter, the accordion valve 116 is used to prevent air that is injected into the air intake opening 112 from exiting the air exhaust opening 114 when ventilating the patient. A filter 117 is provided for filtering air injected into the housing 101. Optionally, a filter 119 can be provided in the downstream region 104 for preventing excess body fluids and air-borne pathogens from entering into the system 100.

Operation of the valving system 100 during compression of a patient's chest is illustrated in Fig. 11. As the patient's chest is compressed, air is forced from the patient's lungs and into the downstream region 104. The air forced into the downstream region 104 is directed against the diaphragm 106 forcing the diaphragm into an ambient pressure region 118. Air in the downstream region 104 is then allowed to escape into the upstream region 102 where it is exhausted through the air exhaust opening 114. Optionally, the diaphragm 106 can be biased so that it will not be forced into the ambient pressure region 118 until the pressure within the downstream region 104 is about 2 cm H_2O or greater, and more preferably at about 2 cm H_2O to 4 cm H_2O.

Operation of the valving system 100 during decompression (or resting) of the patient's chest is illustrated in Fig. 12. As the patient's chest is actively lifted (or allowed to expand on its own), air is drawn from the downstream region 104 and into the patient's lungs, thereby reducing the pressure in the downstream region 104. The resulting pressure differential between the regions 102, 104 holds the diaphragm 106 over the downstream region 104 to prevent air from the upstream region 102 from flowing to the downstream region 104. In this way, air is inhibited from flowing into the patient's lungs during decompression of the patient's chest, thereby lowering the intrathoracic pressure to increase the coronary perfusion pressure and to force more venous blood into the thorax.

Various ways of providing ventilation to the patient using the valving system 100 are described in Figs. 13-15. Fig. 13 illustrates airflow into the downstream region 104 and to the patient's lungs during decompression of the patient's chest after a threshold amount of negative intrathoracic pressure has been reached. Ventilation in this manner is advantageous in that the valving system 100 can be employed to produce at least a threshold amount of intrathoracic pressure to enhance blood flow into the heart and lungs. Once such as pressure is reached, some air is allowed to flow to the patient's lungs to ventilate the patient.

Air is allowed to enter the downstream region 104 when the threshold amount of intrathoracic pressure is reached by configuring the valve 108 to be a threshold valve. The valve 108 can be configured in a variety of ways, with a primary function being that the valve 108 allows air to flow into the downstream region 104 when a threshold amount of intrathoracic pressure is reached. This is preferably accomplished by configuring the plug 110 to be flexible in one direction so that when the pressure in the downstream region 104 reaches or exceeds the threshold amount, the plug 110 is flexed to provide an opening 126 between the upstream region 102 and downstream region 104. When the plug 110 is flexed, air flows from the lower pressure upstream region 102 into the downstream region 104 and to the patient's lungs. The plug 110 therefore acts as a one-way valve allowing air to flow from the upstream region 102 into the downstream region 104 when the threshold amount is reached, but does not allow airflow from the downstream region 104 to the upstream region 102. Preferably, the plug 110 will flex to open when the pressure within the downstream region 104 is in the range from about 0 mm H_2O to 50 cm H_2O, more preferably at about 10 cm H_2O to 40 cm H_2O, and more preferably at 15 cm H_2O to about 20 cm H_2O. Alternatively, the valve 108 can be placed in the downstream region 104 so that air flows into the downstream region 104 directly from the atmosphere when the valve 108 is open. Although shown as a flexible plug, it will be appreciated that other types of valve arrangements may be used. For example, plug 110 could be replaced with a spring biased valve that closes opening 126 until the negative intrathoracic pressure overcomes the force of the spring to open the valve in a manner similar to that described in connection with Fig. 16A.

Ventilating the patient by injecting air into the upstream region 102 is illustrated in Fig. 14. As air is injected through the intake opening 112, it passes into the accordion valve 116 and forces the valve 116 against a wall 120 and covers a hole 122 in the wall 120 to prevent airflow through the exhaust opening 114. When the accordion valve 116 is closed, air flows through a wall 124 of the valve 116 and into the upstream region 102. Alternatively, a fish mouth valve can be used in place of the accordion valve 116. Upon injection of the air into the upstream region 102, the pressure within the upstream region 102 becomes greater than the pressure in the ambient pressure region 118 and causes the diaphragm 106 to be drawn into the ambient pressure region 118. An opening between the upstream region 102 and the downstream region 104 is created allowing air to flow into the

downstream region 104 and into the patient's lungs. Preferably, the patient will be manually ventilated by injecting air into the intake opening 112 one time every five compressions of the chest, and more preferably about two times every 15 compressions of the chest using two rescuers. Similarly, ventilating the patient can occur through the same port where the spring-biased valve is located, such as through valve 160 of Fig. 16A.

Configuration of the valving system 100 upon return of spontaneous circulation is illustrated in Fig. 15. When the patient's circulation is restored, the valve 108 is manually opened by translating the valve 108 to remove the plug 110 from aperture 126. The upstream region 102 and downstream region 104 are then placed in communication to allow air to be freely exchanged between each of the regions 102, 104. Although shown extending through the upstream region 102, the valve 108 can alternatively be placed anywhere along the downstream region 104.

The valve 108 can be configured as a pressure-responsive valve (see Fig. 13), as a manually operable valve (see Fig. 15), or both. Further, the valving system 100 can alternatively be provided with two or more valves that are similar to the valve 108. For example, one valve could be non-translatably held in the housing 101 and provided with a pressure-responsive plug 110, with the other valve being translatably mounted. In this manner, the valve with the flexible plug functions as a pressure-responsive valve and opens when the threshold pressure is reached, while the translatable valve functions to place the regions 102, 104 in communication upon manual operation after spontaneous circulation is achieved.

Referring to Figs. 16A and 16B, an exemplary embodiment of a valving system 130 will be described. The valving system 130 is constructed of a housing 132 having an intake opening 134, an exhaust opening 136, and a delivery opening 138. Included in the exhaust opening 136 is a one-way valve 140 which allows air to flow from the housing 132 and out the exhaust opening 136. An accordion valve 140 is provided between the intake opening 134 and an exhaust opening 136 to prevent air injected into the intake opening 134 from exiting through the exhaust opening 136. Preferably, the intake opening 134 is configured to be attachable to a respiratory device, such as a respiratory bag (including an AMBU bag), a ventilator, a mouthpiece or port for mouth-to-mouth breathing through the system 130, or the like. The delivery opening 138 is preferably configured for connection to an endotracheal tube or other airway tube, a sealed facial mask, a laryngeal mask, or the like.

Within the housing 132 is an upstream region 142, a downstream region 144, and an ambient pressure region 146. Separating the upstream region 142 from the downstream region 144 is a diaphragm 148. The diaphragm 148 is preferably constructed of an elastomeric material. The housing 132 is preferably cylindrical in geometry at the downstream region 144, with the diaphragm 148 resting on the cylinder during ambient conditions. During decompression of the patient's chest, the reduction in pressure in the downstream region 144 draws the diaphragm 148 against the end of the cylinder to prevent exchange of air between the upstream region 142 and downstream region 144. During compression of the patient's chest, air is forced into the downstream region 144 to force the diaphragm 148 into the ambient pressure region 146 so that the air exhausted from the patient's chest can be exhausted through the exhaust opening 136.

As shown best in Fig. 16B, the valving system 130 is further provided with a fenestrated mount 150. In one aspect, the fenestrated mount 150 serves as a mount for holding the diaphragm 148 over the downstream region 144. The fenestrated mount 150 further provides the ambient pressure region 146. Fenestrations 152 are provided in the mount 150 to allow air to be exchanged through the mount 150. Included on the mount 150 is a deflector 154 for deflecting air around the fenestrated mount 150. Various other deflectors 156 are provided in the housing 132 for directing airflows between the regions 142 and 144. A filter 158 is provided in the housing 132 to filter air injected into the housing 132. Optionally, a filter 159 can be provided to prevent excess body fluids from entering into the system 130.

The valving system 130 further includes a threshold valve 160 at the downstream region 144. When the pressure within the downstream region 144 is less than the threshold amount, the threshold valve 160 is opened to allow air to flow into the downstream region 144. The threshold valve 160 includes a spring 162 which is configured to extend when the threshold amount is reached. Alternatively, the threshold valve 160 can be configured similar to the valve 110. Other configurations which allow the for air to enter the downstream region 144 when the desired intrathoracic pressure is reached or exceeded can also be provided. For example, in a further alternative, the diaphragm 148 can be constructed to function as a threshold valve to allow air to flow into the patient's lungs when a threshold amount of intrathoracic pressure is reached. The diaphragm 148 can be fashioned as a threshold valve by constructing the diaphragm 148 of an elastomeric material and by

providing at least one hole near the periphery. When the diaphragm rests on the cylinder forming the downstream region 144, the hole is positioned beyond the periphery of the cylinder and in the upstream region 142. As a vacuum is created in the downstream region 144, the diaphragm is drawn into the downstream region 144 until the hole is stretched over the cylinder and overlaps with both the upstream region 142 and the downstream region 144. In this way, a fluid path is provided between the regions 142 and 144 when the threshold pressure is reached in the downstream region 144. Another alternative of a threshold valve 111 is illustrated in Fig. 16C. The valve 111 is pivot mounted within the downstream region 144 and is biased closed by a spring 113. When the threshold pressure within the downstream region 144 is reached, the spring 113 is compressed and air is drawn into the downstream region 144.

Referring back to Fig. 16A, the threshold valve 160 can optionally be provided within the housing 132 at the upstream region 142. The threshold valve 160 can further optionally be provided with an on/off switch for opening the valve 160 when spontaneous circulation is achieved. In this manner, a rescuer can open the valve 160 to allow for free exchange of air to the patient's lungs when needed. In one alternative as shown in Fig. 16C, the mount 150 can be slidably mounted within the housing 132 so that the mount 150 can be vertically raised to lift the diaphragm 148 from the downstream region 144 upon successful resuscitation of the patient, thereby providing a free flow of air to the patient. The mount 150 can be slidably mounted within the housing 132 by attaching the mount 150 to an extension member 133 that is slidable within the housing 132. The member 133 preferably includes the intake and exhaust openings 134 and 136. In this way, an easy grasping surface is provided when translating the member 133 to open or close the diaphragm 148. If the diaphragm 148 were also fashioned as a threshold valve as previously described, the need for the valves 108 or 111 could be eliminated.

The housing 132 can conveniently be constructed in several parts which are connected together at various connection points. In this manner, the housing can be taken apart for connection to other devices, for repair, for cleaning, and the like. For example, one connection point can be conveniently provided near the filter 158 for removably connecting the portion of the housing having the intake opening 134, the valve 140, and the exhaust opening 136. Alternatively, a connection point can be provided near the mount 150 to provide easy access to the mount 150 for cleaning.

The valving system 130 can conveniently be incorporated with a variety of devices useful in CPR procedures. For example, the valving system 130 can be incorporated within a respiratory bag, such as an AMBU bag. Alternatively, the valving system 130 can be included as part of a respiratory circuit having both a respiratory bag and an endotracheal tube or other airway tube, with the valving system 130 positioned between the bag and the tube. In further alternative, the valving system 130 can be added to an endotracheal tube alone. Alternatively, the valving system can be incorporated into a mask, an oralpharyngeal airway, a laryngeal mask or other ventilatory devices.

In some cases, patient ventilation may be provided through threshold valve 160 as shown in Fig. 16D. In such a case, intake opening and valve 140 are optional since all ventilation may occur through threshold valve 160. Of course, ventilation could be provided through both avenues. Further, although shown in the context of valving system 130, it will be appreciated that the other embodiments described herein may be modified to include a pressure source that is coupled to the threshold valve.

As shown in Fig. 16D, a tank 300 of pressurized gas, such as O_2.is coupled to housing 132 by a length of tubing 302. In this way, a pressurized gas may be supplied to the back side of threshold valve 160. A regulator 304 is coupled to tank 300 to regulate the pressure supplied to threshold valve 160 so that it is less than the pressure required to open valve 160. For example, if respiratory gases are to be supplied to the patient when the negative intrathoracic pressure exceeds -14 cm H_20, then the actuating valve pressure may be set at -14 cm H_20, and the pressure of the gas from tank 300 may be set less than -14 cm H_2O. In this way, valve 160 will not prematurely open. In some cases, regulator 304 may also be used to regulate the flow rate of the gas through valve 160.

By coupling tank 300 to valve 160, respiratory gases are pulled into downstream region 144 when valve 160 opens due to the decrease in negative intrathoracic pressure as previously described. In this way, more respiratory gases are supplied to the patient each time the patient's chest is decompressed. This approach allows for negative pressure ventilation, unlike positive pressure ventilation which impedes venous return to the chest with each active rescuer ventilation. The negative pressure ventilation with this approach allows for adequate oxygenation and maximum venous blood return during CPR. Tank 300 may also function to provide oxygen once the trigger pressure has been achieved.

Referring to Fig. 17, an alternative valving system 164 will be described. The valving system 164 is shown schematically and operates essentially identical to the valving system 100, the difference being that the valving system 164 includes a ball or spherical member 166 as the diaphragm. During decompression of the patient's chest, the pressure in a downstream region 168 is less than the pressure in an upstream region 170 which draws the ball 166 over the downstream region 168. The valving system 164 can optionally be provided with a spring 172 or other biasing mechanism to hold the ball 166 over the downstream region 168 during compression of the patient's chest until a threshold pressure is reached or exceeded in the downstream region 168 as previously described.

Referring now to Fig. 18, another exemplary device 200 which is useful when performing cardiopulmonary resuscitation will be described. As described in greater detail hereinafter, one important feature of device 200 is that it may be interfaced to the patient's airway to periodically supply air to the patient's lungs when performing cardiopulmonary resuscitation. In this way, the patient may be ventilated with air (or other desired gases, such as O_2) rather than with respiratory gases from the rescuer's lungs as is typically the case when performing mouth-to-mouth resuscitation.

Device 200 comprises a facial mask 202 and a housing 204 that is operably attached to facial mask 202 at an interface 206. Housing 204 includes an upper region 208 and a lower region 210. Lower region 210 includes a pressure responsive valving system 212 which operates in a manner similar to the embodiments previously described herein to prevent the flow of gases into the patient's lungs until a threshold negative intrathoracic pressure is exceeded. At this point, pressure responsive valving system 212 allows gases to flow into the patient's lungs in a manner similar to that previously described herein. Lower region 210 further includes a fish mouth valve 214 and one-way outflow valves 216. Valves 214 and 216 operate together to allow gases exhausted from the patient's lungs to exit device 200 as indicated by arrow 218. In particular, when gases are forced out of the patient's lungs, fish mouth valve 214 will be closed and the exhausted gases will escape from device 200 through valves 216.

Upper region 208 includes a mouth piece 219 to allow a rescuer to blow into device 200 when attempting to ventilate a patient (similar to conventional CPR). Upper region 208 defines an air chamber 220 for holding room air and has a volume of about 200 ml to about 800 ml. Chamber 200 may also be connected to an oxygen source. Disposed within

upper region 208 is a diaphragm 222 and a spring 224. With this configuration, when a rescuer blows air into mouth piece 219, spring 224 will compress as diaphragm 222 moves downward. In turn, air or oxygen held within air chamber 220 will be compressed and hence forced through valving system 212 and into facial mask 202. In this way, air (rather than respiratory gases) from the rescuer will be supplied to the patient when the rescuer performs mouth-to-mouth resuscitation by blowing into mouth piece 219.

Upper region 208 further includes a one-way inflow valve 226 which allows air chamber 220 to be replenished with room air following ventilation. In particular, as spring 224 expands valve 226 will open to allow room air to fill chamber 230 due to the negative pressure created in chamber 230 by spring 224. Inflow valve 226 will also open when the threshold negative intrathoracic pressure is exceeded causing pressure responsive valving system 212 to open. In this way, inflow valve 226 also serves as a venting mechanism to vent air into housing 204 when the negative intrathoracic pressure limit is exceeded.

Hence, device 200 allows a rescuer to ventilate a patient with room air simply by blowing into mouth piece 219. Of course, it will appreciated that other desirable gases may be placed within air chamber 220 so that such gases may be supplied to the patient when the rescuer blows into mouth piece 219. For example, a volume of O_2 may be placed within chamber 220.

As previously described, one aspect of the invention is the ability to prevent respiratory gasses from entering the lungs until a certain negative intrathoracic pressure is met or exceeded. One aspect of the invention is the ability to vary the pressure at which respiratory gasses are permitted to flow to the lungs. In some cases, this may be accomplished by varying the actuating or cracking pressure of the pressure-responsive inflow valve. However, other mechanisms may be provided to vary the pressure at which respiratory gasses are permitted to flow to the lungs without modifying the cracking pressure of the pressure-responsive inflow valve. Hence, mechanisms for varying the pressure at which respiratory gasses are permitted to flow to the lungs may be incorporated in the pressure-responsive inflow valve, another valve in the valving system, or may be a separate part of the overall valving system.

Such a system may be configured so that the actuating pressure may vary between about 0 cm H_2O to about -30 cm H_2O. Further, such a valving system may be used

alone with a spontaneous breathing patient or with a patient receiving standard manual closed-chest CPR. Such a valving system may also be used in conjunction with other resuscitation techniques and/or devices, including, for example, ACD CPR, Vest CPR, or the like. In some cases, such a valving system may be used in connection with a diaphragmatic stimulator for purposes of resuscitation from cardiac arrest as well as for increasing blood pressure by advancing venous return. Exemplary systems and techniques for diaphragmatic stimulation for purposes of resuscitation are described in U.S. Patent Application Nos. 09/095,916, filed 06/11/98; 09/197,286, filed 11/20/98; 09/315,396, filed 05/20/99; and 09/533,880, filed 03/22/00, incorporated herein by reference. As a further example, such a valving system may be used to improve central blood return to the heart in patients in cardiac arrest, patients with low blood pressure and patients in right heart failure and in shock.

A variety of mechanisms may be used to vary the degree at which respiratory gasses are permitted to flow to the lungs. For example, such a mechanism may be mechanical or electronic or may include various combinations of mechanical and electronic components, and may be regulated within a larger system by, for example, electronic communication between the device used for resuscitation and the pressure-responsive inflow valve. Such a mechanism may also be adjustable based upon the in-line measurement of gasses, such as the measurement of end-tidal CO_2, the average minute ventilations, peak negative inspiratory pressures, and the like.

Referring to Fig. 19, one embodiment of a valving system 400 having an adjustable pressure-responsive inflow valve 402 will be described. Valving system 400 is shown schematically and may be constructed similar to any of the embodiments described herein. As such, when valving system 400 is interfaced with a patient's airway, the patient may freely exhale through valving system 400. When attempting to inhale, or during a decompression step of CPR, respiratory gasses are prevented from entering the lungs until a threshold actuating pressure is reached. At such time, respiratory gasses are permitted to flow to the lungs through inflow valve 402 in a manner similar to that previously described with other embodiments.

Inflow valve 402 includes a tension adjust knob 404 that may be turned by the rescuer to adjust the threshold actuating pressure of inflow valve 402 and will be described in greater detail with reference to Figs. 20-22. As best shown in Fig. 20, inflow valve 402 comprises an outer housing 406 having a set of tracking channels 408 (see Fig. 22). Outer

housing 406 is configured to hold an O-ring housing 410 having a top segment 412 and a bottom segment 414. Disposed between top segment 412 and bottom segment 414 is an O-ring 416. Top segment 412 further includes a set of tracking rails 418 that slide within tracking channels 408. A tension spring 420 sits between tension adjust knob 404 and top segment 412 and biases O-ring 416 against outer housing 406. When O-ring 416 is biased against outer housing 406 the valve is in the closed position where respiratory gasses are prevented from passing through ventilation ports 422 and to the patient's lungs. When the negative intrathoracic pressure meets or exceeds the threshold actuating pressure of inflow valve 402, the tension in spring 420 is overcome, causing O-ring 416 to separate from outer housing 406. At this point, respiratory gasses are free to rush through ventilation ports 422 and to the patient's lungs.

To vary the actuating pressure of inflow valve 402, knob 404 is turned to advance or retract a threaded nut 424 along a threaded bolt 426 that in turn is coupled to top segment 412. In so doing, the tension of spring 420 is varied to vary the actuating pressure of inflow valve 402. Hence, knob 404 provides a convenient way for a rescuer to adjust the actuating pressure simply by turning knob 404. Although not shown, a pressure gauge may be disposed within valving system 400 and a display may be provided to display the negative intrathoracic pressure. In this way, the rescuer may readily visualize the pressures generated within valving system 400 and may adjust knob 404 to vary the pressure at which respiratory gasses are permitted to flow to the lungs.

Another feature of the invention is the use of a safety mechanism to permit respiratory gasses to freely flow to the patient through the valving system until the rescuer places the valving system in an operative mode. Once in the operative mode, the valving system will remain in that mode indefinitely or for a finite period of time, at which the safety mechanism would revert back to its initial state where respiratory gasses may freely flow to the lungs. In some embodiments, this may be accomplished by having the safety mechanism maintain the pressure responsive inflow valve in the open position (without any impedance to inspiratory air flow) until actuated by the rescuer. Actuation may be accomplished in a variety of ways, such as by injected respiratory gasses into the valving system (such as when ventilating the patient), by operating a button or switch on the valving system, or the like.

One advantage of such a safety mechanism is that it ensures that the patient can freely breathe through the valving system (assuming the patient is spontaneously

breathing or begins to spontaneous breathe) without any resistance from the pressure-responsive inflow valve. Once the rescuer is ready to begin a procedure, such as performing CPR, the valving system is placed in the operative mode where respiratory gas flow to the lungs is prevented through the pressure-responsive inflow valve until the threshold negative intrathoracic pressure is met or exceeded. As with other embodiments described herein, respiratory gasses may also be injected into the patient's lungs through the valving system, thereby bypassing the pressure-responsive inflow valve.

The safety mechanism may operate as a purely mechanical device, a purely electronic device, or may include various combinations of mechanical and electronic components. One way for placing the valving system in the operative mode is by utilizing a sensor to detect when respiratory gasses are injected into the valving system through the ventilator port. The signal from the sensor may then be used to close a ventilation passage within the valving system. In some cases, the ventilation passage may extend through the pressure-responsive inflow valve. To close this passage, the inflow valve is simply closed. In some embodiments, if rescuer ventilation is not provided within a certain time, the safety mechanism may be used to take the valving system out of its operative mode so that respiratory gasses may freely flow to the patient's lungs.

Referring now to Figs. 23 and 24, one embodiment of a valving system 430 with such a safety feature will be described. This configuration may be used in series with any of the previously described valving systems so that it will have a means of impeding airflow to the patient's lungs. Hence, it will be appreciated that valving system 430 may be constructed to have, or used in combination with, components similar to the other valving systems described herein and will not be illustrated to simplify discussion. Valving system 430 includes a housing 432 that may be similar to the housings of the other valving systems described herein except that housing 432 includes a safety ventilation port 434 that permits respiratory gasses to flow into and through housing 432 so that respiratory gasses may flow to the patient's lungs as shown by the dashed line in Fig. 23. Hence, as shown in Fig. 23, valving system 430 is in a passive mode where the patient may freely breathe through housing 432.

Valving system 430 further includes a safety mechanism 436 that is operative to maintain ventilation port 434 open until actuated by a rescuer. When actuated, safety mechanism 436 closes ventilation port 434 to place valving system 430 in the operative mode

where respiratory gasses are prevented from reaching the lungs through a pressure-responsive inflow valve until a threshold negative intrathoracic pressure is met or exceeded in a manner similar to that described in other embodiments.

Safety mechanism 436 comprises an electronic air flow sensor 438 that is electrically connected to control circuitry 440. In turn, control circuitry 440 is electrically connected to a micro-solenoid 442 having a valve stop 444. A battery 445 is used to supply power to the electrical components. When a rescuer is ready to place valving system 430 in the operative mode, the rescuer injects respiratory gasses into housing 432 (such as by blowing air or injecting a pressurized gas into a ventilation port, not shown). As the respiratory gasses flow to the patient's lungs through housing 432, sensor 438 is moved to trigger a switch and to send an electrical signal to control circuitry 440. Control circuitry 440 then sends a signal to solenoid 442 to move stop 444 and thereby close the valve, thus preventing airflow to the patient through safety ventilation port 434. Such a state is illustrated in Fig. 24 where valving system 430 is in the operative mode. At this point, a spontaneously breathing patient will need to breathe through a pressure-responsive inflow valve. For a non-breathing patient, respiratory gasses will be prevented from reaching the lungs during the performance of CPR until a threshold negative intrathoracic pressure is overcome, at which point respiratory gasses may flow through the inflow valve and to the patient's lungs in a manner similar to that described with other embodiments. If, after a certain time, sensor 438 is not actuated by the rescuer, control circuitry 440 may be configured to operate solenoid 442 to take valving system 430 out of the operative mode where respiratory gasses may flow through safety ventilation port 434.

In some embodiments, the valving systems of the invention may incorporation a safety mechanism having essentially all mechanical elements. One such embodiment of a valving system 480 is illustrated in Figs. 25 through 33 and 36 through 40. Valving system 480 comprises a housing 482 that houses various components that may be similar to the other embodiments described herein. As such, housing 482 includes a ventilation port 484 and an exit opening 486. Valving system 480 further includes a pressure-responsive inflow valve 488 that prevents respiratory gasses from flowing to the patient's lungs until a certain negative intrathoracic pressure level has been met or exceeded in a manner similar to that described with other embodiments. Valving system 480 further includes a safety mechanism 490 to permit respiratory gasses to freely flow to the patient's lungs until operated to place

valving system 480 in an operative mode where pressure-responsive inflow valve 488 controls when respiratory gasses are permitted to flow to the lungs. As described in greater detail hereinafter, safety mechanism 490 also includes an inflow valve 492. In some embodiments, inflow valve 492 may be configured as a pressure-responsive inflow valve and thereby eliminate the need for inflow valve 488.

Safety mechanism 490 further comprises a flow sensor 494 that is in the form of a flap. Flow sensor 494 pivots about a pivot point 496 to move a cam mechanism 498, thereby rotating a wheel 500. In Figs. 25 and 30, valving system 480 is in the inactive state where flow sensor 494 has not yet been activated. When respiratory gasses are directed through housing 482, flow sensor 494 pivots about pivot point 496 as previously described to rotate wheel 500 as illustrated in Figs. 27, 28 and 30.

As best shown in Fig. 29, wheel 500 is connected to a gear system 502 having a recoil spring 504 and a valve cam 506. Recoil spring 504 is employed to bias cam 506 in the position illustrated in Figs. 25 and 30 where valve 492 is in the open position. When gasses flow through housing 482, flow sensor 494 is moved to cause wheel 500 to rotate and thereby operate gear system 502. In so doing, cam 506 is rotated to the position shown in Figs. 27 and 31 where valve 492 moves to the closed position. Gear system 502 and recoil spring 504 operate to open valve 492 after a certain period of time has elapsed, such as about 10 to 20 seconds.

As best shown in Figs. 30 and 31, valve 492 comprises a valve housing 508 in which is held a valve shaft 510 that holds an O-ring 512. A tension spring 514 is positioned between housing 508 and a projection 516 on shaft 510 to bias the valve 492 in the closed position as illustrated in Fig. 31. When a rescuer injects respiratory gasses into the housing of the valving system, cam 506 moves to the position shown in Fig. 30 where it engages shaft 510 and disengages O-ring 512 from housing 508 to place valve 492 in the open position. In the open position, respiratory gasses are free to flow through valve 492 and into housing 482 where they may flow to the patient's lungs through exit opening 486.

The invention further provides systems having safety features that allow for the patient to inhale to a given degree to release the mechanism that is used to impede or prevent respiratory gases from flowing to the lungs, thereby allowing for resistance free inspiration until a timer resets the systems or until the rescuer resets the system. One embodiment of a safety valve 600 that may be used with such systems is illustrated in Figs.

32 and 33. Safety valve 600 may be used as a replacement for any of the pressure responsive valves described herein, such as, for example, valves 108, 160 and 111. Valve 600 comprises a housing 602 which is covered by a slit membrane 604. A valve member 606 is biased by a spring 608 into a closed position as shown in Fig. 32. In the closed position, a wedge 610, that may conveniently be colored for easy identification, extends above the slit in membrane 604. As such, wedge 610 serves as a visual indicator to the rescuer that valve 600 is in the closed position. When interfaced with a patient and in the closed position, respiratory gases may be prevented from flowing to the lungs until the negative intrathoracic pressure meets or exceeds a threshold value in a manner similar to that described with other embodiments. At such time, a seal 612 on valve member 606 moves away from a stop 614 on housing 602 to permit respiratory gases to flow to the lungs. Spring 608 then forces valve member 606 back to the closed position.

If the patient gasps and begins to breath, the amount of negative pressure created by the patient compresses spring 608 far enough so that wedge 610 is pulled through the slit in membrane 604 as shown in Fig. 33. Wedge 610 then holds valve 600 in the open position where gases may freely flow to the lungs. The rescuer may easily determine valve 600 is in the open position by noticing that wedge 610 is no longer visible. The rescuer may reset valve 600 at any time by simply pulling on a pull tab 616 to pull wedge 610 back through membrane 604.

Another embodiment of a safety valve 620 that may be used in the systems described herein is illustrated in Figs. 34 and 35. Valve 620 comprises a housing 622 having a stop 624. A micro-solenoid 626 is disposed within housing an includes an arm 628 having a pole magnet 629 and a visual indicator 630 at an opposite end. Spaced apart from pole magnet 629 is another pole magnet 632 of opposite polarity that is coupled to a valve member 634 having a seal 636. Coupled to housing 622 is a normally open contact strip switch 638, and valve member 634 includes a conductive strip 640. A spring 642 is disposed between strip 640 and stop 624.

Fig. 34 illustrates valve 620 in the closed or active position. During CPR, seal 636 will separate from stop 624 to permit respiratory gases to flow to the lungs when the negative intrathoracic pressure exceeds a threshold value. Valve 620 then returns back to the closed position. If the patient gasps, valve member 634 moves to the position shown in Fig. 35 where conductive strip 640 contacts switch 638. (During normal CPR, valve member 634

is not moved far enough for this contact to occur). This closes the open circuit and activates solenoid 626 to extend arm 628 and trigger a timing circuit within a control circuitry and battery compartment 644. Magnets 629 and 632 have opposite poles causing valve to remain in the open and inactive position as shown in Fig. 35 as long as solenoid 626 is actuated. In this way, the patient may continue to freely breath through valve 620. Although shown with opposing pole magnets, it will be appreciated that magnets may be substituted with a solenoid arm that may act as a plunger to make physical contact with valve member 634, and thus hold the valve open and inactive. The rescuer may note that valve 620 is in the open position by noting that indicator 630 has been retracted and is no longer visible.

Valve 620 may include an auto/manual switch 646 that may be set in automatic mode. In this mode, the timing circuit automatically deactivates solenoid 626 and returns valve 620 back to the closed and active position shown in Fig. 34 after a preset timing interval has expired. If switch 646 is set to manual, solenoid 626 remains active and valve 620 remains open and inactive as shown in Fig. 35 where respiratory gases may freely flow to the lungs. Valve 620 remains open until the rescuer manually resets solenoid 626 by pressuring a manual reset switch 648. The rescuer may note that valve 620 is closed and active by observing indicator 630 that is now extended.

Figs. 36 and 37 illustrate a further embodiment of a safety valve 650 that may be used with the systems described herein. Valve 650 comprises a housing 652 having a stop 654. Disposed within housing 652 is a valve member 656 having a seal 658 that contacts stop 654 to prevent gases from flowing through valve 650 when in the closed or active position shown in Fig. 36. In the closed position, a spring 660 biases seal 658 against stop 654 until the negative intrathoracic pressure exceeds a threshold value and seal 658 moves away from stop 654 to permit respiratory gases to flow to the lungs. Once the negative intrathoracic pressure falls below the threshold value, valve 650 moves back to the closed position.

When the patient gasps, the force created is great enough to move valve member 656 such that a pair of spring loaded pins 662 lodge within grooves 664 of a locking pin receptacle 666 on valve member 656 as shown in Fig. 37. In this way, valve 650 is locked into an open or inactive position that is created by the patient's gasp. As pins 662 move into grooves 664, the ends of pins 662 move into housing 652 to indicate to the rescuer that the valve is inactive. Conveniently, the ends of pins 662 may be colored to make them

more visible to the rescuer. To reactivate valve 650, the rescuer may pull upward on a pull tab 668 on valve member 656. This releases pins 662 from grooves 664 and permit the valve to spring back to the closed position of Fig. 36.

Referring now to Figs. 38-40, a modified version valve 650 is shown incorporated into a valve system 670 that may be coupled to a patient's airway in a manner similar to the other valve system embodiments described herein to regulate the airflow to the patient's lungs during a CPR procedure. For convenience of discussion, identical elements of valve 650 will use the same reference numerals in describing Figs. 38-40. The use of valve 650 allows the patient to gasp and breathe free of airway resistance after the initial gasp has occurred. Alternatively, valve 650 may be initially set in the inactive position and placed in the active state upon the initial ventilation through valve system 670, or upon subsequent ventilations if the patient gasps and locks valve 650 open and inactive.

Valve 650 is incorporated into a system housing 672 having an inlet end 674 and an outlet end 676. Conveniently, patient ventilation may occur through inlet end 674 using a ventilatory source similar to other embodiments. Outlet end 676 may be coupled to an interface that permits system 670 to be interfaced with the patient's airway. Disposed within housing 672 is a one way membrane valve 678 that is spaced apart from port 680. In Fig. 38, system 670 is in the resting state where no gasp or ventilation has occurred. When performing CPR, the chest is compressed and air forced from the patient is permitted to flow through port 680 and through valve 678. During decompression of the patient's chest, valve membrane 678 moves against port 680 to close the valve as the negative intrathoracic pressure is increased. If a threshold pressure is overcome, valve 650 opens to permit respiratory gases to flow through opening 676 after passing through valve 650. Valve 650 then moves back to the closed position and the cycle is repeated.

If valve system 670 is coupled to a patient's airway and the patient gasps or begins spontaneously breathing, valve system 670 automatically adjusts to the configuration shown in Fig. 39 so that the patient may breathe through a resistance fee airway path so that respiratory gas exchange may occur. When the patient gasps or begins to breathe, valve 678 closes and the negative pressure causes valve 650 to open and lock in place in a manner similar to that previously described in connection with Fig. 37. In this way, valve 650 remains open and inactive until reset by the rescuer by pulling on pull tab 668.

Another way to place valve 650 back into the closed or active position is by ventilating the patient through inlet 674 as shown in Fig. 40. When injecting a respiratory gas into inlet 674, the injected gases flow through valve 678 and through port 680 where the exit through outlet 676 and to the patient. In so doing, the flow of gases moves a ventilation flap 682 that in turn moves an arm 684 that is coupled to a wedge 686. Movement of wedge 686 causes lateral movement of an arm 688 that is connected to a reset wedge 690. Wedge 690 rests on top of an upward movement ramp 692. As arm 688 is laterally moved, wedge 690 moves up ramp 692 and contacts pull tab 668. In so doing, valve member 656 is pulled up until pins 662 are pulled from grooves 664 and valve 650 moves back to the closed and active position by force of spring 660. A reset spring 694 then resets ventilation flap 682 back to its home position and wedge 690 slides back down ramp 692 so that valve 650 may be reset back to the closed position if subsequently needed. Valve 650 remains in the closed and active position until another gasp or spontaneous breathing occurs.

Fig. 41 schematically illustrates another embodiment of a valving system 700 that is configured to display the pressure within the patient's chest during CPR. Valving system 700 may be configured to be similar to any of the valving systems described herein. Hence, for convenience of discussion, valving system 700 will only be briefly described. Valving system 700 comprises a housing 702 having an inlet 704 and an outlet 706. A pressure responsive valve 708 is used to control the inflow of gases into housing 702 during decompression of the patient's chest in a manner similar to that described with other embodiments. A pressure gauge 710 is provided to measure and display the pressure within housing 702 which corresponds to the pressure within the patient's chest. In this way, pressure gauge 710 may be used to provide immediate feedback to the rescuer and may be used as a guide to determine if chest compressions and/or decompressions are being appropriately performed.

A pressure sensing port 712 is connected to a tube 714 that is connected to a pressure sensing control unit 716. In this manner, a change in pressure may be detected during either chest compressions or decompressions and act as a counting circuit to trigger ventilation control circuitry 718 to automatically ventilate the patient using a ventilator 720 after a certain number have been detected.

Alternatively, a digital control unit may be used that displays the pressure within the chest as well as the number of compressions between ventilations. With such a

configuration, pressure sensing port 712 transmits pneumatically the pressure information. As such, a pressure gauge on housing 702 would not be required.

The valving systems of the invention may also be used to treat shock. Shock may conveniently be defined as a critically low blood pressure that, when untreated, may lead to death or disability. Types of shock that may be treated using techniques of the invention include, but are not limited to, low blood pressure secondary to blood loss, heat stroke, vasovagal syncope (the common faint), drowning, drug overdose, heart attack, right heart failure, return to earth after space flight, sepsis, pericardial effusion, tamponade, and the like. Further, the valve systems of the invention may be used to alter the carotid cardiopulmonary reflex sensitivity that controls blood pressure (by decreasing intra thoracic pressures with inspiration).

The valve system that are employed to treat shock are configured to completely prevent or provide resistance to the inflow of respiratory gases into the patient while the patient is breathing. For valve systems that completely prevent the flow of respiratory gases, such valves may be configured as pressure responsive valves that open after a threshold negative intra thoracic pressure has been reached. Valve systems that simply provide resistance to the inflow of respiratory gases may also be variable so that once a desired negative intra thoracic pressure is reached, the resistance to flow may be lessened. Further, the valves of the invention may be configured to be variable, either manually or automatically. The extent to which the resistance to flow is varied may be based on physiological parameters measured by one or more sensors that are associated with the person being treated. As such, the resistance to flow may be varied so that the person's physiological parameters are brought within an acceptable range. Examples of physiological parameters that may be measured include, but are not limited to, negative intra thoracic pressure, respiratory rate, end tidal CO_2, positive end expiratory pressure, blood pressure, oxygen saturation, tissue CO_2 content, and the like. If an automated system is used, such sensors may be coupled to a controller which is employed to control one or more mechanisms that vary the resistance or actuating pressure of the inflow valve.

Referring now to Figs. 42 and 43, one embodiment of a system 800 that may be used to treat a person in shock will be described. System 800 comprises a housing 802 that is coupled to a facial mask 804. Housing 802 includes an inspiratory fenestrated port 806 where inspired gases are permitted to enter housing 802. Disposed below port 806 is a

slotted airway resistance mechanism 808 that may be used to completely prevent or provide resistance to the respiratory gases flowing into housing 802 through port 806. Resistance mechanism 808 is also illustrated in Figs. 46A and 46B and may be constructed of a slotted member 810 and a slotted plate 812. Slotted member 810 is movable relative to plate 812 to partially or fully cover the slots in plate 812 as illustrated in Fig. 46B. In this way, the resistance to the flow of inspired gases may be increased simply by moving slotted plate 812 relative to slotted member 810. As best shown in Fig. 42, a motor 814 that moves a shaft 816 may be employed to translate slotted member 810 over slotted plate 812 to vary the resistance to flow. Optionally, a filter 818 may be disposed below resistance mechanism 808.

System 800 further includes a one-way valve 820 that prevents expired gases from flowing back up through resistance mechanism 808. Disposed upstream of one-way valve 820 is an oxygen port 822 to permit oxygen to be supplied to the person during inspiration. System 800 further includes another one-way valve 824 that opens when the person expires to permit expired gases from exiting housing 802 through an expiratory port 826.

System 800 may also include one or more sensors 828 that measure various physiological parameters, such as flow rate, internal pressures within the patient, end tidal CO_2, and the like. These sensors may be coupled to a circuit board or controller 830 that may be programmed to vary operation of motor 814 based on the sensed parameters. In this way, the measured parameters may be kept within a desired range simply by controlling the resistance provided by resistance mechanism 808 in an automated manner. Although not shown, it will be appreciated that other sensors may also be coupled to circuit board 830 and may not necessarily be incorporated into housing 802 or mask 804. System 800 may also include a battery 832 to provide power to the various electrical components of system 800. A control button 834 may also be employed to actuate system 800.

Optionally, to ensure that the inspiratory lumen is never completely occluded by the airway resistance mechanisms, molded stops may be fabricated in a manner that the airway may always have a slight opening for inspiration to occur. As another option, the valve and sensing system may be attached to other airway devices, including an endo tracheal tube, a laryngeal mask, or the like.

Fig. 44 illustrates system 800 when mask 804 is coupled to a person and the person inhales. As shown, the inspired gases pass through resistance mechanism 808 which

has been operated to increase the resistance to flow. Optionally oxygen may also be supplied to the person through oxygen port 822. Fig. 45 illustrates when the person exhales. As shown, the expired gases pass through one-way port 824 and through expiratory port 826.

Although system 800 has been shown with one particular type of valve, it will be appreciated that a variety of inflow valves may be used including any of those previously described. Further, Figs. 47-53 illustrate other types of inflow valves that may be used to prevent or increase the resistance to flow during an inspiratory effort. Further, any of these inflow valves may be coupled to other mechanisms that may be used to operate the valve to vary the flow resistance. In this way, a controller may be used to automatically control the amount of resistance. Further, the controller may be coupled to one or more sensors so that various physiological parameters of the person may be kept within a desired range simply by measuring the parameters and using those parameters to vary the amount of resistance.

Figs. 47A and 47B illustrate an inflow valve 836 that comprises an airway 838 and a movable disk 840. Disk 840 may be moved by any type of mechanical mechanism to occlude airway 838 as shown to increase flow resistance.

Fig. 48A and Fig. 48B illustrate another embodiment of an inflow valve 842 that comprises an airway 844 and a rotatable disk 846. As shown in Fig. 48B, disk 846 may be rotated to increase the amount of flow resistance through airway 844.

Figs. 49A and 49B illustrate an inflow valve 848 that comprises an airway 850 that is positioned between a pair of plates 852 and 854. As shown in Fig. 49B, a rotatable cam 856 may be employed to move plate 854 to compress airway 850 and thereby increase flow resistance. Conveniently, cam 856 may be rotated by a motor 858 that in turn may be controlled by a controller in a manner similar to that previously described.

Figs. 50A and 50B illustrate a further embodiment of an inflow valve 860 that comprises an airway 862 that is positioned between two plates 864 and 866. In turn, plate 866 is coupled to a threaded shaft 868 that is movable back and forth by a stepper motor 870 that may also be coupled to a controller. In operation, stepper motor 870 is employed to move plate 866 against airway 862 as shown in Fig. 50B to increase the resistance to flow.

Figs. 51A and 51B illustrate an inflow valve 872 that comprises an airway 874 that is positioned between a pair of plates 876 and 878. These plates are coupled to a caliper mechanism 880 that in turn is coupled to a lead screw 882 that is movable by a stepper motor

884. In this way, stepper motor 884 may be used to operate caliper mechanism 880 to in turn squeeze airway 874 as shown in Fig. 51B to increase flow resistance.

Figs. 52A and 52B illustrate an inflow valve 886 that comprises an iris occluding mechanism 888. As shown in Fig. 52B, iris occluding mechanism 888 may be operated to decrease the size of the airway and thereby increase flow resistance.

Figs. 53A and 53B illustrate another embodiment of an inflow valve 890 that comprises an airway 892 and a rotatable arm 894 that in turn may be coupled to a stepper motor. As shown in Fig. 53B, arm 894 is rotatable over airway 892 to increase resistance to flow.

Figs. 54A through 54C illustrate one exemplary method for treating a person in shock. The process begins at step 900 where the treatment system may be coupled to the patient's airway. For example, the system previously described in connection with Fig. 42 may be coupled to the patient's face. The power is turned on as shown in step 902 and the airway resistance mechanism may be set to an open position as shown in step 904. The treatment mechanism may include various preset physiological parameters that may initially be read to determine the person's condition. At step 908, a determination is made as to whether a breath has been sensed based on the physiological parameters previously read in step 906. If no breath has been sensed, the process is reversed back to step 904 to ensure that the airway resistance mechanism is in the open position.

If a breath has been sensed, the process proceeds to step 910 where the airway resistance mechanism is set to a preset position. This position may be based on the initial physiological parameters that were sensed in step 906. Further, the airway resistance may be set manually or may be done automatically using a controller that is programmed with various preset positions based on measured physiological parameters. The process then proceeds to step 912 where the physiological parameters are evaluated to determine whether the negative inspiratory pressure is acceptable as the patient inhales. If the negative inspiratory pressure is too low, the process proceeds to step 914 where the airway resistance is increased. This may be done in an automated manner using the controller which operates the airway resistance mechanism to increase the airway resistance. After the resistance has been increased, the process proceeds to step 916 where sensors are employed to determine whether a breath is sensed. If not, the process reverts back to step 904 where the airway

resistance is moved back to its original position or to a fully open position and the process continues.

If the negative inspiratory pressure is too high, the process may proceed to step 918 where airway resistance is reduced. A breath measurement is then taken in step 920 to determine whether a breath is sensed. If not, the process proceeds back to step 904 where the airway resistance mechanism may be opened. If a breath is sensed in either step 920 or step 916, the process goes back to step 912 where another check on the negative inspiratory pressure is made. Once the negative inspiratory pressure is acceptable, the process proceeds to step 922 where the respiratory rate is evaluated. If the respiratory rate is unacceptable, the process proceeds to step 924 where the airway resistance is reduced. An evaluation as to whether a breath is sensed is made in step 926. If no breath is sensed, the process reverts back to step 904 where the airway resistance mechanism may be open. If a breath is sensed, the process proceeds back to step 922 where another evaluation of the respiratory rate is made. If the respiratory rate is acceptable, the process proceeds to step 928 and an evaluation as to the end tidal CO_2 is made. If too low, airway resistance is increased as shown in step 930 and another evaluation is made as to whether the patient is breathing in step 932. If not, the process proceeds back to step 904 where the airway resistance mechanism is opened. If the end tidal CO_2 is too high, the process proceeds to step 934 where the airway resistance is reduced and the patient's breathing is again sensed at step 936. If no breath is sensed, the process proceeds back to step 904 where the airway resistance mechanism is opened. If a breath is sensed in either steps 932 or 936, the process proceeds back to step 928 where the end tidal CO_2 is re-evaluated. Once acceptable, the process proceeds to step 938 where the oxygen saturation is evaluated. If too low, the airway resistance may be decreased as shown in step 940 and an evaluation is made as to whether the person is breathing as shown in step 942. If not, the process proceeds back to step 904 and the airway resistance mechanism is opened. If the oxygen saturation is acceptable, the process proceeds to step 912 so that the negative inspiratory pressure, respiratory rate, end tidal CO_2, and oxygen saturation may be continuously monitored and the airway resistance may be modified based on the parameters.

Hence, the method set forth in Figs. 54A through 54C permits various physiological parameters to be continuously monitored and to permit the resistance to inspiratory flow to be modified so that these parameters remain within an acceptable range when treating a patient suffering from shock. Further, as previously described, the

augmentation of negative inspiratory pressure permits increased blood flow back to the right heart to increase the patient's blood pressure. Although shown monitoring the various physiological parameters in a certain order, it will be appreciated that the parameters may be monitored in other orders as well. Further, other physiological parameters may be measured to ensure that the patient remains in a stable condition when treating the patient for shock. Optionally, the method of Figs. 54A through 54C may also be used to evaluate the patient's positive end expiratory pressure. Further, similar airway resistance mechanisms may be applied to the expiratory port and the airway resistance of the expiratory port may be varied based on the sensed parameters. For example, the expiratory pressure may be varied to aid in the prevention of alveoli collapse (atelectasis) which may occur when the negative intrathoracic pressure is too low for a prolonged period of time.

Although the foregoing invention has been described in some detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that certain changes and modifications may be practiced within the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A device for facilitating an increase in blood pressure in a breathing patient, said device comprising:

a housing having an opening that is adapted to be interfaced with a patient's airway;

an inflow flow valve that is operable to increase or decrease respiratory gas flow through the housing due to patient inhalation, the inflow valve assisting in manipulating intrathoracic pressures to increase blood flow back to the patient's chest;

a mechanism for operating the inflow valve to vary the respiratory gas flow through the housing; and

a sensor that is adapted and configured to sense at least one physiological parameter of the patient.

2. A device as in claim 1, wherein the inflow valve is operable to achieve a negative intrathoracic pressure within the range from about 0 cm H_20 to about -50 cm H_20 when the patient breathes at flow rates in the range from about zero flow to about 70 liters per minute.

3. A device as in claim 1, further comprising a controller that is coupled to the sensor and the mechanism, and wherein the controller is configured to send signals to the mechanism to operate the inflow valve based on the sensed physiological parameter from the sensor.

4. A device as in claim 1, wherein the sensor is selected from a group consisting of pressure sensors, flow sensors, CO_2 sensors, and oxygen sensors.

5. A device as in claim 1, wherein the inflow valve comprises a slotted opening and a slotted plate that is movable across the slotted opening.

6. A device as in claim 1, wherein the inflow valve comprises an airway and an occlusion member that is movable across the airway.

7. A device as in claim 1, wherein the inflow valve comprises an airway and a compression occluding system to compress the airway.

8. A device as in claim 1, wherein the inflow valve comprises an airway and an iris occluding system.

9. A device as in claim 1, wherein the mechanism comprises a stepper motor and a shaft extending from the stepper motor.

10. A device as in claim 1, wherein the housing includes an inspiratory port and an expiratory port, and further comprising a face mask that is coupled to the housing.

11. A device as in claim 1, further comprising means to add supplemental oxygen or periodic assisted ventilation to the patient.

12. A method for increasing the blood pressure in a spontaneously breathing person, the method comprising the steps of:

sensing at least one physiological parameter of the person;

interfacing an inflow valve to the person's airway that is operable to increase or decrease respiratory gas flow to the person's lungs;

operating the inflow valve based on the sensed parameter to increase or decrease respiratory gas flow to the person's lungs while the person is inhaling to create a vacuum within the thorax and increase blood flow back to the right heart of the person, thereby enhancing the person's blood pressure.

13. A method as in claim 12, wherein the person has low blood pressure due to conditions selected from a group consisting of blood loss, the administration of a drug, a high gravitational state, vasovagal syncope, cardiac tamponade, drowning, heat stroke, heart attack, right heart failure, return to earth after space flight, and sepsis.

14. A method as in claim 12, further comprising sending a signal to a controller that is representative of the sensed parameter, and sending a signal from the controller to a mechanism to operate the valve based on the sensed parameter.

15. A method as in claim 12, wherein the parameter sensed is selected from a group consisting of negative intrathoracic pressure, blood pressure, respiratory rate, end tidal CO_2, positive end expiratory pressure, and oxygen saturation.

16. A method as in claim 12, wherein the inflow valve is operated to achieve a negative intrathoracic pressure within the range from about 0 cm H_20 to about -50 cm H_20 when the person breathes at flow rates in the range from about zero flow to about 70 liters per minute.

17. A method as in claim 12, wherein the inflow valve comprises an airway and an occlusion member, wherein the occlusion member is moved across the airway to vary the flow rate through the inflow valve.

18. A method as in claim 12, wherein the physiological parameter is repeatedly sensed, and wherein the valve is repeatedly operated based the sensed parameters.

19. A method as in claim 12, further comprising supplying supplemental ventilation or oxygen to the person.

20. A method as in claim 12, further comprising supplying a drug or a medicament to the person upstream or downstream of the inflow valve.

21. A method for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation, by augmenting negative intrathoracic pressures, said method comprising the steps of:

interfacing a pressure responsive inflow valve to a patient's airway;

performing chest compression and chest decompression, wherein during chest decompression the inflow valve prevents respiratory gases from entering the lungs until a negative intrathoracic pressure level in the range from about -3 cm H_2O to -30 cm H_2O is exceeded at which time the inflow valve opens, said inflow valve assisting in increasing the magnitude and duration of negative intrathoracic pressure during decompression and thereby enhancing the amount of blood flow into the heart and lungs; and

supplying the patient with a pressurized respiratory gas through the inflow valve when the inflow valve opens to ventilate the patient.

22. The method of claim 21, further comprising interfacing an exhalation valve to the patient's airway, wherein the exhalation valve prevents air from leaving the lungs until a positive intrathoracic pressure threshold is exceeded at which time said exhalation valve opens, said exhalation valve assisting in forcing more blood out of the thorax.

23. The method of claim 22, wherein the positive intrathoracic pressure is in the range from about 2 cm H_2O to 20 cm H_2O.

24. The method of claim 21, further comprising providing a pressurized respiratory gas source that is operably coupled to the inflow valve, with the respiratory gas being at a pressure that is less than the opening pressure of the inflow valve, and wherein the respiratory gas is supplied from the respiratory gas source.

25. The method of claim 21, wherein the decompressing step comprises allowing the patient's chest to expand in response to the chest's resilience.

26. The method of claim 21, wherein the decompressing step comprises lifting or actively expanding the patient's chest to expand the thorax.

27. The method of claim 21, wherein the chest is compressed in the range from about 3.5 cm to 5 cm per compression, and wherein the chest is compressed in the rate from 60 to 100 per minute.

28. A method for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation, by augmenting negative intrathoracic pressures, said method comprising the steps of:

interfacing a valving system with a patient's airway, the valving system comprising a housing having an upstream region and a downstream region, a pressure-responsive valve between the upstream region and the downstream region for preventing respiratory gases from flowing from the upstream region to the downstream region until the pressure in the downstream region falls below a threshold level;

performing chest compression and decompression, wherein said pressure-responsive valve is closed to prevent respiratory gases from entering the lungs until a certain negative intrathoracic pressure is exceeded at which time the pressure-responsive valve

opens, said pressure-responsive valve assisting in increasing the magnitude and duration of negative intrathoracic pressure during decompression and thereby enhancing the amount of blood flow into the heart and lungs; and

supplying the patient with a pressurized respiratory gas through the pressure-responsive valve when the pressure-responsive valve opens to ventilate the patient.

29. The method of claim 28, further comprising, during chest compression, preventing air from leaving the lungs until a positive intrathoracic pressure threshold is exceeded to assist in forcing more blood out of the thorax.

30. The method of claim 29, wherein the positive intrathoracic pressure is in the range from about 2 cm H_2O to 20 cm H_2O.

31. The method of claim 28, further comprising providing a pressurized respiratory gas source that is operably coupled to the pressure-responsive valve, with the respiratory gas being at a pressure that is less than the opening pressure of the pressure-responsive valve and wherein the respiratory gas is supplied from the respiratory gas source.

32. The method of claim 28, wherein the decompressing step comprises allowing the patient's chest to expand in response to the chest's resilience.

33. The method of claim 28, wherein the decompressing step comprises lifting or actively expanding the patient's chest to expand the thorax.

34. The method of claim 28, wherein the chest is compressed in the range from about 3.5 cm to 5 cm per compression, and wherein the chest is compressed in the rate from 60 to 100 per minute.

35. A device for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation, said device comprising:

a housing having an opening that is adapted to be interfaced with a patient's airway;

a pressure responsive inflow flow valve which prevents respiratory gases from entering the lungs through the housing until a threshold negative intrathoracic pressure level

is exceeded during decompression of the patient's chest at which time the inflow valve opens, the inflow valve assisting in increasing the magnitude and duration of negative intrathoracic pressure during decompression and thereby enhancing the amount of blood flow into the heart and lungs; and

a source of pressurized gas operably coupled to the inflow valve to supply a pressurized gas to the patient through the housing when the inflow valve is open.

36. A device as in claim 35, further comprising a one way valve disposed in the housing to permit respiratory gases to exit the housing during compression of the patient's chest.

37. A device as in claim 35, further comprising a regulator disposed between the gas source and the inflow valve to regulate the pressure of the gas such that the gas pressure is less than the actuating pressure of the inflow valve.

38. A device as in claim 35, wherein the inflow valve is configured to open when the negative intrathoracic pressure is in the range from -3 cm H_2O to -30 cm H_2O.

39. A method for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation, by augmenting negative intrathoracic pressures, said method comprising the steps of:

interfacing a housing having a pressure responsive inflow valve to a patient's airway;

performing chest compression and chest decompression, wherein during chest decompression, the inflow valve prevents respiratory gases from entering the lungs until a threshold negative intrathoracic pressure level is exceeded at which time the one inflow valve opens, the inflow valve assisting in increasing the magnitude and duration of negative intrathoracic pressure during decompression and thereby enhancing the amount of blood flow into the heart and lungs; and

supplying a pressurized gas to the patient through the inflow valve when the inflow valve opens to ventilate the patient through the inflow valve.

40. A method as in claim 39, wherein the inflow valve opens when the negative intrathoracic pressure in the range from -3 cm H_2O to -30 cm H_2O, and wherein the pressurized gas is less than the opening pressure of the inflow valve.

41. A device for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation, said device comprising:

a housing having an opening that is adapted to be interfaced with a patient's airway;

a pressure responsive inflow flow valve which prevents respiratory gases from entering the lungs through the housing until a threshold negative intrathoracic pressure level is exceeded during decompression of the patient's chest at which time an actuating pressure of the inflow valve is exceeded and the inflow valve opens, the inflow valve assisting in increasing the magnitude and duration of negative intrathoracic pressure during decompression and thereby enhancing the amount of blood flow into the heart and lungs; and

a mechanism for varying the actuating pressure of the inflow valve.

42. A device as in claim 41, wherein the mechanism is configured to vary the actuating pressure to a pressure within the range from about 0 cm H_2O to about -30 cm H_2O.

43. A device as in claim 41, wherein the inflow valve comprises a threaded shaft having a seal that is configured to block an opening in the housing, and a spring that biases the seal against the housing, and wherein the mechanism comprises a threaded knob that is rotatable to vary the biasing force of the spring by increasing or decreasing the longitudinal distance of the shaft.

44. A device as in claim 43, further comprising a pressure gauge in the housing to sense the amount of pressure within the chest.

45. A device for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation, said device comprising:

a housing having an exit opening that is adapted to be interfaced with a patient's airway and a safety ventilation passageway;

a pressure responsive inflow flow valve which prevents respiratory gases from entering the lungs through the housing until a threshold negative intrathoracic pressure level is exceeded during decompression of the patient's chest at which time the inflow valve opens, the inflow valve assisting in increasing the magnitude and duration of negative intrathoracic pressure during decompression and thereby enhancing the amount of blood flow into the heart and lungs; and

a safety mechanism to maintain the safety ventilation passageway open to permit respiratory gases to freely flow to the patient's lungs until actuated by a rescuer to close the safety ventilation passageway.

46. A device as in claim 45, wherein the safety ventilation passageway is provided through the inflow valve when the inflow valve is in an open position, and wherein the safety mechanism is configured to maintain the inflow valve in the open position until actuated by the rescuer to move the inflow valve to a closed position.

47. A device as in claim 46, wherein the housing includes a ventilation port to permit respiratory gases to be injected into the housing, and wherein the safety mechanism comprises a sensor to sense when the rescuer injects respiratory gases into the housing and a control system to move the inflow valve from the open position to the closed position.

48. A device as in claim 47, wherein the sensor is movable upon injection of respiratory gases into the housing, and wherein control system comprises a set of gears that are coupled to the sensor and a cam that is movable by the gears to close the inflow valve.

49. A device as in claim 47, wherein the sensor comprises a movable flap that moves upon injection of respiratory gases into the housing, and wherein control system comprises a set of mechanical components that move a wedge against the safety mechanism upon movement of the flap to close the inflow valve.

50. A device as in claim 47, wherein the sensor is selected from a group of sensors consisting of electronic switches, thermistors, mechanical flaps, and materials that experience of change of resistance when flexed.

51. A device as in claim 46, wherein the inflow valve comprises a shaft having a seal that is configured to block an opening in the housing, and a spring that biases the seal against the housing.

52. A device for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation, said device comprising:

a housing having an opening that is adapted to be interfaced with a patient's airway;

a pressure responsive inflow flow valve having a closed position and an open position, wherein the inflow valve prevents respiratory gases from entering the lungs through the housing when in the closed position, and wherein the inflow valve moves to the open position when a threshold negative intrathoracic pressure level is exceeded during decompression of the patient's chest, the inflow valve assisting in increasing the magnitude and duration of negative intrathoracic pressure during decompression when in the closed position and thereby enhancing the amount of blood flow into the heart and lungs; and

a safety mechanism to maintain the inflow valve in the open position to permit respiratory gases to freely flow to the lungs until actuated by a rescuer to place the inflow valve in the closed position.

53. A device as in claim 52, wherein the housing includes a ventilation port to permit respiratory gases to be injected into the housing, and wherein the safety mechanism comprises a sensor to sense when the rescuer injections respiratory gases into the housing and a control system to move the inflow valve from the open position to the closed position.

54. A device as in claim 53, wherein the sensor is movable upon injection of respiratory gases into the housing, and wherein control system comprises a set of gears that are coupled to the sensor and a cam that is movable by the gears to close the inflow valve.

55. A device as in claim 53, wherein the sensor comprises a movable flap that moves upon injection of respiratory gases into the housing, and wherein control system comprises a set of mechanical components that move a wedge against the safety mechanism upon movement of the flap to close the inflow valve.

56. A device as in claim 53, wherein the sensor is selected from a group of sensors consisting of electronic switches, thermistors, mechanical flaps, and materials that experience of change of resistance when flexed.

57. A device as in claim 52, wherein the inflow valve comprises a shaft having a seal that is configured to block an opening in the housing, and a spring that biases the seal against the housing.

58. A method for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation, by augmenting negative intrathoracic pressures, said method comprising the steps of:

interfacing a valve system comprising a housing, a pressure responsive inflow valve, a safety gas flow passage and a safety mechanism to a patient's airway, wherein during chest decompression the inflow valve is configured to prevent respiratory gases from entering the lungs until a negative intrathoracic pressure level in the range from about 0 cm H_2O to -30 cm H_2O is exceeded at which time the inflow valve is configured to open, said inflow valve assisting in increasing the magnitude and duration of negative intrathoracic pressure during decompression and thereby enhancing the amount of blood flow into the heart and lungs, and wherein the safety mechanism is configured to permit respiratory gases to freely flow to the patient's lungs until actuated; and

actuating the safety mechanism to close the gas passage.

59. A method as in claim 58, further comprising performing chest compressions and decompressions after actuating the safety mechanism.

60. A method as in claim 58, wherein the actuating step comprises injecting a respiratory gas into the housing, wherein the injection is sensed by a sensor to cause the safety mechanism to close the gas passage.

61. A method as in claim 58, wherein the gas passage passes through the inflow valve, and wherein the actuating step comprises closing the inflow valve to close the gas passage.

62. A method for increasing the blood pressure in a spontaneously breathing person, said method comprising the steps of:

interfacing a pressure responsive inflow valve to the person's airway;

inhaling and exhaling while the inflow valve is coupled to the person's airway, wherein during inhalation the inflow valve prevents respiratory gases from entering the lungs until a negative intrathoracic pressure level in the range from about 0 cm H_2O to -30 cm H_2O is exceeded at which time the inflow valve opens, said inflow valve assisting in increasing blood flow back to the right heart of the person and thereby enhancing the person's blood pressure.

63. A method as in claim 62, wherein the person has low blood pressure due to blood loss.

64. A method as in claim 62, wherein the person has low blood pressure due to the administration of a drug.

65. A method as in claim 62, wherein the person has low blood pressure due to a high gravitational state.

66. A method as in claim 62, wherein the person has low blood pressure secondary to vasovagal syncope.

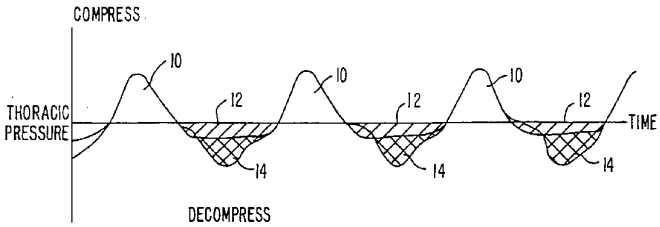


FIG. 1.

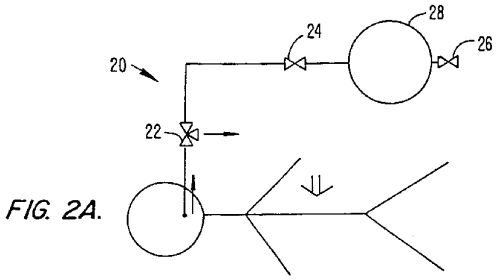


FIG. 2A.

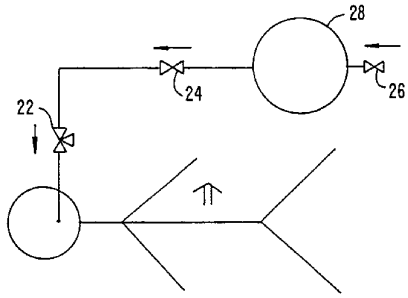


FIG. 2B.

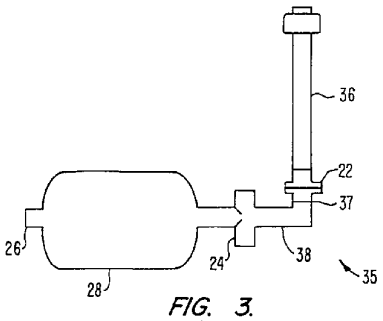


FIG. 3.

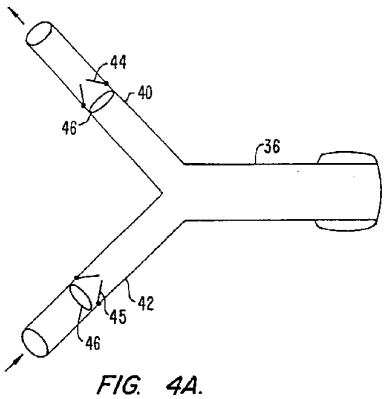


FIG. 4A.

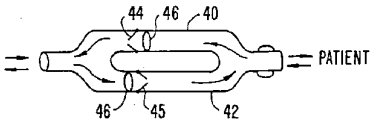


FIG. 4B.

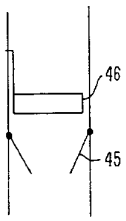


FIG. 5A.

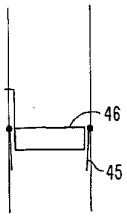


FIG. 5B.

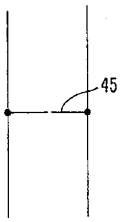


FIG. 5C.

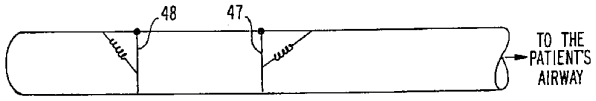


FIG. 6A

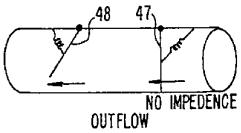


FIG. 6B.

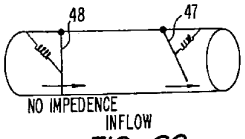


FIG. 6C.

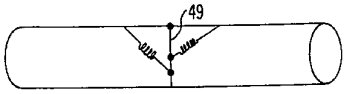


FIG. 7.

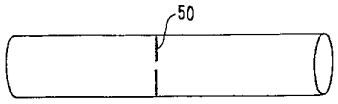


FIG. 8.

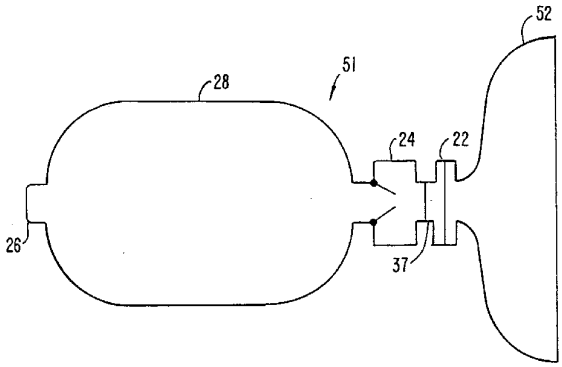


FIG. 9.

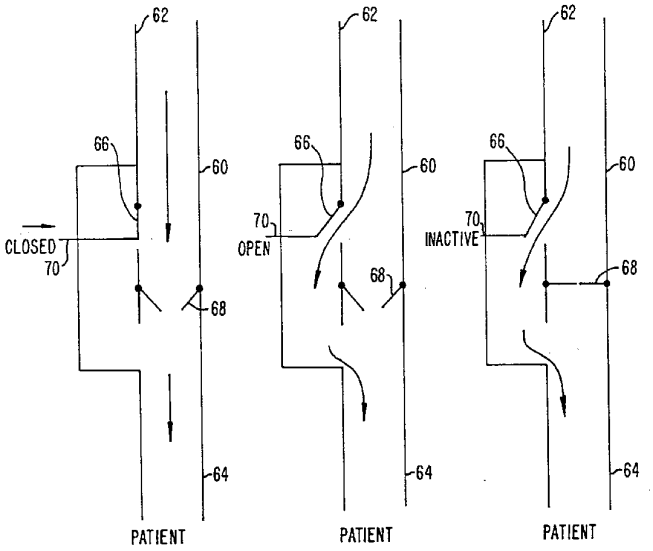


FIG. 10A. FIG. 10B. FIG. 10C.

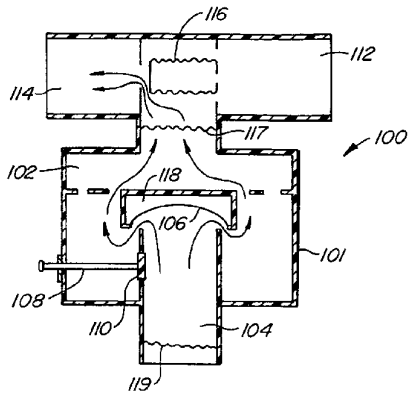

116
112
114
117
100
102
118
106
101
108
110
104
119

FIG. 11.

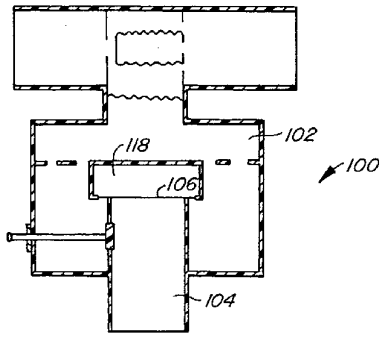

102
118
100
106
104

FIG. 12.

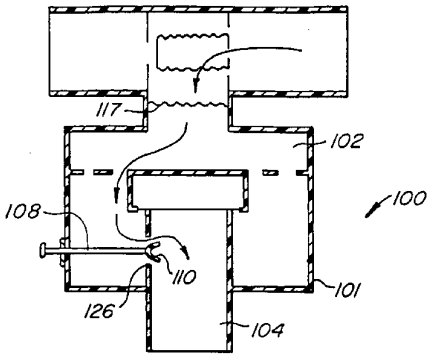

117
102
100
108
110
101
126
104

FIG. 13.

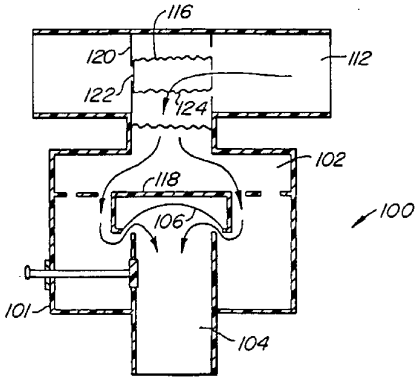

116
120
112
122
124
102
118
100
106
101
104

FIG. 14.

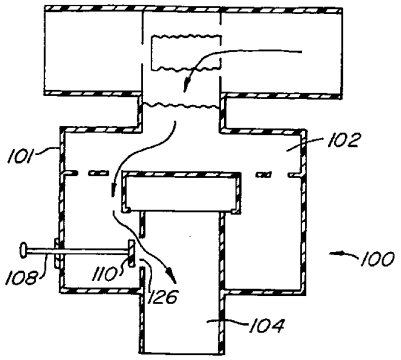


FIG. 15.

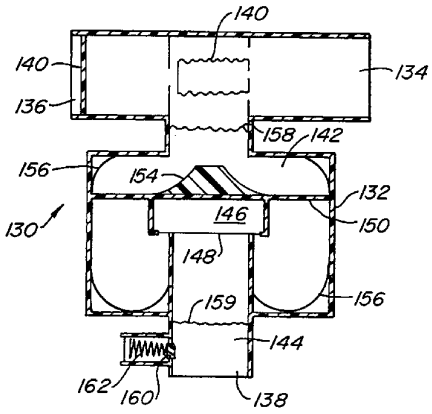


FIG. 16A.

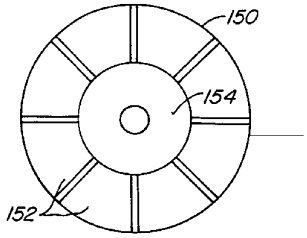


FIG. 16B.

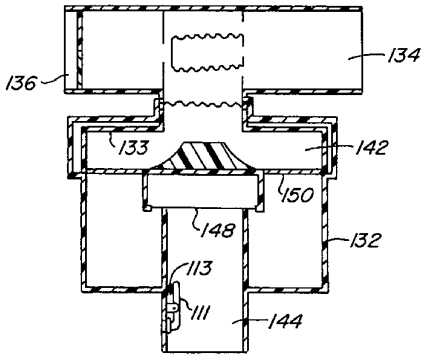


FIG. 16C.

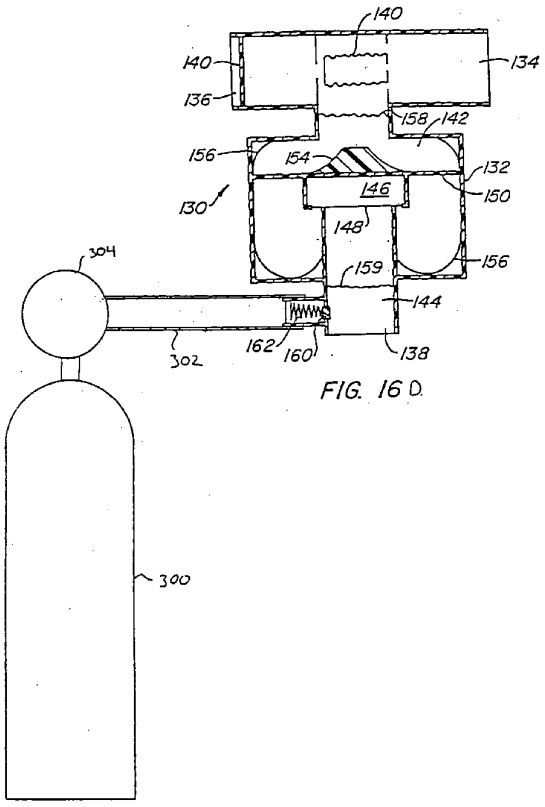

140
140
134
136
158
142
156
154
132
146
150
130
148
304
159
156
144
302
162
160
138
300

FIG. 16D.

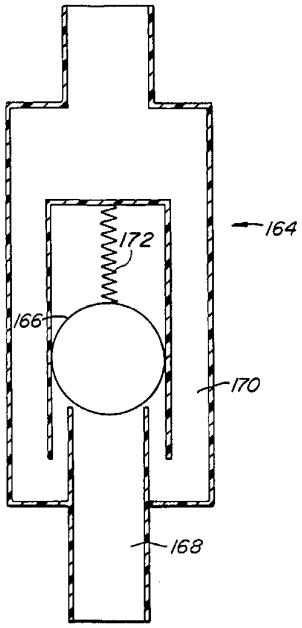


FIG. 17.

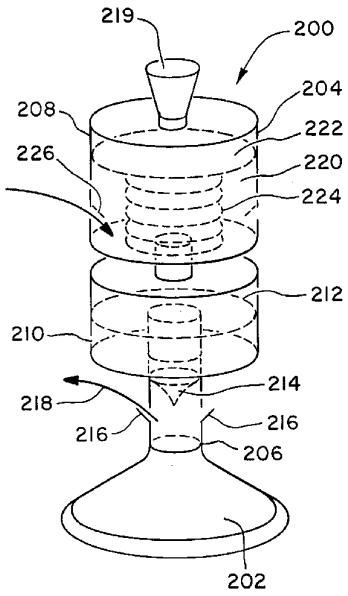


Fig. 18

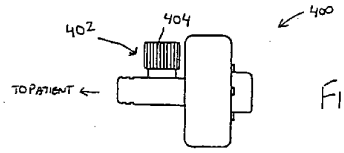


FIG. 19

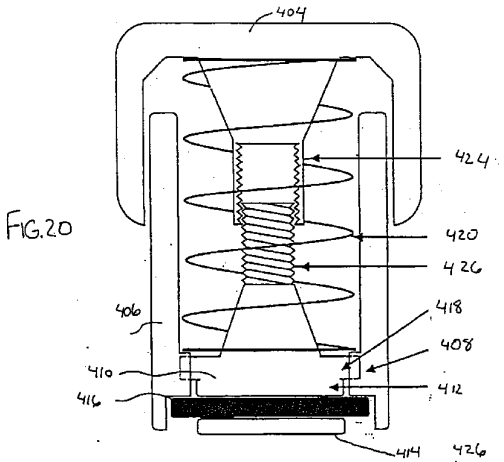


FIG. 20

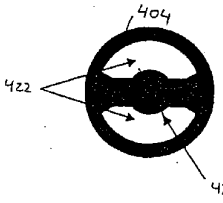


FIG. 21

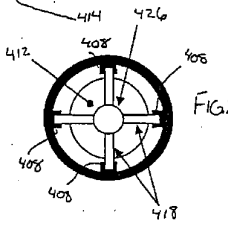


FIG. 22

FIG.24

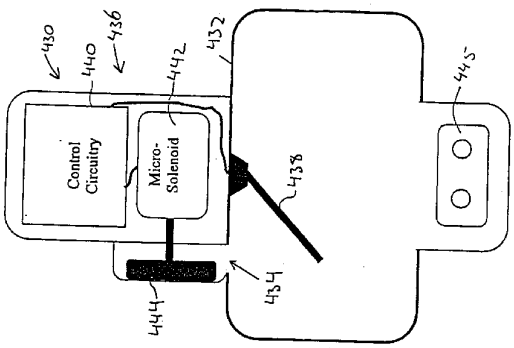

430
440
436
442
432
445
Control Circuitry
Micro-Solenoid
438
434
444

FIG.23

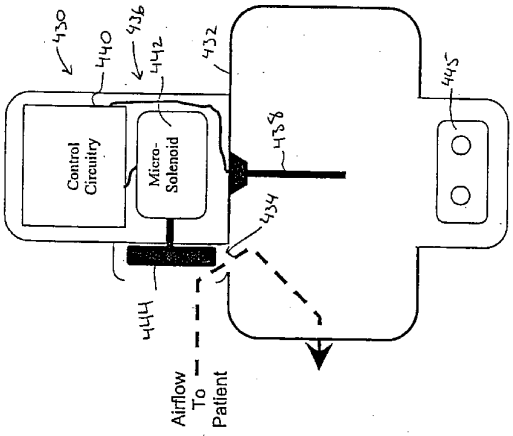

430
440
436
442
432
445
Control Circuitry
Micro-Solenoid
438
434
444
Airflow To Patient

FIG.25

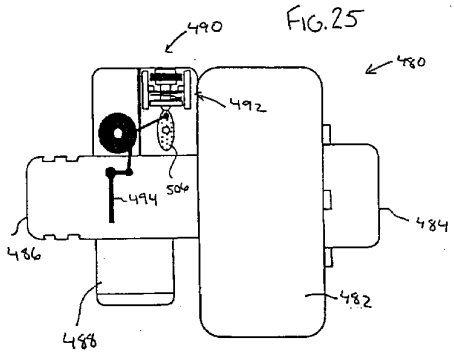


FIG.26

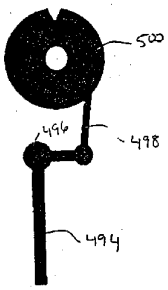


FIG.27

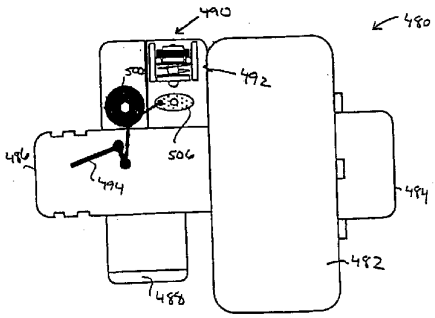


FIG.28

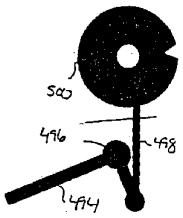
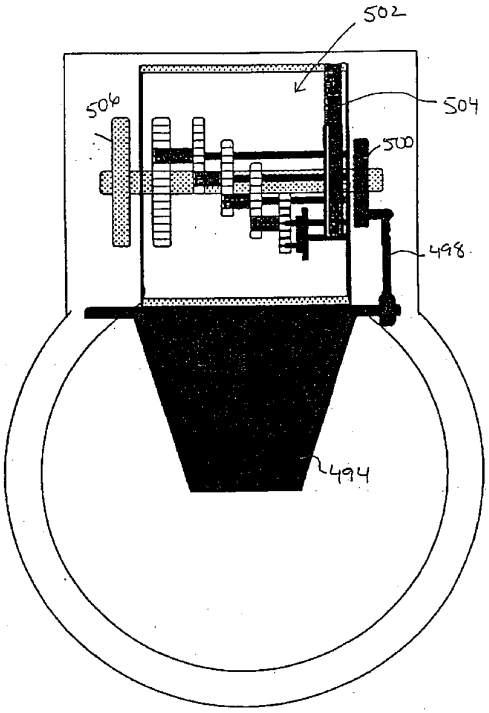


FIG.29



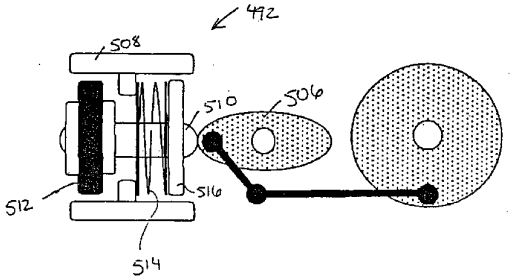


FIG.30

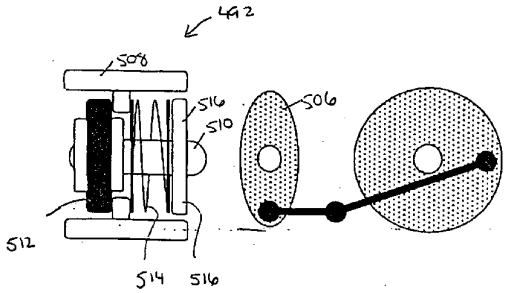
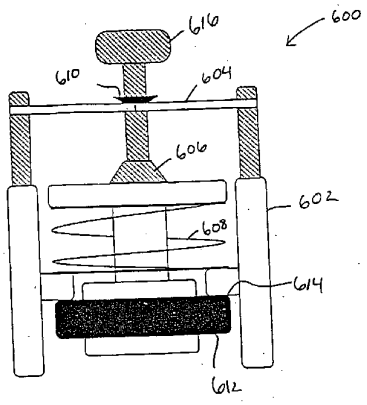


FIG.31

FIG. 32


616
600
610
604
606
602
608
614
612

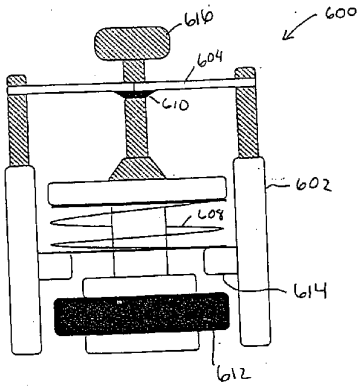

616
600
604
610
602
608
614
612

FIG. 33

FIG.34

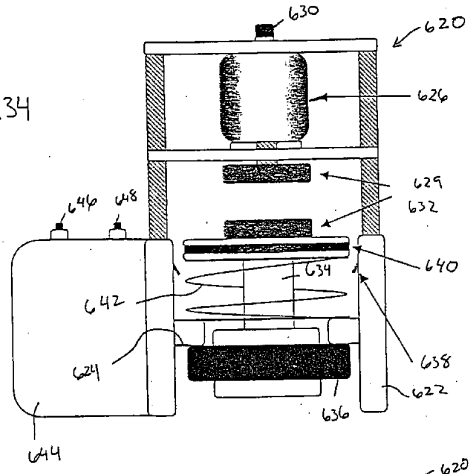

630
620
626
629
632
646
648
640
634
642
624
638
622
636
644

FIG.35

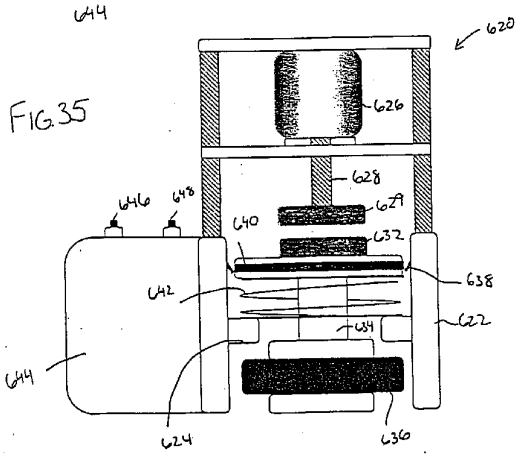

620
626
628
646
648
629
640
632
638
642
622
634
644
624
636

FIG. 36

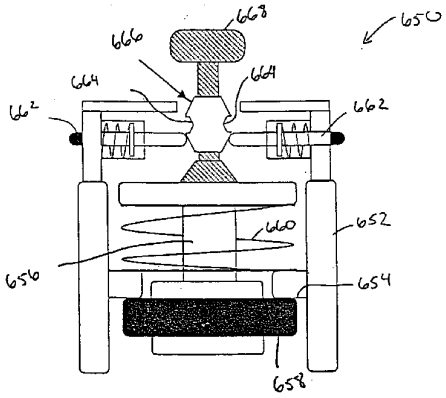
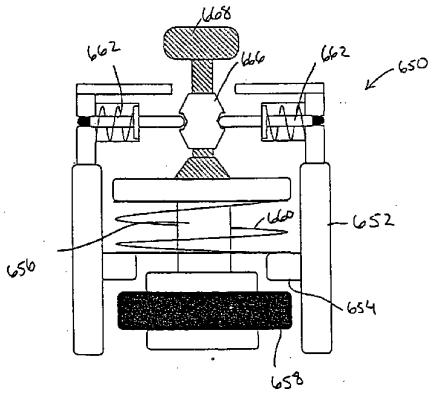

668
666
650
664
664
662
662
660
652
656
654
658

FIG. 37


668
662
666
662
650
660
652
656
654
658

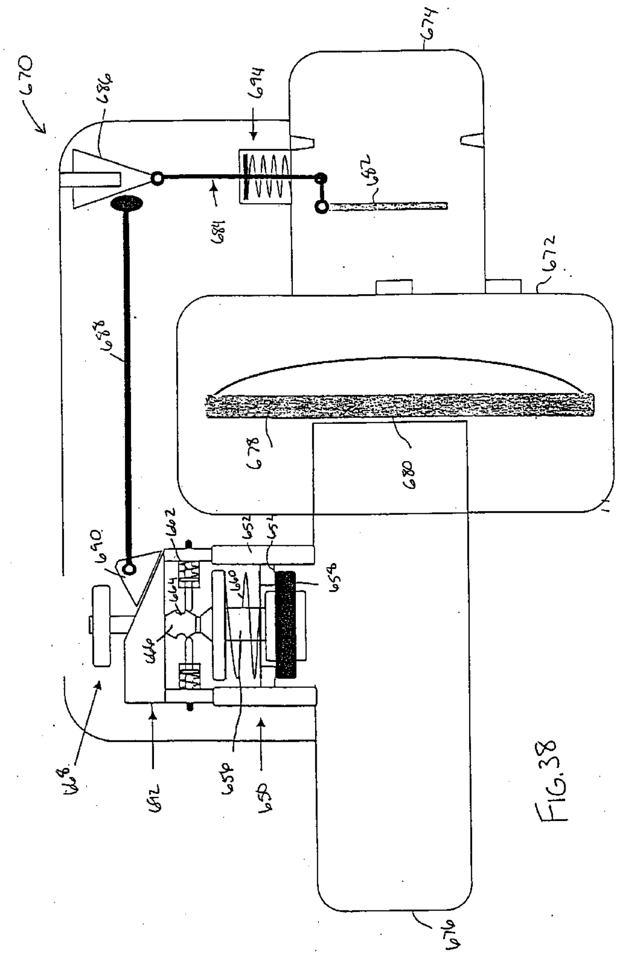

670
686
694
674
682
684
672
688
678
680
690
662
664
666
652
654
660
658
668
692
656
650
676

FIG. 38

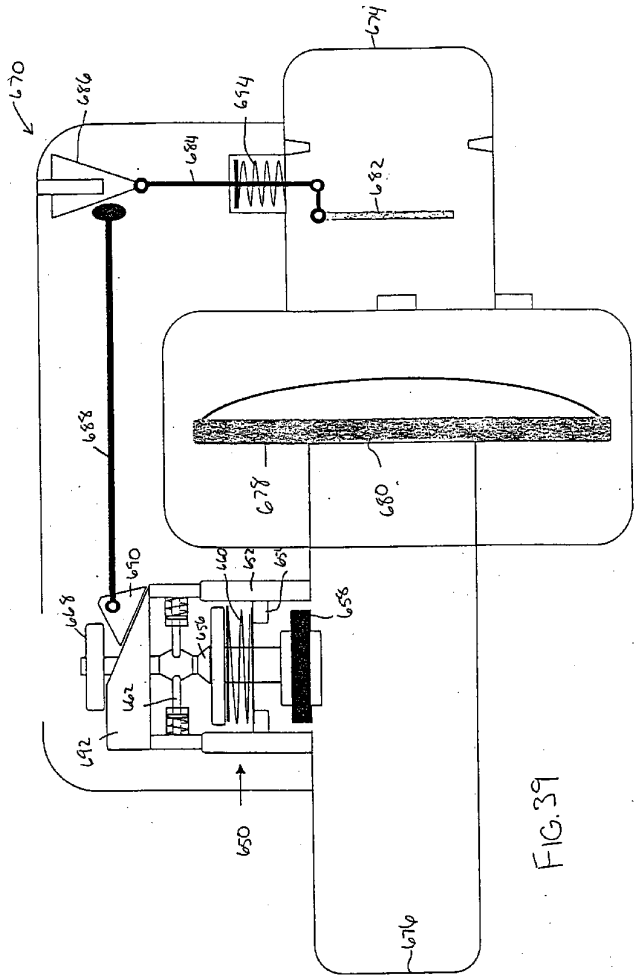


FIG. 39

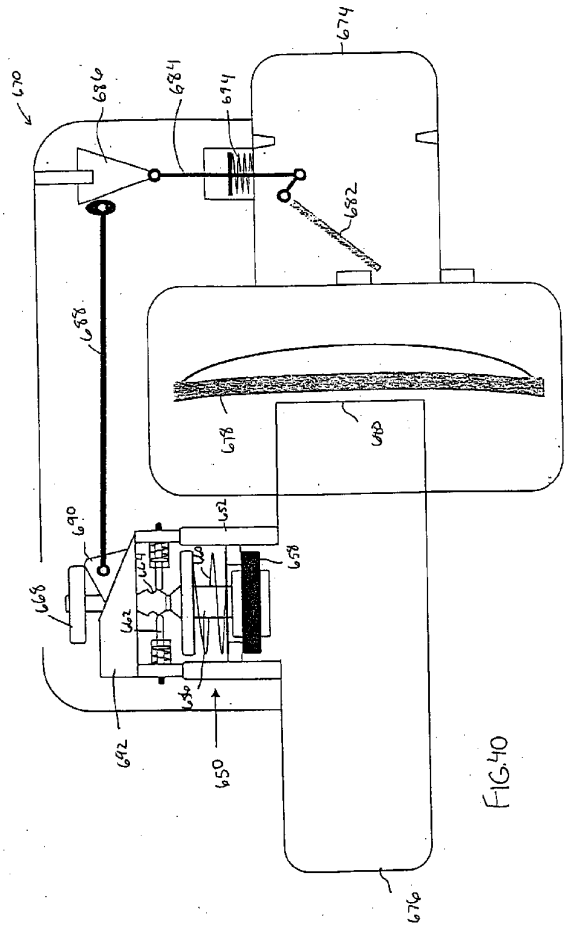


FIG. 40

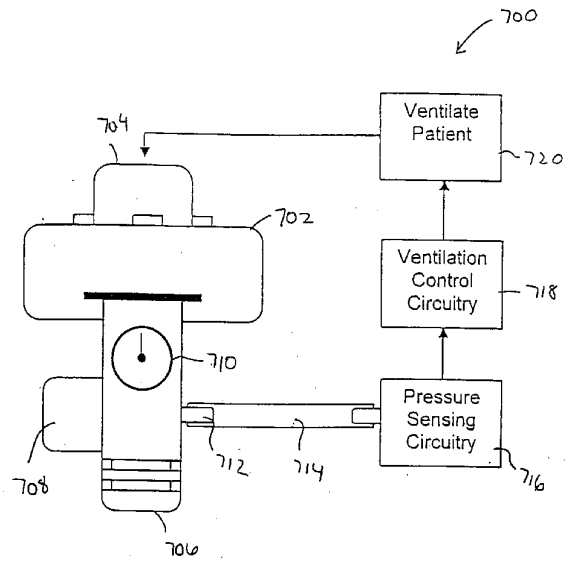
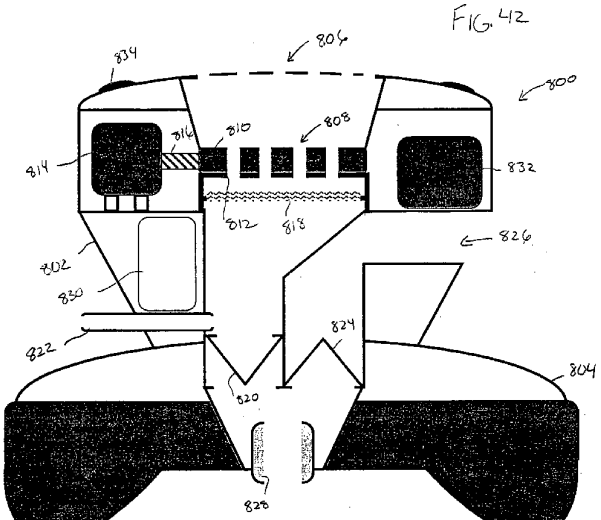

700
704
Ventilate Patient
720
702
Ventilation Control Circuitry
718
710
Pressure Sensing Circuitry
708
712
714
716
706

FIG.41

FIG. 42


834
806
800
808
810
816
814
832
812
818
826
802
830
822
824
820
804
828

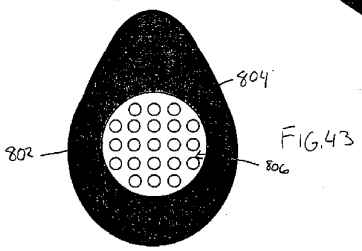

804
802
806

FIG. 43

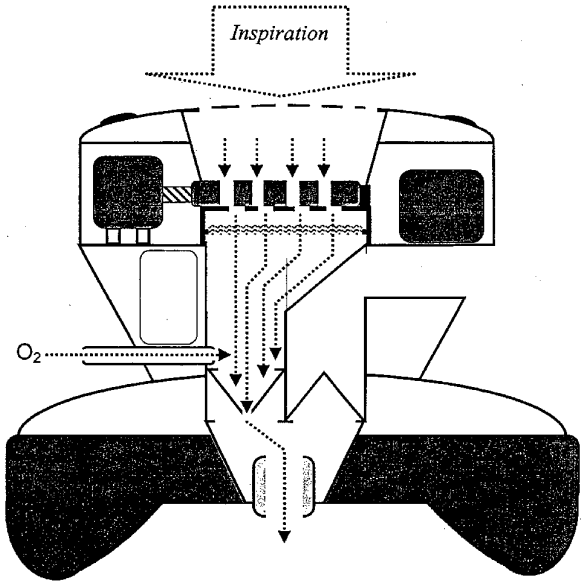


FIG.44

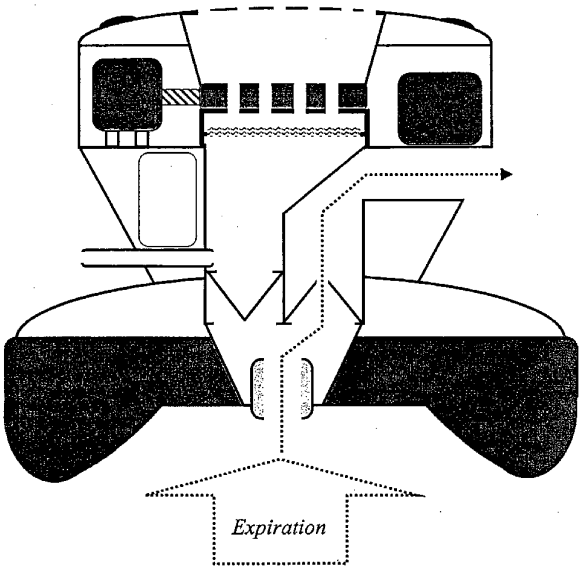


FIG.45

FIG.46A

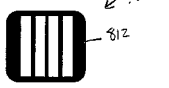


FIG.46B

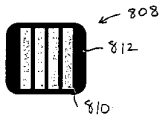


FIG.47A

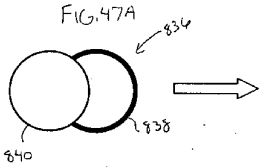


FIG.47B

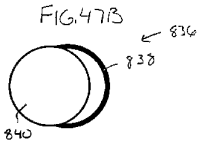


FIG.48A

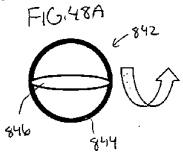
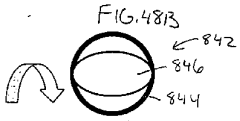


FIG.48B



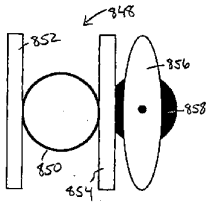


FIG.49A

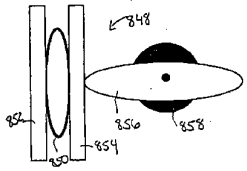


FIG.49B

FIG. 50A

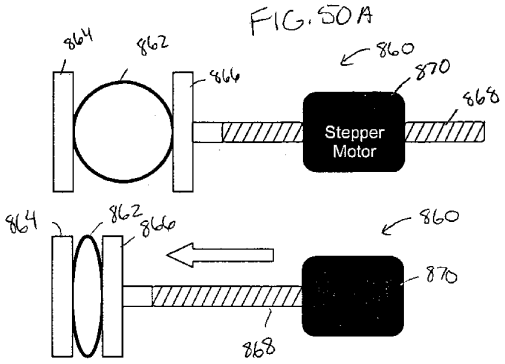


FIG. 50B

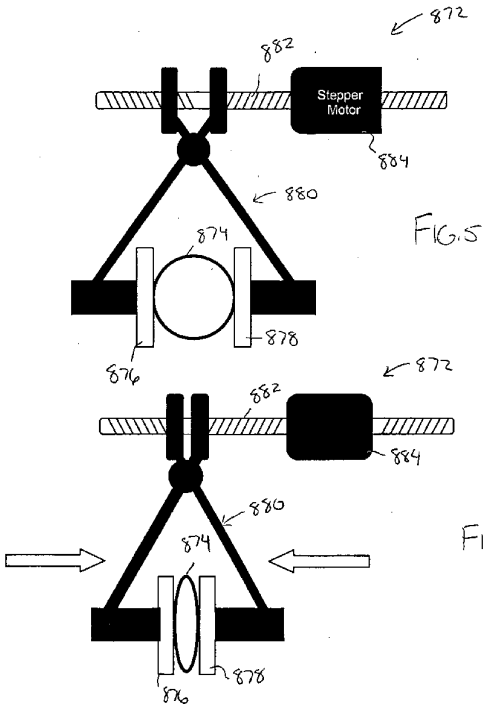


FIG. 51A

FIG. 51B

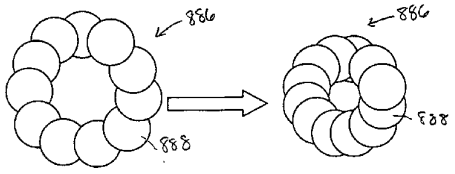


FIG. 52A FIG. 52B

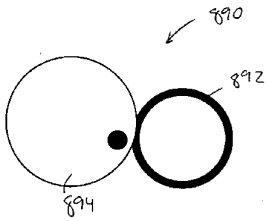


FIG.53A

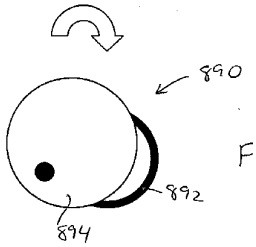


FIG.53B

FIG. 54A

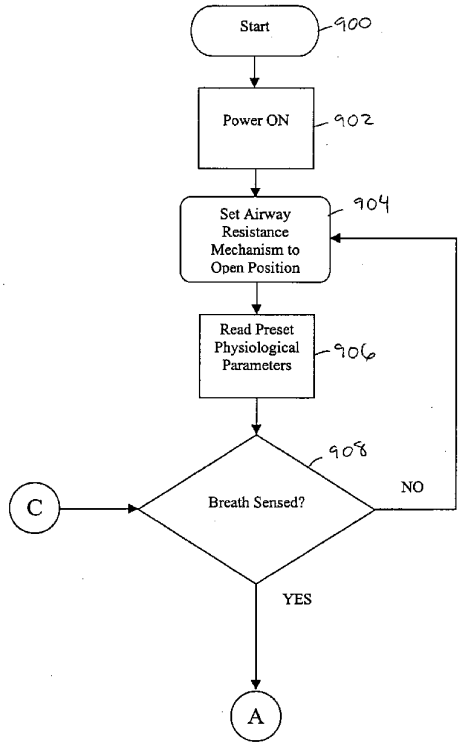

Start
900
Power ON
902
Set Airway Resistance Mechanism to Open Position
904
Read Preset Physiological Parameters
906
908
Breath Sensed?
NO
YES
C
A

FIG. 54B

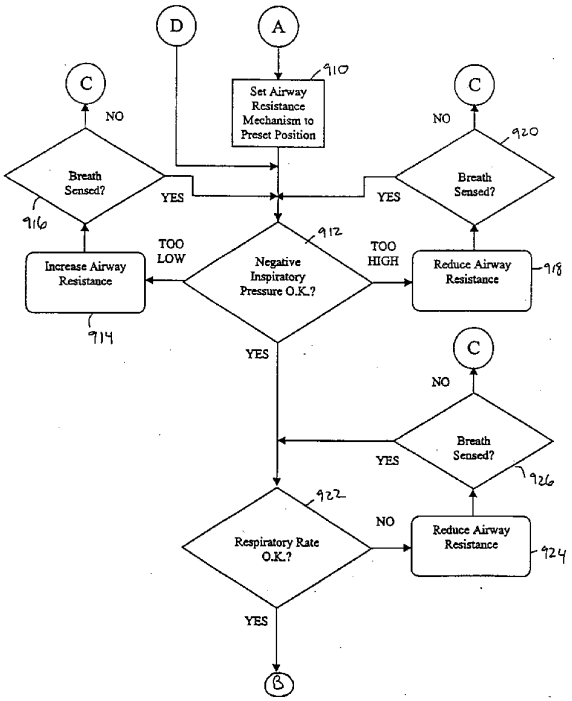
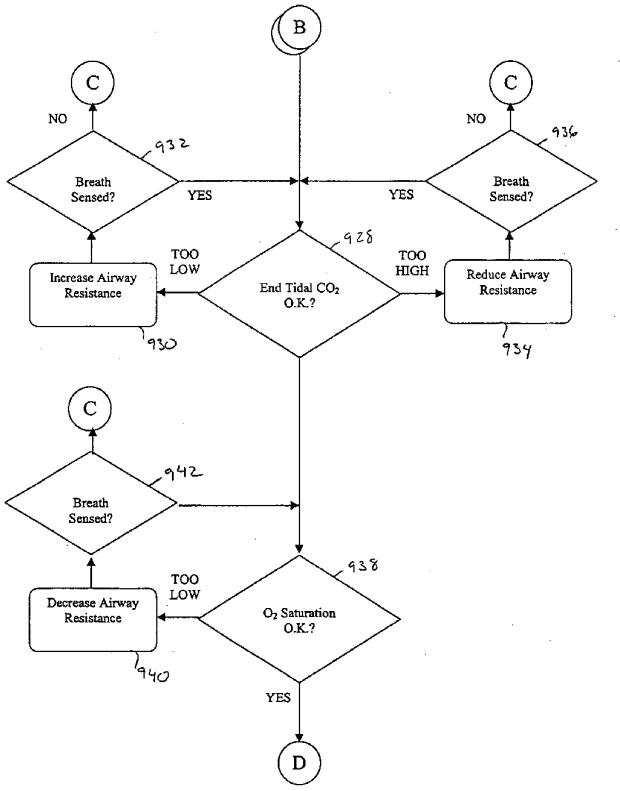

D
A
C
C
C
C
910
Set Airway Resistance Mechanism to Preset Position
NO
NO
NO
920
Breath Sensed?
Breath Sensed?
Breath Sensed?
YES
YES
YES
916
912
TOO LOW
TOO HIGH
Increase Airway Resistance
Negative Inspiratory Pressure O.K.?
Reduce Airway Resistance
918
914
YES
922
NO
Respiratory Rate O.K.?
Reduce Airway Resistance
924
YES
B

FIG. 54C


B
C
NO
932
Breath Sensed?
YES
C
NO
936
Breath Sensed?
YES
928
End Tidal CO_2 O.K.?
TOO LOW
Increase Airway Resistance
930
TOO HIGH
Reduce Airway Resistance
934
C
942
Breath Sensed?
938
O_2 Saturation O.K.?
TOO LOW
Decrease Airway Resistance
940
YES
D

【国際公開パンフレット（コレクトバージョン）】

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

CORRECTED VERSION

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 November 2002 (21.11.2002)

PCT

(10) International Publication Number
WO 2002/092169 A1

(51) International Patent Classification?: A62B 9/02, 7/04, A61M 16/00, F16K 31/26

(21) International Application Number: PCT/US2002/014039

(22) International Filing Date: 1 May 2002 (01.05.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/854,238 11 May 2001 (11.05.2001) US
10/119,203 8 April 2002 (08.04.2002) US

(71) Applicant: ADVANCED CIRCULATORY SYSTEMS, INC. [US/US]; 7615 Golden Triangle Drive, Suite A, Technology Park #5, Eden Prairie, MN 55344 (US).

(72) Inventors: LURIE, Keith, G.; 4751 Girard Avenue South, Minneapolis, MN 55409 (US). ZIELINSKI, Todd, M.; 3549 43rd Ave. South, Minneapolis, MN 55406 (US).

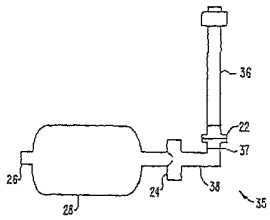
(74) Agents: GIBBY, Darin, J. et al.; Townsend and Townsend and Crew LLP, Two Embarcadero Center, Eighth Floor, San Francisco, CA 94111-3834 (US).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: SHOCK TREATMENT SYSTEMS AND METHODS



(57) Abstract: According to the invention, methods and devices for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation are provided. According to one method, a pressure responsive inflow valve (24) is coupled to a patient's airway. Chest compressions and chest decompressions are performed. During chest decompression the inflow valve (24) prevents respiratory gases from entering the lungs until a certain negative intrathoracic pressure level is exceeded at which time the inflow valve (24) opens. In this way, the inflow valve (24) assists in increasing the magnitude and duration of negative intrathoracic pressure during decompression to enhance the amount of blood flow into the heart and lungs. Further, the patient is supplied with a pressurized respiratory gas through the inflow valve (24) when the inflow valve (24) opens to ventilate the patient.

WO 2002/092169 A1

WO 2002/092169 A1

Published:
— *with international search report*

(48) Date of publication of this corrected version:
22 April 2004

(15) Information about Correction:
see PCT Gazette No. 17/2004 of 22 April 2004, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

SHOCK TREATMENT SYSTEMS AND METHODS

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation in part application of U.S. Patent Application Serial No. 09/854,238, filed May 11, 2001, which is a continuation in part application of U.S. Patent Application Serial No. 09/546,252, filed April 10, 2000, which is a continuation of U.S. Patent Application No. 08/950,702, filed October 15, 1997 (now U.S. Patent No. 6,062,219), which is a continuation-in-part application of U.S. Patent Application Serial No. 08/403,009, filed March 10, 1995 (now U.S. Patent No. 5,692,498), which is a continuation-in-part application of U.S. Patent Application Serial No. 08/149,204, filed November 9, 1993 (now U.S. Patent No. 5,551,420), the disclosures of which are herein incorporated by reference.

BACKGROUND OF THE INVENTION

The present invention relates generally to devices and methods used in conjunction with cardiopulmonary resuscitation procedures. In particular, the present invention relates to devices and methods for increasing cardiopulmonary circulation in patients with severe low blood pressure or cardiac arrest.

Worldwide, sudden cardiac arrest is a major cause of death and is the result of a variety of circumstances, including heart disease and significant trauma. In the event of a cardiac arrest, several measures have been deemed to be essential in order to improve a patient's chance of survival. These measures must be taken as soon as possible to at least partially restore the patient's respiration and blood circulation. One common technique, developed approximately 40 years ago, is an external chest compression technique generally referred to as cardiopulmonary resuscitation (CPR). CPR techniques have remained largely unchanged over the past three decades.

With traditional CPR, pressure is applied to a patient's chest in order to increase intrathoracic pressure. An increase in intrathoracic pressure induces blood

movement from the region of the heart and lungs towards the peripheral arteries. Such pressure partially restores the patient's circulation. Traditional CPR is performed by actively compressing the chest by direct application of an external pressure to the chest. After active compression, the chest is allowed to expand by its natural elasticity which causes expansion of the patient's chest wall. This expansion allows some blood to enter the cardiac chambers of the heart. The procedure as described, however, is insufficient to ventilate the patient. Consequently, conventional CPR also requires periodic ventilation of the patient. This is commonly accomplished by mouth-to-mouth technique or by using positive-pressure devices, such as a self-inflating bag which relies on squeezing an elastic bag to deliver air via a mask, endotracheal tube or other artificial airway.

In order to increase cardiopulmonary circulation induced by chest compression, a technique referred to as active compression-decompression (ACD) has been developed. According to ACD techniques, the active compression phase of traditional CPR is enhanced by pressing an applicator body against the patient's chest to compress the chest. Such an applicator body is able to distribute and apply force substantially evenly over a portion of the patient's chest. More importantly, however, the applicator body is sealed against the patient's chest so that it may be lifted to actively expand the patient's chest during the decompression step. The resultant negative intrathoracic pressure induces venous blood to flow into the heart and lungs from the peripheral venous vasculature of the patient.

Also of importance to the invention are ventilation sources that are used in connection with CPR techniques to properly ventilate the patient. One type of ventilation source is the AMBU bag available from AMBU International, Copenhagen, Denmark. The AMBU bag can also be used in connection with a positive end-expiratory pressure (PEEP) valve, available from AMBU International, to treat some patients with pulmonary and cardiac diseases. However, until the present invention, a positive end-expiratory pressure valve in connection with a ventilation source has not been used with any CPR techniques.

With both traditional CPR and ACD-CPR techniques, an increase in the amount of venous blood flowing into the heart and lungs from the peripheral venous vasculature would be desirable to increase the volume of oxygenated blood leaving the thorax during the subsequent compression phase. It would therefore be desirable to provide improved methods and apparatus for enhancing venous blood flow into the heart and lungs of a patient from the peripheral venous vasculature during both conventional CPR and ACD-

CPR techniques. It would be particularly desirable to provide techniques which would enhance oxygenation and increase the total blood return to the chest during the decompression step of CPR and ACD-CPR, more particularly of ACD-CPR. This can be accomplished according to the present invention by augmentation of both negative and positive intrathoracic pressure, thereby amplifying the total intrathoracic pressure swing. An invention for providing this crucial improvement is described.

Severe hypotension or very low blood pressure can lead to passing out and in some circumstances cardiac arrest. Like cardiac arrest, patients with low blood pressure often suffer from insufficient blood returning to the heart after each beat. This results in a decrease in forward blood flow out of the heart and eventually to low blood pressure. It would therefore be desirable to provide techniques or devices that would increase venous blood flow to the heart when a person suffers from low blood pressure. According to the invention, such an approach could help return blood flow to the heart and result in an increase in blood flow to the vital organs.

ACD-CPR techniques are described in detail in Todd J. Cohen et al., *Active Compression-Decompression Resuscitation: A Novel Method of Cardiopulmonary Resuscitation*, American Heart Journal, Vol. 124, No. 5, pp. 1145-1150, November 1992; and Todd J. Cohen et al., *Active Compression-Decompression: A New Method of Cardiopulmonary Resuscitation*, The Journal of the American Medical Association, Vol. 267, No. 21, June 3, 1992. These references are hereby incorporated by reference.

The use of a vacuum-type cup for actively compressing and decompressing a patient's chest during ACD-CPR is described in a brochure of AMBU International A/S, Copenhagen, Denmark, entitled Directions for Use of AMBU® CardioPump™, published in September 1992. The AMBU® CardioPump™ is also disclosed in European Patent Application No. 0 509 773 A1. These references are hereby incorporated by reference.

BRIEF SUMMARY OF THE INVENTION

According to the invention, methods and devices for increasing cardiopulmonary circulation are provided. The methods and devices may be used in connection with any generally accepted CPR methods or with active compression-decompression (ACD) CPR techniques. Preferably, the methods and devices will be used in connection with ACD-CPR. In one

aspect, they may be used in patients with severe low blood pressure and who are not in cardiac arrest and breathe spontaneously.

Cardiopulmonary circulation is increased according to the invention by impeding airflow into a patient's lungs during the CPR decompression phase or during a spontaneous inhalation. This increases the magnitude and prolongs the duration of negative intrathoracic pressure during in the patient's chest, i.e., increases the duration and degree that the intrathoracic pressure is below or negative with respect to the pressure in the peripheral venous vasculature. By enhancing the amount of venous blood flow into the heart and lungs, since equilibration of intrathoracic pressure during decompression occurs to a greater extent from enhanced venous return rather than rapid inflow of gases into the chest via the patient's airway, cardiopulmonary circulation is increased.

In a specific embodiment, impeding the airflow into the patient's lungs is accomplished by decreasing or preventing ventilation during the decompression phase of CPR. The method employs the use of a flow restrictive or limiting member, such as a flow restrictive orifice disposed within or connected in series with a lumen of a ventilation tube, or a pressure-responsive valve within a lumen of the tube to impede the inflow of air. The pressure-responsive valve is biased to open to permit the inflow of air when the intrathoracic pressure falls below a threshold level. In order to properly ventilate the patient, the method preferably provides for periodically ventilating the patient through the ventilation tube after compression of the patient's chest. When periodic ventilation is performed, gases can be delivered either through the impeding step or in another embodiment they can bypass the impeding step. In some cases, an oxygen enriched gas may be supplied to the patient through the pressure-responsive valve once this valve opens.

An exemplary embodiment provides for covering the patient's mouth and nose with a facial mask. This mask contains means for impeding airflow into the patient's airway during decompression of the patient's chest, e.g. either an orifice or valve as just discussed.

A specific embodiment further provides means for impeding air from leaving the lungs during compression of the patient's chest to further enhance cardiopulmonary circulation by enhancing positive intrathoracic pressure during the compression phase.

When performing cardiopulmonary resuscitation to enhance circulation according to the invention, an operator compresses a patient's chest to force blood out of the patient's thorax. The patient's chest is then decompressed to induce venous blood to flow into

the heart and lungs from the peripheral venous vasculature either by actively lifting the chest (via ACD-CPR) or by permitting the chest to expand due to its own elasticity (via conventional CPR). During the decompression step, airflow is impeded from entering into the patient's lungs which enhances negative intrathoracic pressure and increases the time during which the thorax is at a lower pressure than the peripheral venous vasculature. Thus, venous blood flow into the heart and lungs from the peripheral venous vasculature is enhanced. This is because the intrathoracic pressure equilibrium during decompression occurs as a result of enhanced venous return rather than from inflow of air via the trachea. In a particular embodiment, compression and decompression of the patient's chest may be accomplished by pressing an applicator body against the patient's chest to compress the chest, and lifting the applicator to actively expand the patient's chest.

An apparatus for enhancing cardiopulmonary circulation according to the method comprises an improved endotracheal tube having a flow restrictive element for impeding airflow from the patient's lungs during chest decompression. A second apparatus according to the invention provides for an improved air-delivery system comprising a compressible structure having a flow restrictive element included in or attached to an opening of the compressible structure to impede the flow of gases to the patient's lungs. Also, a connector is provided for interfacing the compressible structure to the patient, preferably by attaching a facial mask or endotracheal tube to the structure.

In another aspect of the invention, a valving system is provided for regulating airflow into a patient's lungs when performing cardiopulmonary resuscitation. The system includes a housing having an upstream region and a downstream region. A means is provided between the upstream region and the downstream region for inhibiting air from flowing from the upstream region to the downstream region when the pressure in the downstream region is less than the pressure in the upstream region. In this manner, air is inhibited from flowing into the patient's lungs during decompression of the patient's chest thereby forcing more venous blood into the chest and enhancing vital organ perfusion. A means is further provided for allowing air to flow into the downstream region when ventilating the patient. In this way, adequate ventilation can be provided to the patient during the procedure.

In one particular aspect, the inhibiting means comprises a valve which inhibits airflow from the upstream region to the downstream region when the pressure in the

downstream region is less than the pressure in the upstream region. The valve preferably includes a diaphragm which is closed when the pressure in the downstream region is less than or equal to the pressure in the upstream region. Such a configuration prevents air from flowing into the patient's lungs during decompression of the patient's chest while allowing air to be exhausted from the patient's lungs during compression. Preferably, the diaphragm is constructed of a flexible membrane. Alternatively, the diaphragm can be constructed using a ball.

In another particular aspect, the diaphragm is biased to open when the pressure in the downstream region is about 2 cm H_2O or greater, and more preferably at about 2 cm H_2O to 10 cm H_2O. Biasing of the diaphragm in this manner increases intrathoracic pressure during compression of the patient's chest to further enhance vital organ perfusion.

In still a further aspect, the means for allowing air into the downstream region includes a means for opening the diaphragm when air is injected into the upstream region to ventilate the patient. The means for opening the diaphragm preferably includes an ambient pressure region that is adjacent the diaphragm. When air is injected into the upstream region, the pressure within the upstream region increases thereby drawing the diaphragm into the ambient pressure region and allowing the air to flow to the patient's lungs.

In yet another aspect, the means for allowing air into the downstream region includes a manually operable valve at the downstream region which is manually opened to allow air to flow into the downstream region upon return of spontaneous circulation. In this manner, a rescuer can manually open the valve when the patient begins breathing.

In an alternative aspect, the means for allowing air into the downstream region comprises a pressure-responsive valve at the downstream region. The pressure-responsive valve allows air into the downstream region when the pressure in the downstream region falls below a threshold level, usually in the range from –3 cm H_2O to -30 cm H_2O. The pressure-responsive valve is advantageous in allowing ventilation to be provided to the patient while still employing the diaphragm to enhance the extent and duration of negative intrathoracic pressure. Examples of pressure-responsive valves that may be used include, for example, a spring biased valve, an electromagnetically driven valve, or a valve constructed of any deflectable material that will deflect when the threshold pressure is exceeded. As one specific example, the valve may be constructed of a magnetically charged piece of material with a narrow tolerance that is attracted to a gate. This valve will open when the

magnetically charged gate pressure is exceeded. In this way, when the negative intrathoracic pressure is exceeded, the valve will be pulled away from the gate to permit gases to flow to the lungs. Such a valve could also be used in place of the diaphragm valve discussed above.

In one option, a source of oxygen-enriched gas may be coupled to the pressure-responsive valve to supply an oxygen-enriched gas to the patient when the pressure-responsive valve is opened. A regulator may be employed to regulate the pressure and/or flow rate of the gas. For example, the pressure may be regulated to be less than the actuating pressure of the valve so that the pressurized gas will not flow to the patient's lungs until the valve is opened when the negative intrathoracic pressure is exceeded.

The system of the invention in another aspect is provided with an air exhaust opening in the housing at the upstream region for exhausting air from the housing. A valve is provided in the exhaust opening which inhibits air from flowing into the housing through the exhaust opening. In this manner, air exhausted from the patient is in turn exhausted from the housing through the exhaust opening. In a further aspect, means are provided for preventing air from exiting the housing through the exhaust opening during injection of air into the housing when ventilating the patient. Preferably air is injected into the housing from a respiratory device, such as a respiratory bag, a ventilator, or the like, or by mouth-to-mouth breathing through a port or a mouthpiece.

In still a further aspect of the invention, an endotracheal tube, a sealed facial mask, a laryngeal mask, or other airway tube, or the like is provided and is connected to the housing at the downstream region for attachment to the patient. The endotracheal tube or like device is for insertion into the patient's airway and provides a convenient attachment for the valving system to the patient.

The invention further provides an exemplary device for increasing cardiopulmonary circulation that is induced by chest compression and decompression when performing cardiopulmonary resuscitation. The device comprises a facial mask and a housing that is operably attached to the mask. The housing includes a mouth piece and at least one inflow valve which prevents respiratory gases from entering the lungs until a threshold negative intrathoracic pressure level is exceeded at which time the inflow valve opens. The housing further includes an air chamber in communication with the mouth piece, and a valve member to force air from the air chamber and into the facial mask when air is supplied through the mouth piece. In this way, a rescuer may blow into the mouth piece to

periodically ventilate the patient with air or oxygen-enriched gas stored in the chamber, rather than introducing respiratory gases from the rescuer's lungs.

In a similar vein, the invention provides an exemplary method for increasing cardiopulmonary circulation that is induced by chest compression and decompression when performing cardiopulmonary resuscitation. According to the method, at least one inflow valve and an air chamber are interfaced to a patient's airway. Chest compression and chest decompression is then performed, with the inflow valve preventing respiratory gases from entering the lungs during decompression until a threshold negative intrathoracic pressure is exceeded. Air is periodically transferred from the air chamber into the patient's lungs so as to properly ventilate the patient with air. In one exemplary aspect, the air is transferred from the air chamber to the patient's lungs by manually blowing into the chamber. In this way, the rescuer may blow into the chamber to transfer air to the patient's lungs without introducing respiratory gases from the rescuer's lungs.

In one embodiment, the invention provides a mechanism to vary the actuating pressure of the inflow valve. In this way, the rescuer is able to operate the mechanism to vary the impedance depending upon the condition of the patient. In some cases, the valve systems of the invention may include a pressure gauge to display the intrathoracic pressures. By having this information readily available, the rescuer has more information to assist in setting the desired actuating pressure of the inflow valve.

In one aspect, the varying mechanism is configured to vary the actuating pressure to a pressure within the range from about 0 cm H_20 to about -30 cm H_20. In another aspect, the inflow valve comprises a shaft having a seal that is configured to block an opening in the housing, and a spring that biases the seal against the housing. With such a configuration, the mechanism may comprise a knob that is movable to vary the biasing force of the spring. For example, the knob may be rotatably coupled to the shaft so that the rescuer may simply turn the knob to vary the actuating pressure.

In another embodiment, the valve systems of the invention may be provided with a safety ventilation passage. If the valve system is inappropriately applied to a patient who is spontaneously breathing, the patient may breath through this passage while the valve system is coupled to the patient's airway. A safety mechanism is used to maintain the safety ventilation passageway open to permit respiratory gases to freely flow to the patient's lungs until actuated by a rescuer to close the safety ventilation passageway. With such an

arrangement, the patient is able to freely breathe if they are capable of so doing. If the patient stops breathing on their own, the rescuer may set the valve system so that the ventilation passage is closed and the inflow valve provides the desired resistance during CPR. In this way, respiratory gases are permitted only once the cracking pressure of the threshold valve is exceeded, or when the patient is actively ventilated. As with other embodiments, the cracking pressure may be exceeded by decompressing the patient's chest during CPR, by the patient's own inhalation, or the like.

In one aspect, the safety ventilation passageway is provided through the inflow valve when the inflow valve is in an open position. With this configuration, the safety mechanism is configured to maintain the inflow valve in the open position until actuated by the rescuer to move the inflow valve to a closed position. A variety of ways may be used to actuate the safety mechanism. For example, the housing may include a ventilation port to permit respiratory gases to be injected into the housing, and the safety mechanism may comprise a sensor to sense when the rescuer injects respiratory gases into the housing. In one embodiment, a signal from the sensor is used by a control system to move the inflow valve from the open position to the closed position. As an example, the sensor may be movable upon injection of respiratory gases into the housing, and the control system may comprise a set of gears that are coupled to the sensor and a cam that is movable by the gears to close the inflow valve. Alternatively, the control system may comprise an electronic controller, a solenoid and a cam. This mechanism may be configured to take electrical signals from the sensor and to operate the solenoid to move the cam and thereby close the inflow valve. As another example, a flap may be moved upon injection of the gases. The flap may cause the movement of a variety of mechanical components that physically reset the inflow valve to the closed position.

A variety of sensors may be used to sense injection of the respiratory gases. For example, sensors that may be used include electronic switches that move in a gas stream, thermistors to sense temperature changes, CO_2 detectors, materials that experience a change of resistance when flexed, mechanical flaps that move in a gas stream, and the like.

The invention also provides methods for increasing the blood pressure in a spontaneously breathing person. According to the method, an inflow valve is coupled to the person's airway and the person inhales and exhales. During inhalation, the inflow valve inhibits or completely prevents respiratory gases from entering the lungs for at least some

time to augment the person's negative intrathoracic pressure and thereby assist in increasing blood flow back to the right heart of the person. In so doing, the person's blood pressure is enhanced. The resistance or actuating pressure of the inflow valve may be based on one or more sensed physiological parameters. For example, one parameter may be the negative intrathoracic pressure. For instance, the inflow valve may be used to achieve a negative intrathoracic pressure in the range from about 0 cm H_20 to -50 cm H_20 for flow rates in the range from about zero flow to about 70 liters per minute. Other parameters that may be sensed include respiratory rate, end tidal CO_2, tissue CO_2 content, positive end expiratory pressure, blood pressure and oxygen saturation. These parameters may be used individually or in combination when adjusting the resistance of the inflow valve. For example, even if the sensed negative intrathoracic pressure is within a desired range, the end tidal CO_2 may be outside of a desired range. As such, the resistance of the valve may be adjusted until the end tidal CO_2 is acceptable. Conveniently, the inflow valve may be manually operated or operated in an automated fashion. For example, a controller may be used to receive the sensed parameters and then to send signals to an adjustment mechanism that operates the valve to vary the resistance or actuating pressure.

Such a process may be used to treat a variety of conditions where the person's blood pressure is low. For example, such a procedure may be used where the person has low blood pressure due to blood loss, due to the administration of a drug, due to a high gravitational state, due to vasodepressor syncope, due to drowning, due to heat stroke, due to heart attack, due to hypothermia, due to right heart failure, after a return to earth from space, due to sepsis, pericardial effusion, cardiac tamponade, or the like.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a graph illustrating thoracic pressure changes over time when compressing and decompressing a patient's chest according to the present invention.

Fig. 2A is a schematic view illustrating airflow through a ventilation circuit when compressing a patient's chest according to the present invention.

Fig. 2B is a schematic view illustrating airflow through a ventilation circuit when decompressing a patient's chest according to the present invention.

Fig. 3 is a schematic illustration of a first alternative embodiment of a device for impeding airflow into a patient's lungs according to the present invention.

Fig. 4A is a schematic illustration of a second alternative embodiment of the device for impeding airflow into a patient's lungs according to the present invention.

Fig. 4B is a schematic illustration of the device in Fig. 4A with a common inhalation/exhalation port.

Fig. 5A is a schematic view of a one-way valve used in the device for impeding airflow according to the present invention.

Fig. 5B is a schematic view of the one-way valve in Fig. 5A that is held open after ACD-CPR has ceased.

Fig. 5C is a schematic view of a one-way valve that is closed until a threshold pressure is present in the tube according to the present invention.

Fig. 6A is a schematic view of a spring biased inflow valve and a spring biased expiration valve to be used in accordance with the present invention.

Fig. 6B is a schematic view of Fig. 6A showing the operation of the valves during outflow of air.

Fig. 6C is a schematic view of Fig. 6A showing the operation of the valves during inflow of air.

Fig. 7 is a schematic view of a single valve that is spring biased from both sides to be used as an inflow valve and an expiration valve according to the present invention.

Fig. 8 is a schematic view of a flow restricting orifice to be used with a flow restrictive device according to the present invention.

Fig. 9 is a schematic view of an exemplary embodiment of the device for impeding airflow into a patient's lungs according to the present invention.

Figs. 10A-10C are schematic views illustrating another embodiment of the present invention allowing for periodic patient ventilation through a bypassing valve.

Fig. 11 is a schematic view of an exemplary valving system for regulating airflow into a patient's lungs according to the present invention. The valving system is shown with air being exhausted from a patient's lungs during compression of the patient's chest.

Fig. 12 illustrates the valving system of Fig. 11 during decompression or resting of the patient's chest.

Fig. 13 illustrates the valving system of Fig. 11 with a pressure-responsive valve being opened when the negative intrathoracic pressure in the patient's chest exceeds a threshold amount during decompression of the patient's chest.

Fig. 14 illustrates the valving system of Fig. 11 with a diaphragm being opened during injection of air into the housing when ventilating the patient.

Fig. 15 illustrates the valving system of Fig. 11 with a manually operable valve being opened to allow air into the patient's lungs upon return of spontaneous circulation.

Fig. 16A is a cutaway side view of exemplary valving system according to the present invention.

Fig. 16B is a top view of a deflector and a fenestrated mount of the valving system of Fig. 16A.

Fig. 16C is an alternative embodiment of the valving system of Fig. 16A.

Fig. 16D illustrates the valving system of Fig. 16A with a source of pressurized gas coupled to a pressure-responsive valve according to the invention.

Fig. 17 is a schematic view of an alternative embodiment of a valving system having a ball as a diaphragm.

Fig. 18 is a schematic view of a device for impeding air flow into the patient's lungs and for providing air to the patient's lungs when needed for ventilation.

Fig. 19 is a side view of one embodiment of a valving system having an adjustable pressure responsive valve according to the invention.

Fig. 20 is a cross sectional side view of the adjustable pressure responsive valve of Fig. 19.

Fig. 21 is a top view of the valve of Fig. 20.

Fig. 22 illustrates the valve of Fig. 21 with a cap being removed.

Fig. 23 is a schematic side view of a safety mechanism for a valving system that permits respiratory gases to freely flow to the patient's lungs through a ventilation passage according to the invention.

Fig. 24 illustrates the safety mechanism of Fig. 23 when actuated to prevent respiratory gases from flowing through the ventilation passage.

Fig. 25 is a schematic side view of a valving system having an integrated safety mechanism that permits respiratory gases to freely flow to the patient's lungs through an inflow valve according to the invention.

Fig. 26 illustrates a flow sensor and lever arm of the safety mechanism of Fig. 25 prior to actuation by the rescuer.

Fig. 27 illustrates the valving system of Fig. 25 when the safety mechanism is actuated by the rescuer to closed the inflow valve.

Fig. 28 illustrates the flow sensor and lever arm of Fig. 26 when actuated by the rescuer.

Fig. 29 is an end view of the valving system of Fig. 25.

Fig. 30 is a more detailed view of the inflow valve of Fig. 25 when in the open position.

Fig. 31 illustrates the inflow valve of Fig. 30 when in the closed position.

Fig. 32 is a side schematic view of one embodiment of a safety valve shown in a closed position according to the invention.

Fig. 33 illustrates the safety valve of Fig. 32 in an open position.

Fig. 34 is a side schematic view of another embodiment of a safety valve shown in a closed position according to the invention.

Fig. 35 illustrates the safety valve of Fig. 34 in an open position.

Fig. 36 is a side schematic view of yet another embodiment of a safety valve shown in a closed position according to the invention.

Fig. 37 illustrates the safety valve of Fig. 36 in an open position.

Fig. 38 is a schematic side view of an embodiment of a valving system having a safety valve that is in a closed position according to the invention.

Fig. 39 illustrates the valving system of Fig. 38 when the safety valve is moved to the open position during a gasp by a patient.

Fig. 40 illustrates the valving system of Fig. 38 during ventilation which causes the safety valve to move back to the closed position.

Fig. 41 is a schematic diagram of a valving system having a pressure gauge to measure pressures within the valving system according to the invention.

Fig. 42 is a cross-sectional schematic view of one embodiment of a system for treating a breathing person who is in shock according to the invention.

Fig. 43 is top schematic view of the system of Fig. 42.

Fig. 44 illustrates the system of Fig. 42 when the person is inspiring.

Fig. 45 illustrates the system of Fig. 42 when the person is exhaling.

Fig. 46A illustrates one embodiment of an inflow valve according to the invention.

Fig. 46B illustrates the inflow valve of Fig. 46A when the resistance to flow has been increased.

Fig. 47A illustrates another embodiment of an inflow valve according to the invention.

Fig. 47B illustrates the inflow valve of Fig. 47A when a disk has been moved to increase flow resistance according to the invention.

Fig. 48A illustrates yet another embodiment of an inflow valve according to the invention.

Fig. 48B illustrates the inflow valve of Fig. 48A when a disk has been rotated to increase resistance according to the invention.

Fig. 49A illustrates a further embodiment of an inflow valve according to the invention.

Fig. 49B illustrates the inflow valve of Fig. 49A when compressed to increase flow resistance.

Fig. 50A illustrates yet another embodiment of an inflow valve according to the invention.

Fig. 50B illustrates the inflow valve of Fig. 50A when compressed to increase flow resistance.

Fig. 51A illustrates a further embodiment of an inflow valve according to the invention.

Fig. 51B illustrates the inflow value of Fig. 51A when compressed to increase flow resistance.

Fig. 52A illustrates still a further embodiment of an inflow valve according to the invention.

Fig. 52B illustrates iris mechanisms that have been operated to increase the resistance to flow of the inflow valve of Fig. 52A.

Fig. 53A illustrates still a further embodiment of an inflow valve according to the invention.

Fig. 53B illustrates the inflow valve of Fig. 53A when a disk has been pivoted to increase flow resistance.

Figs. 54A through 54C illustrate one embodiment of a method for treating shock according to the invention.

DETAILED DESCRIPTION OF THE INVENTION

According to the present invention, methods and devices for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation are provided. Such methods and devices may be used in connection with any method of CPR in which intrathoracic pressures are intentionally manipulated to improve cardiopulmonary circulation. For instance, the present invention would improve standard manual CPR, "vest" CPR where a circumferential collar is compressed in a repetitive manner to promote blood flow from the heart, CPR with a newly described Hiack Oscillator ventilatory system which operates essentially like an iron-lung-like device, phrenic nerve stimulators, including those described in copending U.S. Application Nos. 09/095,916, filed 06/11/98; 09/197,286, filed 11/20/98; 09/315,396, filed 05/20/99; and 09/533,880, filed 03/22/00, the complete disclosures of which are herein incorporated by reference, interposed abdominal compression-decompression CPR, and active compression-decompression (ACD) CPR techniques. Although the present invention may improve all such techniques, the following description will refer primarily to improvements of ACD-CPR techniques in order to simplify discussion. However, the claimed methods and devices are not exclusively limited to ACD-CPR techniques.

The proper performance of ACD-CPR to increase cardiopulmonary circulation is accomplished by actively compressing a patient's chest with an applicator body. Preferably, this applicator body will be a suction-type device that will adhere to the patient's chest, such as the AMBU® CardioPump™, available from AMBU International, Copenhagen, Denmark. After the compression step, the adherence of the applicator body to the patient's chest allows the patient's chest to be lifted to actively decompress the patient's chest. The result of such active compression-decompression is to increase intrathoracic pressure during the compression step, and to increase the negative intrathoracic pressure

during the decompression step thus enhancing the blood-oxygenation process and enhancing cardiopulmonary circulation. ACD-CPR techniques are described in detail in Todd J. Cohen et al., *Active Compression-Decompression Resuscitation: A Novel Method of Cardiopulmonary Resuscitation*, American Heart Journal, Vol. 124, No. 5, pp. 1145-1150, November 1992; Todd J. Cohen et al., *Active Compression-Decompression: A New Method of Cardiopulmonary Resuscitation*, The Journal of the American Medical Association, Vol. 267, No. 21, June 3, 1992; and J. Schultz, P. Coffeen, et al., *Circulation*, 89:684-693, 1994. These references are hereby incorporated by reference.

The present invention is especially useful in connection with standard and ACD-CPR techniques. In particular, the invention improves standard and ACD-CPR by providing methods and devices which impede airflow into a patient's lungs to enhance negative intrathoracic pressure during the decompression of the patient's chest, thus increasing the degree and duration of a pressure differential between the thorax (including the heart and lungs) and the peripheral venous vasculature. Enhancing negative intrathoracic pressure with simultaneous impedance of movement of gases into the airway thus enhances venous blood flow into the heart and lungs and increases cardiopulmonary circulation.

In a broad sense, the present invention provides for occluding a patient's airway to prevent foreign (outside) air from flowing to a patient's lungs during the active decompression step of ACD-CPR to enhance and sustain the duration of negative intrathoracic pressure and enhance blood oxygenation and cardiopulmonary circulation during both active decompression and the subsequent compression phase. The patient's airway may be occluded or inflow of gases impeded by any suitable device or mechanism such as by an endotracheal tube, a device attached to an endotracheal tube, a facial mask, a mouth piece used in mouth-to-mouth resuscitation, oropharyngeal airway, laryngeal mask airway, and the like.

A further aspect of the present invention provides for allowing impeded air to flow into the patient's lungs during the active decompression step of ACD-CPR in order to provide some ventilation to the patient while still enhancing the extent and duration of negative intrathoracic pressure to enhance blood oxygenation. Impeding airflow to the patient's lungs may be accomplished by any flow restrictive element such as an orifice, a one-way valve, a spring biased or other valve which is set to open when the negative intrathoracic pressure is in the range from about 0 cm H_2O to -100 cm H_2O, and more preferably from

about -3 cm H_2O to about -30 cm H_2O. A valve designed to open at a threshold pressure value may be either fixed or variable, i.e., the pressure at which the valve opens may be adjusted or may be permanently fixed. Further, examples of pressure-responsive valves that may be used include, for example, an electromagnetically driven valve or a valve constructed of any deflectable material that will deflect when the threshold pressure is exceeded. As one specific example, the valve may be constructed of a magnetically charged piece of material with a narrow tolerance that is attracted to a gate. This valve will open, i.e. separate from the gate, when the magnetically charged gate pressure is exceeded. In this way, when the negative intrathoracic pressure is exceeded, the valve will be pulled away from the gate to permit gases to flow to the lungs.

In some cases, a safety mechanism may be provided to permit respiratory gases to freely flow to the patient's lungs until the safety mechanism is actuated by the rescuer. In this way, the valving system may be coupled to the patient but will only impede patient inspiration until actuated by the rescuer.

Another aspect of the invention provides for air to be impeded from leaving the patient's lungs during compression of the patient's chest to further enhance cardiopulmonary circulation by enhancing intrathoracic pressure during the compression phase. Typically, air is impeded from leaving the lungs during the compression phase when the positive intrathoracic pressure is in the range from about 2 cm H_2O to 50 cm H_2O, and more preferably from about 2 cm H_2O to about 20 cm H_2O. Valves that may be used to accomplish such a feature include, for example, a spring valve, a diaphragm valve, include diaphragms constructed of silicone, and a magnetically charged plate that is coupled to a gate. In this manner, when the positive pressure exceeds the magnetic force, the plate is forced away from the gate to permit the gases to exit the lungs.

Another aspect of the present invention provides for ventilating the patient during CPR. Ventilation of the patient in one embodiment is performed at about every two to 20 compressions, preferably twice every fifteen compressions, thus providing sufficient fresh air for adequate gas exchange with the blood in the lungs to the patient. Ventilating the patient may be accomplished by any device or method suitable such as by mouth-to-mouth resuscitation, by a compressible or collapsible structure, by a ventilatory bag such as the AMBU bag available from AMBU, Copenhagen, Denmark, or the like. Ventilation could also be superimposed on the compression phase to further augment positive intrathoracic

pressure. Furthermore, periodic ventilation could be performed either through the impeding step or by bypassing the impeding step altogether.

In an alternative embodiment, ventilation may be provided by introducing oxygen-enriched respiratory gases through the pressure-responsive valve that permits gases into the lungs during the decompression step once a certain threshold negative intrathoracic pressure is exceeded. This could be introduced under pressure or at atmospheric pressure In this way, during each decompression step, respiratory gases may be supplied to the lungs to ventilate the patient. Use of a pressurized gas is advantageous in that more respiratory gases may be supplied to the lungs once the pressure responsive valve opens. The pressurized gas may be supplied by connecting a pressurized gas source, such as a pressurized tank or bag of O_2, to the back side of the pressure-responsive valve using a length of tubing. Conveniently, a regulator may be positioned between the pressure source and the valve to regulate the pressure and/or flow rate of the gas supplied from the pressure source. The pressure may be regulated such that it is less than the actuating pressure of the valve, e.g. by about 1 to 3 cm H_2O, so that the valve will not prematurely open. For example, if respiratory gases are to be supplied to the patient when the negative intrathoracic pressure exceeds –14 cm H_20, the pressure of the gas from the gas source must be set to less than 14 cm H_2O.

When ventilating a patient, the valves of the invention may be modified to regulate the flow rate of air into the lungs. This may be accomplished for example, by including a flow regulator, valve, restriction, reduced size orifice or the like within or associated with the valve so that as respiratory gases are injected into the valve, their flow rate is limited below a threshold amount as the gases enter the patient's airway. By regulating the flow rate of injected respiratory gases, the pressure on the esophagus may be kept within certain limits to prevent gastronomic distention. For example, a reduced size orifice may be provided at or near the exit opening of the valve system housing to regulate the gas flow rate before the gases enter the patient's airway. In this way, a technique is provided to ensure that substantially all of the injected respiratory gases enter the patient's lungs.

One significant advantage of the invention is the ability to increase a person's blood pressure. By interfacing the valving systems of the invention with spontaneously breathing patients, the valving systems are able to increase the negative intrathoracic pressure when the person inhales. By so doing, more blood is returned to the right heart, thereby

increasing the person's blood pressure. The valving systems used to increase the person's blood pressure may initially completely prevent gas flow to the lungs during an inspiratory effort, or provide some measure of resistance. The complete prevention or initial resistance may be adjusted sometime during the breathing maneuver so that gas flow may proceed to the person's lungs for at least a portion of the inspiratory cycle. For example, if using a pressure responsive valve, the valve may be set to open when reaching a pressure in the range from about 0 cm H_2O to about -50 cm H_2O, more preferably from about 0 cm H_2O to about -20 cm H_2O, and most preferably from about -5 cm H_2O to about -15 cm H_2O for flow rates of about zero flow to about 70 liters per minute. For valves that simply provide resistance, the valve may be configured to provide similar resistances during the inspiratory effort. Further, one or more sensors may be used to sense various physiological parameters and may be used to manually or automatically vary the cracking pressure of the valve or the amount of resistance produced by the valve.

Examples of situations where the valving systems of the invention may be used to increase blood pressure include those where a spontaneously breathing patient has experienced blood loss, or after receiving a drug (including an anesthetic agent) that causes a decrease in blood pressure. Patients with low blood pressure often suffer from insufficient blood returning to the heart after each beat. This results in a decrease in forward blood flow out of the heart and eventually to low blood pressure. By interfacing the valving systems to the airway, the amount of venous return to the right heart is increased to increase blood pressure. Another example is where a spontaneously breathing patient is in shock secondary to profound blood loss and needs increased blood flow to the right heart. As a further example, such techniques may be used with pilots or astronauts to increase blood flow back to the right heart in high gravitational states or when returning to earth after space flight, and in patients who suffer from a rapid decrease in blood pressure due to vasovagal or vasodepressor syncope. Further examples include low blood pressure due to heat stroke, drowning, heart attack, right heart failure, sepsis, pericardial effusion, tamponade, or the like.

In one option, any of the valving systems may include an electronic device and an associated speaker to produce voice prompts on how to perform CPR using the valving systems. Such voice prompts may have instructions for interfacing the valving system, applying chest compressions, giving ventilations, and the like. Also, a metronome may be provided to assist the rescuer in providing appropriate chest compressions. Such techniques

are described in copending U.S. Application No. 09/854,404, filed 5/11/01 (attorney docket no. 16354-004300), the complete disclosure of which is herein incorporated by reference.

The valving systems of the invention may also incorporate or be associated with sensors that are used to detect changes in intrathoracic pressures or other physiological parameters. In this way, spontaneous patient breathing may be detected. This in turn may be used to control the valving system so that the patient may breathe without any resistance once the sensor is activated by achieving a certain intrathoracic pressure one or more times. Examples of such sensors are described in U.S. Patent No. 6.155,257, the complete disclosure of which is herein incorporated by reference.

Any of the sensors described herein may be configured to wirelessly transmit their measured signals to a remote receiver that is in communication with a controller. In turn the controller may use the measured signals to vary operation of the valve systems described herein. For example, sensors may be used to sense blood pressure, pressures within the heart, or the like and to wirelessly transmit this information to a receiver. This information may then be used by a controller to control the actuating pressure or the resistance of an inflow valve, to control the actuating pressure or resistance of an expiratory valve, to control the injection of oxygen or other gases, to control the administration of drugs or medications, or the like.

The valve systems and/or facial masks of the invention may also include one or more ports for the administration of drugs or other medicaments to the patient's respiratory system. For example, ports may be provided for injecting medicaments by a syringe or pressurized canister. As another example, a nebulized liquid medicament may be supplied through such a port. As a further example, a powdered medicament may be supplied through such a port.

Another feature of the invention is that it may be used to decrease intracranial pressures that often result from trauma to the head. By decreasing intrathoracic pressures using the valve systems and techniques of the invention, the resistance of venous return from the brain to the heart is decreased. As such, more venous blood may be removed from the brain, thereby decreasing intracranial pressures. For example, any of the valve systems of the invention may be coupled to the patient's airway so that as the patient breathes, the negative intrathoracic pressures generated by the patient are augmented to draw venous blood out of the brain.

Referring now to Fig. 1, a graph illustrating thoracic pressure changes over time when compressing and decompressing the patient's chest is shown. Area 10 represents the amount of thoracic pressure during the compression phase of ACD-CPR. Cross-hatched area 12 represents the negative thoracic pressure during the decompression step of ACD-CPR without a flow restrictive means to restrict the flow of air into the patient's lungs. Double cross-hatched area 14 represents the increase in negative thoracic pressure when the patient's airway is occluded according to the present invention during the decompression step of ACD-CPR. The significance of the increase in negative intrathoracic pressure during the decompression step is that more venous blood is forced into the chest from the peripheral venous vasculature. Consequently, more blood is allowed to be oxygenated and more blood is forced out of the chest during the next compression.

In an exemplary embodiment, airflow may be impeded to the patient's lungs during decompression of the patient's chest by placing a ventilatory mask over the patient's mouth and nose. The ventilatory mask also has a pressure-responsive valve attached to prevent airflow to the patient's lungs until the negative intrathoracic pressure of the patient reaches a threshold amount. Also attached to the mask and the pressure-responsive valve is a ventilatory source to provide ventilation to the patient. The ventilatory source may be any device or apparatus suitable for properly ventilating the patient. Preferably, the ventilation source will be an AMBU bag. When ventilation is needed, the AMBU bag may be squeezed to force air into the patient's lungs. The AMBU bag is described in U.S. Patent No. 5,163,424 which is incorporated herein by reference.

In an alternative embodiment, a ventilation source, preferably an AMBU bag, is used in connection with an improved endotracheal tube. A pressure-responsive valve or other flow restrictive element is placed between the AMBU bag and the endotracheal tube. Preferably, the valve will be positioned within a tube that connects the AMBU bag to the endotracheal tube. The combination of the endotracheal tube with the AMBU bag with adapter can be included in the definition of a "ventilation tube." Before ACD-CPR is performed on the patient, the endotracheal tube is placed in the patient's trachea. During decompression of the patient's chest, the valve prevents airflow to the patient's lungs until the intrathoracic pressure reaches a threshold amount. Additionally, the AMBU bag may be used to ventilate the patient at a desired time. Also included in this embodiment is a one-way

expiration valve. This valve allows for expiration of air from the patient during the compression step.

In a modification of either of the first two embodiments, a pressure-responsive expiration valve may also be inserted between the AMBU bag (or comparable ventilation source) and the mask or endotracheal tube. This valve works in a similar manner to the pressure-responsive valve which restricts airflow into the patient's lungs. However, the pressure-responsive expiration valve restricts airflow from the patient's lungs during the compression step of ACD-CPR. An equivalent valve is a positive end-expiratory pressure (PEEP) valve available from AMBU International, Copenhagen, Denmark. Use of such an pressure-responsive expiration valve during compression may further increase intrathoracic pressure and thereby force more blood out of the thorax.

In another alternative embodiment, an improved endotracheal tube is used to restrict airflow into the patient's lungs during the active decompression step. Included in the endotracheal tube is a flow restrictive element which operates to impede air from flowing into the patient's lungs. When the endotracheal tube is inserted into the patient's trachea and the patient's chest is actively decompressed, the flow restrictive element impedes air from flowing to the patient's lungs slowing the rise in intrathoracic pressure and thus enhancing blood oxygenation.

When using the improved endotracheal tube during ACD-CPR, periodic ventilation of the patient will usually still be performed to enhance gas exchange to the patient. With the improved endotracheal tube, such manual ventilation may be accomplished by placing a ventilation source at the opening of the endotracheal tube to force oxygen through the endotracheal tube and into the patient's lungs.

Referring now to Fig. 2A, a schematic view illustrating airflow through a ventilation circuit 20 when compressing a patient's chest according to the present invention is shown. During ACD-CPR, the chest is actively compressed forcing air out of the lungs. This air is allowed to expire through a one-way expiration valve 22 within a ventilation circuit 20.

Referring now to Fig. 2B, the same schematic is shown illustrating airflow through the ventilation circuit 20 when decompressing the patient's chest. When the patient's chest is actively decompressed, a negative intrathoracic pressure is created. When this pressure reaches a threshold amount, the inflow valve 24 will open causing air to flow through the ventilation circuit 20 into the patient's lungs. Air is allowed into the ventilation

circuit 20 through a ventilation valve 26 and into a ventilation bag 28. From the ventilation bag 28, the air passes through the inflow valve 24 when the negative intrathoracic pressure reaches the threshold amount. The ventilation bag 28 is also used to manually ventilate the patient during ACD-CPR as required.

The method as discussed in connection with Figs. 2A and 2B requires the chest to be compressed in the range from about 3.5 cm to 5 cm per compression and at a rate from about 60 to 100 compressions per minute for adults.

Referring now to Fig. 3, a schematic illustration of a first alternative embodiment of a device 35 for impeding airflow into a patient's lungs according to the present invention is shown. The device 35 comprises an endotracheal tube 36 which is placed into the patient's trachea and provides a ventilation passageway. Connected to the endotracheal tube 36 is a transition tube 38 which connects the endotracheal tube 36 to the ventilation bag 28. Although the endotracheal tube 36 is shown connected to the ventilation bag 28, the endotracheal tube 36 can be used alone or in connection with the ventilation bag 28. The ventilation bag 28 can comprise any type of ventilation source capable of ventilating the patient such as a compressible or collapsible structure. Preferably, the ventilation bag 28 consists of an AMBU bag. Attached or connected to the end of the ventilation bag 28 is a one-way ventilation valve 26. The ventilation valve 26 serves to introduce air into the device 35. Attached or connected to the transition tube 38 is an inflow pressure-responsive valve 24. The inflow valve 24 is biased so that it opens when the negative intrathoracic pressure in the patient's chest reaches a threshold amount. As shown, only one inflow valve 24 is included in the device 35. However, the invention is not limited to only one inflow valve 24. Alternatively, a plurality of inflow valves 24 could be connected in series along the ventilation tube 38. The inflow valve 24 is also not limited to being connected in the center of the transition tube 38, but may be positioned anywhere along the transition tube 38. The inflow valve 24 could be permanently attached to the ventilation bag 28 or transition tube 38 or could be detachable. Alternatively, the inflow valve 24 could be connected to the ventilation bag 28 itself or to the endotracheal tube 36.

The device 35 also contains a one-way expiration valve 22 which allows for air to be expired from the patient's lungs. This generally occurs during the compression phase of ACD-CPR. To insure that the air expired from the patient's lungs will exit through the expiration valve 22, a one-way fish mouth valve 37 (the preferred valve) or any other type

of one-way valve can be placed between the inflow valve 24 and the expiration valve 22. Alternatively, the inflow valve 24 itself may be configured as a one-way valve. In either case, air flowing from the endotracheal tube 36 toward the ventilation bag 28 will be forced to expire through the expiration valve 22.

The device 35 may be further modified to include a pressure-responsive expiration valve 39 (not shown) located between the endotracheal tube 36 and the transition tube 38. The pressure-responsive expiration valve works in a reverse manner to that of the inflow valve 24. Specifically, the pressure-responsive expiration valve is biased so that during the compression step of ACD-CPR, air will be allowed to expire from the patient's lungs only when the intrathoracic pressure reaches a threshold amount. The increase in intrathoracic pressure caused by the pressure-responsive expiration valve 39 during compression may assist in forcing more blood out of the thorax and reduce atelectasis of the lungs.

The purpose of the ventilation bag 28 is to provide ventilation to the patient during ACD-CPR. When the ventilation bag 28 comprises an AMBU bag or similar bag used for ventilation, ventilation of the patient may be performed by merely squeezing the AMBU bag with a human hand. This forces air to the patient's lungs as desired.

Referring to Fig. 4A, a second alternative embodiment of the device for impeding airflow into a patient's lungs according to the present invention is shown. This particular embodiment is a modified and improved endotracheal tube. Hence, the second alternative embodiment comprises an endotracheal tube 36 having two lumens at its proximal end. The first lumen is an outflow lumen 40, and the second lumen is an inflow lumen 42. Located within outflow lumen 40 is a one-way pressure-responsive expiration valve 44 which operates in a manner similar to that discussed in connection with Fig. 3, except that the expiration valve 44 is specifically designed as a one-way valve. Located within inflow lumen 42 is a one-way pressure-responsive inflow valve 45 which operates to impede airflow to the lungs as discussed in connection with Fig. 3, except that the inflow valve 45 is also specifically designed as a one-way valve. Also shown in inflow lumen 42 and outflow lumen 40 is an O-ring 46 which will be discussed subsequently. Inflow valve 45 and expiration valve 44 are designed as one-way valves so that during the compression phase, air can only be expired from the patient through the endotracheal tube 36 when the intrathoracic pressure reaches a threshold amount. At that moment, expiration valve 44 opens and air expires from

the patient through the outflow lumen 40. During decompression, air cannot flow through the endotracheal tube 36 to the patient's lungs until the negative intrathoracic pressure reaches a threshold amount. At that moment, inflow valve 45 opens allowing air to flow through inflow lumen 42 to the patient's lungs. Air is prevented from entering through the outflow lumen 40 because of the one-way expiration valve 44.

Ventilation is possible with the embodiment disclosed in Figs. 4A and 4B if the inflow lumen 42 is connected to a ventilation source such as a ventilation bag. When the ventilation bag is squeezed, air is allowed to flow through the inflow lumen 42, through the endotracheal tube 36, and to the patient's lungs. In this embodiment, expiration valve 44 is designed so that during ventilation, expiration valve 44 will remain temporarily closed preventing air flowing through inflow lumen 42 escape through outflow lumen 40.

Fig. 5A is a schematic view of a one-way inflow valve 45 used in a device for impeding airflow according to the present invention. The inflow valve 45 operates so as to allow air only to flow in one direction. As shown, the spring biased inflow valve 45 is completely open. However, the invention also functions properly if the spring biased inflow valve 45 or the spring biased expiration valve 44 are not fully open. Upon successful completion of ACD-CPR, the O-ring 46 that is positioned above the inflow valve 45 is repositioned so that inflow valve 45 is held open as shown in Fig. 5B. Such a positioning of O-ring 46 allows for unimpeded airflow to the patient once there is a return of spontaneous circulation and the inflow valve 45 is no longer needed. An O-ring 46 is also used in a similar manner to lock the one-way expiration valve 44 in an open position upon return of spontaneous circulation. Fig. 5C illustrates the one-way inflow valve 45 in a closed position. When closed, the inflow of air through the inflow valve 45 is occluded.

Fig. 6A illustrates an inflow valve 47 that is spring biased and an expiration valve 48 that is also spring biased. The inflow valve 47 and the expiration valve 48 are connected in series and may be used in the first alternative embodiment as discussed in connection with Fig. 3, or with the preferred embodiment discussed following in connection with Fig. 9. As shown in Fig. 6C, during the active decompression step, the inflow valve 47 is biased such that it will open when the negative intrathoracic pressure reaches a threshold amount. During the compression phase of ACD-CPR the expiration valve 48 will open to allow air to expire from the patient's lungs when the intrathoracic pressure within the patient's chest reaches a threshold amount as shown in Fig. 6B. Since neither inflow valve 47 nor

expiration valve 48 are one-way valves, a fish mouth valve 37 used in connection with a one-way expiration valve 22 as discussed in connection with Fig. 3 must be used. Other valves designed upon a similar principle as the fish mouth valve combination with a one-way expiration valve could also be used. Only one inflow valve 24 and one positive end pressure valve 44 are shown in Figs. 6A-6C. However, a plurality of inflow valves 47 and/or expiration valves 48 may be connected in a permanent or detachable manner in series to impede the inflow and outflow of air.

Although the valves in Figs. 6A-6C are shown as being spring-biased, any other valves designed upon a similar principle would work equally as well. The use of such valves as disclosed in Figs. 6A-6C is only one embodiment and valves constructed according to various other methods and materials is also within the scope of the invention.

As shown in Fig. 7, the inflow valve 47 and the expiration valve 48 may be combined into one joint valve 49 as shown. The joint valve 49 will operate in a manner similar to the two valves 47 and 48 as described in connection with Fig. 6.

Fig. 8 illustrates a flow restricting orifice 50 to be used to either impede the airflow into or out of a patient's lungs. The flow restricting orifice 50 operates so that during the decompression step of ACD-CPR airflow is impeded from entering into the patient's lungs, thus increasing the negative intrathoracic pressure. During the compression step, the flow restricting orifice 50 operates to increase the thoracic pressure in the patient's chest by restricting air from existing from the patient's lungs.

Fig. 9 illustrates an exemplary embodiment for impeding airflow into a patient's lungs according to the present invention. As shown, the device 51 comprises a ventilation bag 28 that is connected to a facial mask 52 by an inflow valve 24 and an expiration valve 22. Although the facial mask 52 is shown connected to the ventilation bag 28, the facial mask 52 can be used alone or in connection with the ventilation bag. Between the inflow valve 24 and the expiration valve 22 is a one-way fish mouth valve 37 or any other type of one-way valve to prevent air from exiting the patient's lungs and flowing to the ventilation bag 28. The ventilation bag 28 also contains a one-way ventilation valve 26 for allowing air to inflow into the device 51. The exemplary embodiment operates in a manner similar to that of the first alternative embodiment as discussed in connection with Fig. 3. However, instead of inserting an endotracheal tube 36 into the patient's airway, the facial mask 52 is placed over the patient's mouth and nose. A facial strap 54 (not shown) may also

be wrapped around the head of the patient to secure the ventilation mask 52 to the patient's face.

Device 51 is preferably used in connection with an oral airway device (not shown) to prevent the patient's airway from becoming occluded, e.g. by the patient's tongue. The oral airway device can be any device that is used to keep the patient's tongue from slipping backward and occluding the airway. Preferably, the oral airway device will be curved and constructed of a plastic material and may or may not be attached to the device 51.

During the decompression phase of ACD-CPR, air is prevented from entering into the patient's lungs through the threshold inflow valve 24 thus increasing the negative intrathoracic pressure. During the compression phase, air is allowed to expire from the patient's lungs through the expiration valve 22. Also, the patient can be ventilated during ACD-CPR by manually squeezing the ventilation bag 28. Consequently, the preferred embodiment serves to enhance cardiopulmonary circulation by increasing the negative intrathoracic pressure to force more blood into the chest from the peripheral venous vasculature.

Figs. 10A - 10C show another embodiment of the present invention which allows the patient to be ventilated by bypassing the impeding step. The embodiment comprises a ventilation tube 60 with a proximal end 62 and a distal end 64 that is connected to the patient. The ventilation tube 60 has a one-way bypass valve 66 and a one-way pressure responsive valve 68. The ventilation tube 60 may also have a manual switch 70 attached to the bypass valve 66 and extending through a side of the ventilation tube 60. As shown in Fig. 10A, the switch 70 may be set in a closed position so that the one-way pressure responsive valve 68 opens when the threshold pressure of the valve 68 has been exceeded. At this point, the valve 68 opens allowing for ventilation of the patient. As shown in Fig. 10B, the one-way pressure responsive valve 68 may be bypassed altogether by manually placing the switch 70 in the open position so that the bypass valve 66 is opened allowing air to flow to the patient. Fig. 10C illustrates the operation of the bypass valve 66 with the switch 70 in an inactive mode. Here, the rescuer performing ventilation may do so without added resistance from the impedance step as in Fig. 10A. Instead, bypass valve 66 opens only when the pressure at the proximal end of the tube 62 is greater than atmospheric pressure (0 mmHg), preferably in a range from about 0 mmHg to 5 mmHg. During decompression of the patient's chest, the one-way bypass valve 66 remains closed unless atmospheric pressure is exceeded. Thus, the

patient is ventilated only when the rescuer performing ventilation causes the pressure at the proximal end of the tube 62 to exceed atmospheric pressure. The function of the one-way bypass valve 66 may be performed by many different threshold valve designs which are known in the art.

In another aspect of the invention, an exemplary valving system is provided for enhancing the duration and extent of negative intrathoracic pressure during the decompression phase of CPR while still providing adequate ventilation to the patient. The valving system is employed to slow the rapid equilibrium of intrathoracic pressure in the chest during decompression by impeding or inhibiting the flow of air into the patient's chest. Lowering of the intrathoracic pressure in this manner provides a greater coronary perfusion pressure and hence forces more venous blood into the thorax. The valving system can be employed in a variety of CPR methods where intrathoracic pressures are intentionally manipulated to improve cardiopulmonary circulation, including "vest" CPR, CPR incorporating a Heimlich ventilatory system, intraposed abdominal compression-decompression CPR, standard manual CPR, and the like, and will find its greatest use with ACD-CPR.

Referring to Figs. 11-15, an exemplary embodiment of a valving system 100 is shown schematically. The valving system 100 includes a housing 101 having an upstream region 102 and a downstream region 104. Held between the upstream region 102 and downstream region 104 is a diaphragm 106. The diaphragm 106 is preferably a flexible or elastomeric membrane that is held over the downstream region 104 to inhibit air from flowing from the upstream region 102 to the downstream region 104 when the pressure in the downstream region 104 is less than the pressure in the upstream region 102, except when positive pressure, i.e. greater than atmospheric, is developed in the upstream region 102 when ventilating the patient. The valving system 100 further includes a valve 108 having a plug 110. As described in greater detail hereinafter, the valve 108 is included to provide ventilation to the patient when opened. The valve 108 can be manually opened by axial translation or it can be automatically opened when the pressure in the downstream region 104 reaches or exceeds a threshold amount, or both. Included at the upstream region 102 is an air intake opening 112 and an air exhaust opening 114. Air is delivered into the housing 101 through the air intake opening 112, while air is exhausted from the housing 101 through the air exhaust opening 114. An accordion valve 116, fish mouth valve, or the like is provided

between the air intake opening 112 and the air exhaust opening 114. As described in greater detail hereinafter, the accordion valve 116 is used to prevent air that is injected into the air intake opening 112 from exiting the air exhaust opening 114 when ventilating the patient. A filter 117 is provided for filtering air injected into the housing 101. Optionally, a filter 119 can be provided in the downstream region 104 for preventing excess body fluids and air-borne pathogens from entering into the system 100.

Operation of the valving system 100 during compression of a patient's chest is illustrated in Fig. 11. As the patient's chest is compressed, air is forced from the patient's lungs and into the downstream region 104. The air forced into the downstream region 104 is directed against the diaphragm 106 forcing the diaphragm into an ambient pressure region 118. Air in the downstream region 104 is then allowed to escape into the upstream region 102 where it is exhausted through the air exhaust opening 114. Optionally, the diaphragm 106 can be biased so that it will not be forced into the ambient pressure region 118 until the pressure within the downstream region 104 is about 2 cm H_2O or greater, and more preferably at about 2 cm H_2O to 4 cm H_2O.

Operation of the valving system 100 during decompression (or resting) of the patient's chest is illustrated in Fig. 12. As the patient's chest is actively lifted (or allowed to expand on its own), air is drawn from the downstream region 104 and into the patient's lungs, thereby reducing the pressure in the downstream region 104. The resulting pressure differential between the regions 102, 104 holds the diaphragm 106 over the downstream region 104 to prevent air from the upstream region 102 from flowing to the downstream region 104. In this way, air is inhibited from flowing into the patient's lungs during decompression of the patient's chest, thereby lowering the intrathoracic pressure to increase the coronary perfusion pressure and to force more venous blood into the thorax.

Various ways of providing ventilation to the patient using the valving system 100 are described in Figs. 13-15. Fig. 13 illustrates airflow into the downstream region 104 and to the patient's lungs during decompression of the patient's chest after a threshold amount of negative intrathoracic pressure has been reached. Ventilation in this manner is advantageous in that the valving system 100 can be employed to produce at least a threshold amount of intrathoracic pressure to enhance blood flow into the heart and lungs. Once such as pressure is reached, some air is allowed to flow to the patient's lungs to ventilate the patient.

Air is allowed to enter the downstream region 104 when the threshold amount of intrathoracic pressure is reached by configuring the valve 108 to be a threshold valve. The valve 108 can be configured in a variety of ways, with a primary function being that the valve 108 allows air to flow into the downstream region 104 when a threshold amount of intrathoracic pressure is reached. This is preferably accomplished by configuring the plug 110 to be flexible in one direction so that when the pressure in the downstream region 104 reaches or exceeds the threshold amount, the plug 110 is flexed to provide an opening 126 between the upstream region 102 and downstream region 104. When the plug 110 is flexed, air flows from the lower pressure upstream region 102 into the downstream region 104 and to the patient's lungs. The plug 110 therefore acts as a one-way valve allowing air to flow from the upstream region 102 into the downstream region 104 when the threshold amount is reached, but does not allow airflow from the downstream region 104 to the upstream region 102. Preferably, the plug 110 will flex to open when the pressure within the downstream region 104 is in the range from about 0 mm H_2O to 50 cm H_2O, more preferably at about 10 cm H_2O to 40 cm H_2O, and more preferably at 15 cm H_2O to about 20 cm H_2O. Alternatively, the valve 108 can be placed in the downstream region 104 so that air flows into the downstream region 104 directly from the atmosphere when the valve 108 is open. Although shown as a flexible plug, it will be appreciated that other types of valve arrangements may be used. For example, plug 110 could be replaced with a spring biased valve that closes opening 126 until the negative intrathoracic pressure overcomes the force of the spring to open the valve in a manner similar to that described in connection with Fig. 16A.

Ventilating the patient by injecting air into the upstream region 102 is illustrated in Fig. 14. As air is injected through the intake opening 112, it passes into the accordion valve 116 and forces the valve 116 against a wall 120 and covers a hole 122 in the wall 120 to prevent airflow through the exhaust opening 114. When the accordion valve 116 is closed, air flows through a wall 124 of the valve 116 and into the upstream region 102. Alternatively, a fish mouth valve can be used in place of the accordion valve 116. Upon injection of the air into the upstream region 102, the pressure within the upstream region 102 becomes greater than the pressure in the ambient pressure region 118 and causes the diaphragm 106 to be drawn into the ambient pressure region 118. An opening between the upstream region 102 and the downstream region 104 is created allowing air to flow into the

downstream region 104 and into the patient's lungs. Preferably, the patient will be manually ventilated by injecting air into the intake opening 112 one time every five compressions of the chest, and more preferably about two times every 15 compressions of the chest using two rescuers. Similarly, ventilating the patient can occur through the same port where the spring-biased valve is located, such as through valve 160 of Fig. 16A.

Configuration of the valving system 100 upon return of spontaneous circulation is illustrated in Fig. 15. When the patient's circulation is restored, the valve 108 is manually opened by translating the valve 108 to remove the plug 110 from aperture 126. The upstream region 102 and downstream region 104 are then placed in communication to allow air to be freely exchanged between each of the regions 102, 104. Although shown extending through the upstream region 102, the valve 108 can alternatively be placed anywhere along the downstream region 104.

The valve 108 can be configured as a pressure-responsive valve (see Fig. 13), as a manually operable valve (see Fig. 15), or both. Further, the valving system 100 can alternatively be provided with two or more valves that are similar to the valve 108. For example, one valve could be non-translatably held in the housing 101 and provided with a pressure-responsive plug 110, with the other valve being translatably mounted. In this manner, the valve with the flexible plug functions as a pressure-responsive valve and opens when the threshold pressure is reached, while the translatable valve functions to place the regions 102, 104 in communication upon manual operation after spontaneous circulation is achieved.

Referring to Figs. 16A and 16B, an exemplary embodiment of a valving system 130 will be described. The valving system 130 is constructed of a housing 132 having an intake opening 134, an exhaust opening 136, and a delivery opening 138. Included in the exhaust opening 136 is a one-way valve 140 which allows air to flow from the housing 132 and out the exhaust opening 136. An accordion valve 140 is provided between the intake opening 134 and an exhaust opening 136 to prevent air injected into the intake opening 134 from exiting through the exhaust opening 136. Preferably, the intake opening 134 is configured to be attachable to a respiratory device, such as a respiratory bag (including an AMBU bag), a ventilator, a mouthpiece or port for mouth-to-mouth breathing through the system 130, or the like. The delivery opening 138 is preferably configured for connection to an endotracheal tube or other airway tube, a sealed facial mask, a laryngeal mask, or the like.

Within the housing 132 is an upstream region 142, a downstream region 144, and an ambient pressure region 146. Separating the upstream region 142 from the downstream region 144 is a diaphragm 148. The diaphragm 148 is preferably constructed of an elastomeric material. The housing 132 is preferably cylindrical in geometry at the downstream region 144, with the diaphragm 148 resting on the cylinder during ambient conditions. During decompression of the patient's chest, the reduction in pressure in the downstream region 144 draws the diaphragm 148 against the end of the cylinder to prevent exchange of air between the upstream region 142 and downstream region 144. During compression of the patient's chest, air is forced into the downstream region 144 to force the diaphragm 148 into the ambient pressure region 146 so that the air exhausted from the patient's chest can be exhausted through the exhaust opening 136.

As shown best in Fig. 16B, the valving system 130 is further provided with a fenestrated mount 150. In one aspect, the fenestrated mount 150 serves as a mount for holding the diaphragm 148 over the downstream region 144. The fenestrated mount 150 further provides the ambient pressure region 146. Fenestrations 152 are provided in the mount 150 to allow air to be exchanged through the mount 150. Included on the mount 150 is a deflector 154 for deflecting air around the fenestrated mount 150. Various other deflectors 156 are provided in the housing 132 for directing airflows between the regions 142 and 144. A filter 158 is provided in the housing 132 to filter air injected into the housing 132. Optionally, a filter 159 can be provided to prevent excess body fluids from entering into the system 130.

The valving system 130 further includes a threshold valve 160 at the downstream region 144. When the pressure within the downstream region 144 is less than the threshold amount, the threshold valve 160 is opened to allow air to flow into the downstream region 144. The threshold valve 160 includes a spring 162 which is configured to extend when the threshold amount is reached. Alternatively, the threshold valve 160 can be configured similar to the valve 110. Other configurations which allow the for air to enter the downstream region 144 when the desired intrathoracic pressure is reached or exceeded can also be provided. For example, in a further alternative, the diaphragm 148 can be constructed to function as a threshold valve to allow air to flow into the patient's lungs when a threshold amount of intrathoracic pressure is reached. The diaphragm 148 can be fashioned as a threshold valve by constructing the diaphragm 148 of an elastomeric material and by

providing at least one hole near the periphery. When the diaphragm rests on the cylinder forming the downstream region 144, the hole is positioned beyond the periphery of the cylinder and in the upstream region 142. As a vacuum is created in the downstream region 144, the diaphragm is drawn into the downstream region 144 until the hole is stretched over the cylinder and overlaps with both the upstream region 142 and the downstream region 144. In this way, a fluid path is provided between the regions 142 and 144 when the threshold pressure is reached in the downstream region 144. Another alternative of a threshold valve 111 is illustrated in Fig. 16C. The valve 111 is pivot mounted within the downstream region 144 and is biased closed by a spring 113. When the threshold pressure within the downstream region 144 is reached, the spring 113 is compressed and air is drawn into the downstream region 144.

Referring back to Fig. 16A, the threshold valve 160 can optionally be provided within the housing 132 at the upstream region 142. The threshold valve 160 can further optionally be provided with an on/off switch for opening the valve 160 when spontaneous circulation is achieved. In this manner, a rescuer can open the valve 160 to allow for free exchange of air to the patient's lungs when needed. In one alternative as shown in Fig. 16C, the mount 150 can be slidably mounted within the housing 132 so that the mount 150 can be vertically raised to lift the diaphragm 148 from the downstream region 144 upon successful resuscitation of the patient, thereby providing a free flow of air to the patient. The mount 150 can be slidably mounted within the housing 132 by attaching the mount 150 to an extension member 133 that is slidable within the housing 132. The member 133 preferably includes the intake and exhaust openings 134 and 136. In this way, an easy grasping surface is provided when translating the member 133 to open or close the diaphragm 148. If the diaphragm 148 were also fashioned as a threshold valve as previously described, the need for the valves 108 or 111 could be eliminated.

The housing 132 can conveniently be constructed in several parts which are connected together at various connection points. In this manner, the housing can be taken apart for connection to other devices, for repair, for cleaning, and the like. For example, one connection point can be conveniently provided near the filter 158 for removably connecting the portion of the housing having the intake opening 134, the valve 140, and the exhaust opening 136. Alternatively, a connection point can be provided near the mount 150 to provide easy access to the mount 150 for cleaning.

The valving system 130 can conveniently be incorporated with a variety of devices useful in CPR procedures. For example, the valving system 130 can be incorporated within a respiratory bag, such as an AMBU bag. Alternatively, the valving system 130 can be included as part of a respiratory circuit having both a respiratory bag and an endotracheal tube or other airway tube, with the valving system 130 positioned between the bag and the tube. In further alternative, the valving system 130 can be added to an endotracheal tube alone. Alternatively, the valving system can be incorporated into a mask, an oralpharyngeal airway, a laryngeal mask or other ventilatory devices.

In some cases, patient ventilation may be provided through threshold valve 160 as shown in Fig. 16D. In such a case, intake opening and valve 140 are optional since all ventilation may occur through threshold valve 160. Of course, ventilation could be provided through both avenues. Further, although shown in the context of valving system 130, it will be appreciated that the other embodiments described herein may be modified to include a pressure source that is coupled to the threshold valve.

As shown in Fig. 16D, a tank 300 of pressurized gas, such as O_2.is coupled to housing 132 by a length of tubing 302. In this way, a pressurized gas may be supplied to the back side of threshold valve 160. A regulator 304 is coupled to tank 300 to regulate the pressure supplied to threshold valve 160 so that it is less than the pressure required to open valve 160. For example, if respiratory gases are to be supplied to the patient when the negative intrathoracic pressure exceeds –14 cm H_20, then the actuating valve pressure may be set at –14 cm H_20, and the pressure of the gas from tank 300 may be set less than –14 cm H_2O. In this way, valve 160 will not prematurely open. In some cases, regulator 304 may also be used to regulate the flow rate of the gas through valve 160.

By coupling tank 300 to valve 160, respiratory gases are pulled into downstream region 144 when valve 160 opens due to the decrease in negative intrathoracic pressure as previously described. In this way, more respiratory gases are supplied to the patient each time the patient's chest is decompressed. This approach allows for negative pressure ventilation, unlike positive pressure ventilation which impedes venous return to the chest with each active rescuer ventilation. The negative pressure ventilation with this approach allows for adequate oxygenation and maximum venous blood return during CPR. Tank 300 may also function to provide oxygen once the trigger pressure has been achieved.

Referring to Fig. 17, an alternative valving system 164 will be described. The valving system 164 is shown schematically and operates essentially identical to the valving system 100, the difference being that the valving system 164 includes a ball or spherical member 166 as the diaphragm. During decompression of the patient's chest, the pressure in a downstream region 168 is less than the pressure in an upstream region 170 which draws the ball 166 over the downstream region 168. The valving system 164 can optionally be provided with a spring 172 or other biasing mechanism to hold the ball 166 over the downstream region 168 during compression of the patient's chest until a threshold pressure is reached or exceeded in the downstream region 168 as previously described.

Referring now to Fig. 18, another exemplary device 200 which is useful when performing cardiopulmonary resuscitation will be described. As described in greater detail hereinafter, one important feature of device 200 is that it may be interfaced to the patient's airway to periodically supply air to the patient's lungs when performing cardiopulmonary resuscitation. In this way, the patient may be ventilated with air (or other desired gases, such as O_2) rather than with respiratory gases from the rescuer's lungs as is typically the case when performing mouth-to-mouth resuscitation.

Device 200 comprises a facial mask 202 and a housing 204 that is operably attached to facial mask 202 at an interface 206. Housing 204 includes an upper region 208 and a lower region 210. Lower region 210 includes a pressure responsive valving system 212 which operates in a manner similar to the embodiments previously described herein to prevent the flow of gases into the patient's lungs until a threshold negative intrathoracic pressure is exceeded. At this point, pressure responsive valving system 212 allows gases to flow into the patient's lungs in a manner similar to that previously described herein. Lower region 210 further includes a fish mouth valve 214 and one-way outflow valves 216. Valves 214 and 216 operate together to allow gases exhausted from the patient's lungs to exit device 200 as indicated by arrow 218. In particular, when gases are forced out of the patient's lungs, fish mouth valve 214 will be closed and the exhausted gases will escape from device 200 through valves 216.

Upper region 208 includes a mouth piece 219 to allow a rescuer to blow into device 200 when attempting to ventilate a patient (similar to conventional CPR). Upper region 208 defines an air chamber 220 for holding room air and has a volume of about 200 ml to about 800 ml. Chamber 200 may also be connected to an oxygen source. Disposed within

upper region 208 is a diaphragm 222 and a spring 224. With this configuration, when a rescuer blows air into mouth piece 219, spring 224 will compress as diaphragm 222 moves downward. In turn, air or oxygen held within air chamber 220 will be compressed and hence forced through valving system 212 and into facial mask 202. In this way, air (rather than respiratory gases) from the rescuer will be supplied to the patient when the rescuer performs mouth-to-mouth resuscitation by blowing into mouth piece 219.

Upper region 208 further includes a one-way inflow valve 226 which allows air chamber 220 to be replenished with room air following ventilation. In particular, as spring 224 expands valve 226 will open to allow room air to fill chamber 230 due to the negative pressure created in chamber 230 by spring 224. Inflow valve 226 will also open when the threshold negative intrathoracic pressure is exceeded causing pressure responsive valving system 212 to open. In this way, inflow valve 226 also serves as a venting mechanism to vent air into housing 204 when the negative intrathoracic pressure limit is exceeded.

Hence, device 200 allows a rescuer to ventilate a patient with room air simply by blowing into mouth piece 219. Of course, it will appreciated that other desirable gases may be placed within air chamber 220 so that such gases may be supplied to the patient when the rescuer blows into mouth piece 219. For example, a volume of O_2 may be placed within chamber 220.

As previously described, one aspect of the invention is the ability to prevent respiratory gasses from entering the lungs until a certain negative intrathoracic pressure is met or exceeded. One aspect of the invention is the ability to vary the pressure at which respiratory gasses are permitted to flow to the lungs. In some cases, this may be accomplished by varying the actuating or cracking pressure of the pressure-responsive inflow valve. However, other mechanisms may be provided to vary the pressure at which respiratory gasses are permitted to flow to the lungs without modifying the cracking pressure of the pressure-responsive inflow valve. Hence, mechanisms for varying the pressure at which respiratory gasses are permitted to flow to the lungs may be incorporated in the pressure-responsive inflow valve, another valve in the valving system, or may be a separate part of the overall valving system.

Such a system may be configured so that the actuating pressure may vary between about 0 cm H_2O to about -30 cm H_2O. Further, such a valving system may be used

alone with a spontaneous breathing patient or with a patient receiving standard manual closed-chest CPR. Such a valving system may also be used in conjunction with other resuscitation techniques and/or devices, including, for example, ACD CPR, Vest CPR, or the like. In some cases, such a valving system may be used in connection with a diaphragmatic stimulator for purposes of resuscitation from cardiac arrest as well as for increasing blood pressure by advancing venous return. Exemplary systems and techniques for diaphragmatic stimulation for purposes of resuscitation are described in U.S. Patent Application Nos. 09/095,916, filed 06/11/98; 09/197,286, filed 11/20/98; 09/315,396, filed 05/20/99; and 09/533,880, filed 03/22/00, incorporated herein by reference. As a further example, such a valving system may be used to improve central blood return to the heart in patients in cardiac arrest, patients with low blood pressure and patients in right heart failure and in shock.

A variety of mechanisms may be used to vary the degree at which respiratory gasses are permitted to flow to the lungs. For example, such a mechanism may be mechanical or electronic or may include various combinations of mechanical and electronic components, and may be regulated within a larger system by, for example, electronic communication between the device used for resuscitation and the pressure-responsive inflow valve. Such a mechanism may also be adjustable based upon the in-line measurement of gasses, such as the measurement of end-tidal CO_2, the average minute ventilations, peak negative inspiratory pressures, and the like.

Referring to Fig. 19, one embodiment of a valving system 400 having an adjustable pressure-responsive inflow valve 402 will be described. Valving system 400 is shown schematically and may be constructed similar to any of the embodiments described herein. As such, when valving system 400 is interfaced with a patient's airway, the patient may freely exhale through valving system 400. When attempting to inhale, or during a decompression step of CPR, respiratory gasses are prevented from entering the lungs until a threshold actuating pressure is reached. At such time, respiratory gasses are permitted to flow to the lungs through inflow valve 402 in a manner similar to that previously described with other embodiments.

Inflow valve 402 includes a tension adjust knob 404 that may be turned by the rescuer to adjust the threshold actuating pressure of inflow valve 402 and will be described in greater detail with reference to Figs. 20-22. As best shown in Fig. 20, inflow valve 402 comprises an outer housing 406 having a set of tracking channels 408 (see Fig. 22). Outer

housing 406 is configured to hold an O-ring housing 410 having a top segment 412 and a bottom segment 414. Disposed between top segment 412 and bottom segment 414 is an O-ring 416. Top segment 412 further includes a set of tracking rails 418 that slide within tracking channels 408. A tension spring 420 sits between tension adjust knob 404 and top segment 412 and biases O-ring 416 against outer housing 406. When O-ring 416 is biased against outer housing 406 the valve is in the closed position where respiratory gasses are prevented from passing through ventilation ports 422 and to the patient's lungs. When the negative intrathoracic pressure meets or exceeds the threshold actuating pressure of inflow valve 402, the tension in spring 420 is overcome, causing O-ring 416 to separate from outer housing 406. At this point, respiratory gasses are free to rush through ventilation ports 422 and to the patient's lungs.

To vary the actuating pressure of inflow valve 402, knob 404 is turned to advance or retract a threaded nut 424 along a threaded bolt 426 that in turn is coupled to top segment 412. In so doing, the tension of spring 420 is varied to vary the actuating pressure of inflow valve 402. Hence, knob 404 provides a convenient way for a rescuer to adjust the actuating pressure simply by turning knob 404. Although not shown, a pressure gauge may be disposed within valving system 400 and a display may be provided to display the negative intrathoracic pressure. In this way, the rescuer may readily visualize the pressures generated within valving system 400 and may adjust knob 404 to vary the pressure at which respiratory gasses are permitted to flow to the lungs.

Another feature of the invention is the use of a safety mechanism to permit respiratory gasses to freely flow to the patient through the valving system until the rescuer places the valving system in an operative mode. Once in the operative mode, the valving system will remain in that mode indefinitely or for a finite period of time, at which the safety mechanism would revert back to its initial state where respiratory gasses may freely flow to the lungs. In some embodiments, this may be accomplished by having the safety mechanism maintain the pressure responsive inflow valve in the open position (without any impedance to inspiratory air flow) until actuated by the rescuer. Actuation may be accomplished in a variety of ways, such as by injected respiratory gasses into the valving system (such as when ventilating the patient), by operating a button or switch on the valving system, or the like.

One advantage of such a safety mechanism is that it ensures that the patient can freely breathe through the valving system (assuming the patient is spontaneously

breathing or begins to spontaneous breathe) without any resistance from the pressure-responsive inflow valve. Once the rescuer is ready to begin a procedure, such as performing CPR, the valving system is placed in the operative mode where respiratory gas flow to the lungs is prevented through the pressure-responsive inflow valve until the threshold negative intrathoracic pressure is met or exceeded. As with other embodiments described herein, respiratory gasses may also be injected into the patient's lungs through the valving system, thereby bypassing the pressure-responsive inflow valve.

The safety mechanism may operate as a purely mechanical device, a purely electronic device, or may include various combinations of mechanical and electronic components. One way for placing the valving system in the operative mode is by utilizing a sensor to detect when respiratory gasses are injected into the valving system through the ventilator port. The signal from the sensor may then be used to close a ventilation passage within the valving system. In some cases, the ventilation passage may extend through the pressure-responsive inflow valve. To close this passage, the inflow valve is simply closed. In some embodiments, if rescuer ventilation is not provided within a certain time, the safety mechanism may be used to take the valving system out of its operative mode so that respiratory gasses may freely flow to the patient's lungs.

Referring now to Figs. 23 and 24, one embodiment of a valving system 430 with such a safety feature will be described. This configuration may be used in series with any of the previously described valving systems so that it will have a means of impeding airflow to the patient's lungs. Hence, it will be appreciated that valving system 430 may be constructed to have, or used in combination with, components similar to the other valving systems described herein and will not be illustrated to simplify discussion. Valving system 430 includes a housing 432 that may be similar to the housings of the other valving systems described herein except that housing 432 includes a safety ventilation port 434 that permits respiratory gasses to flow into and through housing 432 so that respiratory gasses may flow to the patient's lungs as shown by the dashed line in Fig. 23. Hence, as shown in Fig. 23, valving system 430 is in a passive mode where the patient may freely breathe through housing 432.

Valving system 430 further includes a safety mechanism 436 that is operative to maintain ventilation port 434 open until actuated by a rescuer. When actuated, safety mechanism 436 closes ventilation port 434 to place valving system 430 in the operative mode

where respiratory gasses are prevented from reaching the lungs through a pressure-responsive inflow valve until a threshold negative intrathoracic pressure is met or exceeded in a manner similar to that described in other embodiments.

Safety mechanism 436 comprises an electronic air flow sensor 438 that is electrically connected to control circuitry 440. In turn, control circuitry 440 is electrically connected to a micro-solenoid 442 having a valve stop 444. A battery 445 is used to supply power to the electrical components. When a rescuer is ready to place valving system 430 in the operative mode, the rescuer injects respiratory gasses into housing 432 (such as by blowing air or injecting a pressurized gas into a ventilation port, not shown). As the respiratory gasses flow to the patient's lungs through housing 432, sensor 438 is moved to trigger a switch and to send an electrical signal to control circuitry 440. Control circuitry 440 then sends a signal to solenoid 442 to move stop 444 and thereby close the valve, thus preventing airflow to the patient through safety ventilation port 434. Such a state is illustrated in Fig. 24 where valving system 430 is in the operative mode. At this point, a spontaneously breathing patient will need to breathe through a pressure-responsive inflow valve. For a non-breathing patient, respiratory gasses will be prevented from reaching the lungs during the performance of CPR until a threshold negative intrathoracic pressure is overcome, at which point respiratory gasses may flow through the inflow valve and to the patient's lungs in a manner similar to that described with other embodiments. If, after a certain time, sensor 438 is not actuated by the rescuer, control circuitry 440 may be configured to operate solenoid 442 to take valving system 430 out of the operative mode where respiratory gasses may flow through safety ventilation port 434.

In some embodiments, the valving systems of the invention may incorporation a safety mechanism having essentially all mechanical elements. One such embodiment of a valving system 480 is illustrated in Figs. 25 through 33 and 36 through 40. Valving system 480 comprises a housing 482 that houses various components that may be similar to the other embodiments described herein. As such, housing 482 includes a ventilation port 484 and an exit opening 486. Valving system 480 further includes a pressure-responsive inflow valve 488 that prevents respiratory gasses from flowing to the patient's lungs until a certain negative intrathoracic pressure level has been met or exceeded in a manner similar to that described with other embodiments. Valving system 480 further includes a safety mechanism 490 to permit respiratory gasses to freely flow to the patient's lungs until operated to place

valving system 480 in an operative mode where pressure-responsive inflow valve 488 controls when respiratory gasses are permitted to flow to the lungs. As described in greater detail hereinafter, safety mechanism 490 also includes an inflow valve 492. In some embodiments, inflow valve 492 may be configured as a pressure-responsive inflow valve and thereby eliminate the need for inflow valve 488.

Safety mechanism 490 further comprises a flow sensor 494 that is in the form of a flap. Flow sensor 494 pivots about a pivot point 496 to move a cam mechanism 498, thereby rotating a wheel 500. In Figs. 25 and 30, valving system 480 is in the inactive state where flow sensor 494 has not yet been activated. When respiratory gasses are directed through housing 482, flow sensor 494 pivots about pivot point 496 as previously described to rotate wheel 500 as illustrated in Figs. 27, 28 and 30.

As best shown in Fig. 29, wheel 500 is connected to a gear system 502 having a recoil spring 504 and a valve cam 506. Recoil spring 504 is employed to bias cam 506 in the position illustrated in Figs. 25 and 30 where valve 492 is in the open position. When gasses flow through housing 482, flow sensor 494 is moved to cause wheel 500 to rotate and thereby operate gear system 502. In so doing, cam 506 is rotated to the position shown in Figs. 27 and 31 where valve 492 moves to the closed position. Gear system 502 and recoil spring 504 operate to open valve 492 after a certain period of time has elapsed, such as about 10 to 20 seconds.

As best shown in Figs. 30 and 31, valve 492 comprises a valve housing 508 in which is held a valve shaft 510 that holds an O-ring 512. A tension spring 514 is positioned between housing 508 and a projection 516 on shaft 510 to bias the valve 492 in the closed position as illustrated in Fig. 31. When a rescuer injects respiratory gasses into the housing of the valving system, cam 506 moves to the position shown in Fig. 30 where it engages shaft 510 and disengages O-ring 512 from housing 508 to place valve 492 in the open position. In the open position, respiratory gasses are free to flow through valve 492 and into housing 482 where they may flow to the patient's lungs through exit opening 486.

The invention further provides systems having safety features that allow for the patient to inhale to a given degree to release the mechanism that is used to impede or prevent respiratory gases from flowing to the lungs, thereby allowing for resistance free inspiration until a timer resets the systems or until the rescuer resets the system. One embodiment of a safety valve 600 that may be used with such systems is illustrated in Figs.

32 and 33. Safety valve 600 may be used as a replacement for any of the pressure responsive valves described herein, such as, for example, valves 108, 160 and 111. Valve 600 comprises a housing 602 which is covered by a slit membrane 604. A valve member 606 is biased by a spring 608 into a closed position as shown in Fig. 32. In the closed position, a wedge 610, that may conveniently be colored for easy identification, extends above the slit in membrane 604. As such, wedge 610 serves as a visual indicator to the rescuer that valve 600 is in the closed position. When interfaced with a patient and in the closed position, respiratory gases may be prevented from flowing to the lungs until the negative intrathoracic pressure meets or exceeds a threshold value in a manner similar to that described with other embodiments. At such time, a seal 612 on valve member 606 moves away from a stop 614 on housing 602 to permit respiratory gases to flow to the lungs. Spring 608 then forces valve member 606 back to the closed position.

If the patient gasps and begins to breath, the amount of negative pressure created by the patient compresses spring 608 far enough so that wedge 610 is pulled through the slit in membrane 604 as shown in Fig. 33. Wedge 610 then holds valve 600 in the open position where gases may freely flow to the lungs. The rescuer may easily determine valve 600 is in the open position by noticing that wedge 610 is no longer visible. The rescuer may reset valve 600 at any time by simply pulling on a pull tab 616 to pull wedge 610 back through membrane 604.

Another embodiment of a safety valve 620 that may be used in the systems described herein is illustrated in Figs. 34 and 35. Valve 620 comprises a housing 622 having a stop 624. A micro-solenoid 626 is disposed within housing an includes an arm 628 having a pole magnet 629 and a visual indicator 630 at an opposite end. Spaced apart from pole magnet 629 is another pole magnet 632 of opposite polarity that is coupled to a valve member 634 having a seal 636. Coupled to housing 622 is a normally open contact strip switch 638, and valve member 634 includes a conductive strip 640. A spring 642 is disposed between strip 640 and stop 624.

Fig. 34 illustrates valve 620 in the closed or active position. During CPR, seal 636 will separate from stop 624 to permit respiratory gases to flow to the lungs when the negative intrathoracic pressure exceeds a threshold value. Valve 620 then returns back to the closed position. If the patient gasps, valve member 634 moves to the position shown in Fig. 35 where conductive strip 640 contacts switch 638. (During normal CPR, valve member 634

is not moved far enough for this contact to occur). This closes the open circuit and activates solenoid 626 to extend arm 628 and trigger a timing circuit within a control circuitry and battery compartment 644. Magnets 629 and 632 have opposite poles causing valve to remain in the open and inactive position as shown in Fig. 35 as long as solenoid 626 is actuated. In this way, the patient may continue to freely breath through valve 620. Although shown with opposing pole magnets, it will be appreciated that magnets may be substituted with a solenoid arm that may act as a plunger to make physical contact with valve member 634, and thus hold the valve open and inactive. The rescuer may note that valve 620 is in the open position by noting that indicator 630 has been retracted and is no longer visible.

Valve 620 may include an auto/manual switch 646 that may be set in automatic mode. In this mode, the timing circuit automatically deactivates solenoid 626 and returns valve 620 back to the closed and active position shown in Fig. 34 after a preset timing interval has expired. If switch 646 is set to manual, solenoid 626 remains active and valve 620 remains open and inactive as shown in Fig. 35 where respiratory gases may freely flow to the lungs. Valve 620 remains open until the rescuer manually resets solenoid 626 by pressuring a manual reset switch 648. The rescuer may note that valve 620 is closed and active by observing indicator 630 that is now extended.

Figs. 36 and 37 illustrate a further embodiment of a safety valve 650 that may be used with the systems described herein. Valve 650 comprises a housing 652 having a stop 654. Disposed within housing 652 is a valve member 656 having a seal 658 that contacts stop 654 to prevent gases from flowing through valve 650 when in the closed or active position shown in Fig. 36. In the closed position, a spring 660 biases seal 658 against stop 654 until the negative intrathoracic pressure exceeds a threshold value and seal 658 moves away from stop 654 to permit respiratory gases to flow to the lungs. Once the negative intrathoracic pressure falls below the threshold value, valve 650 moves back to the closed position.

When the patient gasps, the force created is great enough to move valve member 656 such that a pair of spring loaded pins 662 lodge within grooves 664 of a locking pin receptacle 666 on valve member 656 as shown in Fig. 37. In this way, valve 650 is locked into an open or inactive position that is created by the patient's gasp. As pins 662 move into grooves 664, the ends of pins 662 move into housing 652 to indicate to the rescuer that the valve is inactive. Conveniently, the ends of pins 662 may be colored to make them

more visible to the rescuer. To reactivate valve 650, the rescuer may pull upward on a pull tab 668 on valve member 656. This releases pins 662 from grooves 664 and permit the valve to spring back to the closed position of Fig. 36.

Referring now to Figs. 38-40, a modified version valve 650 is shown incorporated into a valve system 670 that may be coupled to a patient's airway in a manner similar to the other valve system embodiments described herein to regulate the airflow to the patient's lungs during a CPR procedure. For convenience of discussion, identical elements of valve 650 will use the same reference numerals in describing Figs. 38-40. The use of valve 650 allows the patient to gasp and breathe free of airway resistance after the initial gasp has occurred. Alternatively, valve 650 may be initially set in the inactive position and placed in the active state upon the initial ventilation through valve system 670, or upon subsequent ventilations if the patient gasps and locks valve 650 open and inactive.

Valve 650 is incorporated into a system housing 672 having an inlet end 674 and an outlet end 676. Conveniently, patient ventilation may occur through inlet end 674 using a ventilatory source similar to other embodiments. Outlet end 676 may be coupled to an interface that permits system 670 to be interfaced with the patient's airway. Disposed within housing 672 is a one way membrane valve 678 that is spaced apart from port 680. In Fig. 38, system 670 is in the resting state where no gasp or ventilation has occurred. When performing CPR, the chest is compressed and air forced from the patient is permitted to flow through port 680 and through valve 678. During decompression of the patient's chest, valve membrane 678 moves against port 680 to close the valve as the negative intrathoracic pressure is increased. If a threshold pressure is overcome, valve 650 opens to permit respiratory gases to flow through opening 676 after passing through valve 650. Valve 650 then moves back to the closed position and the cycle is repeated.

If valve system 670 is coupled to a patient's airway and the patient gasps or begins spontaneously breathing, valve system 670 automatically adjusts to the configuration shown in Fig. 39 so that the patient may breathe through a resistance fee airway path so that respiratory gas exchange may occur. When the patient gasps or begins to breathe, valve 678 closes and the negative pressure causes valve 650 to open and lock in place in a manner similar to that previously described in connection with Fig. 37. In this way, valve 650 remains open and inactive until reset by the rescuer by pulling on pull tab 668.

Another way to place valve 650 back into the closed or active position is by ventilating the patient through inlet 674 as shown in Fig. 40. When injecting a respiratory gas into inlet 674, the injected gases flow through valve 678 and through port 680 where the exit through outlet 676 and to the patient. In so doing, the flow of gases moves a ventilation flap 682 that in turn moves an arm 684 that is coupled to a wedge 686. Movement of wedge 686 causes lateral movement of an arm 688 that is connected to a reset wedge 690. Wedge 690 rests on top of an upward movement ramp 692. As arm 688 is laterally moved, wedge 690 moves up ramp 692 and contacts pull tab 668. In so doing, valve member 656 is pulled up until pins 662 are pulled from grooves 664 and valve 650 moves back to the closed and active position by force of spring 660. A reset spring 694 then resets ventilation flap 682 back to its home position and wedge 690 slides back down ramp 692 so that valve 650 may be reset back to the closed position if subsequently needed. Valve 650 remains in the closed and active position until another gasp or spontaneous breathing occurs.

Fig. 41 schematically illustrates another embodiment of a valving system 700 that is configured to display the pressure within the patient's chest during CPR. Valving system 700 may be configured to be similar to any of the valving systems described herein. Hence, for convenience of discussion, valving system 700 will only be briefly described. Valving system 700 comprises a housing 702 having an inlet 704 and an outlet 706. A pressure responsive valve 708 is used to control the inflow of gases into housing 702 during decompression of the patient's chest in a manner similar to that described with other embodiments. A pressure gauge 710 is provided to measure and display the pressure within housing 702 which corresponds to the pressure within the patient's chest. In this way, pressure gauge 710 may be used to provide immediate feedback to the rescuer and may be used as a guide to determine if chest compressions and/or decompressions are being appropriately performed.

A pressure sensing port 712 is connected to a tube 714 that is connected to a pressure sensing control unit 716. In this manner, a change in pressure may be detected during either chest compressions or decompressions and act as a counting circuit to trigger ventilation control circuitry 718 to automatically ventilate the patient using a ventilator 720 after a certain number have been detected.

Alternatively, a digital control unit may be used that displays the pressure within the chest as well as the number of compressions between ventilations. With such a

configuration, pressure sensing port 712 transmits pneumatically the pressure information. As such, a pressure gauge on housing 702 would not be required.

The valving systems of the invention may also be used to treat shock. Shock may conveniently be defined as a critically low blood pressure that, when untreated, may lead to death or disability. Types of shock that may be treated using techniques of the invention include, but are not limited to, low blood pressure secondary to blood loss, heat stroke, vasovagal syncope (the common faint), drowning, drug overdose, heart attack, right heart failure, return to earth after space flight, sepsis, pericardial effusion, tamponade, and the like. Further, the valve systems of the invention may be used to alter the carotid cardiopulmonary reflex sensitivity that controls blood pressure (by decreasing intra thoracic pressures with inspiration).

The valve system that are employed to treat shock are configured to completely prevent or provide resistance to the inflow of respiratory gases into the patient while the patient is breathing. For valve systems that completely prevent the flow of respiratory gases, such valves may be configured as pressure responsive valves that open after a threshold negative intra thoracic pressure has been reached. Valve systems that simply provide resistance to the inflow of respiratory gases may also be variable so that once a desired negative intra thoracic pressure is reached, the resistance to flow may be lessened. Further, the valves of the invention may be configured to be variable, either manually or automatically. The extent to which the resistance to flow is varied may be based on physiological parameters measured by one or more sensors that are associated with the person being treated. As such, the resistance to flow may be varied so that the person's physiological parameters are brought within an acceptable range. Examples of physiological parameters that may be measured include, but are not limited to, negative intra thoracic pressure, respiratory rate, end tidal CO_2, positive end expiratory pressure, blood pressure, oxygen saturation, tissue CO_2 content, and the like. If an automated system is used, such sensors may be coupled to a controller which is employed to control one or more mechanisms that vary the resistance or actuating pressure of the inflow valve.

Referring now to Figs. 42 and 43, one embodiment of a system 800 that may be used to treat a person in shock will be described. System 800 comprises a housing 802 that is coupled to a facial mask 804. Housing 802 includes an inspiratory fenestrated port 806 where inspired gases are permitted to enter housing 802. Disposed below port 806 is a

slotted airway resistance mechanism 808 that may be used to completely prevent or provide resistance to the respiratory gases flowing into housing 802 through port 806. Resistance mechanism 808 is also illustrated in Figs. 46A and 46B and may be constructed of a slotted member 810 and a slotted plate 812. Slotted member 810 is movable relative to plate 812 to partially or fully cover the slots in plate 812 as illustrated in Fig. 46B. In this way, the resistance to the flow of inspired gases may be increased simply by moving slotted plate 812 relative to slotted member 810. As best shown in Fig. 42, a motor 814 that moves a shaft 816 may be employed to translate slotted member 810 over slotted plate 812 to vary the resistance to flow. Optionally, a filter 818 may be disposed below resistance mechanism 808.

System 800 further includes a one-way valve 820 that prevents expired gases from flowing back up through resistance mechanism 808. Disposed upstream of one-way valve 820 is an oxygen port 822 to permit oxygen to be supplied to the person during inspiration. System 800 further includes another one-way valve 824 that opens when the person expires to permit expired gases from exiting housing 802 through an expiratory port 826.

System 800 may also include one or more sensors 828 that measure various physiological parameters, such as flow rate, internal pressures within the patient, end tidal CO_2, and the like. These sensors may be coupled to a circuit board or controller 830 that may be programmed to vary operation of motor 814 based on the sensed parameters. In this way, the measured parameters may be kept within a desired range simply by controlling the resistance provided by resistance mechanism 808 in an automated manner. Although not shown, it will be appreciated that other sensors may also be coupled to circuit board 830 and may not necessarily be incorporated into housing 802 or mask 804. System 800 may also include a battery 832 to provide power to the various electrical components of system 800. A control button 834 may also be employed to actuate system 800.

Optionally, to ensure that the inspiratory lumen is never completely occluded by the airway resistance mechanisms, molded stops may be fabricated in a manner that the airway may always have a slight opening for inspiration to occur. As another option, the valve and sensing system may be attached to other airway devices, including an endo tracheal tube, a laryngeal mask, or the like.

Fig. 44 illustrates system 800 when mask 804 is coupled to a person and the person inhales. As shown, the inspired gases pass through resistance mechanism 808 which

has been operated to increase the resistance to flow. Optionally oxygen may also be supplied to the person through oxygen port 822. Fig. 45 illustrates when the person exhales. As shown, the expired gases pass through one-way port 824 and through expiratory port 826.

Although system 800 has been shown with one particular type of valve, it will be appreciated that a variety of inflow valves may be used including any of those previously described. Further, Figs. 47-53 illustrate other types of inflow valves that may be used to prevent or increase the resistance to flow during an inspiratory effort. Further, any of these inflow valves may be coupled to other mechanisms that may be used to operate the valve to vary the flow resistance. In this way, a controller may be used to automatically control the amount of resistance. Further, the controller may be coupled to one or more sensors so that various physiological parameters of the person may be kept within a desired range simply by measuring the parameters and using those parameters to vary the amount of resistance.

Figs. 47A and 47B illustrate an inflow valve 836 that comprises an airway 838 and a movable disk 840. Disk 840 may be moved by any type of mechanical mechanism to occlude airway 838 as shown to increase flow resistance.

Fig. 48A and Fig. 48B illustrate another embodiment of an inflow valve 842 that comprises an airway 844 and a rotatable disk 846. As shown in Fig. 48B, disk 846 may be rotated to increase the amount of flow resistance through airway 844.

Figs. 49A and 49B illustrate an inflow valve 848 that comprises an airway 850 that is positioned between a pair of plates 852 and 854. As shown in Fig. 49B, a rotatable cam 856 may be employed to move plate 854 to compress airway 850 and thereby increase flow resistance. Conveniently, cam 856 may be rotated by a motor 858 that in turn may be controlled by a controller in a manner similar to that previously described.

Figs. 50A and 50B illustrate a further embodiment of an inflow valve 860 that comprises an airway 862 that is positioned between two plates 864 and 866. In turn, plate 866 is coupled to a threaded shaft 868 that is movable back and forth by a stepper motor 870 that may also be coupled to a controller. In operation, stepper motor 870 is employed to move plate 866 against airway 862 as shown in Fig. 50B to increase the resistance to flow.

Figs. 51A and 51B illustrate an inflow valve 872 that comprises an airway 874 that is positioned between a pair of plates 876 and 878. These plates are coupled to a caliper mechanism 880 that in turn is coupled to a lead screw 882 that is movable by a stepper motor

884. In this way, stepper motor 884 may be used to operate caliper mechanism 880 to in turn squeeze airway 874 as shown in Fig. 51B to increase flow resistance.

Figs. 52A and 52B illustrate an inflow valve 886 that comprises an iris occluding mechanism 888. As shown in Fig. 52B, iris occluding mechanism 888 may be operated to decrease the size of the airway and thereby increase flow resistance.

Figs. 53A and 53B illustrate another embodiment of an inflow valve 890 that comprises an airway 892 and a rotatable arm 894 that in turn may be coupled to a stepper motor. As shown in Fig. 53B, arm 894 is rotatable over airway 892 to increase resistance to flow.

Figs. 54A through 54C illustrate one exemplary method for treating a person in shock. The process begins at step 900 where the treatment system may be coupled to the patient's airway. For example, the system previously described in connection with Fig. 42 may be coupled to the patient's face. The power is turned on as shown in step 902 and the airway resistance mechanism may be set to an open position as shown in step 904. The treatment mechanism may include various preset physiological parameters that may initially be read to determine the person's condition. At step 908, a determination is made as to whether a breath has been sensed based on the physiological parameters previously read in step 906. If no breath has been sensed, the process is reversed back to step 904 to ensure that the airway resistance mechanism is in the open position.

If a breath has been sensed, the process proceeds to step 910 where the airway resistance mechanism is set to a preset position. This position may be based on the initial physiological parameters that were sensed in step 906. Further, the airway resistance may be set manually or may be done automatically using a controller that is programmed with various preset positions based on measured physiological parameters. The process then proceeds to step 912 where the physiological parameters are evaluated to determine whether the negative inspiratory pressure is acceptable as the patient inhales. If the negative inspiratory pressure is too low, the process proceeds to step 914 where the airway resistance is increased. This may be done in an automated manner using the controller which operates the airway resistance mechanism to increase the airway resistance. After the resistance has been increased, the process proceeds to step 916 where sensors are employed to determine whether a breath is sensed. If not, the process reverts back to step 904 where the airway

resistance is moved back to its original position or to a fully open position and the process continues.

If the negative inspiratory pressure is too high, the process may proceed to step 918 where airway resistance is reduced. A breath measurement is then taken in step 920 to determine whether a breath is sensed. If not, the process proceeds back to step 904 where the airway resistance mechanism may be opened. If a breath is sensed in either step 920 or step 916, the process goes back to step 912 where another check on the negative inspiratory pressure is made. Once the negative inspiratory pressure is acceptable, the process proceeds to step 922 where the respiratory rate is evaluated. If the respiratory rate is unacceptable, the process proceeds to step 924 where the airway resistance is reduced. An evaluation as to whether a breath is sensed is made in step 926. If no breath is sensed, the process reverts back to step 904 where the airway resistance mechanism may be open. If a breath is sensed, the process proceeds back to step 922 where another evaluation of the respiratory rate is made. If the respiratory rate is acceptable, the process proceeds to step 928 and an evaluation as to the end tidal CO_2 is made. If too low, airway resistance is increased as shown in step 930 and another evaluation is made as to whether the patient is breathing in step 932. If not, the process proceeds back to step 904 where the airway resistance mechanism is opened. If the end tidal CO_2 is too high, the process proceeds to step 934 where the airway resistance is reduced and the patient's breathing is again sensed at step 936. If no breath is sensed, the process proceeds back to step 904 where the airway resistance mechanism is opened. If a breath is sensed in either steps 932 or 936, the process proceeds back to step 928 where the end tidal CO_2 is re-evaluated. Once acceptable, the process proceeds to step 938 where the oxygen saturation is evaluated. If too low, the airway resistance may be decreased as shown in step 940 and an evaluation is made as to whether the person is breathing as shown in step 942. If not, the process proceeds back to step 904 and the airway resistance mechanism is opened. If the oxygen saturation is acceptable, the process proceeds to step 912 so that the negative inspiratory pressure, respiratory rate, end tidal CO_2, and oxygen saturation may be continuously monitored and the airway resistance may be modified based on the parameters.

Hence, the method set forth in Figs. 54A through 54C permits various physiological parameters to be continuously monitored and to permit the resistance to inspiratory flow to be modified so that these parameters remain within an acceptable range when treating a patient suffering from shock. Further, as previously described, the

augmentation of negative inspiratory pressure permits increased blood flow back to the right heart to increase the patient's blood pressure. Although shown monitoring the various physiological parameters in a certain order, it will be appreciated that the parameters may be monitored in other orders as well. Further, other physiological parameters may be measured to ensure that the patient remains in a stable condition when treating the patient for shock. Optionally, the method of Figs. 54A through 54C may also be used to evaluate the patient's positive end expiratory pressure. Further, similar airway resistance mechanisms may be applied to the expiratory port and the airway resistance of the expiratory port may be varied based on the sensed parameters. For example, the expiratory pressure may be varied to aid in the prevention of alveoli collapse (atelectasis) which may occur when the negative intrathoracic pressure is too low for a prolonged period of time.

Although the foregoing invention has been described in some detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that certain changes and modifications may be practiced within the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A device for facilitating an increase in blood pressure in a breathing patient, said device comprising:

a housing having an opening that is adapted to be interfaced with a patient's airway;

an inflow flow valve that is operable to increase or decrease respiratory gas flow through the housing due to patient inhalation, the inflow valve assisting in manipulating intrathoracic pressures to increase blood flow back to the patient's chest;

a mechanism for operating the inflow valve to vary the respiratory gas flow through the housing; and

a sensor that is adapted and configured to sense at least one physiological parameter of the patient.

2. A device as in claim 1, wherein the inflow valve is operable to achieve a negative intrathoracic pressure within the range from about 0 cm H_20 to about -50 cm H_20 when the patient breathes at flow rates in the range from about zero flow to about 70 liters per minute.

3. A device as in claim 1, further comprising a controller that is coupled to the sensor and the mechanism, and wherein the controller is configured to send signals to the mechanism to operate the inflow valve based on the sensed physiological parameter from the sensor.

4. A device as in claim 1, wherein the sensor is selected from a group consisting of pressure sensors, flow sensors, CO_2 sensors, and oxygen sensors.

5. A device as in claim 1, wherein the inflow valve comprises a slotted opening and a slotted plate that is movable across the slotted opening.

6. A device as in claim 1, wherein the inflow valve comprises an airway and an occlusion member that is movable across the airway.

7. A device as in claim 1, wherein the inflow valve comprises an airway and a compression occluding system to compress the airway.

8. A device as in claim 1, wherein the inflow valve comprises an airway and an iris occluding system.

9. A device as in claim 1, wherein the mechanism comprises a stepper motor and a shaft extending from the stepper motor.

10. A device as in claim 1, wherein the housing includes an inspiratory port and an expiratory port, and further comprising a face mask that is coupled to the housing.

11. A device as in claim 1, further comprising means to add supplemental oxygen or periodic assisted ventilation to the patient.

12. A method for increasing the blood pressure in a spontaneously breathing person, the method comprising the steps of:

sensing at least one physiological parameter of the person;

interfacing an inflow valve to the person's airway that is operable to increase or decrease respiratory gas flow to the person's lungs;

operating the inflow valve based on the sensed parameter to increase or decrease respiratory gas flow to the person's lungs while the person is inhaling to create a vacuum within the thorax and increase blood flow back to the right heart of the person, thereby enhancing the person's blood pressure.

13. A method as in claim 12, wherein the person has low blood pressure due to conditions selected from a group consisting of blood loss, the administration of a drug, a high gravitational state, vasovagal syncope, cardiac tamponade, drowning, heat stroke, heart attack, right heart failure, return to earth after space flight, and sepsis.

14. A method as in claim 12, further comprising sending a signal to a controller that is representative of the sensed parameter, and sending a signal from the controller to a mechanism to operate the valve based on the sensed parameter.

15. A method as in claim 12, wherein the parameter sensed is selected from a group consisting of negative intrathoracic pressure, blood pressure, respiratory rate, end tidal CO_2, positive end expiratory pressure, and oxygen saturation.

16. A method as in claim 12, wherein the inflow valve is operated to achieve a negative intrathoracic pressure within the range from about 0 cm H_20 to about -50 cm H_20 when the person breathes at flow rates in the range from about zero flow to about 70 liters per minute.

17. A method as in claim 12, wherein the inflow valve comprises an airway and an occlusion member, wherein the occlusion member is moved across the airway to vary the flow rate through the inflow valve.

18. A method as in claim 12, wherein the physiological parameter is repeatedly sensed, and wherein the valve is repeatedly operated based the sensed parameters.

19. A method as in claim 12, further comprising supplying supplemental ventilation or oxygen to the person.

20. A method as in claim 12, further comprising supplying a drug or a medicament to the person upstream or downstream of the inflow valve.

21. A method for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation, by augmenting negative intrathoracic pressures, said method comprising the steps of:

interfacing a pressure responsive inflow valve to a patient's airway;

performing chest compression and chest decompression, wherein during chest decompression the inflow valve prevents respiratory gases from entering the lungs until a negative intrathoracic pressure level in the range from about -3 cm H_2O to -30 cm H_2O is exceeded at which time the inflow valve opens, said inflow valve assisting in increasing the magnitude and duration of negative intrathoracic pressure during decompression and thereby enhancing the amount of blood flow into the heart and lungs; and

supplying the patient with a pressurized respiratory gas through the inflow valve when the inflow valve opens to ventilate the patient.

22. The method of claim 21, further comprising interfacing an exhalation valve to the patient's airway, wherein the exhalation valve prevents air from leaving the lungs until a positive intrathoracic pressure threshold is exceeded at which time said exhalation valve opens, said exhalation valve assisting in forcing more blood out of the thorax.

23. The method of claim 22, wherein the positive intrathoracic pressure is in the range from about 2 cm H_2O to 20 cm H_2O.

24. The method of claim 21, further comprising providing a pressurized respiratory gas source that is operably coupled to the inflow valve, with the respiratory gas being at a pressure that is less than the opening pressure of the inflow valve, and wherein the respiratory gas is supplied from the respiratory gas source.

25. The method of claim 21, wherein the decompressing step comprises allowing the patient's chest to expand in response to the chest's resilience.

26. The method of claim 21, wherein the decompressing step comprises lifting or actively expanding the patient's chest to expand the thorax.

27. The method of claim 21, wherein the chest is compressed in the range from about 3.5 cm to 5 cm per compression, and wherein the chest is compressed in the rate from 60 to 100 per minute.

28. A method for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation, by augmenting negative intrathoracic pressures, said method comprising the steps of:

interfacing a valving system with a patient's airway, the valving system comprising a housing having an upstream region and a downstream region, a pressure-responsive valve between the upstream region and the downstream region for preventing respiratory gases from flowing from the upstream region to the downstream region until the pressure in the downstream region falls below a threshold level;

performing chest compression and decompression, wherein said pressure-responsive valve is closed to prevent respiratory gases from entering the lungs until a certain negative intrathoracic pressure is exceeded at which time the pressure-responsive valve

opens, said pressure-responsive valve assisting in increasing the magnitude and duration of negative intrathoracic pressure during decompression and thereby enhancing the amount of blood flow into the heart and lungs; and

supplying the patient with a pressurized respiratory gas through the pressure-responsive valve when the pressure-responsive valve opens to ventilate the patient.

29. The method of claim 28, further comprising, during chest compression, preventing air from leaving the lungs until a positive intrathoracic pressure threshold is exceeded to assist in forcing more blood out of the thorax.

30. The method of claim 29, wherein the positive intrathoracic pressure is in the range from about 2 cm H_2O to 20 cm H_2O.

31. The method of claim 28, further comprising providing a pressurized respiratory gas source that is operably coupled to the pressure-responsive valve, with the respiratory gas being at a pressure that is less than the opening pressure of the pressure-responsive valve and wherein the respiratory gas is supplied from the respiratory gas source.

32. The method of claim 28, wherein the decompressing step comprises allowing the patient's chest to expand in response to the chest's resilience.

33. The method of claim 28, wherein the decompressing step comprises lifting or actively expanding the patient's chest to expand the thorax.

34. The method of claim 28, wherein the chest is compressed in the range from about 3.5 cm to 5 cm per compression, and wherein the chest is compressed in the rate from 60 to 100 per minute.

35. A device for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation, said device comprising:

a housing having an opening that is adapted to be interfaced with a patient's airway;

a pressure responsive inflow flow valve which prevents respiratory gases from entering the lungs through the housing until a threshold negative intrathoracic pressure level

is exceeded during decompression of the patient's chest at which time the inflow valve opens, the inflow valve assisting in increasing the magnitude and duration of negative intrathoracic pressure during decompression and thereby enhancing the amount of blood flow into the heart and lungs; and

a source of pressurized gas operably coupled to the inflow valve to supply a pressurized gas to the patient through the housing when the inflow valve is open.

36. A device as in claim 35, further comprising a one way valve disposed in the housing to permit respiratory gases to exit the housing during compression of the patient's chest.

37. A device as in claim 35, further comprising a regulator disposed between the gas source and the inflow valve to regulate the pressure of the gas such that the gas pressure is less than the actuating pressure of the inflow valve.

38. A device as in claim 35, wherein the inflow valve is configured to open when the negative intrathoracic pressure is in the range from -3 cm H_2O to -30 cm H_2O.

39. A method for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation, by augmenting negative intrathoracic pressures, said method comprising the steps of:

interfacing a housing having a pressure responsive inflow valve to a patient's airway;

performing chest compression and chest decompression, wherein during chest decompression, the inflow valve prevents respiratory gases from entering the lungs until a threshold negative intrathoracic pressure level is exceeded at which time the one inflow valve opens, the inflow valve assisting in increasing the magnitude and duration of negative intrathoracic pressure during decompression and thereby enhancing the amount of blood flow into the heart and lungs; and

supplying a pressurized gas to the patient through the inflow valve when the inflow valve opens to ventilate the patient through the inflow valve.

40. A method as in claim 39, wherein the inflow valve opens when the negative intrathoracic pressure in the range from -3 cm H_2O to -30 cm H_2O, and wherein the pressurized gas is less than the opening pressure of the inflow valve.

41. A device for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation, said device comprising:

a housing having an opening that is adapted to be interfaced with a patient's airway;

a pressure responsive inflow flow valve which prevents respiratory gases from entering the lungs through the housing until a threshold negative intrathoracic pressure level is exceeded during decompression of the patient's chest at which time an actuating pressure of the inflow valve is exceeded and the inflow valve opens, the inflow valve assisting in increasing the magnitude and duration of negative intrathoracic pressure during decompression and thereby enhancing the amount of blood flow into the heart and lungs; and

a mechanism for varying the actuating pressure of the inflow valve.

42. A device as in claim 41, wherein the mechanism is configured to vary the actuating pressure to a pressure within the range from about 0 cm H_2O to about -30 cm H_2O.

43. A device as in claim 41, wherein the inflow valve comprises a threaded shaft having a seal that is configured to block an opening in the housing, and a spring that biases the seal against the housing, and wherein the mechanism comprises a threaded knob that is rotatable to vary the biasing force of the spring by increasing or decreasing the longitudinal distance of the shaft.

44. A device as in claim 43, further comprising a pressure gauge in the housing to sense the amount of pressure within the chest.

45. A device for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation, said device comprising:

a housing having an exit opening that is adapted to be interfaced with a patient's airway and a safety ventilation passageway;

a pressure responsive inflow flow valve which prevents respiratory gases from entering the lungs through the housing until a threshold negative intrathoracic pressure level is exceeded during decompression of the patient's chest at which time the inflow valve opens, the inflow valve assisting in increasing the magnitude and duration of negative intrathoracic pressure during decompression and thereby enhancing the amount of blood flow into the heart and lungs; and

a safety mechanism to maintain the safety ventilation passageway open to permit respiratory gases to freely flow to the patient's lungs until actuated by a rescuer to close the safety ventilation passageway.

46. A device as in claim 45, wherein the safety ventilation passageway is provided through the inflow valve when the inflow valve is in an open position, and wherein the safety mechanism is configured to maintain the inflow valve in the open position until actuated by the rescuer to move the inflow valve to a closed position.

47. A device as in claim 46, wherein the housing includes a ventilation port to permit respiratory gases to be injected into the housing, and wherein the safety mechanism comprises a sensor to sense when the rescuer injects respiratory gases into the housing and a control system to move the inflow valve from the open position to the closed position.

48. A device as in claim 47, wherein the sensor is movable upon injection of respiratory gases into the housing, and wherein control system comprises a set of gears that are coupled to the sensor and a cam that is movable by the gears to close the inflow valve.

49. A device as in claim 47, wherein the sensor comprises a movable flap that moves upon injection of respiratory gases into the housing, and wherein control system comprises a set of mechanical components that move a wedge against the safety mechanism upon movement of the flap to close the inflow valve.

50. A device as in claim 47, wherein the sensor is selected from a group of sensors consisting of electronic switches, thermistors, mechanical flaps, and materials that experience of change of resistance when flexed.

51. A device as in claim 46, wherein the inflow valve comprises a shaft having a seal that is configured to block an opening in the housing, and a spring that biases the seal against the housing.

52. A device for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation, said device comprising:

a housing having an opening that is adapted to be interfaced with a patient's airway;

a pressure responsive inflow flow valve having a closed position and an open position, wherein the inflow valve prevents respiratory gases from entering the lungs through the housing when in the closed position, and wherein the inflow valve moves to the open position when a threshold negative intrathoracic pressure level is exceeded during decompression of the patient's chest, the inflow valve assisting in increasing the magnitude and duration of negative intrathoracic pressure during decompression when in the closed position and thereby enhancing the amount of blood flow into the heart and lungs; and

a safety mechanism to maintain the inflow valve in the open position to permit respiratory gases to freely flow to the lungs until actuated by a rescuer to place the inflow valve in the closed position.

53. A device as in claim 52, wherein the housing includes a ventilation port to permit respiratory gases to be injected into the housing, and wherein the safety mechanism comprises a sensor to sense when the rescuer injections respiratory gases into the housing and a control system to move the inflow valve from the open position to the closed position.

54. A device as in claim 53, wherein the sensor is movable upon injection of respiratory gases into the housing, and wherein control system comprises a set of gears that are coupled to the sensor and a cam that is movable by the gears to close the inflow valve.

55. A device as in claim 53, wherein the sensor comprises a movable flap that moves upon injection of respiratory gases into the housing, and wherein control system comprises a set of mechanical components that move a wedge against the safety mechanism upon movement of the flap to close the inflow valve.

56. A device as in claim 53, wherein the sensor is selected from a group of sensors consisting of electronic switches, thermistors, mechanical flaps, and materials that experience of change of resistance when flexed.

57. A device as in claim 52, wherein the inflow valve comprises a shaft having a seal that is configured to block an opening in the housing, and a spring that biases the seal against the housing.

58. A method for increasing cardiopulmonary circulation induced by chest compression and decompression when performing cardiopulmonary resuscitation, by augmenting negative intrathoracic pressures, said method comprising the steps of:

interfacing a valve system comprising a housing, a pressure responsive inflow valve, a safety gas flow passage and a safety mechanism to a patient's airway, wherein during chest decompression the inflow valve is configured to prevent respiratory gases from entering the lungs until a negative intrathoracic pressure level in the range from about 0 cm H_2O to -30 cm H_2O is exceeded at which time the inflow valve is configured to open, said inflow valve assisting in increasing the magnitude and duration of negative intrathoracic pressure during decompression and thereby enhancing the amount of blood flow into the heart and lungs, and wherein the safety mechanism is configured to permit respiratory gases to freely flow to the patient's lungs until actuated; and

actuating the safety mechanism to close the gas passage.

59. A method as in claim 58, further comprising performing chest compressions and decompressions after actuating the safety mechanism.

60. A method as in claim 58, wherein the actuating step comprises injecting a respiratory gas into the housing, wherein the injection is sensed by a sensor to cause the safety mechanism to close the gas passage.

61. A method as in claim 58, wherein the gas passage passes through the inflow valve, and wherein the actuating step comprises closing the inflow valve to close the gas passage.

62. A method for increasing the blood pressure in a spontaneously breathing person, said method comprising the steps of:

interfacing a pressure responsive inflow valve to the person's airway;

inhaling and exhaling while the inflow valve is coupled to the person's airway, wherein during inhalation the inflow valve prevents respiratory gases from entering the lungs until a negative intrathoracic pressure level in the range from about 0 cm H_2O to -30 cm H_2O is exceeded at which time the inflow valve opens, said inflow valve assisting in increasing blood flow back to the right heart of the person and thereby enhancing the person's blood pressure.

63. A method as in claim 62, wherein the person has low blood pressure due to blood loss.

64. A method as in claim 62, wherein the person has low blood pressure due to the administration of a drug.

65. A method as in claim 62, wherein the person has low blood pressure due to a high gravitational state.

66. A method as in claim 62, wherein the person has low blood pressure secondary to vasovagal syncope.

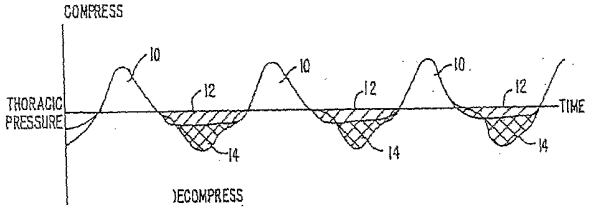


FIG. 1.

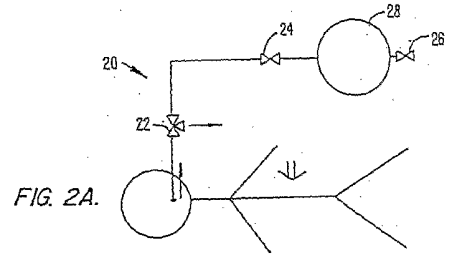


FIG. 2A.

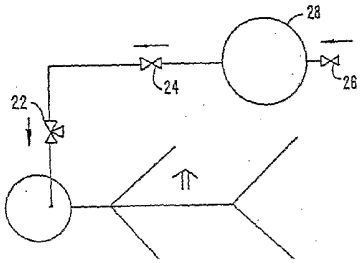


FIG. 2B.

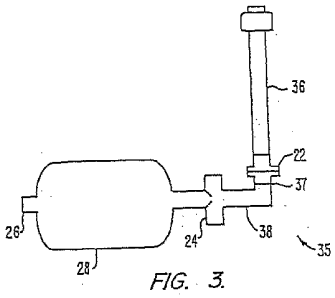


FIG. 3.

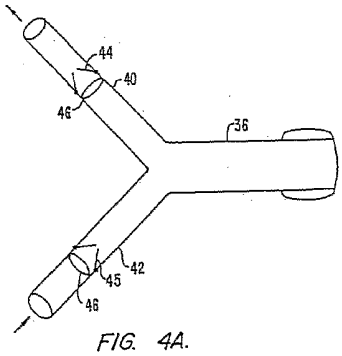


FIG. 4A.

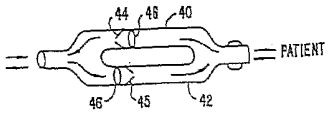


FIG. 4B.

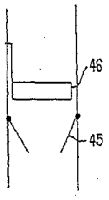


FIG. 5A.

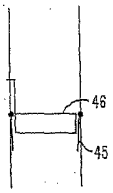


FIG. 5B.

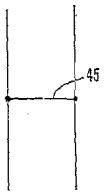


FIG. 5C.

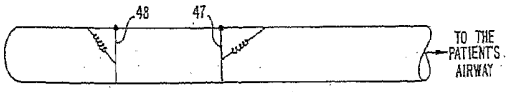


FIG. 6A.

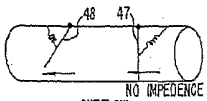


FIG. 6B.

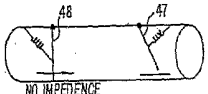


FIG. 6C.

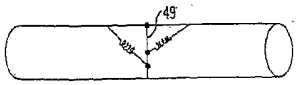


FIG. 7.

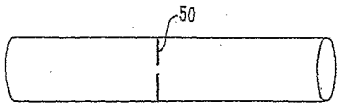


FIG. 8.

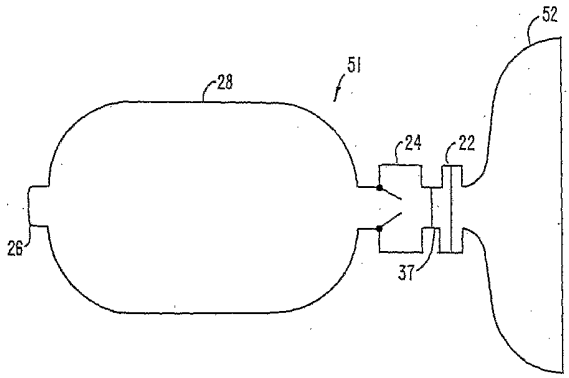


FIG. 9.

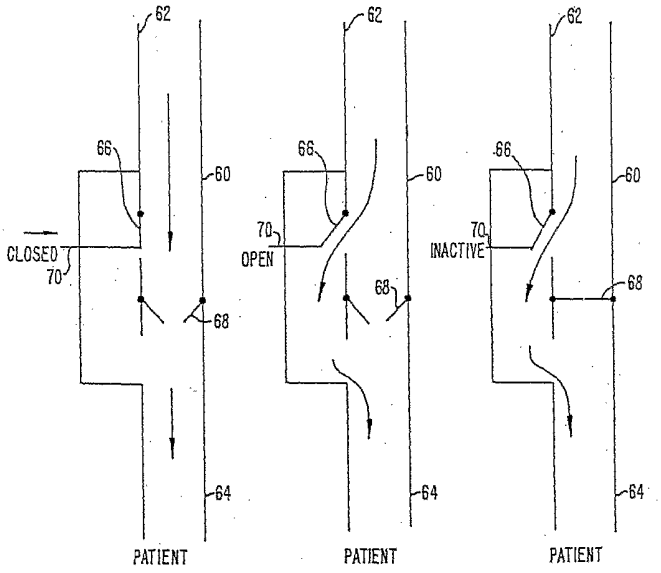


FIG. 10A. FIG. 10B. FIG. 10C.

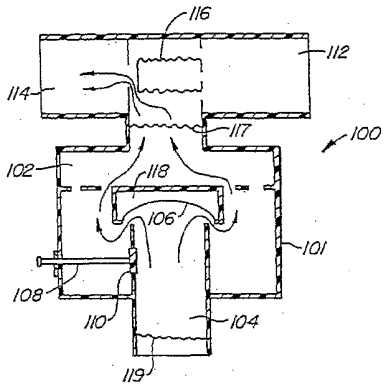

116
112
114
117
100
102
118
106
101
108
110
104
119

FIG. 11.

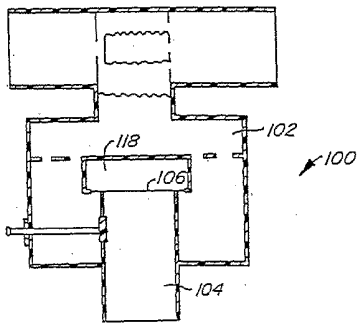

102
118
100
106
104

FIG. 12.

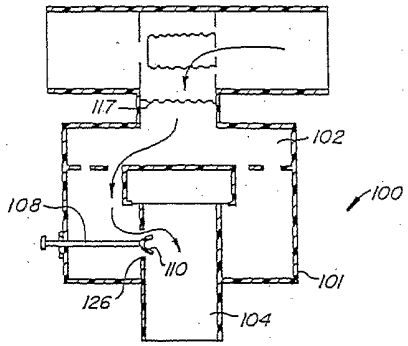
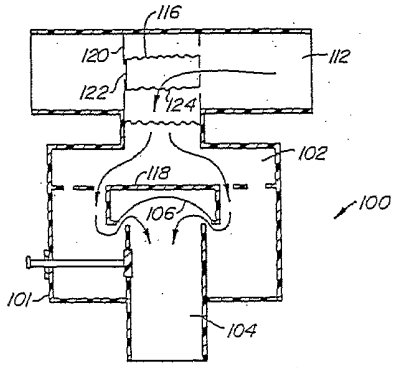

117
102
100
108
110
101
126
104

FIG. 13.


116
120
112
122
124
102
118
100
106
101
104

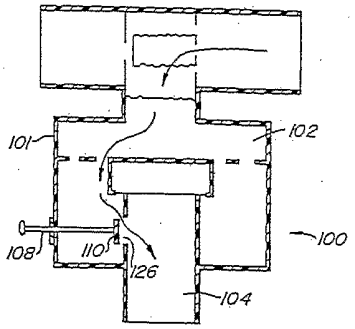


FIG. 15.

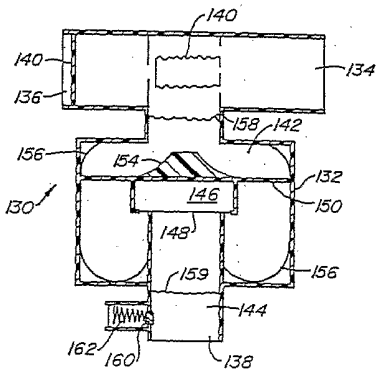


FIG. 16A.

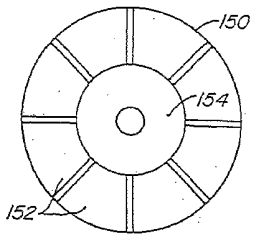


FIG. 16B.

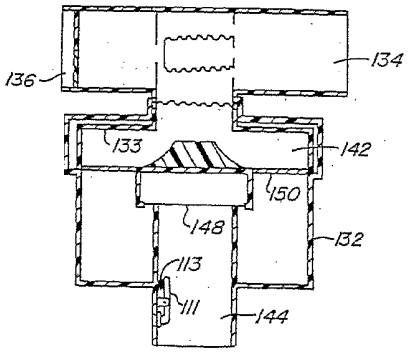


FIG. 16C.

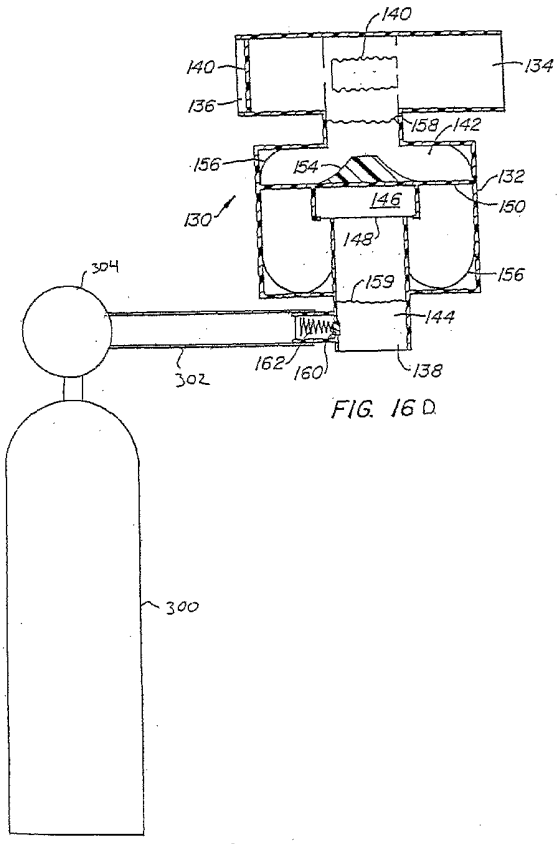

140
140
134
136
158
142
156
154
132
146
150
130
148
156
159
144
304
162
160
138
302
300

FIG. 16D

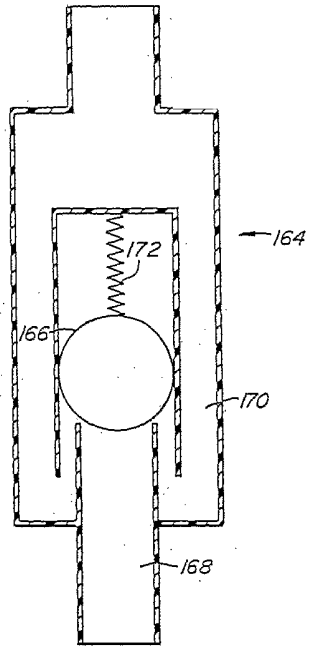


FIG. 17.

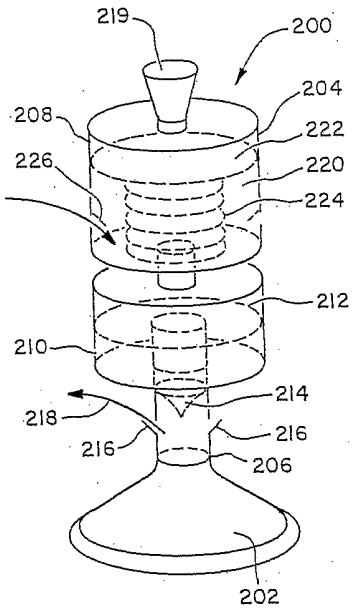


Fig. 18

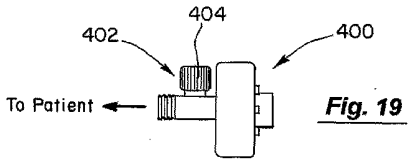


Fig. 19

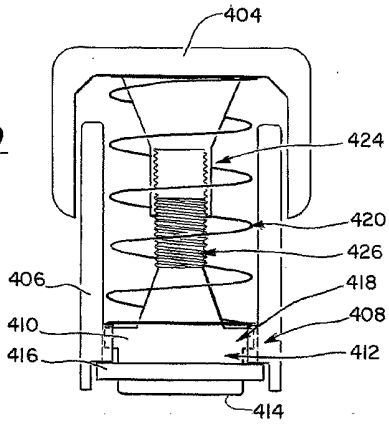


Fig. 20

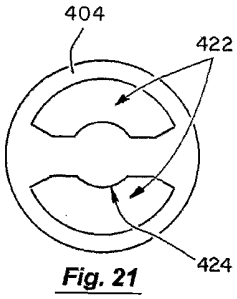


Fig. 21

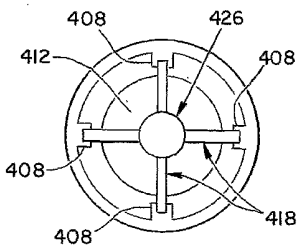


Fig. 22

Fig. 24

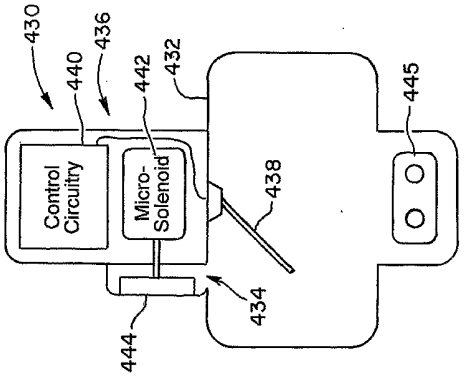

430
440
436
442
432
445
Control Circuitry
Micro-Solenoid
438
434
444

Fig. 23

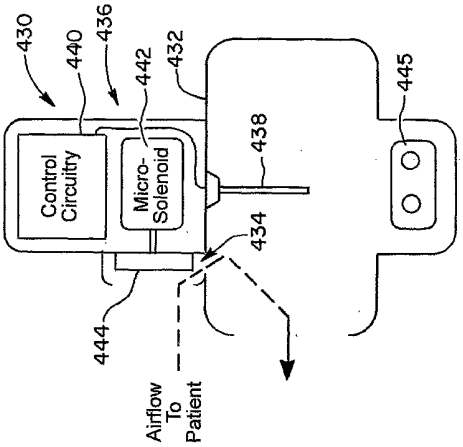

430
440
436
442
432
445
Control Circuitry
Micro-Solenoid
438
434
444
Airflow To Patient

Fig. 25

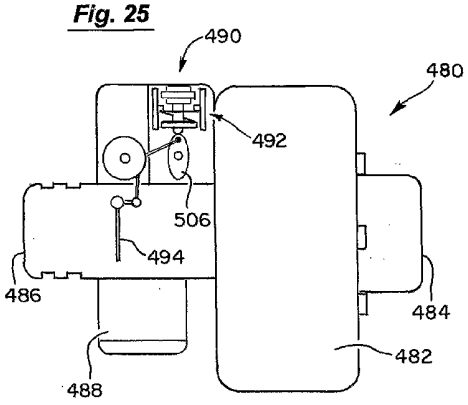
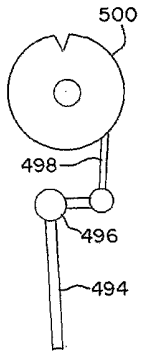


Fig. 26



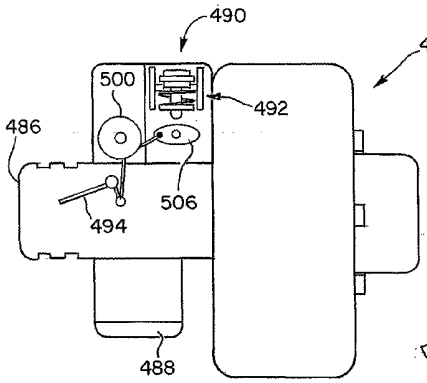


Fig. 28

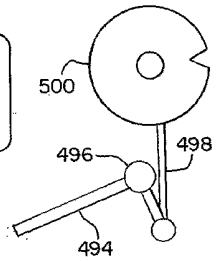


Fig. 27

Fig. 29

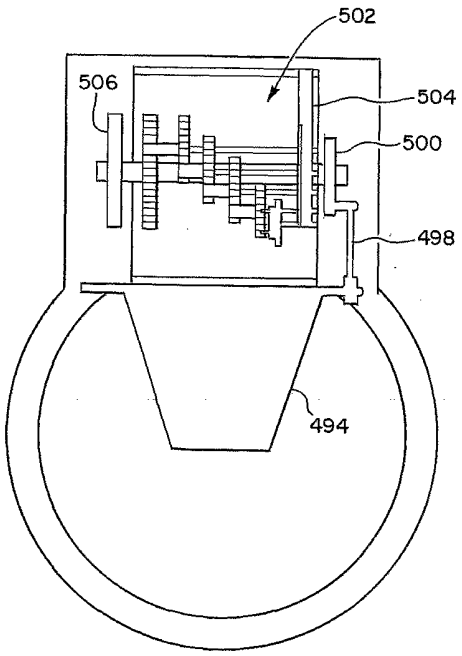
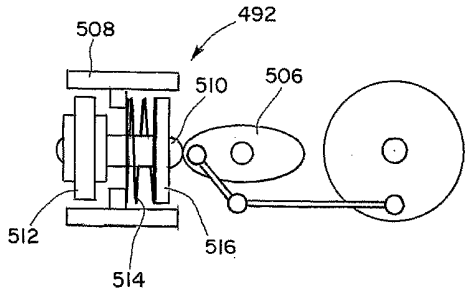


Fig. 30



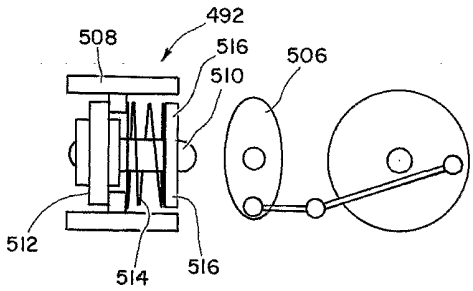


Fig. 31

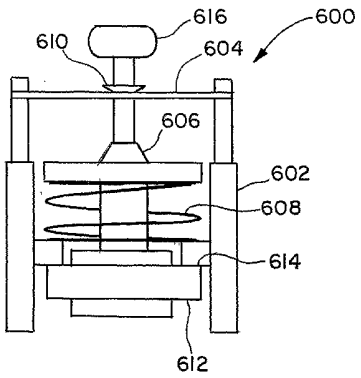

616
600
610
604
606
602
608
614
612

Fig. 32

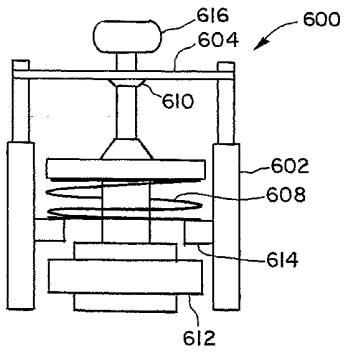

616
600
604
610
602
608
614
612

Fig. 33

Fig. 34

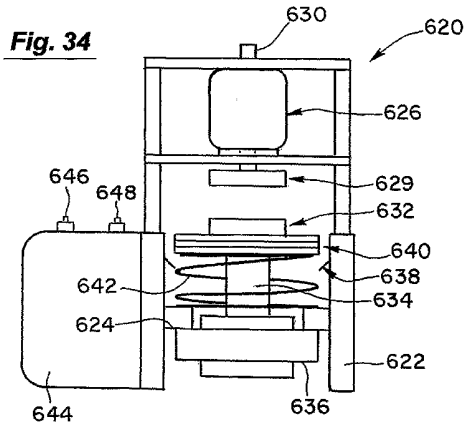
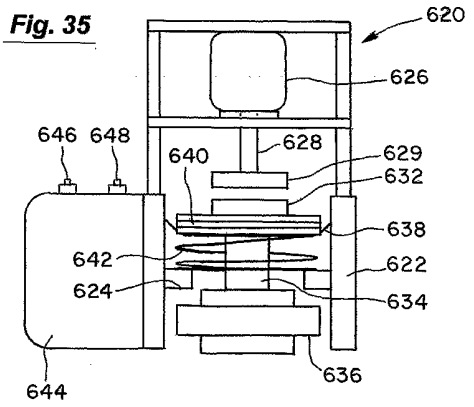

630
620
626
646
648
629
632
640
642
638
634
624
622
644
636

Fig. 35


620
626
646
648
628
640
629
632
638
642
622
624
634
644
636

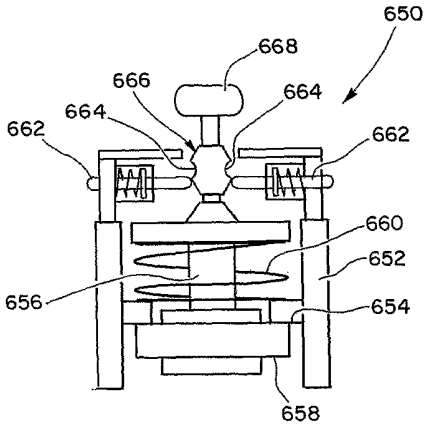

650
668
666
664
664
662
662
660
652
656
654
658

Fig. 36

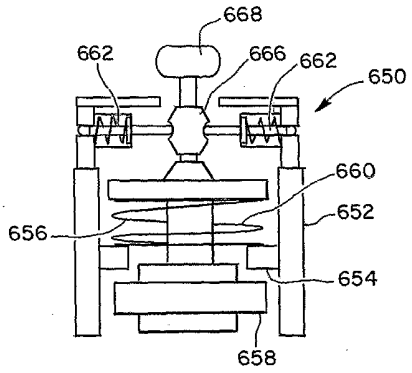

668
662
666
662
650
660
652
656
654
658

Fig. 37

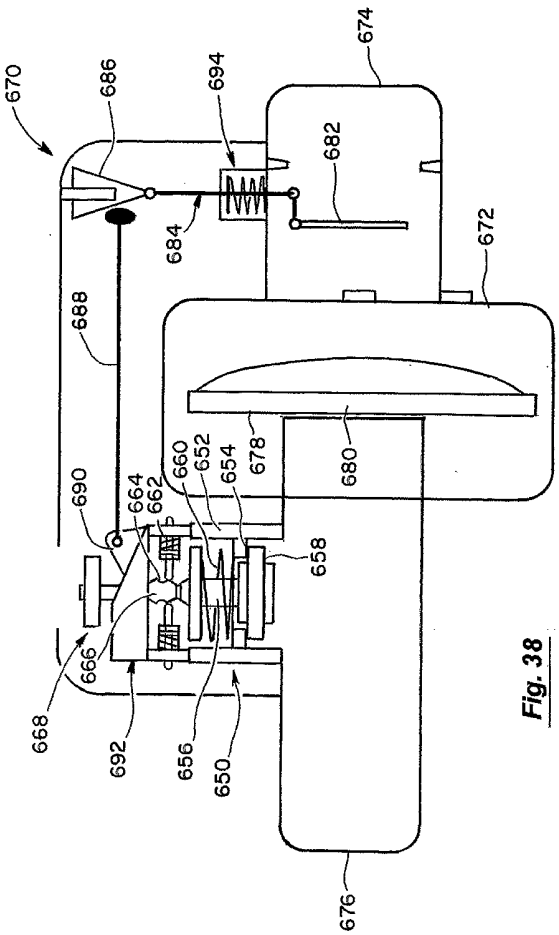

670
686
694
674
682
684
672
688
678
680
660
652
654
690
664
662
658
666
668
692
656
650
676

Fig. 38

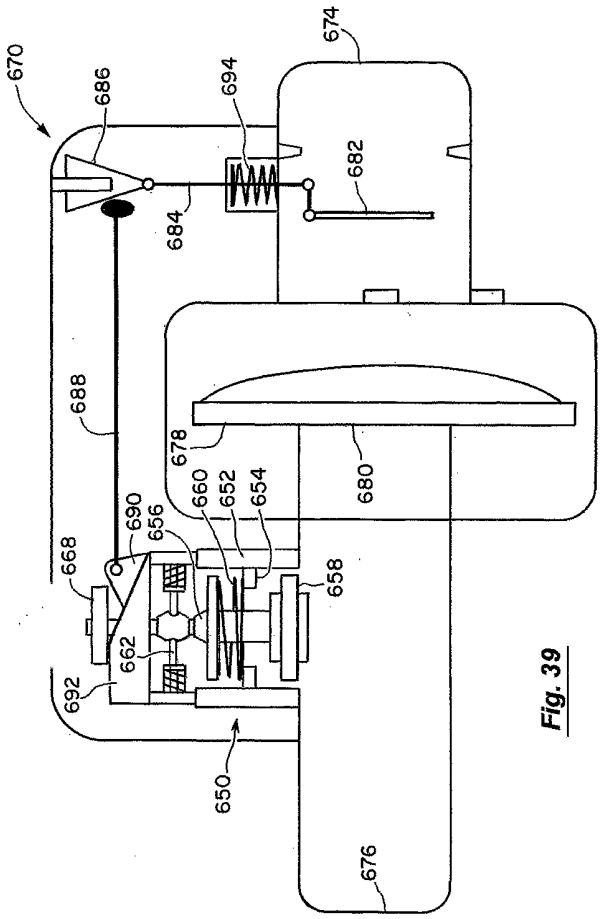

670
686
694
674
682
684
688
678
680
660
652
654
690
656
668
658
662
692
650
676

Fig. 39

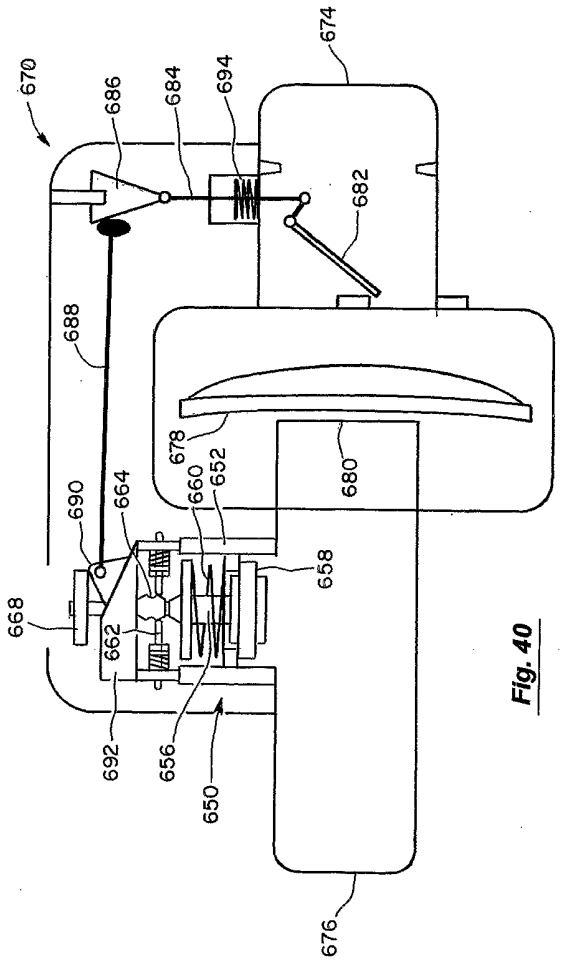

670
686
684
694
674
682
688
678
680
652
660
664
690
658
668
662
692
656
650
676

Fig. 40

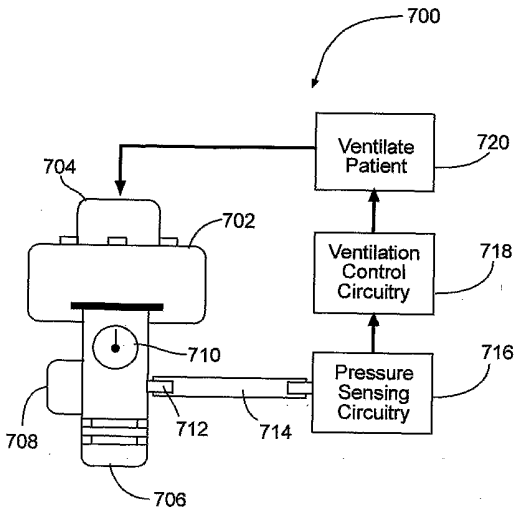

700
Ventilate Patient
720
704
702
Ventilation Control Circuitry
718
710
716
Pressure Sensing Circuitry
708
712
714
706

Fig. 41

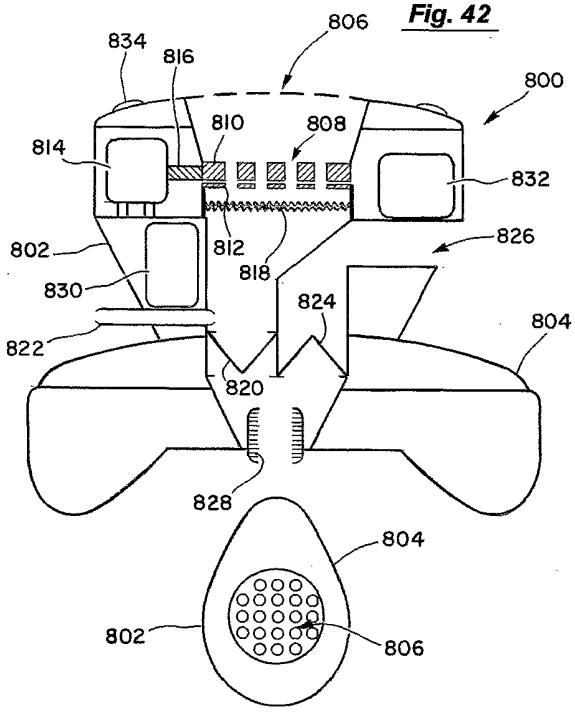

806
834
816
800
810
808
814
832
812
826
802
818
830
824
804
822
820
828
804
802
806

Fig. 42

Fig. 43

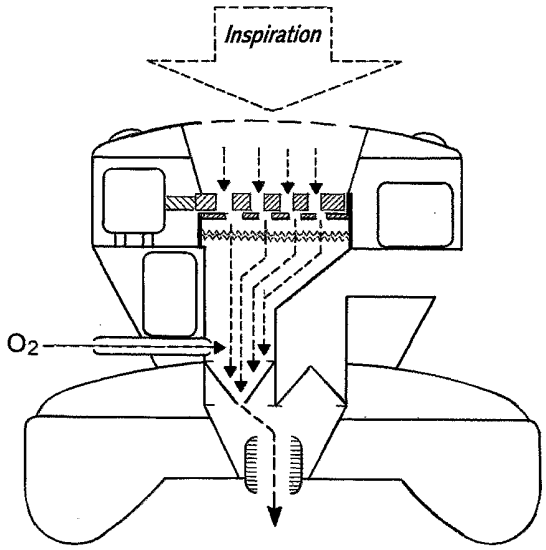


Fig. 44

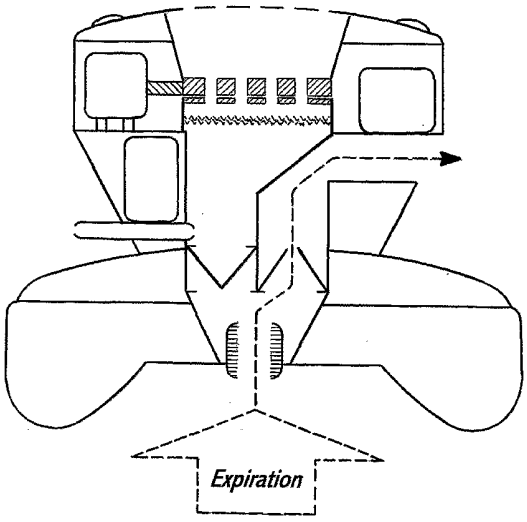


Fig. 45

Fig. 46A

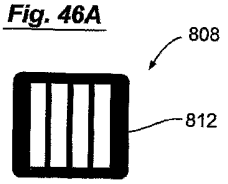


Fig. 46B

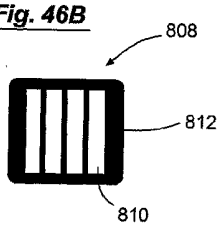


Fig. 47A

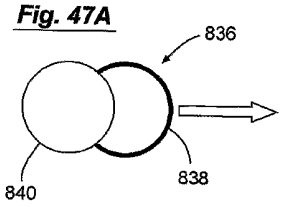


Fig. 47B

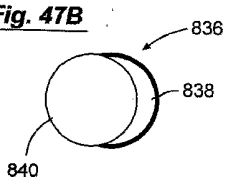


Fig. 48A

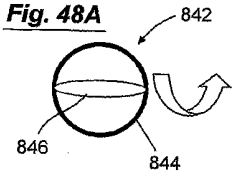


Fig. 48B

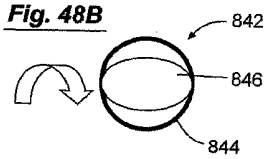


Fig. 49A

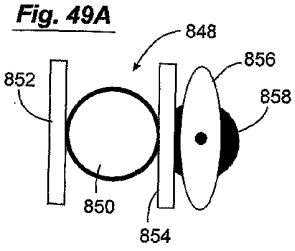


Fig. 49B

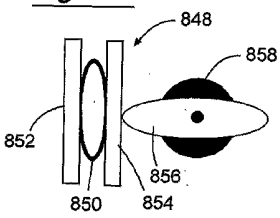
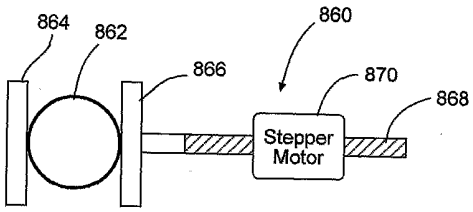


Fig. 50A



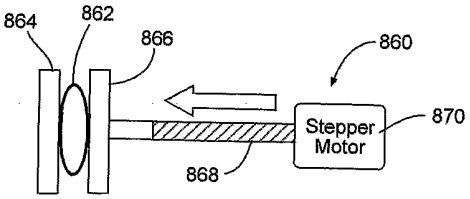


Fig. 50B

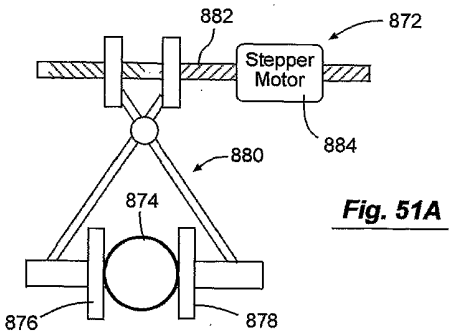


Fig. 51A

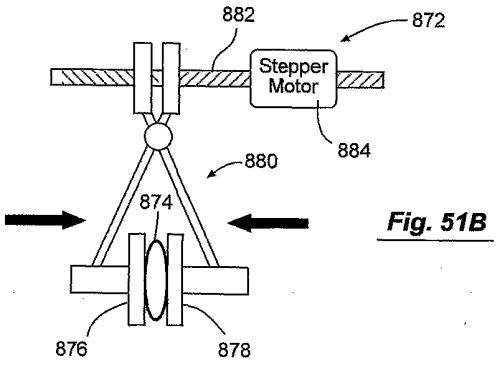


Fig. 51B

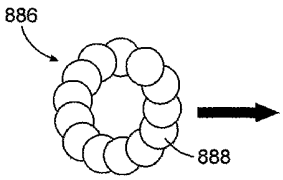


Fig. 52A

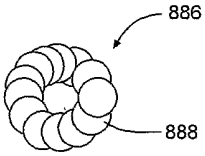


Fig. 52B

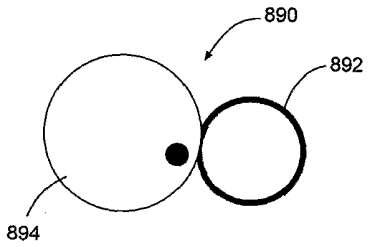


Fig. 53A

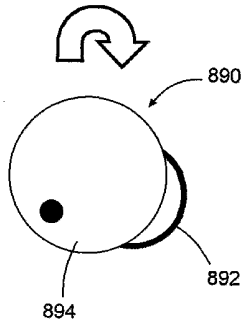


Fig. 53B

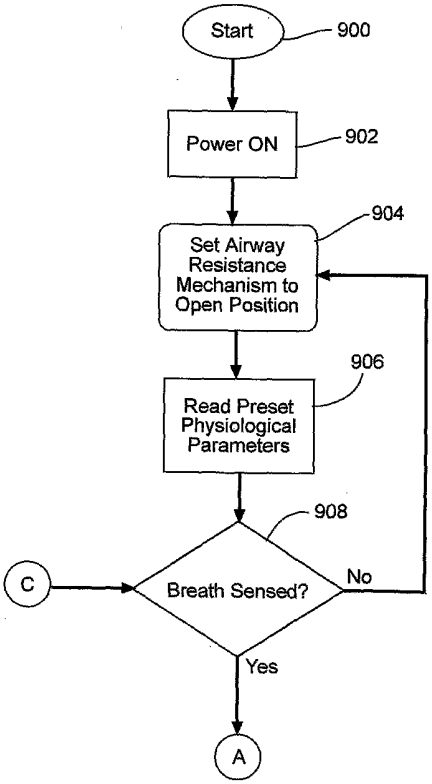

Start
900
Power ON
902
Set Airway Resistance Mechanism to Open Position
904
Read Preset Physiological Parameters
906
Breath Sensed?
908
No
Yes
C
A

Fig. 54A

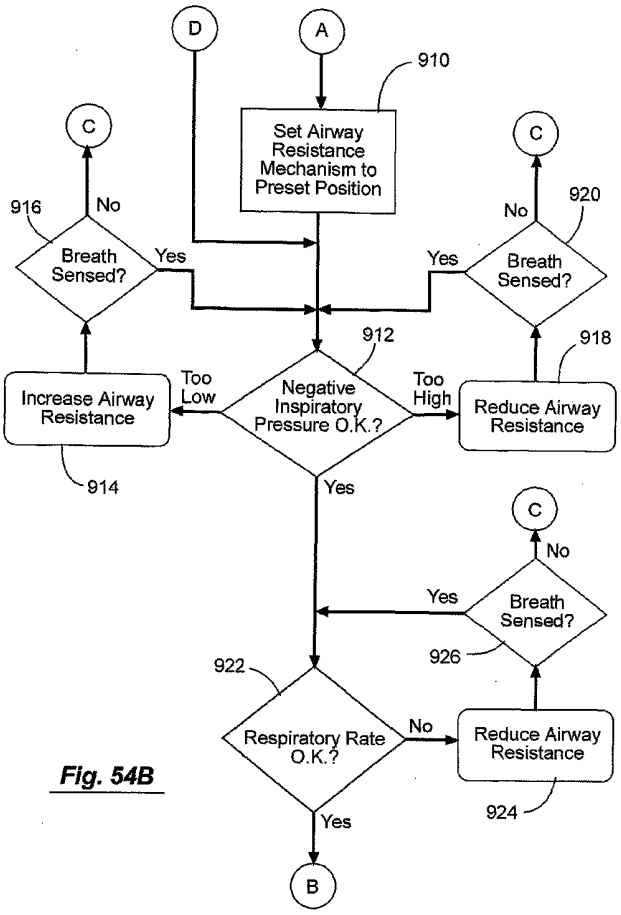

D
A
910
Set Airway Resistance Mechanism to Preset Position
C
916
No
Breath Sensed?
Yes
C
No
920
Yes
Breath Sensed?
912
Too Low
Negative Inspiratory Pressure O.K.?
Too High
Increase Airway Resistance
914
Reduce Airway Resistance
918
Yes
C
No
Yes
Breath Sensed?
926
922
Respiratory Rate O.K.?
No
Reduce Airway Resistance
924
Yes
B

Fig. 54B

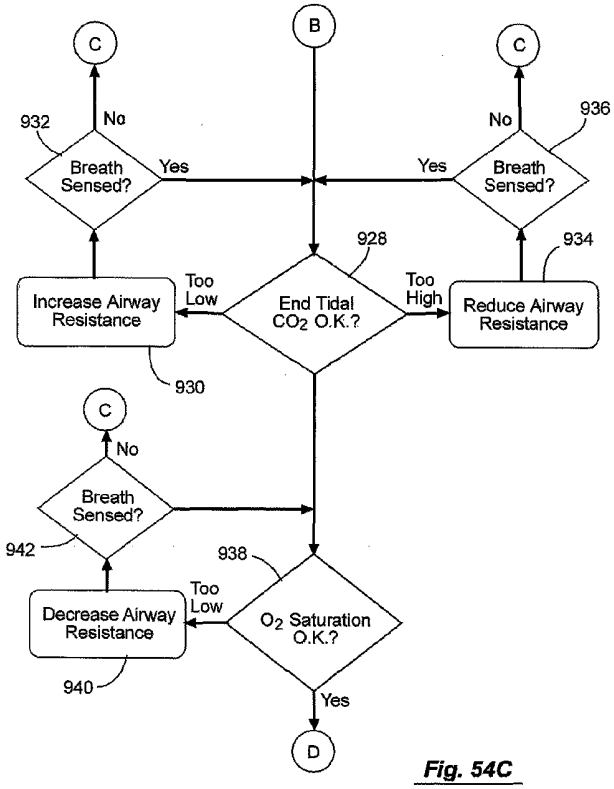

B
C
C
No
No
932
936
Breath Sensed?
Yes
Yes
Breath Sensed?
928
934
Too Low
Too High
Increase Airway Resistance
End Tidal CO_2 O.K.?
Reduce Airway Resistance
930
C
No
Breath Sensed?
942
938
Too Low
Decrease Airway Resistance
O_2 Saturation O.K.?
940
Yes
D

Fig. 54C

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/14039

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A62B 9/02, 7/04; A61M 16/00; F16K 31/26
US CL : 128/205.24, 205.13, 205. 17, 204.26
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 128/205.24, 205.13, 205. 17, 204.26

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,320,754 A (WATSON et al) 23 March 1982 (23.03.1982), see entire document.	1-8,10,11,35-38,41,42,45-47,52,53 and 55
Y	US 5,217,006 A (MCCULLOCH) 08 June 1993 (08.06.1993), see entire document.	1,5-8,10,11,35,36,41,45 and 52
A	US 4,166,458 A (HARRIGAN) 04 September 1979 (04.09.1979), see entire document	1-66
A	US 5,109,840 A (DALEIDEN) 05 May 1992 (05.05.1992), see entire document.	1-66

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search 26 July 2002 (26.07.2002)	Date of mailing of the international search report 22 AUG 2002
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Aaron Lewis Telephone No. 703-308-0858

Form PCT/ISA/210 (second sheet) (July 1998)

フロントページの続き

(51)Int.Cl.[7]	FI		テーマコード（参考）
Ａ６１Ｍ 16/20	Ａ６２Ｂ 9/00	Ｚ	
Ａ６２Ｂ 7/04	Ａ６２Ｂ 9/02		
Ａ６２Ｂ 9/00	Ａ６２Ｂ 18/02		
Ａ６２Ｂ 9/02	Ａ６１Ｂ 5/02	３３０	
Ａ６２Ｂ 18/02	Ａ６１Ｂ 5/14	３１０	

(81)指定国 AP(GH,GM,KE,LS,MW,MZ,SD,SL,SZ,TZ,UG,ZM,ZW),EA(AM,AZ,BY,KG,KZ,MD,RU,TJ,TM),EP(AT,BE,CH,CY,DE,DK,ES,FI,FR,GB,GR,IE,IT,LU,MC,NL,PT,SE,TR),OA(BF,BJ,CF,CG,CI,CM,GA,GN,GQ,GW,ML,MR,NE,SN,TD,TG),AE,AG,AL,AM,AT,AU,AZ,BA,BB,BG,BR,BY,BZ,CA,CH,CN,CO,CR,CU,CZ,DE,DK,DM,DZ,EC,EE,ES,FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KP,KR,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN,MW,MX,MZ,NO,NZ,OM,PH,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TN,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZM,ZW

(72)発明者 ルーリー, キース ジー.
アメリカ合衆国 ミネソタ ５５４０９, ミネアポリス, ギラード アベニュー サウス ４７５１
(72)発明者 ジーリンスキー, トッド エム.
アメリカ合衆国 ミネソタ ５５４０６, ミネアポリス, ４３アールディ アベニュー サウス ３５４９

Ｆターム(参考) 2E185 BA02 CA03 CB07 CC04 CC06 CC16 CC25 DA02 DA05 DA12
4C017 AA08
4C038 KK01 SS04 SS08 ST09 SU01 SU06 SU19
4C074 BB02 CC20 HH01
4C117 XA04 XB01 XB20 XE15 XE24 XE27 XE37 XE57 XR20

专利名称(译)	冲击处理系统和方法		
公开(公告)号	JP2004532681A	公开(公告)日	2004-10-28
申请号	JP2002589085	申请日	2002-05-01
[标]申请(专利权)人(译)	高级循环系统有限公司		
申请(专利权)人(译)	先进的循环率利系统公司		
[标]发明人	ルーリーキースジー ジーリンスキートッドエム		
发明人	ルーリー, キース ジー. ジーリンスキー, トッド エム.		
IPC分类号	A62B7/04 A61B5/00 A61B5/021 A61B5/08 A61B5/083 A61B5/087 A61B5/145 A61H31/00 A61M16/00 A61M16/04 A61M16/20 A62B9/00 A62B9/02 A62B18/02 C09K5/04 F25B9/00 F25B9/02 F25B31/00		
CPC分类号	A61H31/005 A61H31/006 A61H31/007 A61H2201/0173 A61H2201/1238 A61H2201/5007 A61H2201/5048 A61H2201/5058 A61H2201/5071 A61H2201/5089 A61H2201/5097 A61H2230/207 A61H2230/42 A61M16/0078 A61M16/0084 A61M16/022 A61M16/04 A61M16/0858 A61M16/1055 A61M16/106 A61M16/20 A61M16/202 A61M16/208 A61M16/209 A61M2016/0021 A61M2016/0027 A61M2016/0033 C09K5/042		
FI分类号	A61H31/00 A61B5/00.101.M A61B5/08 A61M16/20.Z A62B7/04 A62B9/00.Z A62B9/02 A62B18/02 A61B5/02.330 A61B5/14.310		
F-TERM分类号	2E185/BA02 2E185/CA03 2E185/CB07 2E185/CC04 2E185/CC06 2E185/CC16 2E185/CC25 2E185/DA02 2E185/DA05 2E185/DA12 4C017/AA08 4C038/KK01 4C038/SS04 4C038/SS08 4C038/ST09 4C038/SU01 4C038/SU06 4C038/SU19 4C074/BB02 4C074/CC20 4C074/HH01 4C117/XA04 4C117/XB01 4C117/XB20 4C117/XE15 4C117/XE24 4C117/XE27 4C117/XE37 4C117/XE57 4C117/XR20		
代理人(译)	夏木森下		
优先权	09/854238 2001-05-11 US 10/119203 2002-04-08 US		
其他公开文献	JP2004532681A5		
外部链接	Espacenet		

摘要(译)

根据本发明，提供了一种用于在进行心肺复苏时增强由胸部的压迫和压迫引起的心肺循环的方法和装置。根据一种方法，压力响应流入阀（24）连接到患者的气道。进行胸部按压和胸部减压。在胸部去极化期间，流入阀（24）防止呼吸气体进入肺部直到超过恒定的负胸腔内压力水平，并且当流入阀门超过时流入阀门（24）打开。以这种方式，入口阀（24）有助于在减压期间增加负胸内压的幅度和持续时间并且增加进入心脏和肺的血流量。此外，当流入阀（24）打开以人工呼吸患者时，通过流入阀（24）向患者供应加压呼叫吸气。