US 20080108882A1

(19) **United States**

(12) **Patent Application Publication**

(10) **Pub. No.: US 2008/0108882 A1**

(43) **Pub. Date: May 8, 2008**

Garbin

(54) **METHOD OF ASSESSING BREASTFEEDING**

(75) Inventor: **Catherine Peta Garbin**, Floreat (AU)

Correspondence Address:
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606 (US)

(73) Assignee: **Medela Holding AG**, Baar (CH)

(21) Appl. No.: **11/903,361**

(22) Filed: **Sep. 21, 2007**

Related U.S. Application Data

(60) Provisional application No. 60/846,464, filed on Sep. 22, 2006.

Publication Classification

(51) **Int. Cl.**
A61B 5/00 (2006.01)

(52) **U.S. Cl.** **600/300**

(57) **ABSTRACT**

The invention includes methods of assessing the health of a breastfeeding relationship that include clinical assessment in four categories. A first assessment involves a determination of maternal and infant contentment. A second assessment involves a determination of comfort. A third assessment involves a determination of milk production. A fourth assessment involves a determination assessing infant swallowing.

	The Breast Feeding Assessment Tool					
	Mother's Name			**Date**		**ID No**
	Baby's Name			**Date of Birth**		**Age**
		Clinical Assessment	**Score Yes=1 No=0**	**Objective Assessment**	**Score Yes=1 No=0**	**Average / Range**
22	Maternal/Infant Contentment	Yes: 1 No: 0		Not Scientifically Measurable		
24	Comfort	Yes: 1 No: 0		If Pain Grade 1-10 %Time Spent at <-200mmHg——		95% Time Spent at <-200 mmHg (Range 85%-100%)
26	Milk Production (20)	——Wet Nappies a Day ——Dirty Nappies a Day Mother's Perception		Birth Wt————g Present Wt————g Growth Trajectory——% 24 Hour Production——g		11 Feeds/Day (±3) 24-h Breast milk Intake 788g (±169g)
28	Swallowing (20)	Audible, Jaw Movement, Baby Behaviour, Eyes Open at Beginning of Feed		Test Weight Left—g Right—g		76g (sd ±13g)
30	Tongue	Appearance, Elasticity, Length of and Position of Frenulum,Lateralization, Lift and Extension		Ultrasound Shows Nipple Distortion		No Distortion
32	Nipple and Breast	Condition/Shape/Changes After Feed Nipple: Breast:		Ultrasound Nipple Diameter Tongue Up ———mm Tongue Down——mm Difference———mm		Nipple Diameter (mm) Tongue Up 6.4±0.1 Tongue Down 9.6±1.1 Difference 3.2
34	Attachment Position (42)	Rooting Reflex, Gape Angle, Lip Eversion, Baby Behaviour, Baby and Mother Postural Stability, Chin-Breast, Chest-Chest, Baby's Body Aligned		Ultrasound Nipple-Hard/Soft Palate Junction Tongue Up———mm Tongue Down——mm Difference———mm		Nipple-Hard/Soft Palate Junction (mm) Tongue Up 6.8±1.5 Tongue Down 5.6±1.5 Difference 1.2
36	Milk Ejection Reflex	Time, Sensation, Baby Behaviour		Milk Flow, Ultrasound Time from Start of Feed——sec		Duct Dilation Seen, Visible Flow, Tongue Action, Time to MER 60 Seconds
38	Staying Attached	On/Off Baby Behaviour		Baseline Vacuum mmHg		Baseline Vacuum -61.9±38.1 mm/Hg
40	Respiration	Audible Visual		O_2 Saturation Seconds at <100%—— rrm: Feeding——Pause——		rrm<8 wks Feeding 51 (Range 41-73) Pause 63 (Range 40-87) rrm>8 wks Feeding 48 (Range 37-53) Pause 67 (Range 49-82)
		Totals				

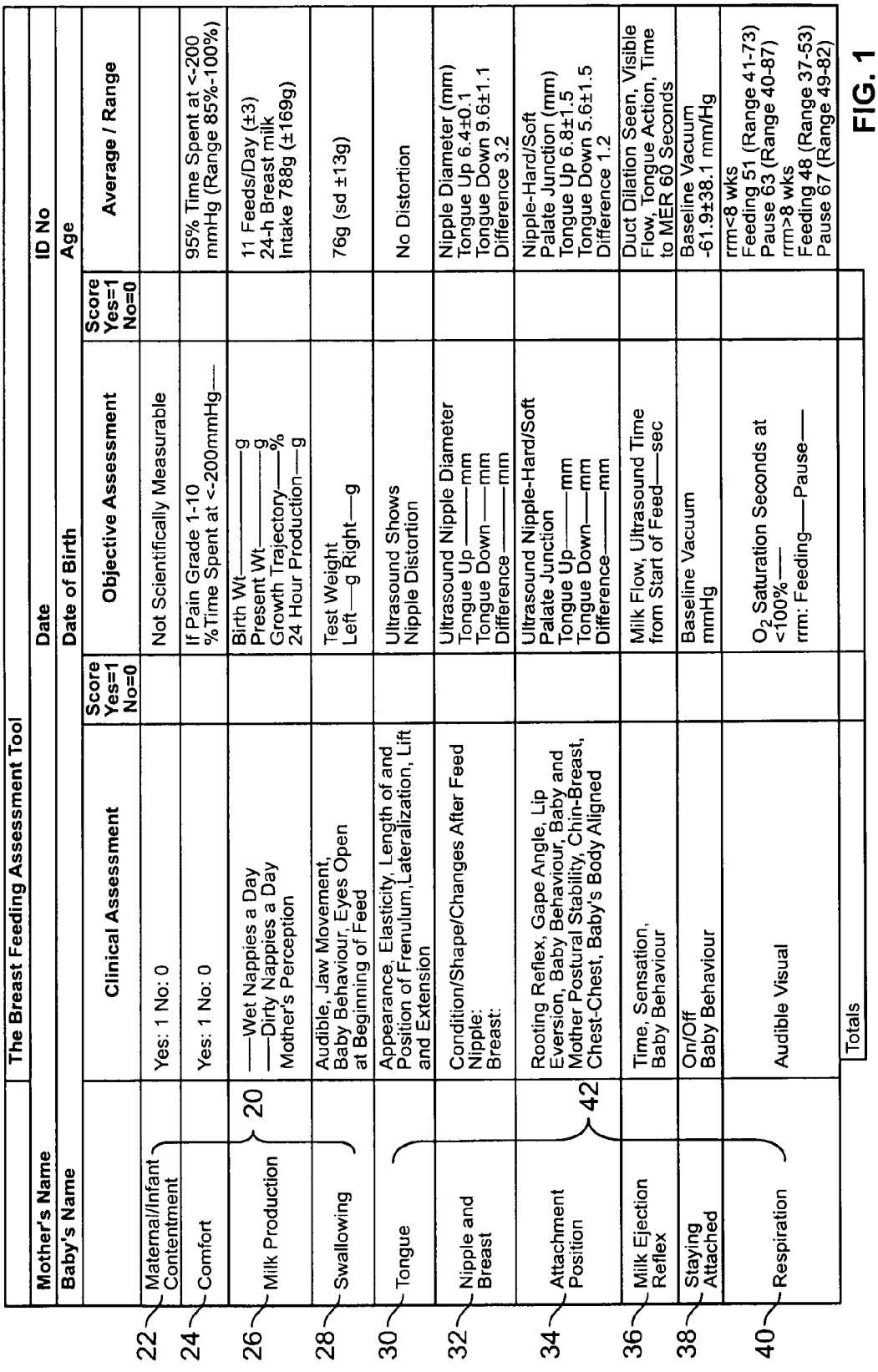

The Breast Feeding Assessment Tool
Mother's Name
Date
ID No
Baby's Name
Date of Birth
Age
Clinical Assessment
Score Yes=1 No=0
Objective Assessment
Score Yes=1 No=0
Average / Range
22 Maternal/Infant Contentment
Yes: 1 No: 0
Not Scientifically Measurable
24 Comfort
Yes: 1 No: 0
If Pain Grade 1-10
%Time Spent at <-200mmHg—
95% Time Spent at <-200 mmHg (Range 85%-100%)
26 Milk Production 20
—Wet Nappies a Day
—Dirty Nappies a Day
Mother's Perception
Birth Wt———g
Present Wt———g
Growth Trajectory——%
24 Hour Production—g
11 Feeds/Day (±3)
24-h Breast milk Intake 788g (±169g)
28 Swallowing
Audible, Jaw Movement, Baby Behaviour, Eyes Open at Beginning of Feed
Test Weight
Left—g Right—g
76g (sd ±13g)
30 Tongue
Appearance, Elasticity, Length of and Position of Frenulum, Lateralization, Lift and Extension
Ultrasound Shows Nipple Distortion
No Distortion
32 Nipple and Breast
Condition/Shape/Changes After Feed
Nipple:
Breast:
Ultrasound Nipple Diameter
Tongue Up ——mm
Tongue Down ——mm
Difference ——mm
Nipple Diameter (mm)
Tongue Up 6.4±0.1
Tongue Down 9.6±1.1
Difference 3.2
34 Attachment Position 42
Rooting Reflex, Gape Angle, Lip Eversion, Baby Behaviour, Baby and Mother Postural Stability, Chin-Breast, Chest-Chest, Baby's Body Aligned
Ultrasound Nipple-Hard/Soft
Palate Junction
Tongue Up——mm
Tongue Down——mm
Difference——mm
Nipple-Hard/Soft
Palate Junction (mm)
Tongue Up 6.8±1.5
Tongue Down 5.6±1.5
Difference 1.2
36 Milk Ejection Reflex
Time, Sensation, Baby Behaviour
Milk Flow, Ultrasound Time from Start of Feed——sec
Duct Dilation Seen, Visible Flow, Tongue Action, Time to MER 60 Seconds
38 Staying Attached
On/Off
Baby Behaviour
Baseline Vacuum
mmHg
Baseline Vacuum
-61.9±38.1 mm/Hg
40 Respiration
Audible Visual
O_2 Saturation Seconds at
<100%——
rrm: Feeding——Pause——
rrm<8 wks
Feeding 51 (Range 41-73)
Pause 63 (Range 40-87)
rrm>8 wks
Feeding 48 (Range 37-53)
Pause 67 (Range 49-82)
Totals

FIG. 1

METHOD OF ASSESSING BREASTFEEDING

[0001] This application claims benefit of U.S. Provisional Application No. 60/846,464, filed Sep. 22, 2006.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The invention is directed to breastfeeding. In particular, the invention is directed to a tool for assessing breastfeeding. More particularly, the invention is an improved method applicable to breastfeeding, which improves breastfeeding success and provides identification of clinical problems and the likely causes of specific aspects of breastfeeding behavior.

[0004] 2. Description of the Prior Art

[0005] Currently, the treatment of breastfeeding problems comprises a number of "hit and miss" methods. For example, a lactation consultant routinely observes a mother with breastfeeding problems and then picks a likely scenario or cause of the problem. If the intervention indicated by the scenario is successful at resolving the problem, the consultant needs to investigate no further. However, if the problem is not resolved, the consultant selects a second likely cause and so on. While experience-based problem solving can be successful, it tends to be subjective and results tend to vary with the investigator.

[0006] In medical disciplines, it is conventional that the investigator collects information before making a diagnosis, which then indicates a course of action. The information collecting process includes the acquisition of data by objective testing, according to one or more standardized method, in order to form a diagnosis. The current practice, with respect to investigating breastfeeding problems, is based on experience of the investigator and not typically the collection of objective evidence, hence the "hit and miss" success of interventions. If a means of clinically assessing (or testing) breastfeeding problems existed, there may be a clearer or more certain course of action suggested to the investigator, when confronted with a breastfeeding problem.

[0007] Therefore, this invention is an objective assessment tool for the diagnosis and treatment of breastfeeding problems.

SUMMARY OF THE INVENTION

[0008] The invention, in one embodiment, is a tool usable by any competent person and in particular, for example, lactation professionals, medical professionals and the like. The tool uses objective measurements and/or assessments. The measurements allow the identification of clinical problems related to breastfeeding and the likely causes of specific aspects of breastfeeding behavior. These aspects can then be targeted for corrective intervention.

[0009] In a most general form, the invention includes a clinical assessment in four categories. A first assessment involves a determination of maternal and infant contentment. A second assessment involves a determination of comfort. A third assessment involves a determination of milk production. A fourth assessment involves a determination assessing infant swallowing.

[0010] The method can advantageously be used by educators to structure antenatal breastfeeding classes, mothers and partners to plan their own breastfeeding care, hospital workers and other health care professionals, community health care workers and breastfeeding products sales teams.

[0011] This, and additional objects, advantages, features and benefits of the invention will become apparent from the following specification.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIG. **1** is a table which illustrates a method according to an embodiment of the invention.

DETAILED DESCRIPTION OF AN EMBODIMENT

[0013] Referring to the drawings, FIG. **1** shows a table summarizing the four main components of the method according to one embodiment of the invention. FIG. **1** shows a tool **20**, including a first assessment component **22** related to baby/maternal contentment. A second assessment component **24** is related to whether the mother is comfortable. A third assessment component **26** is related to the milk production of the mother. A fourth assessment component **28** is related to the swallowing of the infant.

[0014] The assessment tool **20**, including components **22-28** may be used without any associated tests, such as the mother in a hospital making a self-assessment using the four components. If she answers "no" to any of the four assessment components, she should seek help.

[0015] Also, a nurse in a hospital can use the tool **20** in the form of the above-described **4** component assessment to make a general assessment of breastfeeding of a patient. Should her patient answer "no" to any of the 4 assessment components then she should follow up with a more extensive assessment, which may involve more detailed questioning directed to the component which generated the "no" response and further, may elect to order further testing and/or observation, for example, or the suggestion to consult with a lactation professional.

[0016] One example of a method according to the invention includes presenting to the subject a diagnostic survey, which is in an oral or in the alternate, a written form. A first assessment question is asked, which is similar or identical to, "Are you and your baby content?" If the answer is "no," one or more follow up question is asked to determine the cause of the lack of contentedness. For example, if the mother is wondering if her milk supply is sufficient, a milk production assessment is performed to determine the amount of milk generated each feeding in a 24 hour period. In response to the answer to the follow up question, a treatment plan is put into place addressing the cause. If the answer is "yes," a second assessment question is asked.

[0017] The second assessment question is asked, which is similar or identical to, "Is the feeding comfortable for you and your baby?" If the answer is "no," one or more follow up question would be asked to determine the cause of the lack of comfort. For example, a pain grade may be determined (a common practice for assessing pain in increments, such as from 1-10). If the result is greater than a predetermined amount of reported discomfort, steps may be performed to determine the source of the problem. In response to the answer to the follow up question, a treatment plan is put into place addressing the cause of lack of comfort. For

example, if the intra-oral sucking vacuum is measured and the pain is associated with a high sucking vacuum from the baby, the positioning and attachment can be altered or a nipple shield may be used. If the pain is not associated with high vacuum the cause may have another cause, for example, infection, vasospasm in the mother or tongue tie in the infant. In all cases, the "test" of measuring intra-oral vacuum may be used to assist in the diagnosis of the problem(s) and the result sends the health care provider or the health care professional down certain treatment option cascades. If the answer is "yes," a third assessment question is asked.

[0018] The third assessment question is something similar or identical to, "Is your milk production enough for your baby?" If the answer is "no," one or more follow up question would be asked to determine the cause of the insufficient milk. In addition, a study may be performed including an assessment of the number of wet diapers in a 24 hour period, the number of dirty diapers in a 24 hour period and weight gain in a one week period. In response to the answer to the follow up question(s) and study, a treatment plan is put into place addressing the cause of lack of milk. For example, a 24 hour production assessment of maternal milk production, massage, and other treatment options may be performed. If the answer is "yes," a fourth assessment question is asked.

[0019] The fourth assessment question is asked, which is similar or identical to, "Is your baby swallowing and appearing to feed?" If the answer is "no," one or more follow up question would be asked to determine the cause of the lack of swallowing. For example, if the answer reveals that the mother is not confident that the baby is swallowing or feeding enough, a study may be made of the baby's intake over a 24 hour period. In response to the answer to the follow up question and study, a treatment plan is put into place addressing the swallowing problem.

[0020] These four categories comprise the more critical elements relating to a healthy breastfeeding relationship between the mother and baby. As shown in the FIGURE, the assessment **20** may include one or both of clinical assessments as well as objective tests, in some cases.

[0021] No score in the above assessment categories means that help is clearly needed. The order of assessment questions, while not critical, is preferred in the order set forth, which ensures key points are always foremost and problems are addressed early. Prompt, appropriate, well-planned assistance saves breastfeeding and reduces conflicting advice from less focused assessments and subjective methods.

[0022] An embodiment of the method of the invention may further include determinations, observation and/or testing directed to six identified critical breastfeeding areas of assessment **42**. These include, referring to FIG. **1**, breastfeeding behavior or function related to the infant tongue **30**, the mother's nipple and breast **32**, attachment position **34**, milk ejection reflex **36**, attachment **38**, and respiration **40**. As shown in the FIGURE, the assessment **42** may include one or both of clinical assessments as well as objective tests.

[0023] Should the initial tool **20** reveal some breastfeeding problem, a second phase of the test may include investigation related to assessment related to behavior, physiology and/or function related to assessment areas **30-40**. So, in a general form, any person can perform a breastfeeding assessment using the tool **20** described herein, which, if a result of the assessment indicates a problem, negative score or the like a second set of inquiries may be made related to the

[0024] To those skilled in the art to which this invention pertains, the above-described preferred embodiment may be subject to change or modification. Such change or modification can be carried out without departing from the scope of the invention, which is intended to be limited only by the scope of the appended claims.

What is claimed is:

1. A method of assessing the quality of breastfeeding, comprising:

determining the contentment of a breastfeeding infant and/or mother;

determining the comfort of the breastfeeding infant and/or mother;

determining if the mother is generating sufficient milk; and

determining if the infant is swallowing appropriately.

2. A method of assessing the health of a breastfeeding relationship between a baby and mother, comprising:

selecting three or all of: determining the contentment of a breastfeeding infant and/or mother, determining the comfort of the breastfeeding infant and/or mother, determining if the mother is generating sufficient milk, and determining if the infant is swallowing appropriately; and

developing and executing a treatment plan based on said determining steps.

3. A method of assessing the quality of breastfeeding, comprising:

making a first assessment related to the contentment of a breastfeeding infant and/or mother, and assigning a score to the result of the first assessment;

making a second assessment related to comfort of the breastfeeding infant and/or mother if the score to the first assessment is positive, and assigning a score to the result of the second assessment;

making a third assessment related to whether the mother is generating sufficient milk if the score to the second assessment is positive, and assigning a score to the result of the third assessment;

making a fourth assessment related to whether the infant is swallowing appropriately if the score to the third assessment is positive, and assigning a score to the result of the fourth assessment; and

formulating and executing a treatment plan if any of the scores are not positive.

4. A method according to any of claims **1** and **2**, wherein the result of the determining step is a yes or no assessment.

5. A method of assessing the quality of breastfeeding, comprising:

making a first assessment related to the contentment of a breastfeeding infant and/or mother, and assigning a score to the result of the first assessment;

making a second assessment related to comfort of the breastfeeding infant and/or mother if the score to the first assessment is positive, and assigning a score to the result of the second assessment;

making a third assessment related to whether the mother is generating sufficient milk if the score to the second assessment is positive, and assigning a score to the result of the third assessment;

making a fourth assessment related to whether the infant is swallowing appropriately if the score to the third assessment is positive, and assigning a score to the result of the fourth assessment;

performing a second set of inquiries related to one or more of the infant tongue **30**, the mother's nipple and breast **32**, attachment position **34**, milk ejection reflex **36**, attachment **38**, and respiration **40**; and

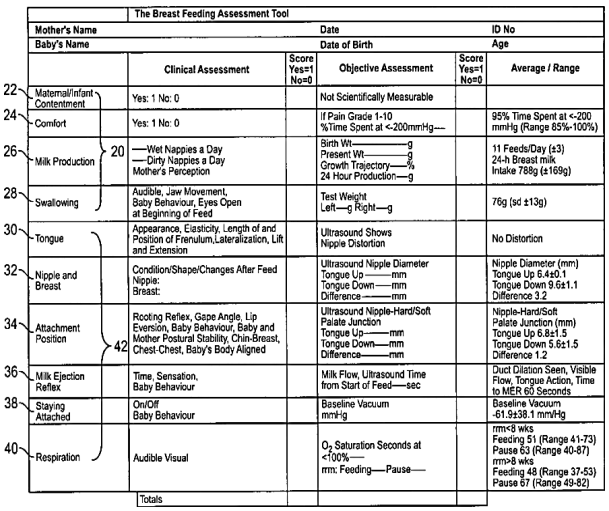
formulating and executing a treatment plan based on the result of the second set of inquiries.

* * * * *

专利名称(译)	评估母乳喂养的方法		
公开(公告)号	US20080108882A1	公开(公告)日	2008-05-08
申请号	US11/903361	申请日	2007-09-21
[标]申请(专利权)人(译)	美德乐控股公司		
申请(专利权)人(译)	美德乐HOLDING AG		
当前申请(专利权)人(译)	美德乐HOLDING AG		
[标]发明人	GARBIN CATHERINE PETA		
发明人	GARBIN, CATHERINE PETA		
IPC分类号	A61B5/00		
CPC分类号	A61B5/4288 G06F19/363 A61B5/4312 G16H10/20		
优先权	60/846464 2006-09-22 US		
外部链接	Espacenet USPTO		

摘要(译)

本发明包括评估母乳喂养关系健康的方法，其包括四类临床评估。第一次评估涉及确定母婴满意度。第二次评估涉及确定舒适度。第三次评估涉及确定产奶量。第四次评估涉及评估婴儿吞咽的决定。



The Breast Feeding Assessment Tool

Mother's Name | Date | ID No

Baby's Name | Date of Birth | Age

		Clinical Assessment	Score Yes=1 No=0	Objective Assessment	Score Yes=1 No=0	Average / Range
22	Maternal/Infant Contentment	Yes: 1 No: 0		Not Scientifically Measurable		
24	Comfort	Yes: 1 No: 0		If Pain Grade 1-10 %Time Spent at <-200mmHg—		95% Time Spent at <-200 mmHg (Range 85%-100%)
26	Milk Production	—Wet Nappies a Day —Dirty Nappies a Day Mother's Perception	20	Birth Wt———g Present Wt———g Growth Trajectory——% 24 Hour Production—g		11 Feeds/Day (±3) 24-h Breast milk Intake 788g (±169g)
28	Swallowing	Audible, Jaw Movement, Baby Behaviour, Eyes Open at Beginning of Feed		Test Weight Left—g Right—g		76g (sd ±13g)
30	Tongue	Appearance, Elasticity, Length of and Position of Frenulum,Lateralization, Lift and Extension		Ultrasound Shows Nipple Distortion		No Distortion
32	Nipple and Breast	Condition/Shape/Changes After Feed Nipple: Breast:		Ultrasound Nipple Diameter Tongue Up———mm Tongue Down——mm Difference———mm		Nipple Diameter (mm) Tongue Up 6.4±0.1 Tongue Down 9.6±1.1 Difference 3.2
34	Attachment Position	Rooting Reflex, Gape Angle, Lip Eversion, Baby Behaviour, Baby and Mother Postural Stability, Chin-Breast, Chest-Chest, Baby's Body Aligned	42	Ultrasound Nipple-Hard/Soft Palate Junction Tongue Up———mm Tongue Down——mm Difference———mm		Nipple-Hard/Soft Palate Junction (mm) Tongue Up 6.8±1.5 Tongue Down 5.6±1.5 Difference 1.2
36	Milk Ejection Reflex	Time, Sensation, Baby Behaviour		Milk Flow, Ultrasound Time from Start of Feed——sec		Duct Dilation Seen, Visible Flow, Tongue Action, Time to MER 60 Seconds
38	Staying Attached	On/Off Baby Behaviour		Baseline Vacuum mmHg		Baseline Vacuum -61.9±38.1 mmHg
40	Respiration	Audible Visual		O_2 Saturation Seconds at <100%— rrm: Feeding——Pause——		rrm<8 wks Feeding 51 (Range 41-73) Pause 63 (Range 40-87) rrm>8 wks Feeding 48 (Range 37-53) Pause 67 (Range 49-82)
		Totals				