K150499

(b)(4)

(b)(4), (b)(6)

Document Mail Center WO66-0609
Center for Devices & Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 23, 2015

Subject: 510(k) Premarket Notification

Medela AG Freestyle®

To Whom It May Concern:

In accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act, Medela AG hereby submits this Traditional 510(k) Premarket Notification for the Freestyle® double electric breastpump. This Traditional 510(k) is submitted to obtain clearance from FDA to commercially distribute this device. There have been no prior submissions for the Freestyle® described within this premarket notification. However, Freestyle has been marketed in the US since 2007. Medela has discussed this with Becky Robinson, PhD, who was then working as a Biomedical Engineer in the Obstetrics and Gynecology Devices Branch, Division of Reproductive, Gastro-Renal, and Urological Devices on January 12, 2015 via telephone and e-mail and the submission includes information recommended by FDA as presented in Section 10 Executive Summary. Mr. Jason Roberts was identified as a point of contact for enquires regarding this submission.

Medela AG believes that the enclosed information will be sufficient for the FDA to reach a decision on this notification. However, should additional information be required, it will be promptly furnished upon request.

This premarket notification has been prepared in accordance with 21 CFR §807.87 and the latest FDA Guidance titled Format for Traditional and Abbreviated 510(k)s issued on August 12, 2005.

Following are the principal factors about the design and use of the device:

TRADE NAME: Freestyle®

COMMON/USUAL NAME: Double electric breastpump

CLASSIFICATION NAMES: 884.5160 Powered breast pump

REVIEW PANEL: Obstetrics/Gynecology

PRODUCT CODE: HGX

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	☐	☒
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	☒	☐
Does the device contain components derived from a tissue or other biologic source?	☐	☒
Is the device provided sterile?	☐	☒
Is the device intended for single use?	☐	☒
Is the device a reprocessed single use device?	☐	☒
If yes, does this device type require reprocessed validation data?	☐	☐
Does the device contain a drug?	☐	☒
Does the device contain a biologic?	☐	☒
Does the device use software?	☒	☐
Does the submission include clinical information?	☒	☐
Is the device implanted?	☐	☒

Two electronic copies are also provided and these eCopies are exact duplicates of the paper copy.

CONFIDENTIALITY

Medela considers the information in this submission to be confidential commercial information. We have not, to our knowledge, released this information through advertising or any other manner to anyone outside the employ of Medela. Medela has taken precautions to protect the confidentiality of this information under Section 807.95, Confidentiality of Information. We ask that this notification and proprietary information herein be treated as confidential in accordance with the Freedom of Information Act.

Medela appreciates the administrative and scientific considerations relevant to this submission, and we look forward to receiving a timely decision by the FDA regarding the information presented. Should you have any questions regarding the contents of this submission, please me at (b)(4) or Orlando Antunes as the alternate contact by telephone +41 (0)41 561 66 71 or e-mail at orlando.antunes@medela.ch.

Sincerely,

(b)(6)

Member

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify, in my capacity as Vice-President Regulatory Affairs of Medela AG, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Orlando Antunes

Date: 3. Feb. 2015

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

TRADITIONAL 510(K)

TABLE OF CONTENTS

Subject	Exhibit	Pages
VOLUME 5		
Section 17 – Electromagnetic Compatibility and Electrical Safety		**3-Volume 7, 150**
IEC 60601-1-2: 2007. Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	**17.1**	5-67
Power Supply FCC Certificate	**17.2**	68-69
VOLUME 6		
IEC 60601-1: 2005, Medical Electrical Equipment - Part 1: General Requirements for Safety	**17.3**	3-104
VOLUME 7		
Continuation of IEC 60601-1: 2005, Medical Electrical Equipment - Part 1: General Requirements for Safety	**17.3**	3-117
IEC 60601-1-11:2010, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	**17.4**	118-145
IEC60601-1-2: (b)(4) [redacted] on the Medela Breastpump Freestyle	**17.5**	146-150
Section 18 – Performance Testing – Bench		**151-331**
18.1 Usability		152
18.2 Performance Testing		152-154
Usability Validation Plan	**18.1**	155-188
Usability Validation Report	**18.2**	189-232
EN ISO 10079-1: 2009 Particular requirements for the safety of electrically powered suction equipment	**18.3**	233-249
(b)(4) [redacted] test report	**18.4**	250-258
Vacuum Performance	**18.5**	259-267
Vacuum Stability	**18.6**	268-278
Vacuum Performance – comparison with predicate	**18.7**	279-304
Freestyle durability	**18.8**	305-316
Pump temperatures during operation	**18.9**	317-331

SECTION 1

MEDICAL DEVICE USER FEE COVER SHEET (FORM FDA 3601)

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted] Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
MEDELA HOLDING AG LAETTICHSTRASSE 4 -- BAAR -- CH	Orlando Antunes 2.1 E-MAIL ADDRESS orlando.antunes@medela.ch 2.2 TELEPHONE NUMBER (include Area code) 4141-5616671 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates	[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 26-Jan-2015

Form FDA 3601 (05/13)

"Close Window" Print Cover sheet

SECTION 2

FDA FORMS

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET, FDA FORM 3514

REFUSE TO ACCEPT CHECKLIST FOR TRADITIONAL 510(K)S

CLINICALTRIALS.GOV CERTIFICATION, FDA FORM 3674

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved:
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
02/23/2015	MD6079786	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Medela AG	3002807523		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	+41 (0)41 561 66 71		
Street Address	**FAX Number *(including area code)***		
Lättichstrasse 4b	+41 (0)41 561 51 00		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Baar		6341	Switzerland
Contact Name			
Orlando Antunes			
Contact Title	**Contact E-mail Address**		
Vice President Regulatory Affairs	orlando.antunes@medela.ch		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

(b)(4) Third Party Information

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	HGX	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K122474	1	Lansinob Powered Breast Pump	1	Lansinoh Laboratories Saglik Gerecleri San. Tic. Ltd. Sti.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Powered Breast Pump

	Trade or Proprietary or Model Name for This Device		Model Number
1	Freestyle Deluxe	1	67060, 67060T
2	Freestyle Solution Set	2	67060BN
3	Freestyle Basic	3	67065, 67065T
4	Freestyle Motor Warranty	4	67064
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
HGX	884.5160	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Obstetrics/Gynecology

Indications *(from labeling)*

The Freestyle® is a powered breastpump to be used by lactating women to express and collect milk from their breasts.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number: 3002807523

☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name: Medela AG (manufacture of pump, canister and tubing)	Establishment Registration Number: 3002807523
Division Name *(if applicable)*	Phone Number *(including area code)*: +41 (0)41 561 66 71
Street Address: Lättichstrasse 4b	FAX Number *(including area code)*: +41 (0)41 561 51 00

City	State / Province	ZIP Code	Country
Baar		6341	Switzerland

Contact Name	Contact Title	Contact E-mail Address
Orlando Antunes	Vice President Regulatory Affair	orlando.antunes@medela.ch

☒ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number:

☐ Manufacturer ☐ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4) [redacted]

☐ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number:

☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	Phone Number *(including area code)*
Street Address	FAX Number *(including area code)*

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601-1	IEC	Medical electrical equipment - part 1: general requirements for basic safety and essential performance	3	'2005
2	60601-1-2/A1;2007	IEC	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests		'2007
3	60601-1-11	IEC	Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems used in the Home Healthcare Environment		'2010
4	10079-1	ISO	Particular requirements for the safety of electrically powered suction equipment		'2009
5	14971	ISO	Medical Devices – Application of Risk Management to Medical Devices		'2007
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Medela AG

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
Feb 3, 2015

3. ADDRESS *(Number, Street, State, and ZIP Code)*
Lättichstrasse 4b
6341 Baar / Switzerland

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) +41 (0)41 561 66 71
(Fax) +41 (0)41 769 51 00

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Freestyle

Freestyle double electric breastpump

Powered Breast Pump

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☒ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. **Warning:** A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Orlando Antunes
(Title) Vice President Regulatory Affairs

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
Lättichstrasse 4b
6341 Baar / Switzerland

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) +41 (0)41 561 66 71
(Fax) +41 (0)41 561 51 00

15. DATE OF CERTIFICATION
3. Feb 2015

Form FDA 3674 (11/08) (FRONT)

PSC Graphics: (301) 443-1090 EF

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. **& 4.** - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.

   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/ submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. **& 14.** - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-250)
5600 Fishers Lane
Rockville, MD 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

Form FDA 3674 (11/08) (BACK)

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K Date Received by DCC:

Lead Reviewer:

Branch: Division: DAGRID Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions **Answers in the shaded blocks indicate consultations with Center advisor is needed**	Yes	No
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination*. If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments? Product is a device per 884.5160 Powered breast pump		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination*. If application should not be reviewed by your Center mark "No."	X	
Comments?		
3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments? No RFD submitted. Freestyle is not a combination product.		
4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments?		

5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		X
Comments? Medela AG is not the subject of an AIP.		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments? Traditional 510(k) with sections labeled and pages numbered. Table of Contents in Volume 1, pages 2 - 7 and page 2 of Volumes 2-7.		

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			X
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
Comments? Form 3514 in Section 2 and Cover Letter in Section 3.				
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			X
Comments? Section 4				
4) Submission contains 510(k) Summary or 510(k) Statement	X			X
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*	X			
b) Statement contains all elements per 21 CFR 807.93			X	
Comments? 510(k) Summary in Section 5 contains all elements of 21 CFR 807.92.				
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			X
Comments? Section 6				
6) Submission contains Class III Summary and Certification. *See recommended* content.			X	X
Comments? Not a Class III 510(k).				
7) Submission contains clinical data			X	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X			X
Comments? Exhibit 9.1 includes form for each referenced standard.				
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X			X

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.			X	
Comments? Statement of no prior submissions included in Section 3 Cover Letter and Section 10 Executive Summary.				
B. Device Description				
10)				X
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
Comments? No special controls, device specific regulation or or device-specific guidance are available. Device Description is presented in Section 11.				
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				X
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
Comments? Section 11 Device Description, Exhibits 11.1-11.5. Device description details are also presented in Section 16.				
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			X
Comments? Section 11 Device Description				
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				X
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.	X			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
Comments? Section 11.8, Exhibits 11.4-11.5.				
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			X
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
Comments? Section 12				
15) Submission includes a comparison of the following for the predicate(s) and subject device				X
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			
Comments? Section 12				
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			X
Comments? Section 12				
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17, 18, & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			X
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X			
Comments? User manuals in Exhibits 13.1. Device and package labeling in Exhibits 13.4-13.5.				

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]			X	X
Comments? Freestyle is not indicated for prescription use.				
19) General labeling provisions				X
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)	X			
Comments? User manual in Exhibits 13.1. Labeling is Exhibits 13.2 - 13.8.				
20)				X
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
Comments? No special controls, device specific regulation or or device-specific guidance are available.				
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	

E. Sterilization

If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				
Submission states that the device and/or accessories are: (one of the below must be checked)				
	provided sterile			
	provided non-sterile but sterilized by the end user			
X	non-sterile when used			
	Information regarding the sterility status of the device is not provided.			
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
22) Assessment of the need for sterilization information				X
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X			
b) Identification of device, and/or accessories, and/or components that are end user sterilized.			X	
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.	X			
Comments? Section 14 states that the device is not sterile. Exhibit 13.1 includes cleaning instructions. Cleaning validation is provided in Exhibits 14.1-14.9.				
25)				X
a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
Comments? No special controls, device specific regulation or or device-specific guidance are available.				
F. Shelf Life				
26) Proposed shelf life/expiration date stated			X	
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.			X	
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X			X
Comments? Section 14				
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				
Submission states that there: (one of the below must be checked)				
X are direct or indirect (e.g., through fluid infusion) patient-contacting components.				

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	X			X
Comments? Section 15				
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	X			X
Comments? Section 15				
31) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X			X
Comments? Section 15				
H. Software				X
Submission states that the device: (one of the below must be checked)				
X does contain software/firmware.				
does not contain software/firmware.				
Information regarding whether the device contains software is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
Comments? Section 16.				
32) Submission includes a statement of software level of concern and rationale for the software level of concern.	X			X
Comments? Section 16 - Software is Moderate Level of Concern.				
33) All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submitter has provided an alternative approach with a rationale.	X			X
Comments? Section 16 and Exhibits 16.1 - 16.9.				
I. EMC and Electrical Safety				X

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
Submission states that the device: (one of the below must be checked)				
× does require EMC and Electrical Safety evaluation.				
does not require EMC and Electrical Safety evaluation.				
Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
Comments? Section 17				
34) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	×			×
Comments? Section 17 and Exhibit 17.3 - 4.				
35) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	×			×
Comments? Section 17 and Exhibit 17.1 and 17.2.				
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.	×			×
Comments? Section 18. Exhibits 18.1 - 18.9.				
37)				×
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			×	

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
Comments? No special controls, device specific regulation or or device-specific guidance are available.				
38) If literature is referenced in the submission, submission includes:				X
a) Legible reprints or a summary of each article.	X			
b) Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	X			
Comments? Section 20				
39) For each completed nonclinical (i.e., animal) study conducted			X	X
Comments? No animal studies conducted.				

K. Performance Characteristics - In Vitro Diagnostic Devices Only

(Also see 21 CFR 809.10(b)(12))

Submission states that the device: (one of the below must be checked)

	is an in vitro diagnostic device.
X	is not an in vitro diagnostic device.

Decision: ○ Accept ○ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

SECTION 3

510(K) COVER LETTER

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

(b)(4), (b)(6)

[redacted]

Document Mail Center WO66-0609
Center for Devices & Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 23, 2015

Subject: 510(k) Premarket Notification

Medela AG Freestyle®

To Whom It May Concern:

In accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act, Medela AG hereby submits this Traditional 510(k) Premarket Notification for the Freestyle® double electric breastpump. This Traditional 510(k) is submitted to obtain clearance from FDA to commercially distribute this device. There have been no prior submissions for the Freestyle® described within this premarket notification. However, Freestyle has been marketed in the US since 2007. Medela has discussed this with Becky Robinson, PhD, who was then working as a Biomedical Engineer in the Obstetrics and Gynecology Devices Branch, Division of Reproductive, Gastro-Renal, and Urological Devices on January 12, 2015 via telephone and e-mail and the submission includes information recommended by FDA as presented in Section 10 Executive Summary. Mr. Jason Roberts was identified as a point of contact for enquires regarding this submission.

Medela AG believes that the enclosed information will be sufficient for the FDA to reach a decision on this notification. However, should additional information be required, it will be promptly furnished upon request.

This premarket notification has been prepared in accordance with 21 CFR §807.87 and the latest FDA Guidance titled Format for Traditional and Abbreviated 510(k)s issued on August 12, 2005.

Following are the principal factors about the design and use of the device:

TRADE NAME: Freestyle®

COMMON/USUAL NAME: Double electric breastpump

CLASSIFICATION NAMES: 884.5160 Powered breast pump

REVIEW PANEL: Obstetrics/Gynecology

PRODUCT CODE: HGX

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	☐	☒
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	☒	☐
Does the device contain components derived from a tissue or other biologic source?	☐	☒
Is the device provided sterile?	☐	☒
Is the device intended for single use?	☐	☒
Is the device a reprocessed single use device?	☐	☒
If yes, does this device type require reprocessed validation data?	☐	☐
Does the device contain a drug?	☐	☒
Does the device contain a biologic?	☐	☒
Does the device use software?	☒	☐
Does the submission include clinical information?	☒	☐
Is the device implanted?	☐	☒

Two electronic copies are also provided and these eCopies are exact duplicates of the paper copy.

CONFIDENTIALITY

Medela considers the information in this submission to be confidential commercial information. We have not, to our knowledge, released this information through advertising or any other manner to anyone outside the employ of Medela. Medela has taken precautions to protect the confidentiality of this information under Section 807.95, Confidentiality of Information. We ask that this notification and proprietary information herein be treated as confidential in accordance with the Freedom of Information Act.

Medela appreciates the administrative and scientific considerations relevant to this submission, and we look forward to receiving a timely decision by the FDA regarding the information presented. Should you have any questions regarding the contents of this submission, please me at (b)(4) or Orlando Antunes as the alternate contact by telephone +41 (0)41 561 66 71 or e-mail at orlando.antunes@medela.ch.

Sincerely,

(b)(6)
Member

SECTION 4

INDICATIONS FOR USE STATEMENT

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Freestyle®

Indications for Use *(Describe)*
The Freestyle® is a powered breastpump to be used by lactating women to express and collect milk from their breasts.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

510(k) Summary

K_____

In accordance with 21 CFR 807.92 the following summary of information is provided:

DATE: February 23, 2015

SUBMITTER:

Medela AG
Lättichstrasse 4b
6341 Baar / Switzerland
Phone +41 (0)41 769 51 51
Fax + 41 (0)41 769 51 00

PRIMARY CONTACT PERSON:

(b)(6)
(b)(4)

SECONDARY CONTACT PERSON:

Orlando Antunes
Vice President Regulatory Affairs
Medela AG

DEVICE:

TRADE NAME: Freestyle®

COMMON/USUAL NAME: Double electric breastpump

CLASSIFICATION NAMES: 884.5160 Powered breast pump

PRODUCT CODE: HGX

PREDICATE DEVICE(S):

Lansinoh powered electric breast pump (K122474)

DEVICE DESCRIPTION:

The Medela Freestyle® double electric breastpump system is comprised of the Freestyle® pump (motor unit), the Freestyle® media separation pump kit including tubing, the rechargeable battery, the AC/DC power supply and soft good accessories (tote bag, cooler bag with ice pack). The Medela Freestyle® pump is a double electric breastpump for pumping breastmilk from a single breast or simultaneously from both breasts of a lactating woman by applying a cyclic negative pressure.

The Freestyle® double electric breastpump is a mobile, personal, medical device that includes Medela's 2-Phase Expression technology and is intended to be used by a single user in a closed space as for example a home or office environment.

The Medela Freestyle® double electric breastpump is AC/DC powered and incorporates a DC-motor with membrane aggregate in its pump motor unit. A user friendly display offers information as for example duration of pump session or set vacuum level. The Freestyle® double electric breastpump is mobile and can be operated by connecting to the power supply and / or by rechargeable battery. The connection port for the power supply is located at the bottom side of the pump unit. The battery compartment is at the back of the pump motor unit and is covered by a battery door. The runtime of the removable lithium-ion battery is influenced by the number and duration of pumping sessions and lasts usually for one day. When the Freestyle® pump motor unit is connected to the power supply, the battery is recharged automatically.

A variety of accessories are available for use with the Freestyle® or are intended to be marketed with these pumps.

INTENDED USE:

The Freestyle® is a powered breastpump to be used by lactating women to express and collect milk from their breasts.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

The Freestyle® double electric breastpump uses the same fundamental technology as the Lansinoh powered electric breast pump (K122474). Its 2-phase expression technology is the same as used in other Medela breast pumps, including the Medela Symphony (K020518).

The table below summarizes the key specifications of the Freestyle® and the predicate devices.

Medela AG

Freestyle® double electric breast pump

Device name	**Freestyle® Breastpump**	**Lansinoh powered electric breast pump, now marketed as Lansinoh Affinity Pro (K122474)**	**Discussion**
Indications for Use	The Freestyle® is a powered breastpump to be used by lactating women to express and collect milk from their breasts.	The Powered Breast Pump is intended to express and collect the breast milk of a nursing woman for the purpose of feeding the collected milk to a baby. The Powered Breast Pump is intended for a single user.	Equivalent. Both devices express and collect milk.
Intended Use	Express and collect milk	Express and collect milk	Identical
Single user device	Yes	Yes	Identical
Environment of Use	Home	Home	Identical
User Interface	Hardware interfaces	Hardware interfaces	
User Control	On-off switch Vacuum/Cycle-adjustment control	On-off switch Vacuum-adjustment control Cycle-adjustment control	Equivalent – Affinity Pro has two independent controls for vacuum and cycles. Freestyle's® uses a single control to adjust vacuum and cycles together. Freestyle's® controls are the same as reference Symphony (K020518).
Visual Indicator	LCD display	LCD display	Equivalent
Pumping Options	Single or Double	Single or Double	Equivalent
Accessories	A variety of accessories for: • Collection of milk • Storage of milk • Breast care • Providing Power • Carrying • Cleaning • Feeding	A variety of accessories for: • Collection of milk • Storage of milk • Breast care • Providing Power • Carrying	Equivalent – both systems come with or make available a variety of accessories that can be used with the pump for collection and storage of breast milk, providing power, carrying and breast pump. Freestyle® has additional accessories for cleaning its components and feeding stored milk.
Media Separation	Yes	Yes	Equivalent

Medela AG

Freestyle® double electric breast pump

Device name	Freestyle® Breastpump	Lansinoh powered electric breast pump, now marketed as Lansinoh Affinity Pro (K122474)	Discussion
Specifications			
Power Supply	• Li-Ion battery or • AC adaptor provided	• 6 AA batteries or • AC adaptor provided	Equivalent
Suction Levels (stimulation)	40 - 140 mmHg	55 - 140 mmHg	Equivalent – vacuum levels are user adjustable, with Freestyle® having the ability to pump at a lower vacuum
Cycles per Second (stimulation)	1.7-1.93	1.55 – 2.4	Equivalent
Suction Levels (expression)	45 – 245 mmHg	80 -220 mmHg	Equivalent – vacuum levels are user adjustable, with Freestyle® having the ability to pump at a lower vacuum
Cycles per Section (Expression)	0.83-1.36	0.61-1.52	Equivalent
Maximum vacuum	270 mmHg	Not available	Equivalent
Suction Settings	9	8	Equivalent
Adjustable Suction Levels	Yes	Yes	Identical
Let-Down Button	Yes	Yes	Identical
Cycling Control Mechanism	Microcontroller	Microcontroller	Equivalent
Back Flow Protection	Yes	Yes	Equivalent

Device name	**Freestyle® Breastpump**	**Lansinoh powered electric breast pump, now marketed as Lansinoh Affinity Pro (K122474)**	**Discussion**
2-phase expression	Yes	Yes	Equivalent. Both devices offer an initial simulation phase that moves to expression phase after two minutes. Freestyle's® 2-phase expression technology is also equivalent to reference device Symphony (K020518). Refer to **Exhibit 12.1** for additional discussion.

SUMMARY OF NON-CLINICAL TESTS:

The Freestyle® double electric breast pump complies with voluntary standards for electrical safety, electromagnetic compatibility, use in the home healthcare environment and powered suction pumps. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Cleaning Validation
- Biocompatibility Evaluation
- Software Validation
- Electrical safety and electromagnetic compatibility testing per IEC 60601-1 and IEC 60601-1-2 standards, respectively
- Safety testing for use in the home per IEC 60601-1-11 standard
- Usability evaluation and validation.
- Performance testing demonstrating compliance with EN ISO 10079-1: 2009 Particular requirements for the safety of electrically powered suction equipment
- Performance Testing to determine the vacuum performance, including minimum and maximum vacuum levels for the pump as compared to the predicate device, vacuum stability, overflow performance, durability and pump temperatures during operation.

SUMMARY OF CLINICAL TESTS:

Clinical testing was not required to demonstrate the substantial equivalence of the Freestyle® double electric breast pump to its predicate device. However, published research studies are referenced support marketing claims.

CONCLUSION:

The differences between the Freestyle® double electric breast pump and its predicate devices do not introduce a new intended use and do not raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended.

From the results of nonclinical testing described, Medela AG concludes that the Freestyle® double electric breast pump is substantially equivalent to the legally marketed predicate device.

SECTION 6

PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify, in my capacity as Vice-President Regulatory Affairs of Medela AG, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Orlando Antunes

Date: 3. Feb. 2015

SECTION 7

CLASS III SUMMARY AND CERTIFICATION

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

This section is not applicable to this submission for the Medela AG Freestyle® powered breast pump. The Freestyle® and its predicate device(s) have been classified as Class II devices in accordance with 21 CFR 884.5160 Powered breast pump.

SECTION 8

FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

MEDELA AG

FREESTYLE® DOUBLE ELECTRIC BREAST PUMP

(b)(4) Financial Information

(b)(4) Financial Information

(b)(4) Financial Information

(b)(4) Financial Information

(b)(4) Financial Information

(b)(4) Financial Information

EXHIBIT 8.1

FDA FORM 3455 FINANCIAL DISCLOSURE

(b)(4) Financial Information

EXHIBIT 8.2

FINANCIAL DISCLOSURE DATA

MEDELA RESEARCH BUDGET 2011

(b)(4)

[redacted]

(b)(4) Financial Information

(b)(4) Financial Information

(b)(4) Financial Information

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(b)(4) Financial Information

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SECTION 9

DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

SECTION 9: DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

9.1 STANDARDS:

The Medela Freestyle® double electric breast pump was designed and tested for compliance to the following standards. FDA Form3654 for each of these standards is located in **Exhibit 9.1**.

Reference	Title
IEC 60601-1:2005 (3rd Edition)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-11:2010	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
ISO 14971:2007	Medical devices - Application of risk management to medical devices
EN ISO 10079-1: 2009	Particular requirements for the safety of electrically powered suction equipment

9.2 GUIDANCE DOCUMENTS:

The following guidance documents were followed:

Date of Issue	Guidance Title
September 17, 2007	Guidance for Industry and FDA Staff; Recognition and Use of Consensus Standards;
August 12, 2005 (Corrections November 17, 2005)	Format for Traditional and Abbreviated 510(k)s
December 31, 2012	Refuse to Accept Policy for 510(k)s.

Date of Issue	Guidance Title
December 31, 2012	eCopy Program for Medical Device Submissions
May 11, 2005	Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices
January 11, 2002	General Principles of Software Validation
prior to February 27, 1997	Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care
April 19, 2001	Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers
prior to February 27, 1997	Human Factors Principles for Medical Device Labelling
July 18, 2000	Medical Device Use-Safety: Incorporating Human Factors into Risk Management
June 22, 2011	Applying Human Factors and Usability Engineering to Optimize Medical Device Design,
May 1, 1995	Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' (Replaces #G87-1 #8294) (blue book memo)
June 14, 2013	Draft Guidance for Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.

EXHIBIT 9.1

FDA FORMS 3654 FOR STANDARDS

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (iec 60601-1:2005, mod). (General I (QS/RM))

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-77	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (iec 60601-1:2005, mod). (General I (QS/RM))

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

See Test Report in Section 17 for options selected and clauses that are not applicable.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2 Edition 3:2007-03, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests. (General I (QS/RM))

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-53	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601-1-2 Edition 3:2007-03, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests. (General I (QS/RM))

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

See Test Report in Section 17 for options selected and clauses that are not applicable.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-11:2010, Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-82	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Medical Device Patient Labeling; Incorporating Human Factors Engineering into Risk Management

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601-1-11:2010, Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

See Test Report in Section 17 for options selected and clauses that are not applicable.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971 Second edition 2007-03-01, medical devices - application of risk management to medical devices. (General I (QS/RM))

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-40	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO 14971 Second edition 2007-03-01, medical devices - application of risk management to medical devices. (General I (QS/RM))

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

See Section 16 for risk management documentation.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EN ISO 10079-1: 2009 Particular requirements for the safety of electrically powered suction equipment

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] #		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
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If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
EN ISO 10079-1: 2009 Particular requirements for the safety of electrically powered suction equipment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Refer to Section 18 for full test report

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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SECTION 10

EXECUTIVE SUMMARY

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

SECTION 10: EXECUTIVE SUMMARY

10.1 DEVICE DESCRIPTION

The Medela Freestyle® double electric breastpump system is comprised of the Freestyle pump (motor unit), the Freestyle media separation pump kit including tubing, the rechargeable battery, the AC/DC power supply and soft good accessories (tote bag, cooler bag with ice pack). The Medela Freestyle pump is a double electric breastpump for pumping breastmilk from a single breast or simultaneously from both breasts of a lactating woman by applying a cyclic negative pressure.

The Freestyle double electric breastpump is a mobile, personal, medical device that includes Medela's 2-Phase Expression technology and is intended to be used by a single user in a closed space as for example a home or office environment.

The Medela Freestyle double electric breastpump is AC/DC powered and incorporates a DC-motor with membrane aggregate in its pump motor unit. A user friendly display offers information as for example duration of pump session or set vacuum level. The Freestyle double electric breastpump is mobile and can be operated by connecting to the power supply and / or by rechargeable battery. The connection port for the power supply is located at the bottom side of the pump unit. The battery compartment is at the back of the pump motor unit and is covered by a battery door. The runtime of the removable lithium-ion battery is influenced by the number and duration of pumping sessions and lasts usually for one day. When the Freestyle pump motor unit is connected to the power supply, the battery is recharged automatically.

A variety of accessories are available for use with the Freestyle® or are intended to be marketed with these pumps.

10.2 INTENDED USE

The Freestyle® is a powered breastpump to be used by lactating women to express and collect milk from their breasts.

10.3 TECHNOLOGY

The Freestyle double electric breastpump uses the same fundamental technology as the Lansinoh powered electric breast pump (K122474), which is now marketed as the Lansinoh Affinity Pro. Its 2-phase expression technology is the same as used in other Medela breast pumps, including the Medela Symphony (K020518).

10.4 COMPARISON SUMMARY

The Freestyle is equivalent to the predicate device in its indications for use. The user interface is also similar to the predicate devices. The table below summarizes the key differences between the Freestyle and the predicate device.

TABLE 10.1 COMPARISON OF FREESTYLE TO PREDICATE DEVICE

Device name	**Freestyle® Breastpump**	**Lansinoh powered electric breast pump, now marketed as Lansinoh Affinity Pro (K122474)**
Indications for Use	The Freestyle® is a powered breastpump to be used by lactating women to express and collect milk from their breasts.	The Powered Breast Pump is intended to express and collect the breast milk of a nursing woman for the purpose of feeding the collected milk to a baby. The Powered Breast Pump is intended for a single user.
Intended Use	Express and collect milk	Express and collect milk
Single user device	Yes	Yes
Environment of Use	Home	Home
User Interface	Hardware interfaces	Hardware interfaces
User Control	On-off switch Vacuum/Cycle-adjustment control	On-off switch Vacuum-adjustment control Cycle-adjustment control
Visual Indicator	LCD display	LCD display
Pumping Options	Single or Double	Single or Double
Accessories	A variety of accessories for: • Collection of milk • Storage of milk • Breast care • Providing Power • Carrying • Cleaning • Feeding	A variety of accessories for: • Collection of milk • Storage of milk • Breast care • Providing Power • Carrying •
Media Separation	Yes	Yes

Device name	**Freestyle® Breastpump**	**Lansinoh powered electric breast pump, now marketed as Lansinoh Affinity Pro (K122474)**
Specifications		
Power Supply	• Li-Ion battery or • AC adaptor provided	• 6 AA batteries or • AC adaptor provided
Suction Levels (stimulation)	40 - 140 mmHg	55 - 140 mmHg
Cycles per Second (stimulation)	1.7-1.93	1.55 – 2.4
Suction Levels (expression)	45 – 245 mmHg	80 -220 mmHg
Cycles per Section (Expression)	0.83-1.36	0.61-1.52
Maximum vacuum	270 mmHg	Not available
Suction Settings	9	8
Adjustable Suction Levels	Yes	Yes
Let-Down Button	Yes	Yes
Cycling Control Mechanism	Microcontroller	Microcontroller
Back Flow Protection	Yes	Yes
2-phase expression	Yes	Yes

10.5 TEST SUMMARY

The Freestyle double electric breast pump complies with voluntary standards for electrical safety, electromagnetic compatibility, use in the home healthcare environment and powered suction pumps. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Cleaning Validation
- Biocompatibility Evaluation
- Software Validation

- Electrical safety and electromagnetic compatibility testing per IEC 60601-1 and IEC 60601-1-2 standards, respectively
- Safety testing for use in the home per IEC 60601-1-11 standard
- Usability evaluation and validation.
- Performance testing demonstrating compliance with EN ISO 10079-1: 2009 Particular requirements for the safety of electrically powered suction equipment
- Performance testing to demonstrate that milk overflow will not occur.
- Performance testing to determine the vacuum performance, including minimum and maximum vacuum levels for the pump as compared to the predicate device and vacuum stability
- Performance testing to establish pump durability for continued operation over its specified life
- Performance testing to confirm pump temperatures remain safe during operation.

Neither animal nor clinical testing were required to demonstrate the substantial equivalence of the Freestyle double electric breast pump to its predicate devices. However, results of published research studies that support marketing claims are provided.

10.6 REGULATORY HISTORY

The Medela Freestyle breastpump is a double electric breastpump intended to be used by lactating women in the home environment for expressing breastmilk. There have been no prior FDA submissions related to this medical device. It's design is similar to Medela's Swing breastpump (K053052) and Freestyle was introduced to the European and US markets in 2007. Medela evaluated the differences between the Freestyle and Swing breastpumps in 2007 and determined they were not significant and therefore a letter to file was documented to introduce the Freestyle breastpump as a variant of the Swing breastpump. Compared to the Swing breastpump, the Freestyle breastpump has different performance specifications, including double pumping, but these differences do not affect the indications for use, did not require clinical data to validate and results of design validation did not raise new questions of safety or effectiveness.

Since the introduction of the Freestyle®, design changes including hardware, motor unit, software, kit or minor functionality updates and changes to improve production yield and efficiency have been made. There have also been minor changes that are corrections in the device master record, or changes that do not have any impact the functionality of the system (e.g. minor documentation corrections). All Engineering Change Orders (ECO) followed the design change procedures that include review and approval of design changes prior to implementation and completion of necessary verification or validation testing depending on the

level of the change. All documentation within this 510(k) is comprehensive for the current design including all prior changes.

Medela has recently determined that a 510(k) Premarket Notification would be appropriate for the Freestyle breastpump as it is a unique device that has diverged in its design from the Swing breastpump over the years. This decision was discussed with Becky Robinson, PhD, who was then working as a Biomedical Engineer in the Obstetrics and Gynecology Devices Branch, Division of Reproductive, Gastro-Renal, and Urological Devices on January 12, 2015 and Medela is submitting this 510(k) Premarket Notification as agreed and incorporating FDA's recommendations. **Exhibit 10.1** includes a list of FDA's recommendations with traceability to the location of the recommended information within this submission.

EXHIBIT 10.1

FDA CORRESPONDENCE AND RECOMMENDATIONS

During a phone call and subsequent e-mail between Medela AG and FDA, FDA made the following recommendations for the submission of a Traditional 510(k) for the Freestyle® breastpump. To facilitate review of this information, a reference to the location of the information within the submission is provided.

(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

medela

SECTION 11

DEVICE DESCRIPTION

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

11.1. Indication for use

The Freestyle® is a powered breastpump to be used by lactating women to express and collect milk from their breasts.

11.2. Contraindications

There are no known contraindications for the Freestyle double electric breastpump.

11.3. Freestyle Overview

The Medela Freestyle double electric breastpump system is comprised of the Freestyle pump (motor unit), the Freestyle media separation pump kit including tubing, the rechargeable battery, the AC/DC power supply and soft good accessories (tote bag, cooler bag with ice pack). The Medela Freestyle pump is a double electric breastpump for pumping breastmilk simultaneously from both breasts of a lactating woman by applying a cyclic negative pressure.

The Freestyle double electric breastpump is a mobile personal care item that includes Medela's 2-Phase Expression technology and is intended to be used by a single user in a closed space as for example a home or office environment.

The Freestyle® breastpump contains the following parts:

a) Freestyle pump (motor unit)
b) Freestyle pump kit with media separation
c) Medela PersonalFit breastshields in 2 sizes (24 mm/size M and 27 mm/size L)
d) Freestyle tubing with a port for single pumping option
e) Freestyle power supply
f) Freestyle rechargeable lithium-ion battery
g) Tote bag
h) Cooler bag with included ice pack
i) Milk bottles
j) Instruction for use and Breastfeeding information guide

The Medela Freestyle double electric breastpump is AC/DC powered and incorporates a DC-motor with membrane aggregate in its pump motor unit. A user friendly display offers information as for example duration of pump session or set vacuum level. The Freestyle double electric breastpump is mobile and can be operated by connecting to the power supply and / or by rechargeable battery. The connection port for the power supply is located at the bottom side of the pump unit. The battery compartment is at the back of the pump motor unit and is covered by a battery door. The runtime of the removable lithium-ion battery is influenced by the number and duration of pumping sessions and lasts usually for one day. When the Freestyle pump motor unit is connected to the power supply, the battery is recharged automatically.

The Freestyle pump kit is connected to the pump motor unit with tubing. The T-arm design of the tubing allows an easy set up for a single pumping or for a double pumping session.

On the front face of the Medela Freestyle double electric breastpump, the LCD display is interacting with the software by five pushbuttons to switch on/off the device as well as to

manipulate the settings on the display. An acoustic buzzer as well as optical signals are triggered for variances from the set values.

11.4. Versions and Model Numbers

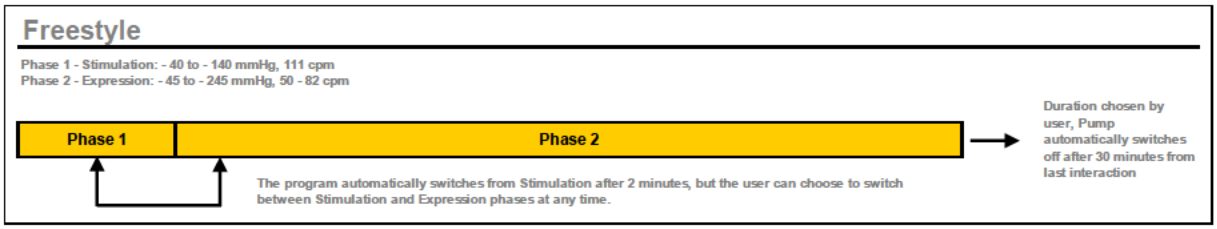
Model #	Description	Description
67060	Freestyle Deluxe	Single unit pack out with complete accessory set (tote, cooler/ice pk, 4 bottles, double pumping kit)
67060T	Freestyle Deluxe	Two unit pack out with complete accessory set (tote, cooler/ice pk, 4 bottles, double pumping kit)
67060BN	Freestyle Solution Set	Single unit pack out of *Deluxe* model with additional box of accessories (Pump & Save Bags, Bra Pads, Lanolin, MicroSteam Bags, Breastfeeding Log, Breastmilk Storage Magnet)
67065	Freestyle Basic	Single unit pack out with limited accessory set (2 bottles, double pumping kit, drawstring dust bag)
67065T	Freestyle Basic	Two unit pack out with limited accessory set (2 bottles, double pumping kit, drawstring dust bag)
67064	Freestyle Motor Warranty	Warranty unit that customer service utilizes for warranty calls. Includes only (motor unit, battery pack, IFU)

11.5. Performance Specifications

The fundamental performance specifications for the Medela Freestyle double electric breastpump system are represented in the table below. The Medela Freestyle double electric breastpump is marketed with a 12-V AC/DC power supply.

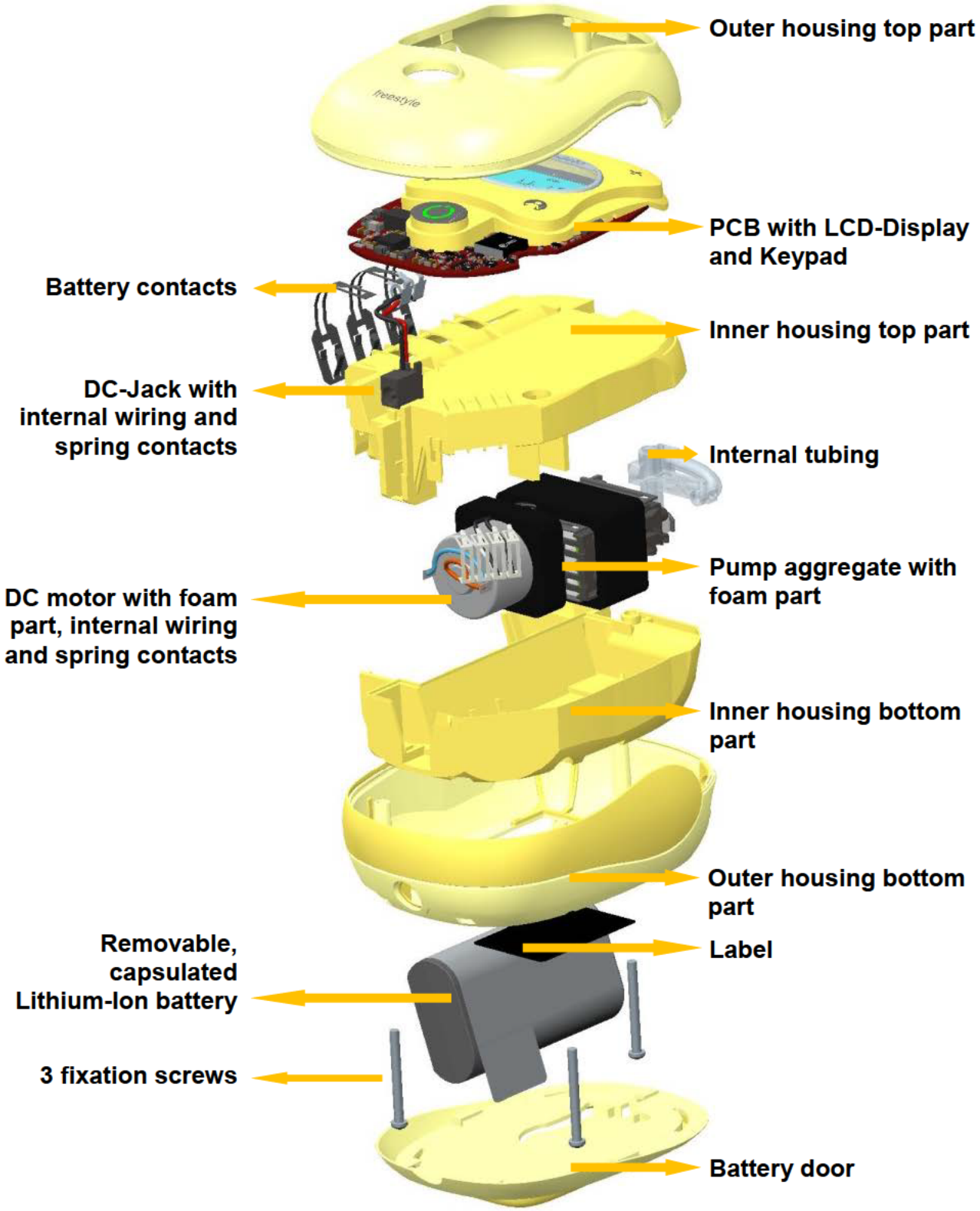
	Medela Freestyle double electric breastpump
Vacuum max	270 mmHg
rated mains voltage	100 - 240 VAC
rated mains frequency	50 -60 Hz
rated voltage power supply	12 VDC
rated current power supply	max. 1.5 ADC
Batteries	Rechargeable battery 7.2 VDC, 2250mAh Lithium-Ion
Weight Freestyle (incl. rechargeable battery)	370 g
dimension l x w x h	90 x 122 x 58 mm
Noise level	< 60dBA
IP code	IP 22

The Freestyle double electric breastpump provides the 2-Phase Expression Technology, which is composed of a "Stimulation" mode of fast cycles and an "Expression" mode of slower cycles. By pressing the milk let down button, the user can switch from the faster Stimulation mode to the slower Expression mode. If the milk let down button is not pressed after two minutes, the pump switches automatically.



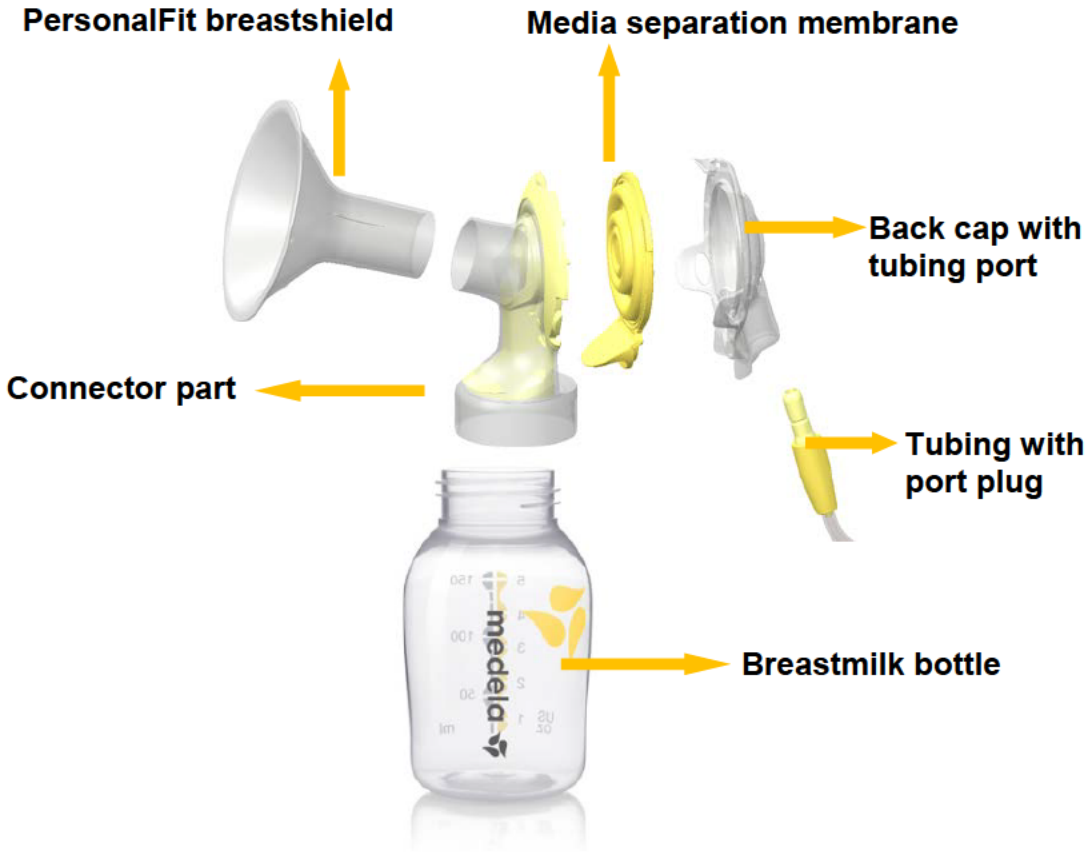
11.6. Construction and principles of operation

The Freestyle double electric breastpump motor unit accommodates the following main elements:



The inner housing parts encapsulate the pump aggregate and the internal tubing. Additionally, it accommodates the spring contacts which connect the PCB to the battery, the DC-Jack and the motor. The inner housing part also accommodates the complete vacuum tubing including tubing connection port. The battery compartment is also built by the two inner housing top and bottom parts. The outer housing top part accommodates the PCB, which is snapped in, and builds in combination with the keyboard an adequate seal against water ingress. The completely pre-assembled inner housing is sandwiched by the outer housing top part with the assembled PCB and the outer housing bottom part and will be secured by 3 screws. The battery door can be easily moved by sliding it on/off so that the removable, capsulated battery can be inserted or removed.

The Freestyle pump kit accommodates the following main elements:

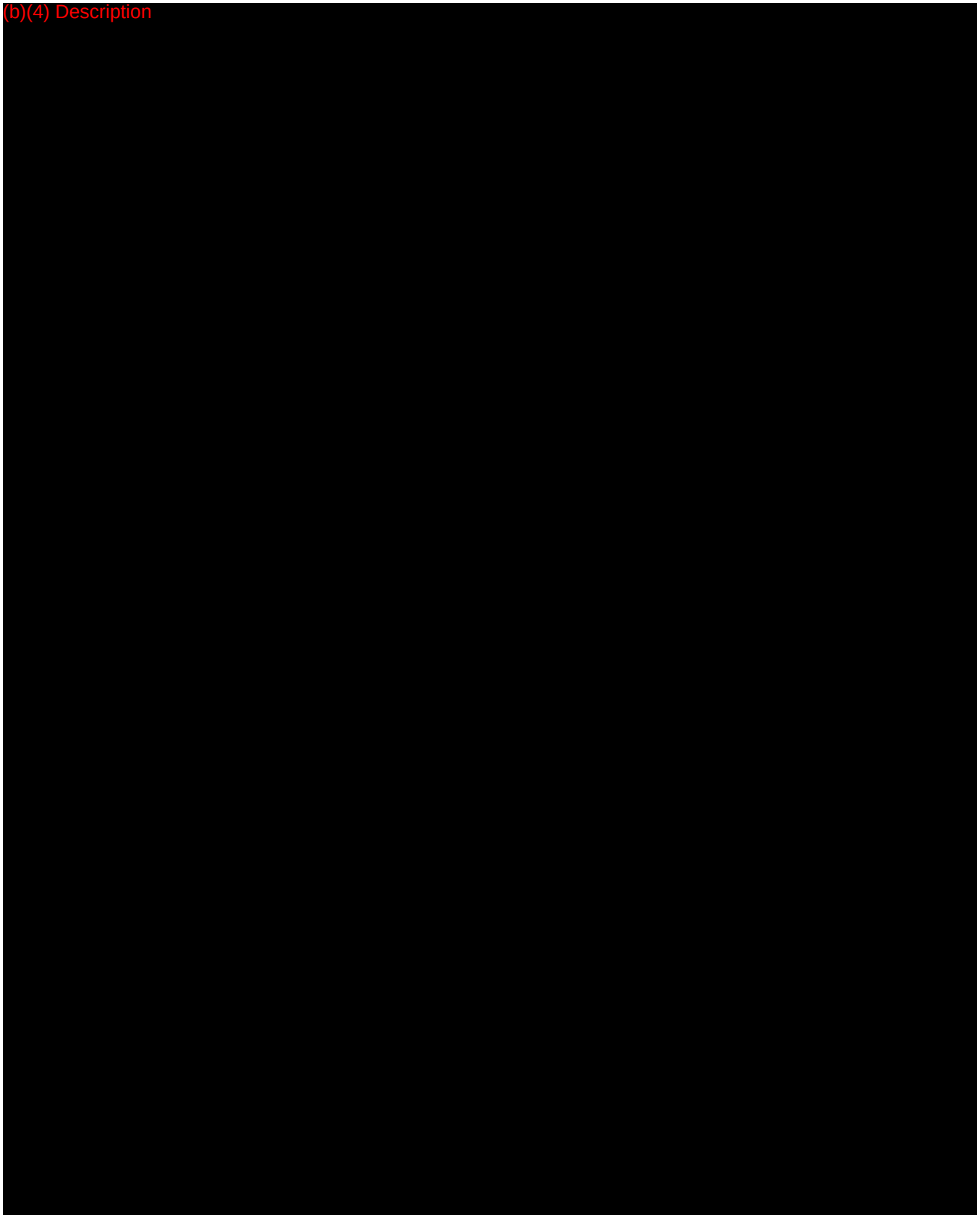


The central part of the Freestyle pump kit is the connector part. It provides a port to connect the full range of PersonalFit breastshields (21mm / size S up to 36 mm / size XXL). At the back of the connector part, the media separation membrane with an included milk valve is assembled and covered by the back cap. The back cap also incorporates the tubing port. Any Medela breastmilk bottle can be screwed to the connector part to collect the milk pumped through the PersonalFit breastshield, the connector part and the milk valve.

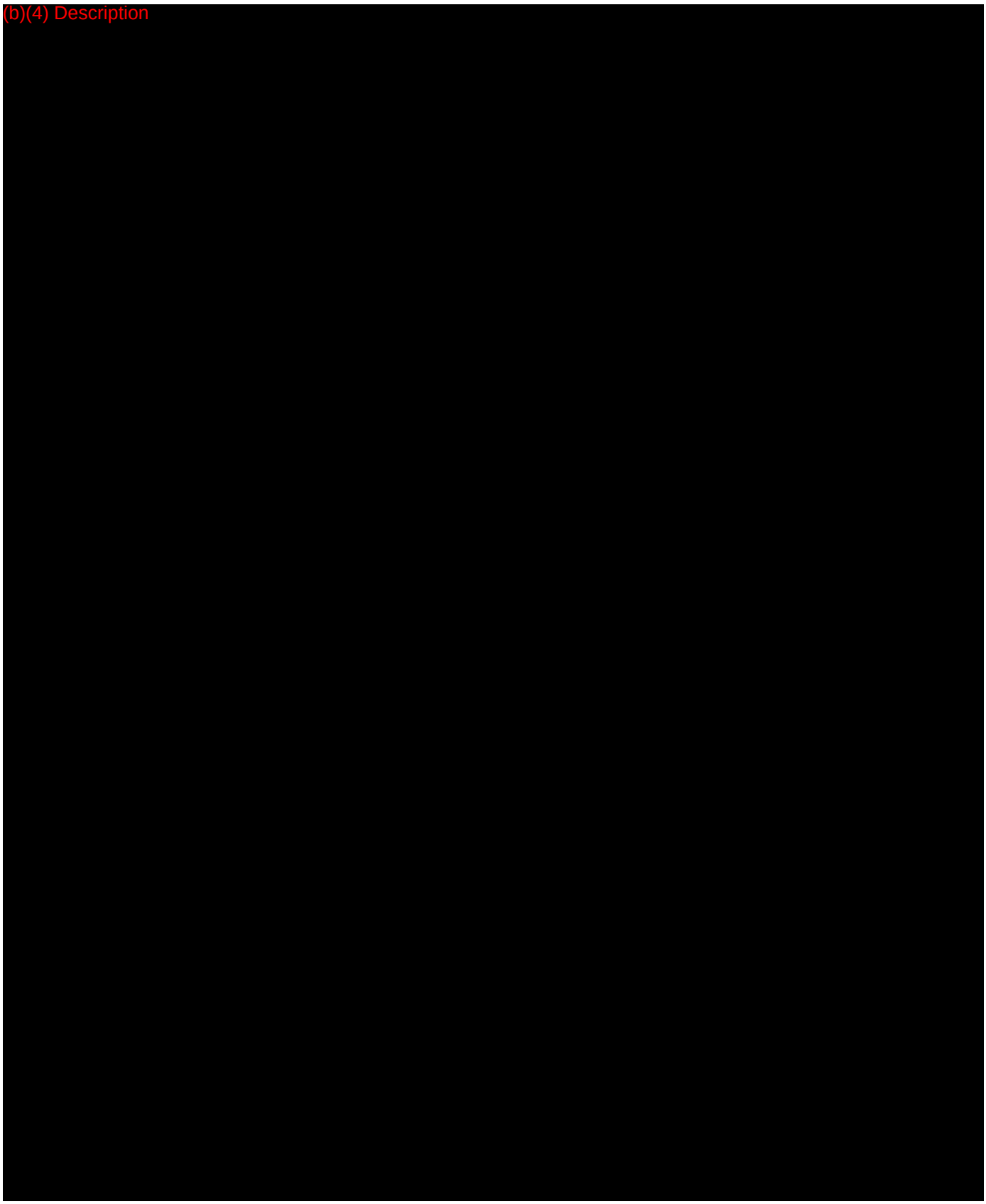
This diagram depicts the functional principle of the Medela Freestyle double electric breastpump system.

(b)(4)

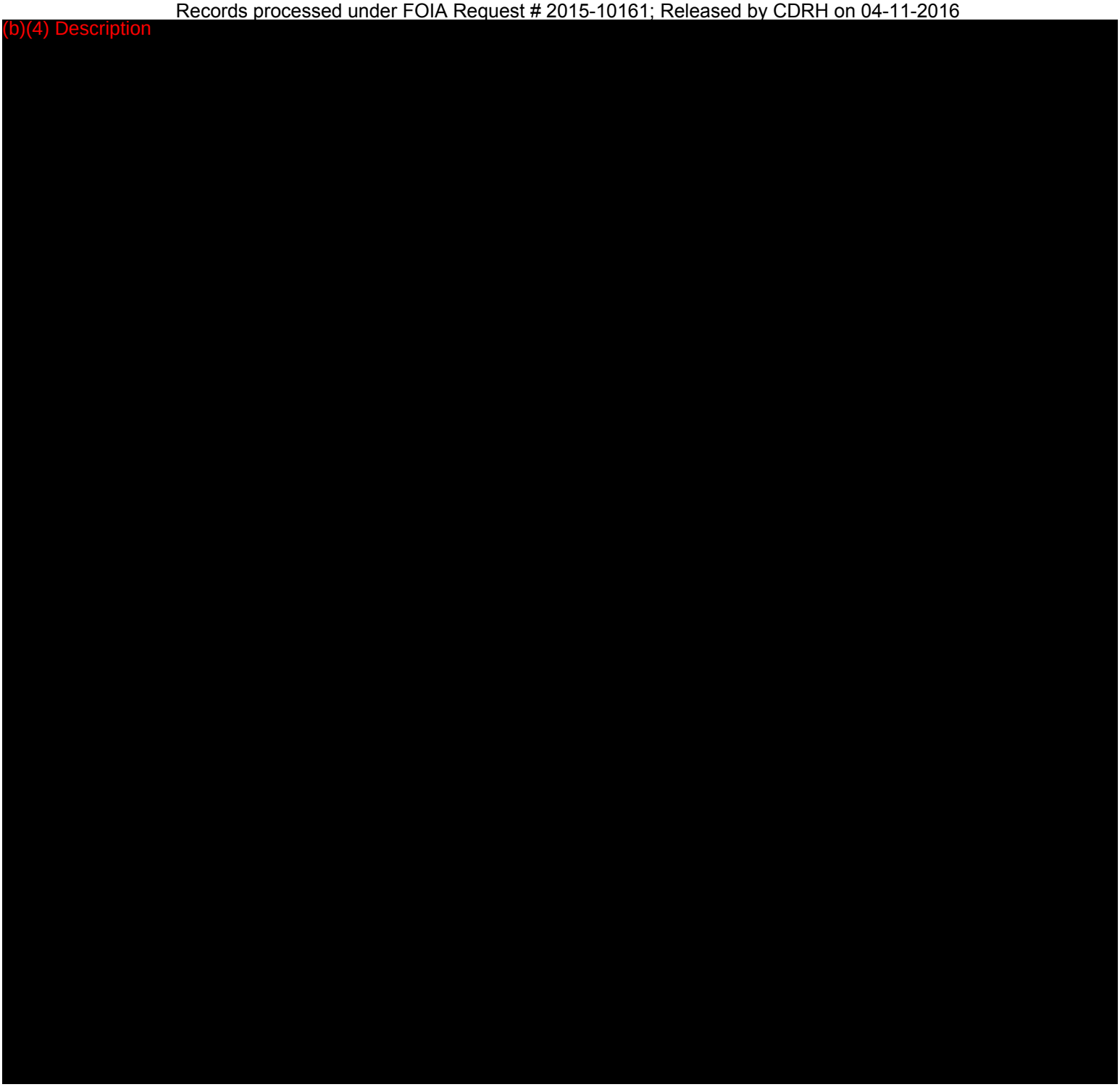
(b)(4) Description



(b)(4) Description



(b)(4) Description



(b)(4) Description

[redacted]

(b)(4) Description

11.6.4. User interface

The Medela Freestyle double electric breastpump is operated via a back lit LCD display and five buttons aligned around the display. The functions of the LCD display and the buttons can be described as following:

a) Power on/off button with green backlight when pump is running
b) " – " Button to decrease the vacuum by one level per activation
c) " + " Button to increase the vacuum by one level per activation
d) "LetDown" Button to manually switch from stimulation to expression mode and vice versa
e) "Memory" Button to save the preferred level setting
f) Numeric display, indicating the vacuum level while increasing / decreasing (for example "L6" for level 6) or indicating the duration of the current pump session (for example 12:47 for 12 minutes and 47 seconds since start of the pump)
g) Level indicator while pump is in stimulation mode
h) Level indicator while pump is in expression mode
i) Indicator when pump is connected to DC-power supply
j) Battery level indicator
k) Memory symbol to indicate successfully saving of preferred level setting

The LCD display is also used for information to the user while charging the battery. In this case, the backlight of the display is turned off. The charging procedure and the battery level indicator reading are described in the instruction for use as shown below:

Before first use, "bAtt" appears in the display. Fully charge the battery until the battery indicator stops flashing and "bAtt" disappears.

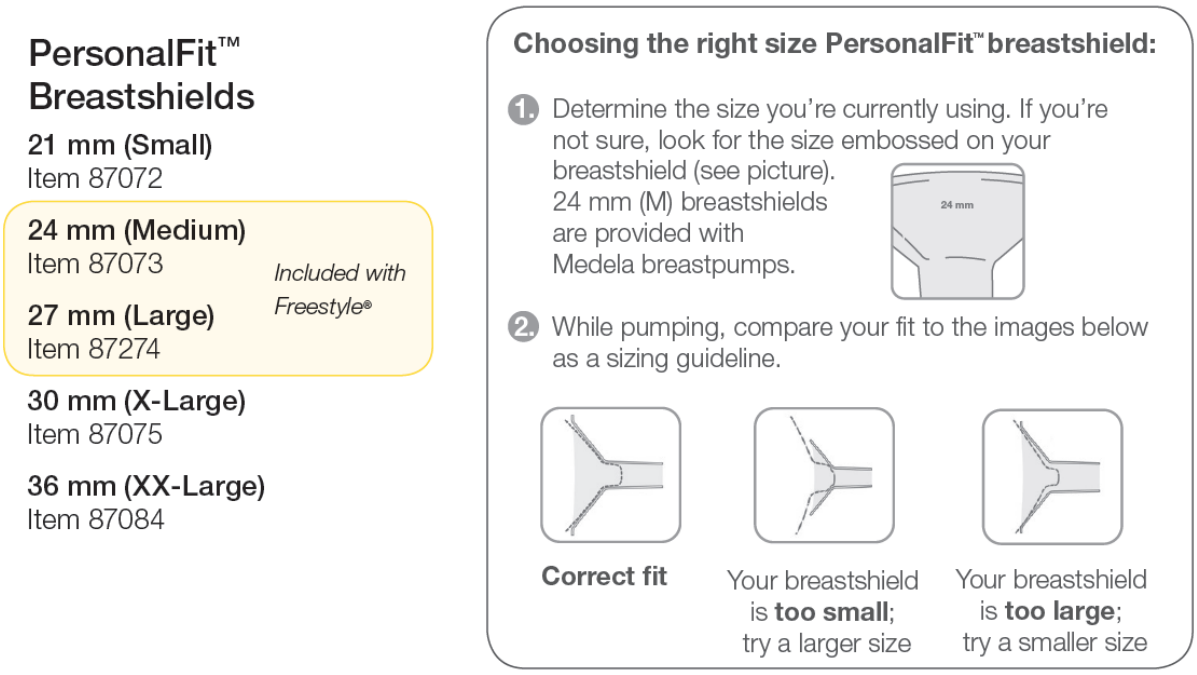
	Power adaptor connected to socket
	Battery charge status
	Battery fully charged, approx. 3 hours' expression
flashing	20 min. expression time remaining. Battery removed from motor unit
flashing	Low battery, needs charging
"bAtt" flashing	Initial charge and charging after removing the battery (up to 24 hours charging time)
"bAtt"	• Appears on display before first use • Will not flash when pump is plugged in to power outlet

11.6.5. Freestyle pump kit

The Freestyle pump kit consists of the following parts:
For a basic description of the Freestyle pump kit components please be referred to section 11.6 of this document.

a) Pair of PersonalFit breastshield in size 24 mm / M
b) Pair of PersonalFit breastshield in size 27 mm / L
c) Medela Freestyle pump kit connector with media separation membrane
d) Tubing with Freestyle port plugs and single pumping port
e) Medela Breastmilk bottles

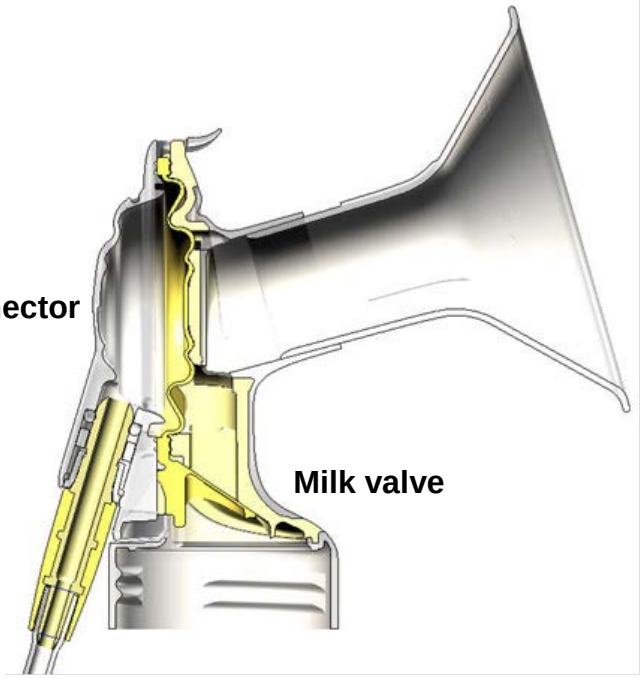
All components in contact to milk or skin are made from polypropylene (PP) and are suitable for food and skin contact. The PersonalFit breastshields provided with the Medela Freestyle double electric breastpump are of size 24mm / M and 27 mm/ L. The instruction for use provides information on the other sizes of PersonalFit breastshields available (size 21 mm / S; size 30 mm / XL or size 36 mm / XXL).



The Freestyle pump kit can be used for single and / or for double pumping. The assembling of the parts is identical. To match the vacuum performance of the Freestyle double electric breastpump motor unit for single pumping, the loose tubing port is plugged into the tubing T-connector single pumping port.

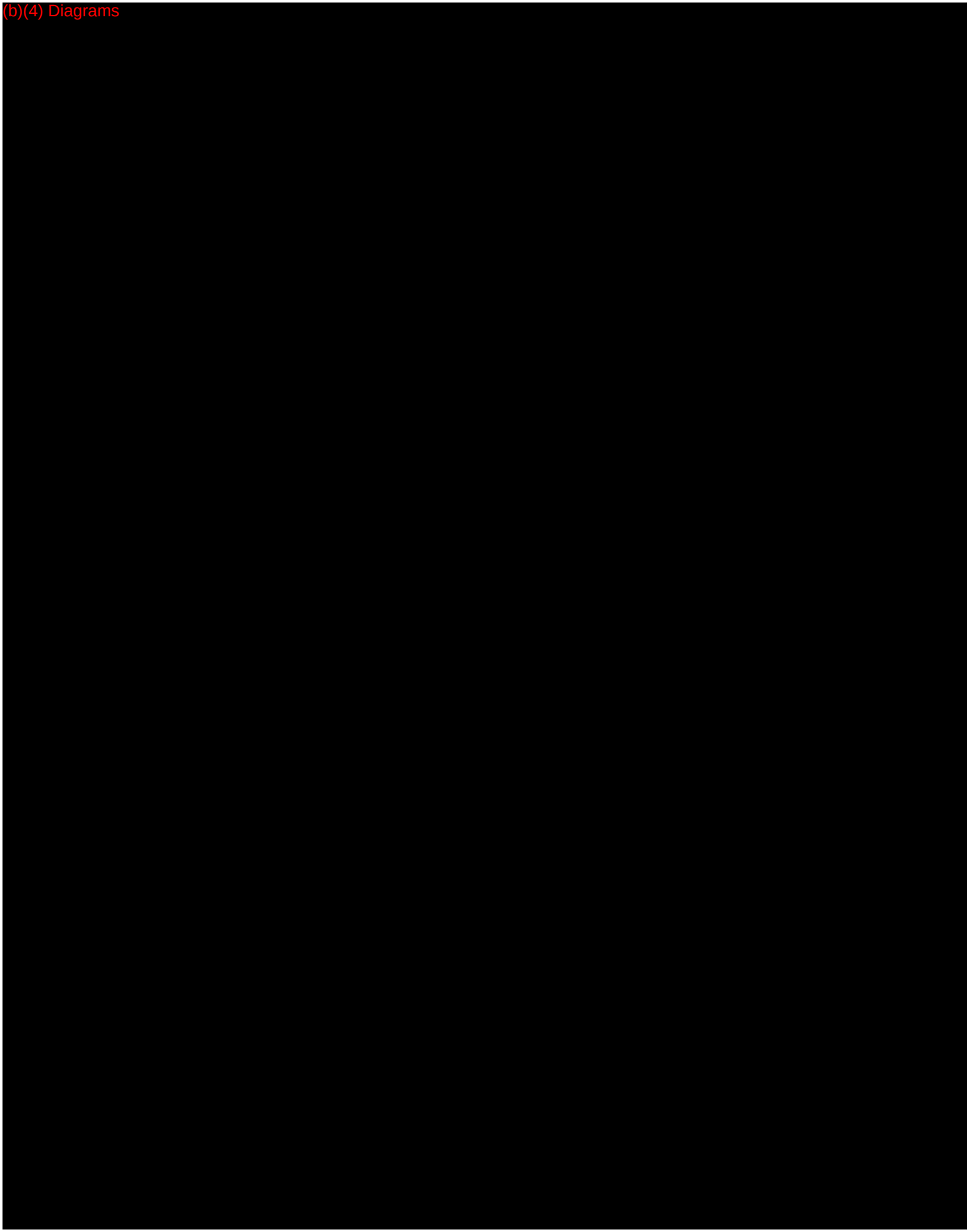
Double pumping

Single pumping

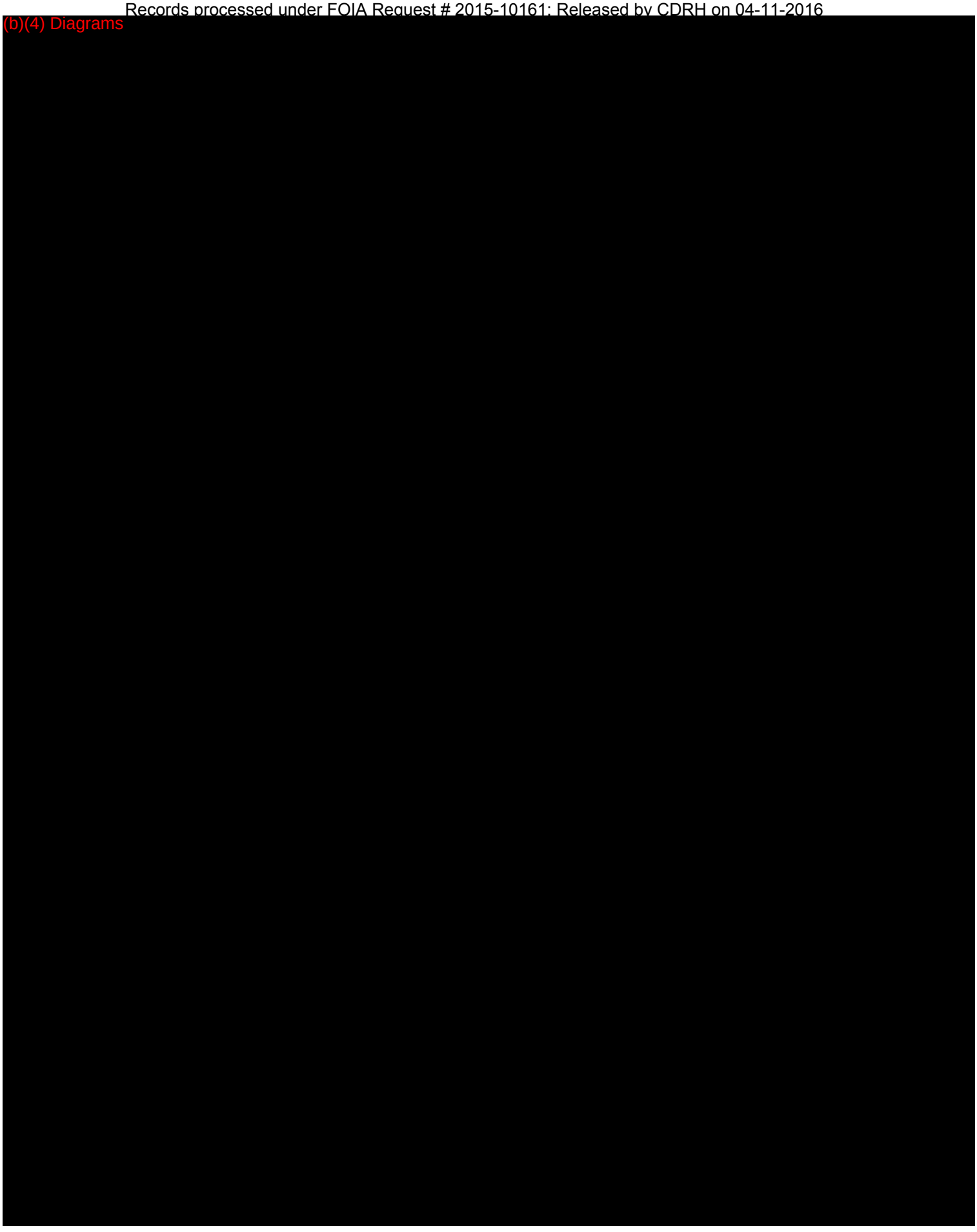


The Freestyle pump kit with its incorporated media separation membrane creates a movable barrier between the breast cavity of the pump set and the pump motor unit. With this, the two cavities are hermetically separated from each other. Therefore, an overflow of milk into the tubing is not possible. The vacuum created from the pump motor unit is transferred to the breast by a dislocation of the media separation membrane towards the back cap wall.

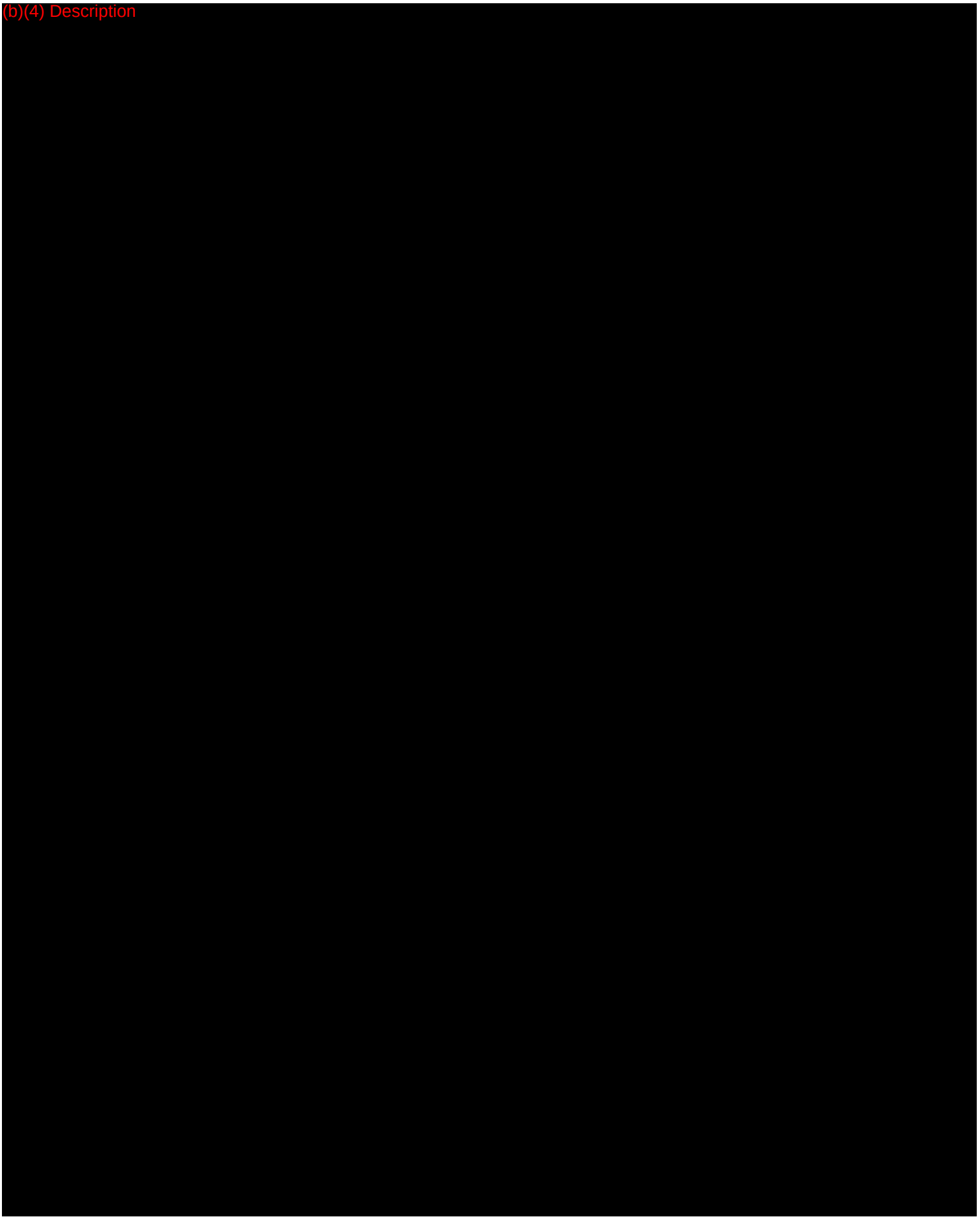
At the beginning of each vacuum cycle, the media separation membrane sits tightly on the connector. The milk valve closes the milk channel in the connector and forms, together with the breast nipple inserted into the PersonalFit breastshield, a closed cavity.


(b)(4) Diagrams

(b)(4) Diagrams



(b)(4) Description



(b)(4) Diagrams

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11.8. Accessories

The following accessories are available for the Medela Freestyle double electric breast pump system. Additional details are presented in the Accessory Descriptions table presented in **Exhibit 11.4** and Accessory Drawings are presented in **Exhibit 11.5**.

Item Sales #	Description	Image
87087 (bulk) 87073 (retail)	Personal Fit 24mm Breastshield	

Item Sales #	Description	Image
87077 (bulk) 87274 (retail)	Personal Fit 27mm Breastshield	
87086 (bulk) 87072 (retail)	Personal Fit 21mm Breastshield	
87079 (bulk) 87075 (retail)	Personal Fit 30mm Breastshield	
87094 (bulk) 87084 (retail)	Personal Fit 36mm Breastshield	
67061	Media separation	

Item Sales #	Description	Image
8007232	Freestyle Tubing	
3007340	Carry Bag	
67068 (retail)	Cooler Carrier	
9207047	Power Adaptor	
87092	Ice Pack	

Item Sales #	Description	Image
6007135	5 oz Breastmilk Bottle Set	
8107183	Lids for Bottle	
9197010	Lithium Ion Battery	
87290 6007142	Accessory Starter Set, including: Pump & Save Bags, Bra Pads, Lanolin, MicroSteam Bags, Breastfeeding Log, Breastmilk Storage Magnet	
89982	Disposable Nursing Pads	
87122NA	Tender Care™ Lanolin – 2 oz	

Item Sales #	Description	Image
87233	Pump & Save™ Bags – 20 count X 2	
1908080	Breastfeeding Log	
1547514	Breastmilk Storage Guidelines Magnet	
87024NA	Quick Clean™ Micro-Steam™ Bags – 5 count	
67801, 67802, 67803, 67804, 67831, 67832, 67833, 67834	Easy Expressions Bustier, white or black, small – X-large	

Item Sales #	Description	Image
67153	12V Portable Vehicle Adaptor	
87240	Quick Clean Breastmilk Removal Soap	
87133	Slow flow silicone nipple	
68020	Calma Breastmilk Feeding Nipple	
87165	Bottle collar (8107182) Bottle travel cap (2001686) Bottle solid discs (8107184)	

Item Sales #	Description	Image
8100462	container stand	
BFS001	Tubing & spare parts kit	

EXHIBIT 11.1

FREESTYLE HARDWARE REQUIREMENTS SPECIFICATION (HRS)

(b)(4)

[redacted]

medela

Hardware Requirements Specifications

(b)(4), (b)(6)

[redacted]

(b)(4) Hardware Requirements Specification

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EXHIBIT 11.2

FREESTYLE HARDWARE DESIGN SPECIFICATION (HDS)

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Hardware Design Specification

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EXHIBIT 11.3

FREESTYLE BATTERY SPECIFICATION

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[redacted]

(b)(4) Battery Specification

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EXHIBIT 11.4

ACCESSORY DESCRIPTIONS

Freestyle Accessories.

Model	Description	Drawing or Specification	Classification	Use	Materials for components contacting skin or milk
Accessories included as part of the system – all models					
(b)(4)					

(b)(4) Accesory Descriptions

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EXHIBIT 11.5

FREESTYLE ACCESSORY DRAWINGS

(b)(4) Schematic Drawings

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Medela Inc., McHenry, IL 60050, USA

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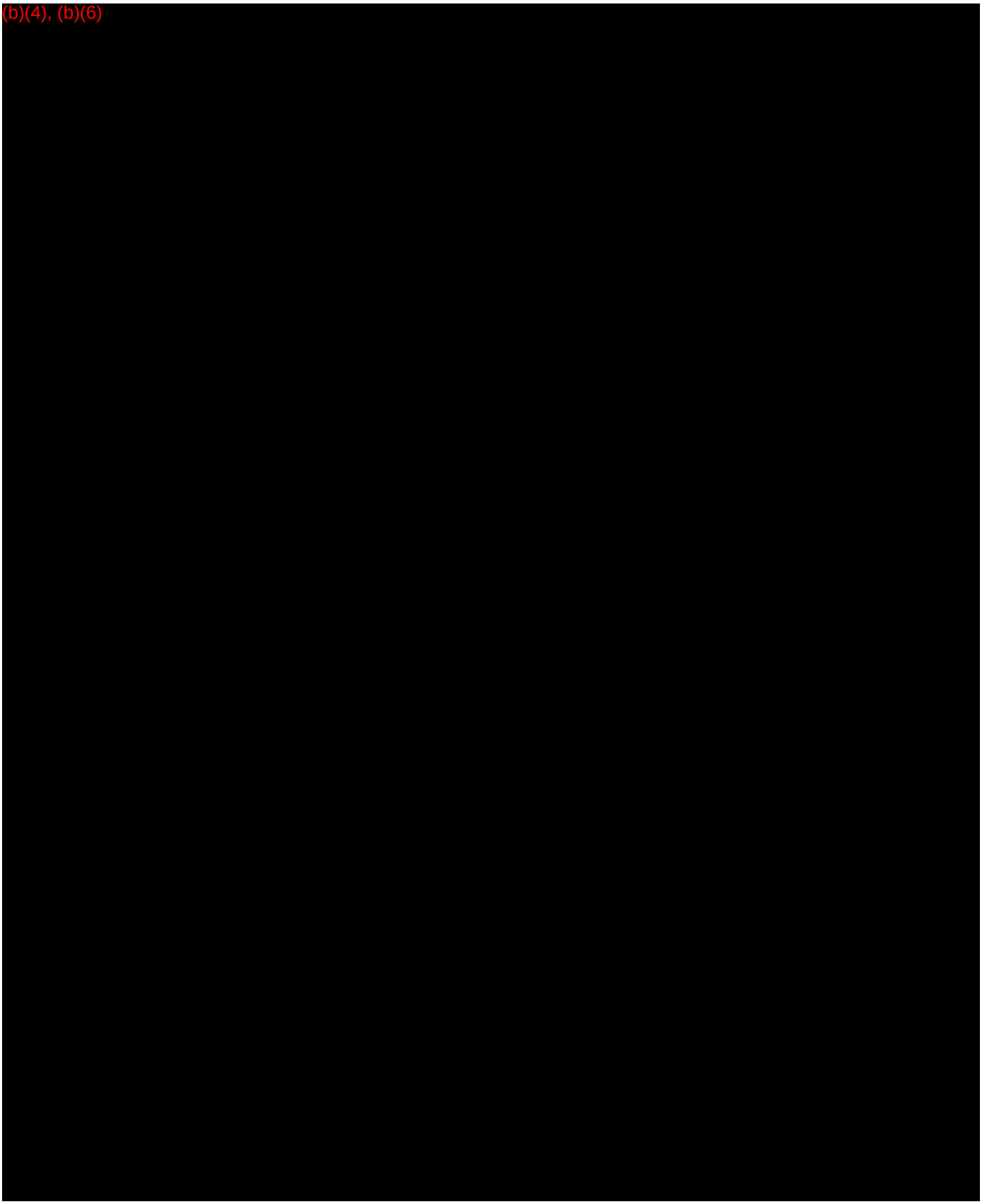

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SECTION 12

SUBSTANTIAL EQUIVALENCE DISCUSSION

MEDELA AG

FREESTYLE BREAST PUMP

12.1 PRODUCT COMPARISON

This comparison identifies the similarities and differences of the proposed Freestyle breast pump to the legally marketed predicate device Lansinoh powered electric breast pump (K122474), now marketed as Lansinoh Affinity Pro. Reference to the Medela Symphony (K020518) breast pump is given to add further support of the user controls and 2-phase expression technology of the Freestyle breast pump.

TABLE 12.1 COMPARISON OF FREESTYLE TO PREDICATE DEVICE

Device name	**Freestyle® Breastpump**	**Lansinoh powered electric breast pump, now marketed as Lansinoh Affinity Pro**	**Discussion**
510(k) Number	not yet assigned	K122474	-
Picture			-
Manufacturer	Medela AG Lättichstrasse 4b CH-6340 Baar	Lansinoh Laboratories Saglik Gerecleri Tasarim San. Tic. Ltd. Sti.	-
Product code	HGX	HGX	Identical

Device name	Freestyle® Breastpump	Lansinoh powered electric breast pump, now marketed as Lansinoh Affinity Pro	Discussion
Indications for Use	The Freestyle® is a powered breastpump to be used by lactating women to express and collect milk from their breasts.	The Powered Breast Pump is intended to express and collect the breast milk of a nursing woman for the purpose of feeding the collected milk to a baby. The Powered Breast Pump is intended for a single user.	Equivalent. Both devices express and collect milk.
Intended Use	Express and collect milk	Express and collect milk	Identical
Single user device	Yes	Yes	Identical
Environment of Use	Home	Home	Identical
User Interface	Hardware interfaces	Hardware interfaces	
User Control	On-off switch Vacuum/Cycle-adjustment control	On-off switch Vacuum-adjustment control Cycle-adjustment control	Equivalent – Affinity Pro has two independent controls for vacuum and cycles. Freestyle's uses a single control to adjust vacuum and cycles together. Freestyle's controls are the same as reference Symphony (K020518).
Visual Indicator	LCD display	LCD display	Equivalent
Pumping Options	Single or Double	Single or Double	Equivalent

Device name	Freestyle® Breastpump	Lansinoh powered electric breast pump, now marketed as Lansinoh Affinity Pro	Discussion
Accessories	• Media separation • Media separation barrier • PersonalFit™ breast shields (21, 24, 27, 30, 36 mm) • Bottle collars • Bottle discs • bottles (5 oz) with lids • bottle holders • AC adapter • Vehicle adapter • Battery • Tubing • tote bag • cooler bag • ice pack • Milk Storage Bags • Nursing pads • Lanolin • Instructions for Use, breastfeeding resource guide, log and storage magnet • Cleaning soap • Microsteam bags • Easy expression bustier • Feeding nipples	• diaphragm caps • diaphragms • breast flange bodies • ComfortFit™ flanges (25 mm) • white valves • container rings • sealing discs • bottles (5 oz) • bottle holders • AC adapter • Y tubing connector • pump connector • silicone tubes • tubing strap • tote bag • Milk Storage Bags • Nursing pads • HPA® Lanolin Sample • Instruction booklet with everything you need to know to get started	Equivalent – both systems come with or make available a variety of accessories that can be used with the pump for collection and storage of breast milk, providing power, carrying and breast pump. Freestyle has additional accessories for cleaning its components and feeding stored milk.

Device name	Freestyle® Breastpump	Lansinoh powered electric breast pump, now marketed as Lansinoh Affinity Pro	Discussion
Media Separation	Yes	Yes	Equivalent
Specifications			
Power Supply	• Li-Ion battery or • AC adaptor provided	• 6 AA batteries or • AC adaptor provided	Equivalent
Suction Levels (stimulation)	40 - 140 mmHg	55 - 140 mmHg	Equivalent – vacuum levels are user adjustable, with Freestyle having the ability to pump at a lower vacuum
Cycles per Second (stimulation)	1.7-1.93	1.55 – 2.4	Equivalent
Suction Levels (expression)	45 – 245 mmHg	80 -220 mmHg	Equivalent– vacuum levels are user adjustable, with Freestyle having the ability to pump at a lower and higher vacuum. The maximum setting is still below 250 mmHg for safety.
Cycles per Section (Expression)	0.83-1.36	0.61-1.52	Equivalent

Device name	Freestyle® Breastpump	Lansinoh powered electric breast pump, now marketed as Lansinoh Affinity Pro	Discussion
Maximum vacuum	270 mmHg	Not available	Equivalent. The Freestyle® vacuum settings include a tolerance of ±25 mmHg, and therefore the highest vacuum may be 270 mmHg. The vacuum has 9 suction settings to reach maximum and can always be decreased if the user finds the pressure uncomfortable.
Suction Settings	9	8	Equivalent
Adjustable Suction Levels	Yes	Yes	Identical
Let-Down Button	Yes	Yes	Identical
Cycling Control Mechanism	Microcontroller	Microcontroller	Equivalent
Back Flow Protection	Yes	Yes	Equivalent

Device name	Freestyle® Breastpump	Lansinoh powered electric breast pump, now marketed as Lansinoh Affinity Pro	Discussion
2-phase expression	Yes	Yes	Equivalent. Both devices offer an initial simulation phase that moves to expression phase after two minutes. Freestyle's 2-phase expression technology is also equivalent to reference device Symphony (K020518). Refer to **Exhibit 12.1** for additional discussion.

12.2 SUBSTANTIAL EQUIVALENCE DISCUSSION

The Freestyle breast pump has been compared to the legally marketed predicate device, Lansinoh powered electric breast pump (K122474), now marketed as Lansinoh Affinity Pro.

Like the predicate device, the Freestyle's indications for use include the expression and collection of breast milk. Thus, the intended use of the Freestyle is also the same as the predicate device.

The Freestyle shares the same or similar device operation, overall technical and functional capabilities as the predicate device. Both breast pumps create the necessary vacuum in an equivalent manner and include two-phase expression with a faster stimulation mode followed by a slower expression mode. Reference to the Medela Symphony (K020518) is given to support the two-phase expression used in the Freestyle since it is the same as this previously cleared Medela pump. Vacuum level can be selected by the user interface of both devices and is controlled by the software.

Verification and validation testing confirms that product specifications are met which are equivalent in design and technological characteristics as the predicate device. The testing results support that the biocompatibility, cleaning, electrical safety, and functionality of the Freestyle were acceptable for the device.

12.3 SUBSTANTIAL EQUIVALENCE CONCLUSION

This comparison of the specifications demonstrates the functional equivalence of the products. The differences discussed in this section do not alter the intended use of the breast pump or raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences.

Medela AG believes that the Freestyle® double electric breast pump is as safe and effective, and performs in a substantially equivalent manner to the predicate device.

EXHIBIT 12.1

EQUIVALENCY OF 2-PHASE EXPRESSION TECHNOLOGY

Equivalency Statement for the 2-Phase Expression Technology for Medela Freestyle double electric breastpump in comparison to Medela Symphony hospital grade breastpump (K020518).

Medela's emphasis on research of the natural feeding behavior of infants led to the innovation of 2-Phase Expression Technology, which Medela has successfully implemented in all breastpumps that came to market since 2002. Through research, Medela learned that there are two distinct phases of how babies breastfeed. When babies first go to breast, they suck faster to start milk flowing. Medela uses the terminology "Stimulation" for the mimicking of this phase. After milk flow or "let-down" starts, babies breastfeed with a slower deeper suck to remove milk. Medela uses the terminology "Expression" for the mimicking of this phase. The Medela Symphony hospital grade breastpump was the first pump ever offering the beneficial 2-Phase technology to pumping mothers. The Figure 1 graphically depicts the 2-Phase pattern implemented in the Medela Symphony hospital grade breastpump over the duration of a pump session.

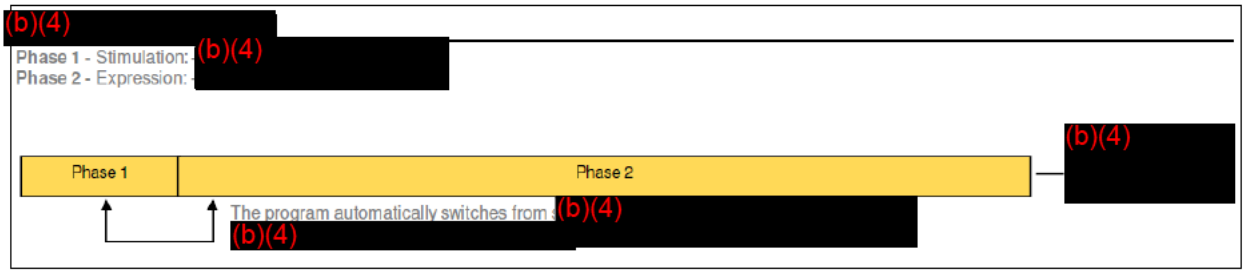


Figure 1: 2-Phase patterns for Medela Symphony hospital grade breastpump

When the Medela Symphony hospital grade breastpump is started, the pump generates a Stimulation pattern (Phase 1) with (b)(4) per minute (cpm) and a vacuum of approximately (b)(4) The user can now adjust the vacuum level between approximately 50 – 200 mmHg. The cycle rate in Stimulation phase is fixed at (b)(4) independent of the vacuum level. When milk ejection occurs, the user can switch to the Expression pattern (Phase 2) by pressing the "Let-Down Button". If the "Let-Down Button" is not pressed (b)(4) of pumping in Stimulation, the Medela Symphony hospital grade breastpump automatically switches to the Expression pattern (Phase 2). The user can now again adjust the vacuum level between approximately (b)(4). In the Expression phase, the cycles rate is fixed fix relation to the vacuum level. (b)(4) (b)(4). If wished, the user can switch from Expression back to Stimulation by pressing the "Let-Down Button" again.

In comparison to the Medela Symphony hospital grade breastpump, the principle of the Medela Freestyle double electric breastpump is depicted below in Figure 2.

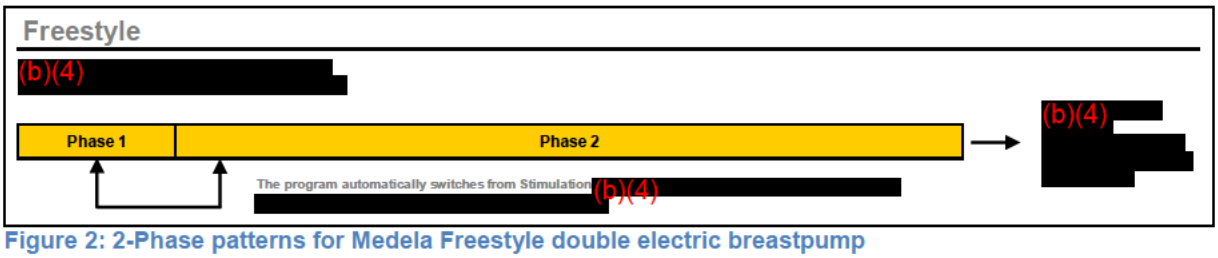


Figure 2: 2-Phase patterns for Medela Freestyle double electric breastpump

When the Medela Freestyle double electric breastpump is started, the pump generates a Stimulation pattern (Phase 1) with (b)(4) (b)(4) and a vacuum of approximately (b)(4) ((. The user can now adjust the vacuum level between approximately (b)(4). The cycle rate in Stimulation phase is fixed (b)(4) independent of the vacuum level. When milk ejection occurs, the user can switch to the Expression pattern (Phase 2) by pressing the "Let-Down Button". If the "Let-Down Button" is not pressed (b)(4) pumping in Stimulation, the Medela Freestyle double electric breastpump automatically switches to the Expression pattern (Phase 2). The user can now again adjust the vacuum level between approximately (b)(4). In the Expression phase, the cycle rate is fixed relation to the vacuum level. (b)(4) (b)(4) If wished, the user can switch from Expression back to Stimulation by pressing the "Let-Down Button" again.

As can be seen from above description, the implementation of the Medela 2-Phase expression technology for the Symphony hospital grade breastpump and the Freestyle double electric breastpump are very similar.

The minimal differences for Stimulation (Phase1) are:

	Symphony hospital grade breastpump	Freestyle double electric breastpump
Stimulation vacuum range:	- 50 to – 200 mmHg	- 45 to – 140 mmHg
Stimulation cycles:	(b)(4)	(b)(4)

The minimal differences for Expression (Phase2) are:

	Symphony hospital grade breastpump	Freestyle double electric breastpump
Expression vacuum range:	- 50 to – 250 mmHg	- 45 to – 245 mmHg
Expression cycles:	(b)(4)	(b)(4)

Discussion of differences:

For the Stimulation phase, the most significant differences between the Symphony hospital grade breastpump and the Freestyle double electric breastpump are the number of cycles (b)(4) and the maximum stimulation vacuum (b)(4). Research[1] has shown that high frequency patterns (greater than (b)(4) per minute) were rated by mothers as being similar in frequency/cpm to their infant. Therefore, both the Symphony hospital grade breastpump as well as the Freestyle double electric breastpump fulfill the criteria for stimulation cycles. Further research[2] has found that there was no relationship between the milk volume expressed during simulation and the stimulation vacuum applied. It can be concluded that the vacuum in stimulation phase is of an inferior importance in comparison to the stimulation cycle rate. Therefore, both the Symphony hospital grade breastpump as well as the Freestyle double electric breastpump fulfill the criteria for successful stimulation.

For the Expression phase, the most significant differences between the Symphony hospital grade breastpump and the Freestyle double electric breastpump are the range of cycles at minimum and maximum expression vacuum level (b)(4) Investigations[3,4] of breastfeeding infants have shown that nutritive sucking usually depends on a flow of milk from the nipple, is organized as a continuous sequence of sucks, and has a basic frequency of about one suck per second. This would lead to an expression cycle rate of around (b)(4), and this is the achieved cycle rate in the Expression phase of both the Symphony hospital grade breastpump and the Freestyle double electric breastpump. The range of the minimum and maximum cycle rates either side of (b)(4) is considered secondarily, and is based upon research[5] which showed that users (80%) rated positively a pattern in which the as the peak vacuum decreased, the frequency increased, and this relationship is upheld for both the Symphony hospital grade breastpump and the Freestyle double electric breastpump. In addition to the cycle rate in the Expression phase, research[6] has shown that mothers should use their individual maximum comfortable vacuum for effective milk removal. The minimum and maximum vacuum that can be reached is substantially equivalent between the Symphony hospital grade breastpump as well as the Freestyle double electric breastpump, and therefore, it is considered that both devices fulfill the criteria for successful expression.

(b)(4)

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

TRADITIONAL 510(K)

VOLUME 2

SECTION 13

TABLE OF CONTENTS

SECTION 13

PROPOSED LABELING

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

13.1 INDICATIONS FOR USE

The Freestyle® is a powered breastpump to be used by lactating women to express and collect milk from their breasts.

13.2 OPERATING INSTRUCTIONS

Refer to the **Exhibit 13.1** for copy of the user instructions for the Freestyle®. Also, the following resources are available with some models of the Freestyle®.

Exhibit	Description
13.2	Breastfeeding Log (1547575)
13.3	Breastmilk Storage Guidelines Magnet (1547514)

13.3 PACKAGE LABELS

Refer to the **Exhibit 13.4** for copy of the Freestyle® package labels.

13.4 PRODUCT LABELS

Exhibit 13.5 presents product labeling for the Freestyle®.

13.5 ACCESSORY LABELING

Exhibit 13.6 presents labeling supplied with the Freestyle® accessories.

13.6 PROPOSED ADVERTISING (DEVICE CLAIMS)

Claims for the Freestyle® are discussed in **Exhibit 13.7**, including traceability to supporting objective evidence which is presented in Section 20.

EXHIBIT 13.1

INSTRUCTIONS FOR USE

medela

Freestyle®

Instructions for use

Read all instructions before using this product.

Table of Contents

IMPORTANT

- Plastic bottles and component parts become brittle when frozen and may break when dropped.
- Bottles and component parts may become damaged if mishandled, e.g. dropped, over-tightened, or knocked over.
- Take appropriate care in handling bottles and components.
- Do not use the breastmilk if bottles or components become damaged.

Indication for use

The Freestyle® is a powered breastpump to be used by lactating women to express and collect milk from their breasts.

Note

It is best to wait until your breastfeeding routine is established (approximately 4 weeks) before expressing breastmilk, unless otherwise advised by your healthcare professional.

If you have medical reasons or other needs for exclusively pumping, it is recommended that you use a hospital grade breastpump such as our Symphony® Breastpump. To learn more, visit www.medelabreastfeedingus.com.

Product Description

Freestyle® is a personal-use electric breastpump that includes 2-Phase Expression® technology and is capable of single and double pumping.

The Freestyle operating life is defined to be approximately three 15 minute sessions per day, for one year.

PLEASE SAVE THESE INSTRUCTIONS.
THIS IS A SINGLE USER PRODUCT.

1. Important Safeguards

When using electrical products, especially when children are present, basic safety precautions should always be followed.

READ ALL INSTRUCTIONS BEFORE USING THIS PRODUCT.

This is a single user product. Use by more than one person may present a health risk and performance questions and voids the warranty.

DANGER: To reduce the risk of electrocution:

- Always unplug electrical product immediately after use.
- Do not use while bathing.
- Do not place or store product where it can fall or be pulled into a tub or sink.
- Do not place or drop into water or other liquid.
- Do not reach for a product if it has fallen into water. Immediately unplug from electrical outlet.

WARNING: To avoid fire, electrocution, or serious burns:

- Danger of electrocution! Keep the device dry! Never immerse in water or other liquids!
- The Freestyle® Breastpump and accessories are not heat-resistant: keep away from radiators and open flames.
- Keep the power adaptor away from heated surfaces.
- Do not reach for any electrical device if it has fallen into water. Unplug immediately.
- Do not use outdoors, or operate where aerosol (spray) products are being used or where oxygen is being administered.
- The Freestyle Breastpump should never be left unattended when plugged into a power source.
- Never operate an electrical device if it has a damaged cord, plug or battery pack, if it is not working properly, if it has been dropped or damaged, or dropped into water. If damage is found, immediately discountinue use of power adaptor or battery pack and call Medela Customer Service at 1-800-435-8316.
- Do not use the Freestyle Breastpump while bathing or showering.
- Close supervision is necessary when the Freestyle Breastpump is used in the vicinity of children.

The warning symbol identifies all instructions that are important to safety. Failure to observe these instructions can lead to injury or damage to the breastpump. When used in conjunction with the following words, the warning symbols stand for:

WARNING Can lead to serious injury or death.

CAUTION Can lead to minor injury.

NOTE Can lead to material damage.

TIP Useful or important information that is not related to safety.

WARNING: To avoid health risk and reduce the risk of injury:

- Repairs must be performed only by an authorized service agency. Do not repair yourself! No modifications to the device are permitted.
- Never use a damaged device. Replace damaged or worn parts.
- Use the Freestyle Breastpump only for its intended use as described in this manual.
- Do not use the Freestyle Breastpump while sleeping or overly drowsy.
- This is a single user product. Use by more than one person may present a health risk.
- Do not drive while pumping.
- Inspect all appropriate pump components before each use.
- Do not thaw frozen breastmilk in a microwave or in a pan of boiling water.
- If tubing becomes moldy, discontinue use and replace tubing.
- Never use while pregnant, as pumping can induce labor.
- Clean and sanitize all parts that come into contact with your breast and breastmilk prior to first use.
- Wash all parts that come into contact with your breast and breastmilk after every use.

CAUTION: Can lead to minor injury:

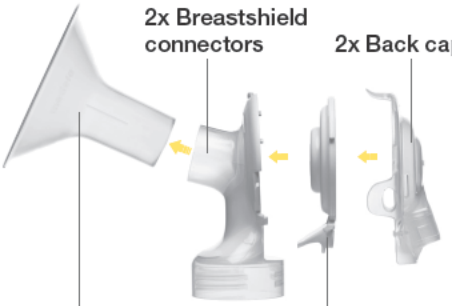
- Do not expose the motor unit to direct sunlight.
- Separation from power is only assured through the disconnection of the power adaptor from the wall socket outlet.
- If you feel pain in your breast or nipple, turn the pump off or slide a finger between the flange and your breast to immediately break the suction.
- Contact a healthcare professional or breastfeeding specialist if you experience problems or pain.
- Portable and mobile radio frequency communications equipment can affect the Freestyle Breastpump.
- Use only the power adaptor that comes with the Freestyle Breastpump or approved power options on page 18.
- Make sure the voltage of the power adaptor is compatible with the power source.

2. Product Description

Your Freestyle breastpump system includes

2x Breastshield assemblies
67061

2x Bottles
6007135



2x Breastshield connectors

2x Back caps

2x membranes

2x PersonalFit™ Breastshields M (24 mm)

2x PersonalFit™ Breastshields L (27 mm)
(for other breastshield sizes see Section 9, page 17)
87073 (24 mm)
87274 (27 mm)

1x Power adaptor
9207047

2x Lids
8107183

1x Rechargeable battery
9197010

Additional contents included with Freestyle Deluxe Configuration
67060

2x Lids
8107183

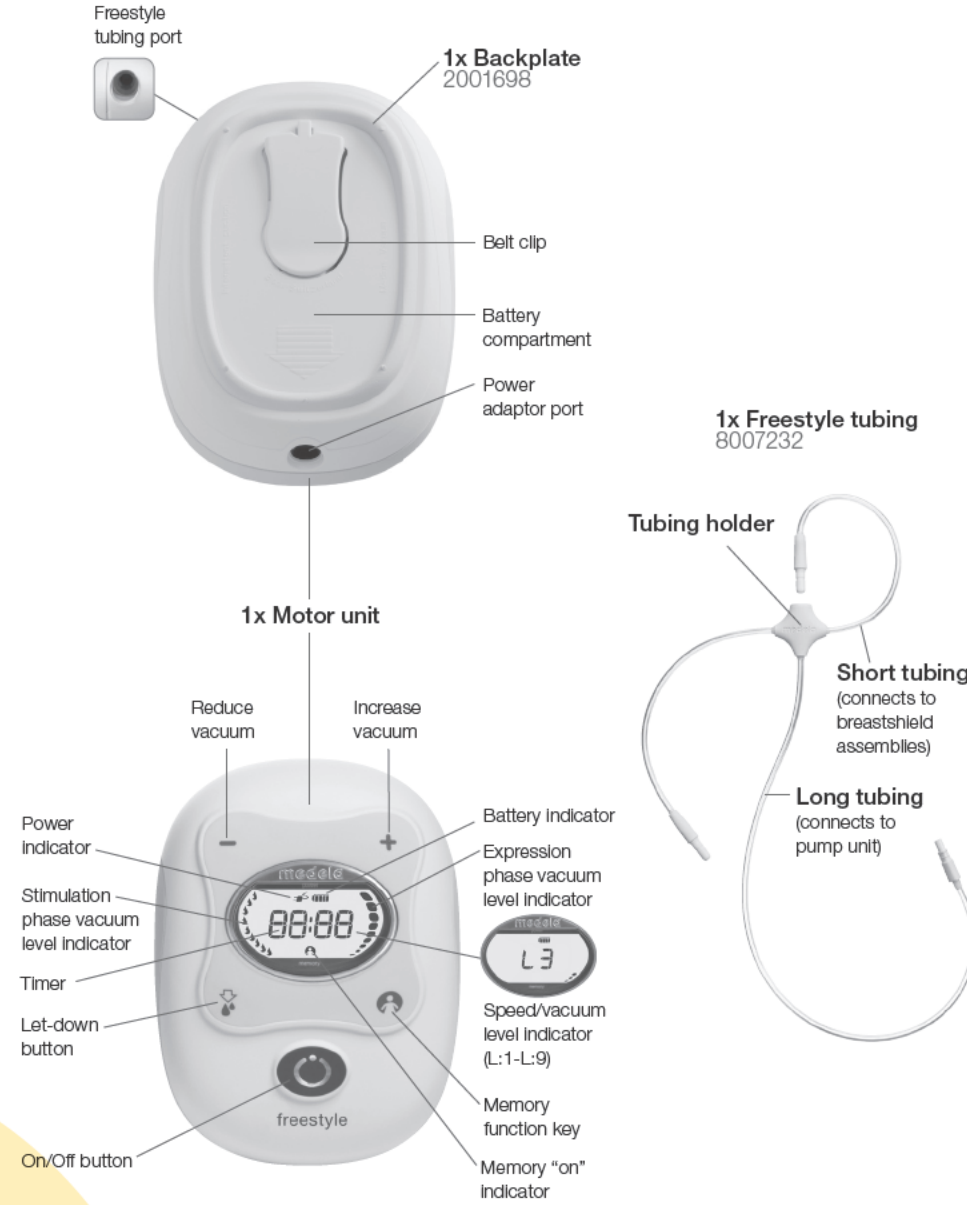
2x Bottles
6007135

1x Freestyle bag
3007340

1x Cooler bag
3007304

1x Ice pack
87092

Quantities and contents may differ depending on Freestyle Breastpump version.



Note

It's important for you to do the following before using Freestyle® for the first time:

1. Fully charge the battery 24 hours, uninterrupted (see Section 10)
2. Separate all parts
3. Clean - see instructions:
   - Wash – Section 5
   - Sanitize – Section 6

Breastshield assemblies come assembled. Separate all parts that will come into contact with the breast and breastmilk before cleaning.

Parts to clean:

- Breastshields
- Breastmilk bottles
- Lids
- Connectors
- Membranes
- Back caps

4. Cleaning Overview

When to Wash	Breastpump kit 	Breastpump bottles 
Before 1st use	✓ wash ✓ sanitize	✓ wash ✓ sanitize
After each use	✓ wash	✓ wash
Once per day	✓ sanitize	✓ sanitize

When to Wash	Tubing 	Motor unit 
As needed	✓ wash **only if** residue or condensation in tubing	✓ wipe with clean, damp cloth

Detailed cleaning instructions on pages 10-15:

- Wash – Section 5
- Sanitize – Section 6
- Tubing and motor unit care – Section 7

Washing and sanitizing are two different activities and must be done separately to protect you and the performance of your breastpump.

5. Wash – Before first use and after each use

Supplies needed:

- Mild dish soap
- Clean dish cloth or soft brush
- Clean sink or bowl
- Drinking quality water

Parts to wash:

- Breastshields
- Breastmilk bottles
- Lids
- Connectors
- Membranes
- Back caps

1

Separate parts for washing

Caution

Separate and wash all parts that come in contact with breastmilk immediately after use to avoid dry up of breastmilk residue and prevent growth of bacteria.

Note

- Wash breastpump kit parts after each use.
- Take care not to damage parts of the pump kit during cleaning.
- **It is not necessary to wash tubing prior to first use.**
- **Only wash tubing if condensation or residue is present.**

Wash in dishwasher

4

- Wash all separated parts on top rack of dishwasher.
- Allow all breastpump parts to air dry in a clean area.
- Store dry parts in a clean, cool place when not in use.

Note

If the individual components of the pump kit are cleaned in a dishwasher, parts may be discolored by food pigments. This will not impact part function.

2

Rinse all separated parts that came in contact with breast and breastmilk in cool water to remove breastmilk residue.

Wash in sink

3

OR

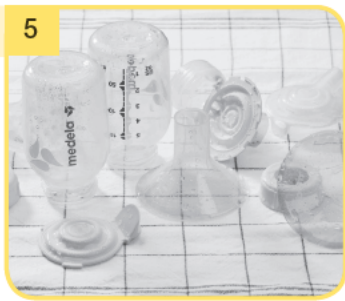
- Soak all separated parts in warm, soapy water for 5 minutes.
- Wash each part with a clean dish cloth or soft brush.
- Rinse all separated parts with clear water.

Caution

Only use drinking-quality tap or bottled water for cleaning.

You may also wash your kit parts by following the instructions on the Quick Clean™ Breastmilk Removal Soap bottle. (sold separately)

5



- Place parts on a clean surface and/or towel.
- Allow all parts to air dry.
- Store dry parts in a clean, cool place when not in use. Do NOT store wet or damp parts.

Note

Store the pump kit in a clean bag/container until next use.

6. Sanitize – Before first use and once per day

Supplies needed:

- Clean pot for boiling water
- Clean dish cloth
- Drinking quality water
- Tongs

Parts to sanitize:

- Breastshields
- Breastmilk bottles
- Lids
- Connectors
- Membranes
- Back caps

1

Separate all parts that come in contact with breastmilk.

Note

Sanitize breastpump kit parts once daily.

4

Allow water to cool and gently remove parts from water with tongs.

2

Wash hands thoroughly.

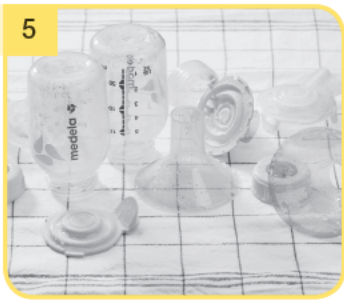
3

- Fill a pot with enough water to cover all parts.
- Bring water to a boil.
- Place parts in boiling water for 10 minutes.

Note

If you notice a white residue on your parts after boiling, you may have a high mineral content in your water. Remove residue by wiping parts with a clean dish cloth and air dry. We recommend that you boil parts with distilled water to prevent substantial mineral build-up over time which may compromise your parts.

5



You may also sanitize your kit parts by following the instructions on Medela's Quick Clean™ Micro-Steam™ bag. (sold separately)

- Place parts on a clean surface and/or towel.
- Allow all parts to air dry.
- Store dry parts in a clean, cool place when not in use. Do NOT store wet or damp parts.

Note

Store the pump kit in a clean bag/container until next use.

7. Tubing & Motor Unit Care

Supplies needed:

- Mild dish soap
- Clean dish cloth
- Clean sink or bowl
- Drinking quality water

Parts needed:

- Tubing
- Motor unit

Note

- Tubing should be washed if dirty or residue is present.
- Tubing should be washed if condensation is present.
- Cleaning tubing is not necessary if condensation present is from previous washings or atmospheric conditions.

7A. Tubing care

Inspect tubing after each pumping session.

Caution

- Do not store wet or damp parts as mold may develop.
- If tubing becomes moldy, discontinue use and replace tubing. Contact Medela Customer Service at customer.service@medela.com or call 1-800-435-8316.
- **Do not run pump with wet tubing. Doing so will harm the pump motor.**

3

Remove tubing by pulling straight out of tubing ports. Do not wiggle or pull tubing at an angle.

6

- Wash tubing in warm soapy water.
- Rinse tubing with clear water.
- Shake out water droplets and hang to air dry.

1

Turn off breastpump.

2

Unplug breastpump from power source.

4

Remove tubing from breastshield.

5

Rinse tubing in cool water to remove residue.

7B. Cleaning the motor unit

1

Wipe pump unit with a clean, damp cloth.

Caution

Do not immerse the pump in water; do not run water over the pump.

Common pumping questions & answers

How often should you pump?

A breastpump is a replacement for when you are separated from your baby. It is important to pump when the baby would normally be breastfeeding. For example, a working mother may pump 2-3 times during an 8 hour working day.

How long should your pumping session last?

Pumping times can vary from mother to mother, usually from 15 minutes to 30 minutes.

How should your breasts feel before and after pumping?

Before pumping, your breasts will have a firm, heavy feeling. After pumping, your breasts should feel soft and there should be no firm areas. Firm areas could indicate that the breast is not draining all over. See below for more information.

Caution

- While some discomfort may be felt when first using a breastpump, using a breastpump should not cause pain.
- If you are experiencing discomfort at the base of the nipple due to rubbing of your breast tissue with the breastshield tunnel, use of a lubricant such as Tender Care™ Lanolin may be beneficial.
- For assistance with correct breastshield sizing and comfort please visit **www.medelabreastshields.com** or see a lactation consultant / breastfeeding specialist.

9. Breastshield Sizing

Correctly fitting breastshields

Properly fitting breastshields will support comfort and efficient milk expression. To determine if you have the correct size, look at the following diagram:

- The nipple should be centered in the tunnel of the shield.
- The nipple should move freely without rubbing when the pump is turned on.
- Minimal or no part of your areola should be pulled into the tunnel of the breastshield.
- You should see a gentle, rhythmic motion in the breast with each cycle of the pump.
- After pumping, your breast should feel soft with no areas of hardness.

Correct fit

PersonalFit™ Breastshields

21 mm (Small)
Item 87072

24 mm (Medium)
Item 87073

27 mm (Large)
Item 87274

Included with Freestyle®

30 mm (X-Large)
Item 87075

36 mm (XX-Large)
Item 87084

Choosing the right size PersonalFit™ breastshield:

1. Determine the size you're currently using. If you're not sure, look for the size embossed on your breastshield (see picture). 24 mm (M) breastshields are provided with Medela breastpumps.

2. While pumping, compare your fit to the images below as a sizing guideline.

Correct fit

Your breastshield is **too small**; try a larger size

Your breastshield is **too large**; try a smaller size

PersonalFit™ Breastshields are available at many local retailers or visit www.shopmedela.com.

10. Powering Your Pump

10A. Charging and operating your pump

There are 2 ways to power your pump:

1 Power Adaptor
- Locate adaptor in bag.
- Plug into pump.
- Plug into wall.

2 Rechargeable Battery
- Locate battery in bag.
- Insert battery in pump by following instructions on page 19.
- Charge battery uninterrupted for 24 hours.

Warning

- Follow the **exact** order of the steps.
- Only use the power adaptor supplied with the Freestyle® Breastpump.
- Make sure the voltage of the power adaptor is compatible with the power source.
- Do not use force to push the battery into the battery compartment.

Note

Before first use, fully charge the battery for 24 hours uninterrupted.

10B. Battery operation

1

Before first use, "bAtt" appears in the display. Fully charge the battery until the battery indicator stops flashing and "bAtt" disappears.

Battery charge status codes

	Power adaptor connected to socket
	Battery charge status
	Battery fully charged, approx. 3 hours expression time remaining
flashing	20 min. expression time remaining. Battery removed from motor unit
flashing	Low battery, needs charging
"bAtt" flashing	Initial charge and charging after removing the battery (up to 24 hours charging time)
"bAtt"	Appears on display before first use Will not flash when pump is plugged in to power outlet

2

Open the battery compartment on the back of the pump by sliding the battery cover in the direction of the arrow.

3

Insert the battery in the direction shown by "This side down" **so that the gold contacts on the battery touch the gold contacts in the device.**

4

Silver tab remains on battery and should point upward when battery is inserted.

5

Close the battery compartment by sliding the battery cover in the direction of the arrow.

Tip

Do not remove the battery from the motor unit. Removing the battery requires a charging time of up to 24 hours.

6

Plug the power adaptor cord into the motor unit.

7

Plug the power adaptor into the power outlet.

Tip

The pump can be used during charging.

The battery is charging as soon as the pump is connected to a power source (even if the pump is not in use).

8

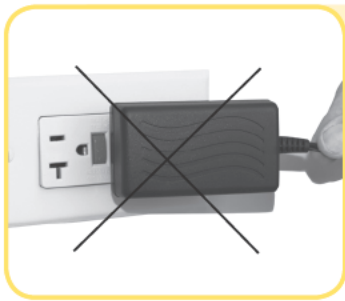
Charge the battery for 24 hours uninterrupted.

10C. Power adaptor care

To care for your adaptor be sure to follow these storage directions.

Do not wrap cord of power adaptor around the plug body.

Correct!



Do not unplug power adaptor by pulling on the cord.

Correct!

10D. Traveling outside of the U.S.

While travelling internationally, we recommend purchasing a Universal Power Plug Adaptor (not included). Please consult with the country you are visiting to find out what type of adaptor will work best. Freestyle's A/C adaptor is two-pronged and does not require a grounded outlet.

Freestyle has a Lithium ION Battery which may be restricted from the country you are visiting. Please consult with the country you are visiting to find out if there are any restrictions that pertain to travelling with Lithium ION.

For information about traveling with your breastpump and expressed breastmilk, visit www.TSA.gov.

11. Assembly of Pump Kit

Tip

Carry out all the steps with care and assemble the pump kit correctly for optimum performance.

Parts Needed:

- Tubing
- Motor Unit
- Breastshields
- Breastmilk bottles
- Lids
- Connectors
- Membranes
- Back caps

Note

- Use Authentic Medela Spare Parts only. See page 6 for details.
- Check pump kit components for wear or damage before use and replace if necessary.
- All components must be completely dry before use for proper performance and to prevent damage to the pump.

1

Caution

Wash hands thoroughly with soap and water before touching breastpump, kit and breasts and avoid touching the inside of containers or lids.

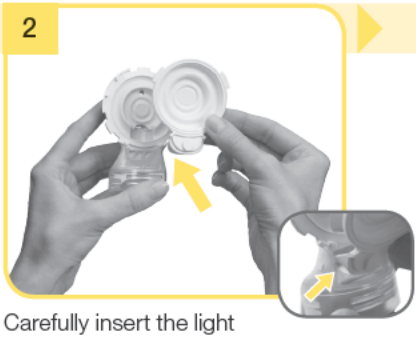
4

Push the breastshield onto the connector.

7

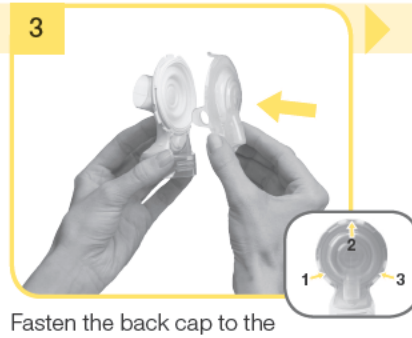
Insert the long tubing into the motor unit.

2



Carefully insert the light yellow membrane into the base of the breastshield connector. **Ensure bottom flap on membrane is inserted into connector.**

3

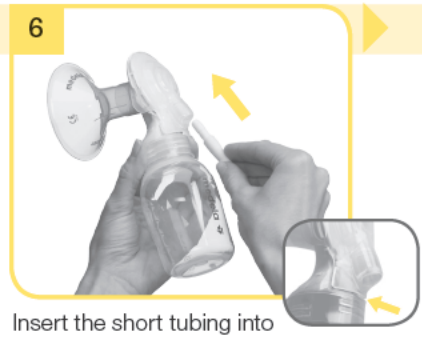


Fasten the back cap to the connector. **Make sure that all three connection points (top and side) snap together.**

5

Screw bottle into connector.

6



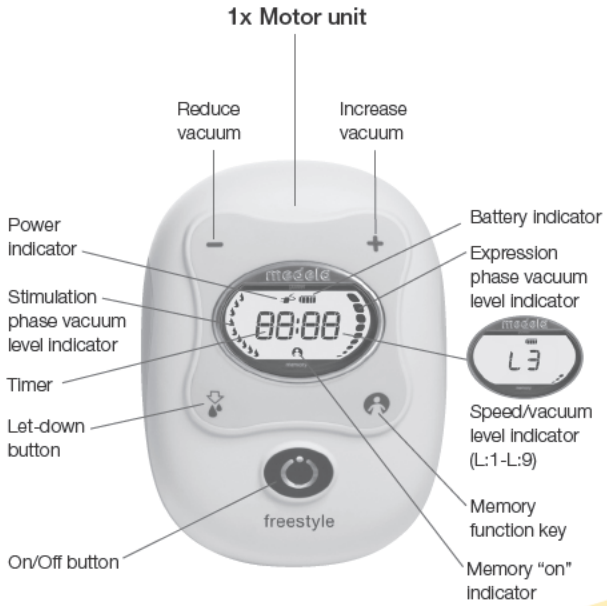
Insert the short tubing into the back cap as far as it will go. You will see a small gap at the bottom of the breastshield assembly when assembled correctly (inset).

8

Accurately assembled kit.

Glossary of Terms

2-Phase Expression®	Through research, Medela found that babies nurse in 2 Phases – Stimulation and Expression. This research is the basis for the technology in all Medela breastpumps.
Stimulation Phase	Fast sucking/pumping rhythm to stimulate milk flow.
Expression Phase	Slower sucking/pumping rhythm for gentle and efficient milk removal after milk has started flowing.
Maximum Comfort Vacuum™	Highest vacuum setting where pumping still feels comfortable. Different for every mother.



12A. Before pumping

Caution

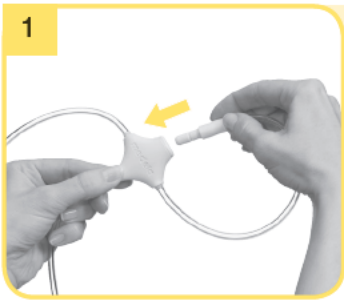
- Wash hands thoroughly with soap and water before touching breastpump, kit and breasts and avoid touching the inside of containers or lids.
- Always inspect breastshields, connectors, valves, membranes and tubing prior to use for cleanliness.

12B. Double pumping

Place the breastshields on your breasts so that your nipples are properly **centered** in the tunnels.

12C. Single pumping

1



Insert the unused short tubing into the tubing holder.

2

Hold the breastshield onto your breast with your thumb and index finger. Support your breast with the palm of your hand.

Refer to Section 9 for breastshield sizing information.

Caution

- Make sure tubing is not kinked or pinched while pumping.
- Do not hold the pump kit by the bottle. This can lead to blockage of the milk ducts and engorgement.

12D. Pump operation

Caution

- Contact your healthcare professional or breastfeeding specialist if you can express only minimal or no milk or if expression is painful. See **Section 8** for more information.
- Do not try and express with vacuum that is too high and uncomfortable (painful). The pain, along with potential breast and nipple trauma, may decrease milk output.

1

Turn on the breastpump by pressing the on/off button .

- Timer will start immediately.
- Adjust the speed/vacuum to a comfortable level.
- Freestyle® will begin pumping in the stimulation phase. The pump will automatically switch to the expression phase after 2 minutes.
- The sound of the pump will change between phases.

2

If your milk starts to flow sooner than 2 minutes, press the let-down button to switch to the expression phase. **Make sure that the milk is flowing into the bottle properly.**

Note

Only fill the bottle to the 150 mL mark.

Tip

- Do not tilt or overfill containers when pumping.

3

Find your Maximum Comfort Vacuum™
Once you are pumping in the expression phase, increase speed/vacuum + until pumping feels slightly uncomfortable (not painful), then decrease – slightly.

Tip

- Research has shown that you will pump more efficiently – get more milk in less time – when pumping at Maximum Comfort Vacuum™ during the expression phase.
- You should reassess your Maximum Comfort Vacuum throughout your pumping experience because it can change during the different stages of lactation.

4

Set and use the memory function
Press and hold the memory button for three seconds during the expression phase to save pumping pattern.

- The memory indicator on the display will flash three times when saved and the pump will beep three times.
- Finish expression as usual.
- To use saved pattern, press the memory button once when you begin a pumping session.

If you are experiencing low or no suction, refer to Troubleshooting, Section 16.

5

Turn off the breastpump by pressing the on/off button .

Note

Always disconnect Freestyle® from the power source after expression (except if the battery is charging).

Tip

Freestyle switches off automatically if it has been running for 30 minutes with no interruptions.

6

When your pumping session is over, unplug tubing from the back of the breastshield(s) before setting down the bottles.

7

Close the bottle with a lid.

- See Section 14 for breastmilk storage instructions.

8

Disassemble and clean per Section 5.

13. Hands-Free Pumping with Easy Expression™

You can pump hands-free using the Easy Expression hands-free bustier!

(The literature within your breastpump package contains a special offer for Easy Expression)

- Gives you the freedom to multi-task while pumping
- Works great with your Medela Freestyle Breastpump
- Easy to wear and wash
- Available in multiple sizes and colors, see the back of a package or visit **www.medela.com** for sizing information.
- Zipper closure makes it easy to slip on over your nursing bra

To purchase visit **www.shopmedela.com** or your local retailer.

Storing breastmilk in Freestyle® cooler bag

- The Freestyle cooler bag requires one contoured ice pack (#87092, included) for cooling up to four 5 oz bottles of breastmilk for up to 10 hours in a room temperature environment inside of your pump bag and up to 8 hours in cooler stored outside of pump bag.
- As soon as you are finished pumping, place the breastmilk bottle or breastmilk storage bag in the cooler bag with the ice pack.
- Transfer breastmilk bottles or breastmilk storage bag to the refrigerator or freezer once you are home.

15. Preparing & Feeding Breastmilk

Freshly Expressed Breastmilk Storage Guidelines
(For Healthy Term Babies)

Room Temperature	Cooler with Ice Pack	Refrigerator	Freezer
4–6 hours at 66–78 °F (19–26 °C)	24 hours at 59 °F (15 °C)	3–8 days at 39 °F or lower (4 °C)	6–12 months 0–-4 °F (-18–-20 °C)

References: www.BreastmilkGuidelines.com

15A. Preparing breastmilk

Caution

- Do not thaw frozen breastmilk in a microwave or in a pan of boiling water.
- Do not microwave breastmilk. Microwaving can cause severe burns to baby's mouth from hot spots that develop in the milk during microwaving. (Microwaving can also change the composition of breastmilk.)

- Thaw breastmilk overnight in the refrigerator. Thawed breastmilk is safe in the refrigerator for 24 hours. Do not refreeze thawed breastmilk.
- Quickly thaw breastmilk by holding the bottle under warm running water.
- Place the sealed bottle in a bowl of warm water for 20 minutes to bring it to body temperature.
- If you are adding expressed breastmilk to a container of already frozen breastmilk, make sure to add a lesser amount than the already frozen amount.

15B. Feeding breastmilk

It is recommended that breastfeeding is well established prior to bottle feeding your baby.

- Always inspect the bottle, nipple and other components immediately before and after each use. If nipple appears cracked or torn, discontinue use immediately.
- To prevent possible choking hazard, test strength of nipple by pulling on bulb portion of the nipple.
- Do not attempt to enlarge the nipple hole.
- Infants must not be bottle fed without adult supervision.
- Nipple should not be used as a pacifier.

For additional breastmilk collection & storage information, please visit **www.BreastmilkGuidelines.com**.

16. Troubleshooting

Low or no suction	**Component Check** • Disassemble breastshields, breastshield bodies, membranes, and back caps. • Inspect all components for chips or cracks. • Clean and dry all components per Section 5. • Reassemble per Section 11. Make sure the components are dry before assembling. • Check that tubing is not kinked. • When single pumping, check that unused end is correctly stored in the tubing holder. **Connection Point Check** Inspect following connection points to ensure attachment is secure • Back cap snapped at all 3 connection points. • Tubing adaptor to back cap. • Tubing adaptor to pump. • If suction is not improved, contact Medela Customer Service at 1-800-435-8316.
Battery charging **"bAtt" symbol on the display**	(T) TIP: Avoid removing the battery as this will reset the battery indicator and requires a recharging time of up to 24 hours. If the battery does not charge and there is no battery symbol on the display verify that the battery is inserted properly. See Section 10. **"bAtt" symbol on the display** • If a "bAtt" symbol appears on the display, it indicates it is in initial charge mode or the battery was removed and reinserted. Plug in and charge for 24 hours uninterrupted. **Flashing Battery Symbol outline and 1 bar** • Low battery. Plug in and charge battery. **Battery indicator flashes with 4 bars** • Disconnect the power cord and remove the battery for at least 10 seconds. Reinsert the battery and plug in to charge for 24 hours. • If you still have a problem, contact Medela Customer Service at 1-800-435-8316.
Pump doesn't run or power on	• If the Power Adaptor Symbol flashes or you see "Err" and hear 3 beeps, contact Medela Customer Service at 1-800-435-8316.
No "let-down" or breastmilk expression	• Ensure your breastpump is assembled correctly and there is suction. • Relax and take a 10-15 minute break if let-down is not achieved. • Consult with your healthcare professional or breastfeeding specialist if expression does not occur after 2 consecutive pumping sessions.

Pump becomes wet	• Unplug the power adaptor from the socket. • Turn off the pump. • Do not place the pump upside down. Control panel must face upwards. • Store the pump in a warm, dry place for 24 hours.
Water or breastmilk in tubing	! NOTE: To prevent damage to the Freestyle Breastpump, water or breastmilk seen in tubing should be cleaned and dried per the instructions in Tubing Cleaning Section 7A before use. T TIP: The Freestyle Breastpump has a membrane in the breastshield assembly to prevent milk from flowing into the tubing during pumping.

If you have not resolved the problem with your breastpump or you have further questions, please contact Medela Customer Service at 1-800-435-8316 or fill out the contact us form at www.medelabreastfeedingus.com.

Supplemental Information

Following are some common breastfeeding related conditions. If you experience any of these symptoms, contact a healthcare professional or breastfeeding specialist.

	Symptom	Potential Causes
Engorgement	Breasts are hard and uncomfortable, possibly with reddened areas.	Milk not draining properly from breast. Milk can drain back into the tissue causing areas to swell and become tender.
Blocked/Plugged Ducts	Area of breast will look reddened and may be tender to touch.	Milk not being drained from a specific duct. The area becomes 'clogged' up and milk is then prevented from flowing.
Mastitis	It often follows engorgement but can just occur suddenly. The initial symptoms are similar to flu – fatigue, headache and muscle aches, fever and localized breast tenderness. It can be in one or even both breasts and needs immediate treatment.	A bacterial infection in the breast tissue which is often accompanied by cracked nipples.
A healthcare professional or Breastfeeding Specialist can give you guidance in breastfeeding your baby and using a breastpump. Their guidance is valuable in terms of the lifetime of health benefits for both you and your baby. A listing of Lactation Professionals are available at www.medelalocator.com or call 1-800-TELL-YOU (1-800-835-5968).		

18. Warranty

This product is warranted by Medela, Inc. to the original retail purchaser to be free from defects in material and workmanship for the period of 1 year for pump mechanism and rechargeable battery (90 days for other parts and accessories) from the date of purchase. In the event of a defect, Medela will repair or, at Medela's option, replace this product, without charge for such replacement parts or labor. Purchaser shall bear all expense for returning this product to Medela. This warranty does not apply to any product used commercially or which has been subjected to misuse, abuse or alteration.

ANY AND ALL IMPLIED WARRANTIES, INCLUDING THE WARRANTY OF MERCHANTABILITY, ARE LIMITED TO A DURATION OF 3 YEARS FROM DATE OF PURCHASE. SOME AREAS DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, SO THE ABOVE LIMITATIONS MAY NOT APPLY TO YOU. THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS AND YOU MAY ALSO HAVE OTHER RIGHTS WHICH VARY FROM STATE TO STATE OR IN YOUR COUNTRY.

Before you make a claim under this warranty, it may save time and expense to call Medela Customer Service (toll free) at 1-800-435-8316. You may also call this number for additional information concerning this warranty. If you wish to make a claim under this warranty, you must return this product to Medela with a return authorization number received from Medela Customer Service, prepaid, together with your dated bill of sale or other proof of purchase and a brief statement of the problem to the following address:

Medela, Inc. – Returns, Door 4501
1101 Corporate Dr.
McHenry, IL 60050
ATTENTION: RETURNS

Call first for authorization number. Returns not accepted without an authorization number.

We recommend recording your serial number here when you first open your pump for easy reference when contacting Medela Customer Service.

Your serial number can be found on the sticker under the battery cover.

SERIAL NUMBER:

19. Meaning of Symbols

Symbols on the device

− +	Decrease/increase vacuum (+/-)
	Let-down button
	Memory button
	On/off
	Power Indicator
	Vacuum level indicator, Expression Phase
	Vacuum level indicator, Stimulation Phase
L3	Speed/Vacuum level indicator (L:1 - L:9)
88:88	Timer indicator
	Battery indicator
	This symbol indicates to follow instructions for use.
CE 0123	This symbol indicates the compliance with the essential requirements of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
	This symbol indicates the manufacturer.
	This symbol indicates do not dispose the device together with unsorted municipal waste (in accordance with local regulations).
	This symbol indicates the compliance with additional USA and Canada safety requirements for medical electrical equipment.
	This symbol indicates compliance with international requirements for protection from electric shock. (Type BF applied parts.)
REF	This symbol indicates manufacturer's catalog number of the battery.
SN	This symbol indicates manufacturer's serial number of the device.
IP22	This symbol indicates the protection against entrance of solid foreign objects and against harmful effects due to the entrance of water.
	This symbol indicates the date of manufacture (four digits for the year and two digits for the month).

19. Meaning of Symbols

Symbols on the power adaptor


This symbol indicates that the power adaptor is a class II device.


This symbol indicates that the power adaptor is for indoor use only.


This symbol indicates the compliance with USA and Canada safety requirements.


This symbol indicates polarity of d.c. power connector.


This symbol indicates alternating current.


This symbol indicates direct current.

20. EMC / Technical Description

The Freestyle® breastpump needs special precautions regarding EMC (Electromagnetic compatibility) and needs to be installed and put into service according to the EMC information provided in these instructions for use. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect the electric breastpump Freestyle and should be kept at least a distance 1.0 m away from the equipment. Electromagnetic Compatibility (EMC, IEC 60601-1-2:2007, Table 1)

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Electromagnetic emissions		
The electric breastpump Freestyle is intended for use in the electromagnetic environment specified below. The customer or the user of the electric breastpump Freestyle should assure that it is used in such an environment.		
Emission tests	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The electric breastpump Freestyle uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The electric breastpump Freestyle is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3		

Warning

Warning – The electric breastpump Freestyle should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the electric breastpump Freestyle should be observed to verify normal operation in the configuration in which it will be used.

Electromagnetic Compatibility (EMC, IEC 60601-1-2:2007, Table 2)

Electromagnetic immunity

The electric breastpump Freestyle® is intended for use in the electromagnetic environment specified below. The customer or the user of the electric breastpump Freestyle should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the electric breastpump Freestyle requires continued operation during power mains interruptions, it is recommended that the electric breastpump Freestyle is powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Electromagnetic Compatibility (EMC, IEC 60601-1-2:2007, Table 4)

Electromagnetic immunity

The electric breastpump Freestyle® is intended for use in the electromagnetic environment specified below. The customer or the user of the electric breastpump Freestyle should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the electric breastpump Freestyle, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Recommended separation distance $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the electric breastpump Freestyle is used exceeds the applicable RF compliance level above, the electric breastpump Freestyle should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the electric breastpump Freestyle.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Electromagnetic Compatibility (EMC, IEC 60601-1-2:2007, Table 6)

Recommended separation distances between portable and mobile RF communications equipment and the electric breastpump Freestyle

The electric breastpump Freestyle® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the electric breastpump Freestyle can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the electric breastpump Freestyle as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter M		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Electromagnetic environments		
Environment	**Locations**	**General characteristics**
Typical health care	Hospital, large clinic, doctor's office	Partly controlled, covered by the general requirements of this collateral standard
Residential	Doctor's office, small clinic	Not controlled, health care professional present
Residential	Home	Not controlled, health care professional not normally present
Transport, mobile	Car, aircraft (fixed-wing and helicopter), ambulance	Not controlled, wide variations, critical receivers nearby, harsh environments for ESD, RF, electric and magnetic fields
Special	Operating theatre, emergency room	Case-by-case examination of environment

21. Technical Specifications/Disposal

Technical Specifications

vacuum (approx.)
-20....-270 mmHg
-3....-35 kPa
45 … 120 cpm

In	Out
100 240V 50/60 Hz	12V ⎓ 1 A / 1 5 A

7.2 V, 2150mAh
Li-Ion

122 x 90 x 58

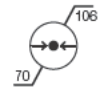
370 g
270 g

Operation
Betrieb
En Service
Utilizzo
Gebruik

Transport / Storage
Transport / Lagerung
Transport / Stockage
Transport / Stoccaggio
Transport / Opslag

Operation
Betrieb
En Service
Utilizzo
Gebruik

Transport / Storage
Transport / Lagerung
Transport / Stockage
Transport / Stoccaggio
Transport / Opslag



kPa

Disposal

The unit is made of various metal and plastics. Before disposal, the device is to be rendered unusable and it must not be disposed of as unsorted municipal waste in accordance with local regulations. Use your local return and collection system for waste electrical and electronic equipment (incl. batteries). Improper disposal may have harmful effects on the environment and on public health.

medela

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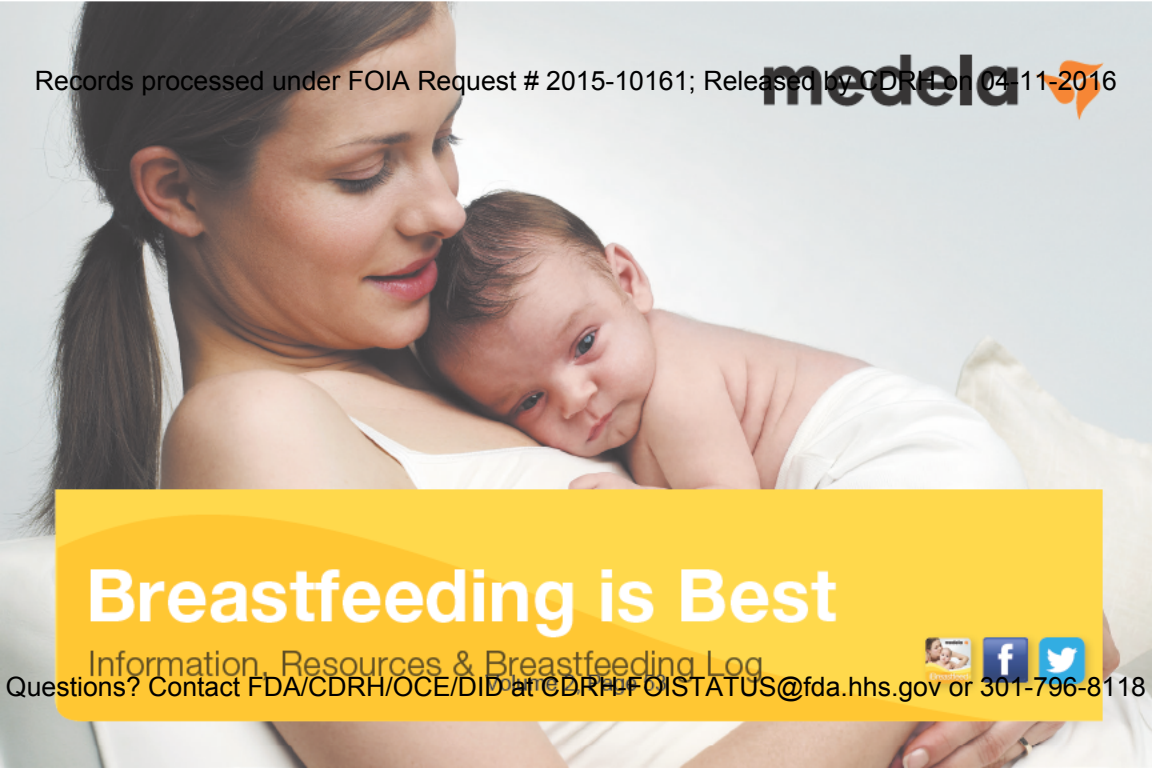
EXHIBIT 13.2

BREASTFEEDING RESOURCE GUIDE



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Congratulations!

Medela congratulates you on your decision to provide your baby the healthy benefits of breastmilk. You play a very important part in giving your baby the food he needs for a bright future. This guide will give you helpful information on breastfeeding, breastmilk, pumping, and breastmilk storage.

Your breastmilk is the perfect food for your baby. Breastmilk has important protective antibodies, unavailable in any other source. That is why leading health organizations including the American Academy of Pediatrics, the World Health Organization, and UNICEF recommend breastfeeding for at least the first 12 months of your baby's life. When you breastfeed, you, your baby and your family benefit.

Benefits to Baby

Research shows that the protective parts of breastmilk help to greatly reduce the risk of health problems and chronic diseases including:

- Allergies
- Ear infections
- Upper respiratory infections
- Gastrointestinal infections
- Diabetes
- Hypertension
- High cholesterol

Breastfeeding and Human Lactation / [edited by] Jan Riordan, Karen Wambach 4th ed

Why is Breastmilk So Important?

Benefits to Mom

Mothers who breastfeed also receive many benefits from breastfeeding including:

- Developing a strong bond with baby.
- Helping the uterus return to pre-pregnancy size more quickly.
- Burning more calories.
- Producing relaxing hormones.
- Reducing the risk of developing premenopausal breast cancer.
- Reducing the risk of ovarian and endometrial cancers.
- Reducing the risk of developing Type-II diabetes.

Breastfeeding and Human Lactation / [edited by] Jan Riordan Karen Wambach 4th ed

Benefits to Family

Did you know?

Your family will also benefit financially when you choose to breastfeed.

- Depending on the cost of formula and how much your baby needs each day, you could save $43.86 to $194.22 in formula costs in just the first month.
- By six months, the cost savings from not feeding formula can add up to be $375.34 to $1,662.22.
- In one year, a family with one infant could save anywhere between $714.42 and $3,163.86 by feeding breastmilk rather than buying formula.[1]
- Breastfeeding also helps save on health care costs as breastfed infants typically need fewer health care visits, prescriptions and hospitalizations.

1 Kelymom *Table 1 Formula costs saved by breastfeeding." October 22 2008 http://www.kelymom.com/bf/start/prepare/bfcostbenefits.html#table1 <http://www.kelymom.com/bf/start/prepare/bfcostbenefits.html#table1> (November 2005)

Did you know?

- A breastfeed lasts an average of 16 minutes.
- Almost three-quarters of moms produce more milk with their right breast (no correlation to being right-or left-handed).
- Babies will take more milk from the first breast offered.
- The average time it takes for a mom's milk to let-down, or start flowing, during a breastfeed is 56 seconds (but this can vary widely – so don't get stressed if you take longer).
- About a third of moms can't sense let-down. Your baby knows...watch them change their sucking pattern.

- Babies breastfeed until they're full, not until they "empty" your breast. On average, babies remove 67% of the milk you have available – this amount can vary widely among moms.
- Whether breastfeeding or pumping, the amount of milk removed and its fat content are similar.
- Your milk sprays out of many holes, not just one.
- Years ago, breastpumps resembled turkey basters. We've come a long way.

Vintage Breastpump

Did you know?

- Babies instinctively know how to get your milk quickly and efficiently: they start breastfeeding with a faster suck for stimulation until you let-down. Then when your milk is flowing, they switch to a slower, deeper suck and eat until they're full.
- Your baby controls your breastmilk flow with an instinctive action that includes sucking, swallowing and breathing - your milk flows during the actual sucking part, when your baby moves his tongue a certain way (We know! We've seen it on an ultrasound!).
- 90% of breastfeeding moms use a breastpump[1].

[1] Medela consumer segmentation study, 2008

Did you know?

- 77% of breastfeeding/breastpumping moms get outside help[1]. There's an entire profession dedicated to successful breastfeeding - Lactation Consultants ("LC's") are passionate about helping you and your baby breastfeed. You can find one in your state at www.iblce.org (click on "Employers and Consumers," then "Find a Lactation Consultant").

- The American Academy of Pediatrics recommends exclusive breastfeeding (that means no formula – but pumped breastmilk is okay) for 6 months and continued breastfeeding for a minimum of 1 year.[2] Actual recent statistics[3]:

  73% of babies have ever breastfed

  43% still breastfeed at 6 months

  22% still breastfeed at 1 year

It's common for babies to have resting periods during breastfeeding – sometimes they "take breaks" in between sucks.

Did you know?

- No matter your breast size, you'll make enough milk for your baby – A cups, rejoice!
- Breastfeeding mothers tend to lose more weight than mothers who do not breastfeed.
- When your child is grown, you'll fondly remember the warm, unique bond you shared while breastfeeding.
- Breastmilk contains special antibodies that help build immunity and fight infections.
- Certain nutrients found in breastmilk are responsible for growing your baby's brain and nervous system.
- Feeding your baby the first breastmilk after birth, called colostrum, is like giving your baby his first immunization.

[1] Medela consumer segmentation study, 2008

[2] American Academy of Pediatrics Policy Statement, Breastfeeding and the Use of Human Milk; Pediatrics, Vol 115 (2) 496

[3] www.cdc.gov/breastfeeding/faq; Centers for Disease Control and Prevention; Breastfeeding Frequently Asked Questions

All research, unless otherwise indicated, was conducted by Dr. Peter Hartmann and his team at the University of Western Australia, Perth and sponsored by Medela, Inc

Your breasts contain an amazing milk production system that is triggered by your pregnancy hormones. As soon as your baby is born, your breastfeeding hormones start working. The baby nursing at your breast signals your body to start making more milk.

- In early weeks of breastfeeding, your baby will need to feed 8-12 times during a 24 hour period.
- The length of a breastfeeding session can vary.
- Try not to breastfeed by the clock, but rather when your baby seems hungry.
- Both the frequency and length of feeding session will continue to change as your baby grows.

Getting Started

Breastfeeding takes a little practice. Sometimes it takes a while for babies to get used to the new world around them. In the first few days after birth, the initial milk produced is called colostrum. It is thick, yellowish in color and contains large amounts of antioxidants, and protective and growth factors that your baby needs. **Colostrum helps your baby's digestive tract and acts like a first vaccination. Although the amounts of colostrum produced seem small, during the first few days it is all your baby needs.** Over the next few weeks, the quantity and consistency of your breastmilk changes as your body adapts to your baby's needs. If you have concerns regarding your baby getting enough to eat, call your pediatric healthcare provider.

Signs Breastfeeding Is Going Well

When breastfeeding is going well, it is convenient and easy. Some mothers find it challenging in the beginning and some worry that they will not make enough milk. Here is a chart (page 11) and some tips you may find reassuring and helpful.

How Often Should You Breastfeed?

- Your baby needs to feed 8 or more times in a 24-hour period.
- It's normal for your baby to want to nurse a lot in the first month.
- When you nurse as long and as often as your baby wants, you are telling your breasts how much milk to make.

Your Baby's Tummy Size

- Your milk supply is made to match the size of your baby's stomach.
- Right after birth, your baby's stomach is small - about the size of a cherry. You will make the right amount of colostrum to meet his early growth needs.
- As your baby grows bigger and gains weight, your breasts make more milk to keep up with his needs.

One helpful way to tell if your baby is getting enough milk is to look at his diapers.

Wet Diapers

- After the first week, your baby should have at least 6 wet diapers every 24 hours. This tells you that the baby is getting enough fluid.

Soiled/Dirty

- Your baby's bowel movements will change in color from very dark and sticky (meconium) to yellow and soft over the first 4-5 days of life.This tells you that your baby is digesting breastmilk.
- By day 5, your baby should have at least 3 large, soft to runny yellow bowel movements every 24 hours.
- It is normal for some babies to have a bowel movement every time they breastfeed.

Your Baby's Age	1 Week							2 Weeks	3 Weeks
	1 Day	2 Days	3 Days	4 Days	5 Days	6 Days	7 Days		
How Often Should You Breastfeed? Per day, on average over 24 hours	At least 8 feeds per day (every 1 to 3 hours). Your baby is sucking strongly, slowly, steadily and swallowing often.								
Your Baby's Tummy Size	Size of a cherry		Size of a walnut		Size of an apricot			Size of an egg	
Wet Diapers: How Many, How Wet Per day, on average over 24 hours	At least 1 WET	At least 2 WET	At least 3 WET	At least 4 WET	At least 6 WET with Pale Yellow or Clear Urine				
Soiled Diapers: Number and Color of Stools Per day, on average over 24 hours	At least 1 to 2 BLACK or DARK GREEN		At least 3 BROWN, GREEN, or YELLOW		At least 3 soft and seedy YELLOW				
Your Baby's Weight	Babies lose an average of 5-7% of their birth weight in the first 3 days after birth. For example, a 7-pound baby will lose about ½ a pound.		From day 4 onward your baby should gain ¾ to 1½ oz. per day and regain his or her birth weight by 10 to 14 days.						
Growth Spurts ✻	Babies often experience a sudden burst in growth - a growth "spurt" - at certain times within their first few weeks. ✻ During these growth spurts, your baby may want to nurse more than usual.								

"Breastfeeding: Guidelines for Consultant's Physician's Desk Reference," Page 1, Best Start Resource Center Breastfeeding, Health Nexus, Revised 9 March 2009, <http://www.beststart.org/resources/breastfeeding/pdf/brstfding ENG.pdf> Modified with approval of Health Nexus

Your Baby's Weight

After birth, it is normal for babies to lose up to 7% of their birth weight.

- Around day 4, babies begin to gain weight and should regain their birth weight by 10-14 days.
- Your baby's healthcare provider will weigh your baby at the first check-up.

Your healthcare professional may decide to weigh your baby before and after you breastfeed on a special BabyWeigh™ scale. This scale can correctly measure very small amounts to determine how much breastmilk your baby received during the breastfeed. BabyWeigh scales are also available for rental use by calling 1-800-TELL YOU (1-800-835-5968).

Growth Spurts

- In the first few weeks, there will be times when your baby seems hungry and wants to nurse more than usual.
- Even if your breasts do not feel full, go ahead and let the baby breastfeed.

BabyWeigh™ Scale

Breastpumping

Breastpumping can help maintain your milk supply when you have to be away from baby (ie: returning to work), and allow you to successfully breastfeed when you are back with your baby again. It is best to establish breastfeeding for 3 to 4 weeks before introducing a bottle.

If you are returning to work or school it is a good idea to begin pumping at least 1 to 2 weeks prior to going back. This allows you to develop a routine, build up a stock of breastmilk and get baby used to drinking out of a bottle.

You and Your Milk Supply

Your milk supply is established in the first days after birth. Breastfeed your baby frequently to help produce lots of milk. Make use of the time after your baby is born to rest and regain your energy. Avoid giving bottles and/or pacifiers until breastfeeding is well-established. Breastfeed often in the evenings and learn how to breastfeed lying down while you rest. Nighttime breastfeeding boosts your supply!

Remember, pumping takes practice. If you only get a small amount of milk the first few times you pump, don't worry. With practice and patience you'll soon be pumping more milk.

Choosing the Right Pump & Accessories

It is important to select the best breastpump and accessories for your work situation.

Choosing the correct size breastshield is important for the flow of breastmilk and comfort to moms who are pumping. If pumping is uncomfortable or if you have questions, check with your lactation consultant or healthcare professional to help provide you with the proper fit. Medela makes PersonalFit™ breastshields in a variety of sizes to fit your needs. Breastpumping should be comfortable. Call 1-800 TELL YOU for a local retail or rental location or visit www.medela.com.

Medela offers breastpumps that are ideal for pumping at work. The Freestyle® and Pump In Style® Advanced include everything you need in convenient carrying bags and feature 2-Phase Expression® technology for more milk in less time.* In addition, Freestyle is uniquely small and lightweight and includes accessories for optional hands-free pumping.

* When pumping at Maximum Comfort Vacuum™

Medela's 2-Phase Expression® technology breastpumps include these phases to mimic your babies' natural sucking behavior.

Through research, Medela learned that there are two distinct phases of how babies breastfeed.

1. **Stimulation phase** – When babies first go to breast, they suck faster to start milk flowing.
2. **Expression phase** – After milk flow or "let-down" starts, babies breastfeed with a slower deeper suck to remove milk.

Need help deciding which breastpump is right for you?

Visit Medela's online product selector at www.medelabreastfeedingus.com/product-selector.

Breastpumping Tips

When separated from baby, pump your milk at the times you would be breastfeeding. The time required for a pumping session varies:

- A high performing double electric pump will take less time. Pumping sessions typically last 12 to 15 minutes.
- A single electric pump will take twice as long, draining each breast one at a time.
- Manual pumps can often take up to 20 minutes per breast.

Helpful Breastpumping Tips

- Begin to pump to store milk one to two weeks before returning to work.
- Plan to return to work mid-week so you can ease into your new routine.
- Pump three times during an eight hour work shift, or every three hours you are away from your baby. If you can't pump three times, pump as much as you can during each day.
- Breastfeeding when you are home with baby helps maintain your milk supply and protects your special bond with your baby.
- When you will be away from baby, before you leave, pump enough milk for the time you will be away. While you are away you should pump when your baby would be breatstfeeding. This milk is then available for when you go away again.
- Exclusively breastpumping: pump each time your baby has had a bottle or would be due to feed.

Collection and Storage of Breastmilk

If you are planning to store your breastmilk from a pumping session, you can pump directly into a storage container (i.e. breastmilk bottle or storage bags) that can go directly into the refrigerator or freezer. Be sure that the collection containers you choose to pump and store your milk in are BPA-free. For more information on BPA-free products, please visit **www.medelabpafree.com**.

If your baby was born prematurely, these guidelines may differ slightly. You should check with your healthcare provider for the recommended storage guidelines for your specific situation.

Never microwave breastmilk. Microwaving can cause severe burns to baby's mouth from hot spots that develop in the milk during microwaving. Microwaving can also change the composition of breastmilk.

Below are general guidelines regarding breastmilk storage.

Freshly Expressed Breastmilk Storage Guidelines
(For Healthy Term Babies)

Room Temperature	Cooler Ice Packs	Refrigerator	Freezer	Thawed Breastmilk
4–6 hours at 66–78 °F (19–26 °C)	24 hours at 59 °F (15 °C)	3–8 days at 39 °F or lower (4 °C)	6–12 months 0–4 °F (-18–-20 °C)	Use within 24 hrs

References: www.breastmilkguidelines.com

Tips for Continued Successful Breastfeeding

The American Academy of Pediatrics recommends exclusive breastfeeding for the first six months. Women everywhere are returning to work and successfully continuing to breastfeed. Advanced planning, family and workplace support, and a high quality breastpump help create success for working moms. The longer babies are breastfed, the greater the health benefits for both mom and baby. Breastfeeding is good for your employer too – it reduces employees' absence from work for baby's illnesses.

Choosing a Childcare Provider for Your Baby

Choose a childcare provider you trust who is comfortable caring for your breastfed baby. You can also check with your state or county for a list of licensed childcare providers. By choosing a childcare provider that is close to your workplace, you may visit your baby and breastfeed during lunch.

First Week of Work

Going back to work can be overwhelming. Start slowly, if possible, by returning to work for only a half-day, or mid-week. It is normal to feel tired at first. On days off, nap with your baby, enjoy your time together, and breastfeed often. Protect your milk supply by pumping often while away and breastfeeding when you are with your baby. Avoid having your breasts become overly full, as engorgement sends a signal to your body to slow down milk production.

Pumping at Work

The milk you pump at work one day may or can be used the next day to feed your baby. After pumping, cool your milk in a refrigerator or cooler. Store your milk in Medela's BPA-free breastmilk collection bottles or storage bags specifically designed for breastmilk, such as Medela Pump & Save™ bags. Freeze milk in 2-4 ounce containers and thaw when needed to use as back-up supply. Use a cooler carrier with frozen ice packs to transport your milk from work or to your daycare provider.

If your work involves overnight travel, milk can be shipped home packed in dry ice, or shipped on the airlines packed in cooler containers with dry ice packs. Check **www.faa.gov** for the most recent rules and regulations.

More Tips for Pumping at Work

- Two-piece clothing that opens easily at the waist makes pumping easier.
- If your supply is low, breastfeeding or pumping more often is the simplest way to increase your supply.
- You may find it helpful to have the support of another pumping mom to talk to.
- Two (2) pump kits make pumping more convenient – one (1) for home and one (1) for work.
- Use Medela's Quick Clean™ Micro-Steam™ bags or wipes for easy clean up. Make sure you bring your pump parts home to wash before using the next day.
- Return to work mid-week so you only have 2 or 3 days before the weekend. It makes the first week back to work a short week and easier to handle.

Visit www.medela.com to educate yourself on products and information available for you and your baby.

To locate Medela products or a breastfeeding specialist in your area, go to www.medela.com or call 1-800 TELL YOU, 24 hours a day, 7 days a week.

Overcoming Challenges

While breastfeeding is a wonderful and rewarding experience, it is a learning process for you and your baby. You might need some help. If you are having any concerns, it is important that you contact your lactation consultant or healthcare professional as soon as possible. They are there to help you continue to provide breastmilk to your baby. For help in finding a lactation consultant near you, go to **www.medelabreastfeedingus.com/bnnsearch**

Hygiene

Before pumping your milk, be sure to wash your hands well with soap and water. Wash all the collection bottles and breastpump parts that come in contact with your breasts or the breastmilk after each use. Refer to breastpump instructions for complete details.

- For breastfeeding support from the Nursing Mothers Council: **www.nursingmothers.org**
- For free advice from a lactation consultant: **www.medelabreastfeedingus.com/ask-the-lc**
- For breastfeeding tips & solutions including:
  - How to breastfeed
  - Challenges & solutions
  - Going back to work
  - Breastpumping

  www.medelabreastfeedingus.com/tips-and-solutions
- For help choosing a breastpump: **www.medelabreastfeedingus.com/product-selector**

Join our communties and share tips and advice with thousands of other breastfeeding moms!

Download
iBreastfeed

Available on the iPhone
App Store

FREE at the App® store.

Breastfeeding Log

Date:

Age Of Baby:

	Time of Day	Minutes/Amount: Left Breast	Minutes/Amount: Right Breast	Total Minutes	Notes
1					
2					
3					
4					
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1 oz = 30 mL

Term Of The Day

Colostrum – The first milk that comes out of a mother's breast up to 5 days after delivery. In the first few days after birth, most mothers express very small amounts of this milk.

Did You Know?

Colostrum, a concentrated form of your milk, has a thick, yellowish appearance. It is rich in proteins and antibodies that provide protection and help your baby grow. It is often called "liquid gold".

Diaper Log

Wet Diapers:

Dirty Diapers:

Note:

Breastfeeding Log

Date:

Age Of Baby:

	Time of Day	Minutes/Amount: Left Breast	Minutes/Amount: Right Breast	Total Minutes	Notes
1					
2					
3					
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1 oz = 30 mL

Term Of The Day

Oxytocin – A hormone that signals the release of milk and the uterus to contract. During the first few days of breastfeeding and/or pumping you may have slight stomach pain as your uterus is signaled to contract.

Did You Know?

Colostrum is yellow in color due to beta-carotene, a protective factor, which helps build your baby's immune system.

Diaper Log

Wet Diapers:

Dirty Diapers:

Note:

Breastfeeding Log

Date:

Age Of Baby:

	Minutes/Amount			
	Time of Day	Left Breast	Right Breast	Total Minutes	Notes
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1 oz = 30 mL

Term Of The Day

Latching On – is when baby first takes in the nipple and areola area of the breast. It is important for your baby to open his mouth wide and latch deeply on the breast to nurse effectively and minimize sore nipples.

Did You Know?

When you are first starting out with breastfeeding, you may feel awkward – that is common. It will take some practice and patience as you figure out breastfeeding together. Remember, both you and your baby are learning a new skill.

Diaper Log

Wet Diapers:

Dirty Diapers:

Note:

Breastfeeding Log

Date:

Age Of Baby:

	Minutes/Amount			
	Time of Day	Left Breast	Right Breast	Total Minutes	Notes
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1 oz = 30 mL

Term Of The Day

Bilirubin – A yellow substance that the body makes as red blood cells are broken down. When bilirubin builds up in the body, skin can turn yellow which is called jaundice. Talk to your doctor if your baby appears to have yellow coloring.

Did You Know?

Doctors and nurses expect you to ask questions so your mind can be put at ease. Don't be afraid to ask any questions that come to mind. Keep a pen and paper close to you to write your questions down.

Diaper Log

Wet Diapers:

Dirty Diapers:

Note:

Breastfeeding Log

Date:

Age Of Baby:

	Minutes/Amount			
	Time of Day	Left Breast	Right Breast	Total Minutes	Notes
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1 oz = 30 mL

Term Of The Day

Engorgement – Overfullness of the breast caused by the milk "coming in" or when the breasts are not emptied frequently and completely.

Did You Know?

Discomfort caused by engorgement can be reduced by breastfeeding at least 10 times per 24 hours *(even at night)* or breastfeed on demand. Even if baby is sleepy, wake every 2-3 hours, allowing one long stretch of 4-5 hours at night.

Diaper Log

Wet Diapers:

Dirty Diapers:

Note:

Breastfeeding Log

Date:

Age Of Baby:

	Minutes/Amount			
	Time of Day	Left Breast	Right Breast	Total Minutes	Notes
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1 oz = 30 mL

Term Of The Day

Rooting – A baby's natural instinct to turn her head and open her mouth in the direction where she was touched on the cheek or lip.

Did You Know?

You can easily take baby off your breast by inserting a clean finger into the baby's mouth between the gums and holding it there while pulling him away. This will help ease the suction and also be less painful to your nipple area.

Diaper Log

Wet Diapers:

Dirty Diapers:

Note:

Breastfeeding Log

Date:

Age Of Baby:

	Minutes/Amount			
Time of Day	Left Breast	Right Breast	Total Minutes	Notes
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1 oz = 30 mL

Term Of The Day

C-Hold – Mother places her thumb well above the areola and the rest of her fingers below and under the breast.

Did You Know?

The C-hold position helps lift the breast and guide your nipple in any direction to assist the baby in taking more of the areola in her mouth to create a good latch.

Diaper Log

Wet Diapers:

Dirty Diapers:

Note:

Breastfeeding Log

Date:

Age Of Baby:

	Minutes/Amount			
Time of Day	Left Breast	Right Breast	Total Minutes	Notes
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1 oz = 30 mL

Term Of The Day

Phototherapy – Common therapy for treating jaundice, which consists of exposing large areas of the baby's skin to special blue lights.

Did You Know?

The most effective phototherapy keeps baby and mother together so breastfeeding can continue. Ask your doctor about treatment options that allow you to continue breastfeeding.

Diaper Log

Wet Diapers:

Dirty Diapers:

Note:

Breastfeeding Log

Date:

Age Of Baby:

	Time of Day	Minutes/Amount: Left Breast	Minutes/Amount: Right Breast	Total Minutes	Notes
1					
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1 oz = 30 mL

Term Of The Day

Prolactin – A hormone that helps stimulate development of the breast for milk production.

Did You Know?

More frequent feeding and/or pumping will help start Prolactin production, increasing your milk supply.

Diaper Log

Wet Diapers:

Dirty Diapers:

Note:

Breastfeeding Log

Date:

Age Of Baby:

	Time of Day	Minutes/Amount: Left Breast	Minutes/Amount: Right Breast	Total Minutes	Notes
1					
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1 oz = 30 mL

Term Of The Day

BPA – Bisphenol-A, a chemical found in polycarbonate plastic baby bottles. There is some concern about the safety of this chemical and more research is needed. Medela products that touch breastmilk are BPA-free.

Did You Know?

You can detect safe plastic by finding the recyle number on the bottom of most bottles. Polypropylene (PP), recycle code "♳", is BPA-free. Recycle code "♳" describes different plastics, including a hard transparent plastic called Polycarbonate, which contains BPA. Contact the manufacturer if you are uncertain your bottle is BPA-free, a recycle code "♳" may or may not contain BPA.

Diaper Log

Wet Diapers:

Dirty Diapers:

Note:

Breastfeeding Log

Date:

Age Of Baby:

	Minutes/Amount			
	Time of Day	Left Breast	Right Breast	Total Minutes	Notes
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10					

1 oz = 30 mL

Term Of The Day

Nutrition – is the process by which you take in and use food material. It is important that you try to eat a healthy, balanced diet, and drink fluids while you are giving your baby breastmilk to help protect the nutrients that are stored in your body.

Did You Know?

While eating a balanced diet is important, research tells us that the quality of your diet has little influence on your breastmilk. Nature is very forgiving – mother's milk is designed to provide for and protect your baby. Your milk actually changes taste and smell depending on what you eat and provides your baby with a variety of flavors and odors.

Diaper Log

Wet Diapers:

Dirty Diapers:

Note:

Breastfeeding Log

Date:

Age Of Baby:

	Minutes/Amount			
	Time of Day	Left Breast	Right Breast	Total Minutes	Notes
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3					
4					
5					
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8					
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10					

1 oz = 30 mL

Term Of The Day

Antibodies – Substances developed in blood that fight toxins. Breastmilk contains antibodies that help the body fight infection.

Did You Know?

When you are with your baby antibodies are produced and are transferred to your baby through your breastmilk. This helps protect your baby from germs around you.

Diaper Log

Wet Diapers:

Dirty Diapers:

Note:

Breastfeeding Log

Date:

Age Of Baby:

	Minutes/Amount			
	Time of Day	Left Breast	Right Breast	Total Minutes	Notes
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1 oz = 30 mL

Term Of The Day

Plugged Duct – A plugged *(or blocked)* duct is an area of the breast where milk flow is blocked. A plugged duct usually comes on slowly and affects only one breast.

Did You Know?

Sometimes massaging the breast during breastfeeding and/or pumping can help relieve plugged ducts. Also, massaging the breast before breastfeeding can help to relieve engorgement.

Diaper Log

Wet Diapers:

Dirty Diapers:

Note:

Breastfeeding Log

Date:

Age Of Baby:

	Minutes/Amount			
	Time of Day	Left Breast	Right Breast	Total Minutes	Notes
1					
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1 oz = 30 mL

Term Of The Day

Mastitis – The inflammation of the breast that can be caused by a block, infection and/or allergy. Mastitis is most common in the first 2-3 weeks but can occur at any stage of breastfeeding.

Did You Know?

Mastitis may come on abruptly, usually involves a fever over 100°F and may affect only one breast. Apply a moist-heating pad or hot wet towel to the infected breast, feed frequently and call your doctor immediately upon experiencing symptoms of mastitis.

Diaper Log

Wet Diapers:

Dirty Diapers:

Note:

Call the Breastfeeding National Network

to locate Medela products in your area.

Get additional information on where to:

1. Rent a Medela hospital-grade electric breastpump
2. Rent or purchase Medela breastpumps and accessories
3. Find a quality baby scale
4. Find the best nursing bras
5. Find a breastfeeding specialist in your area

1-800-TELL YOU

(1-800-835-5968)

24 hours a day • 7 days a week or visit **www.medela.com**

Medela, Inc., 1101 Corporate Dr. McHenry IL 60050
Ph: (800) 435-8316 or (815) 383-1166 Fax: (815) 383-1246 Email: customer.service@medela.com

1908080 D 0215 Printed in the USA

EXHIBIT 13.3

BREASTMILK STORAGE GUIDELINES MAGNET

Freshly Expressed Breastmilk Storage Guidelines
(For Healthy Term Babies)

Room Temperature	Cooler with 3 Frozen Ice Packs	Refrigerator	Freezer
4–6 hours at 66–78 °F (19–26 °C)	24 hours at 59 °F (15 °C)	3–8 days at 39 °F or lower (4 °C)	6–12 months 0–4 °F (-18–-20 °C)

For more information, or to find a lactation consultant near you, call our Breastfeeding National Network (BNN) at **1-800-TELL YOU or visit www.medela.com**

medela

References: www.BreastmilkGuidelines.com

1547514 C 1213

EXHIBIT 13.4

PACKAGE LABELING

medela

freestyle

d bl l t b t

rechargeable | mobile

1 choice of hospitals & mothers~

medela

Congratu at ons

and we come o he

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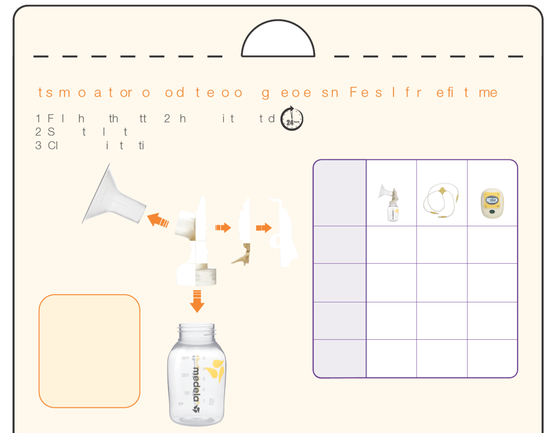

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1 choice of hospitals & mothers~

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2 PHASE EXPRESSION

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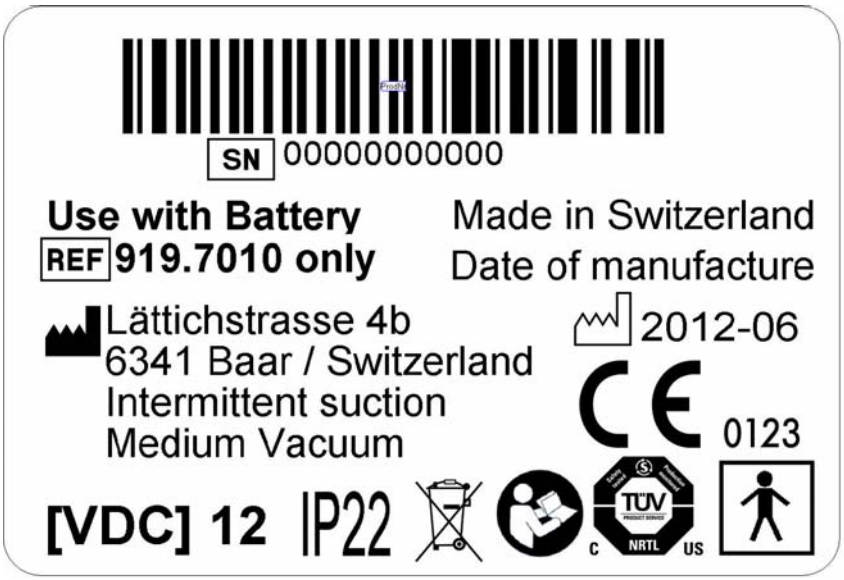
EXHIBIT 13.5

PRODUCT LABELING



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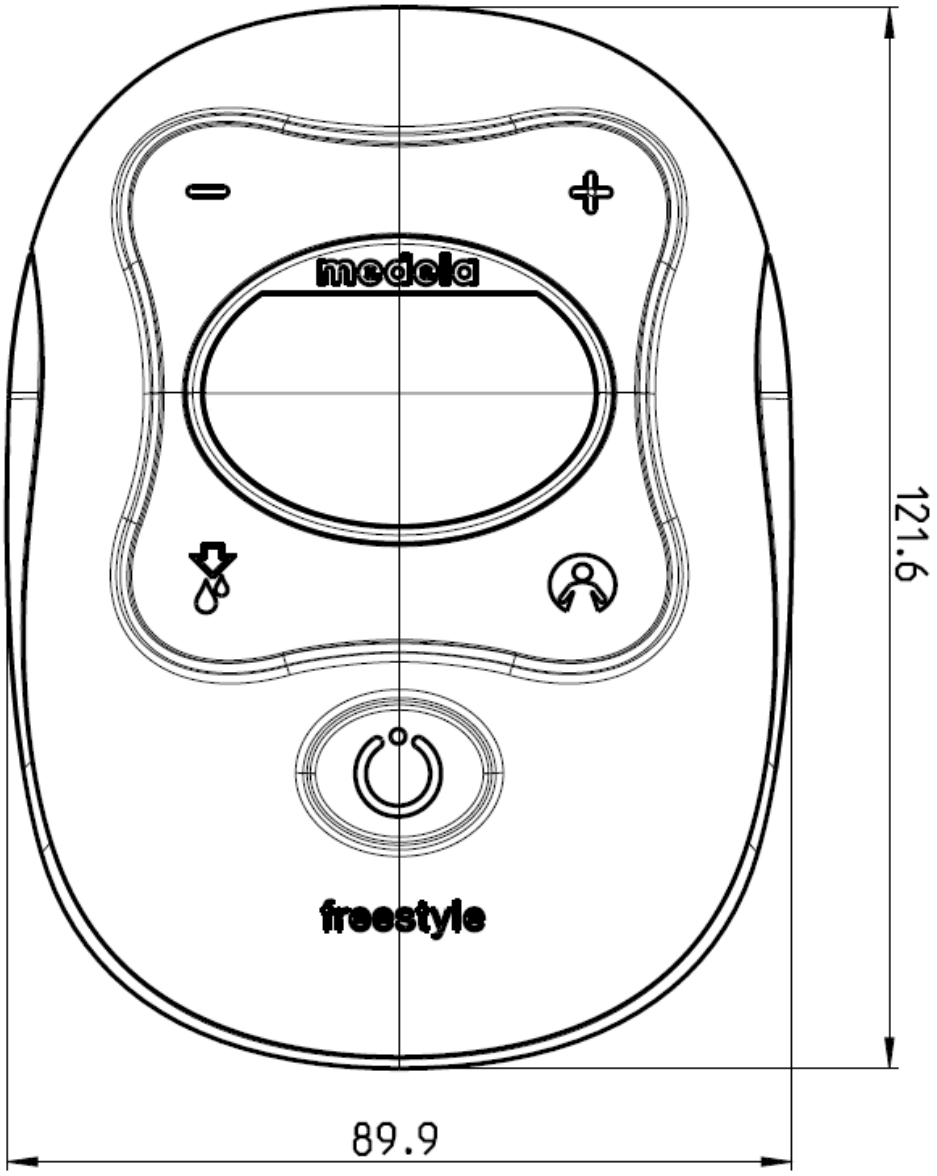
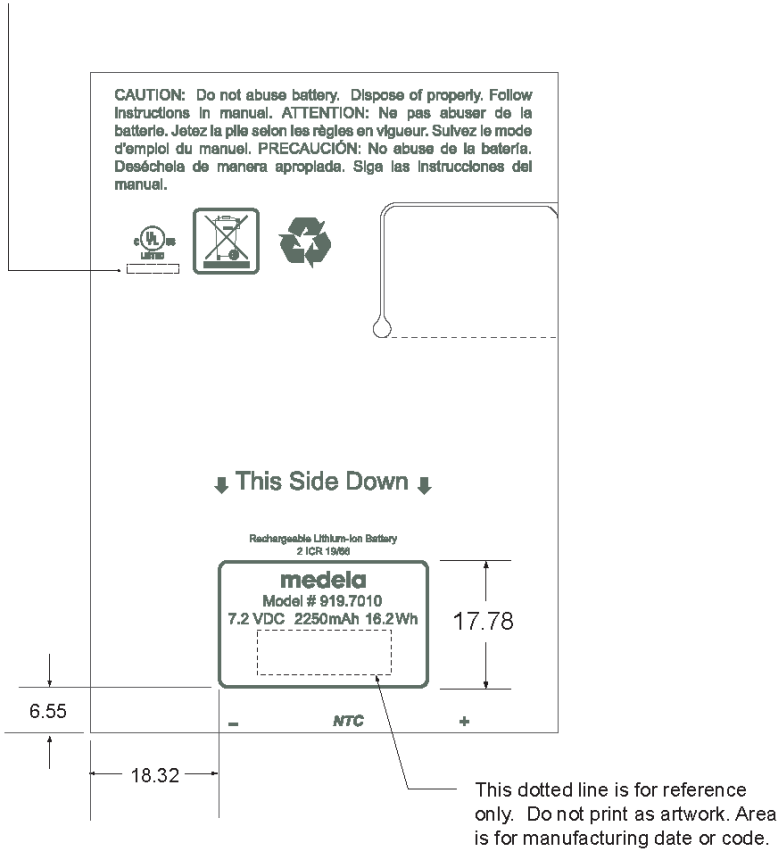
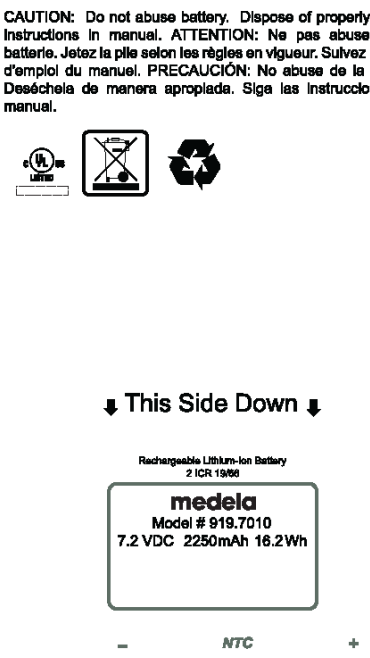


Drawing from 200_0392_c (original in German)

REV	DCO #	CHANGE	DATE	INIT.
B	A5214	Added recycle symbols, battery type, and removed arrow on tab.	04/16/08	J.S.
C	A5433	Added dotted line box under UL symbol Changed "7.4 VDC 2000 mAh" to "7.2 VDC 2250mAh"	07/31/08	TDK
D	A5687	Increased "trash can" icon to 9mm x 9mm Added 16.2Wh	12/12/08	TDK
E	A8524	Changed IEC number, updated medela wordmark	10/03/11	KH

This dotted line is for reference only. Do not print as artwork. This area for the UL File Number.





NOTES:

1. This graphic process is silk screen
2. Fonts used: Ariel
3. Surface finish is: N/A
4. PMS Colors: 445U
5. Graphic artwork is shown for size and color only. Refer to Engineering drawing for location specifications.

	All dimensions in millimeters. Do not scale drawing.	SCALE 1:1	Date: 29 April 2008

Project Liberty- Battery Pack Sticker/Label

medela 1101 Corporate Drive McHenry, IL 60050	This drawing is confidential and cannot be copied, shown, or made available to third parties without written permission.	DRAWN BY	SIZE	PRODUCT GRAPHIC NUMBER	REV
		J. Solberg	A	3010015	E

EXHIBIT 13.6

ACCESSORY LABELS

BACKSIDE OF PACKAGE

1/2" no print area

medela

1. Super absorbent materials prevent leakage and maintain dryness.
2. Soft for added comfort.
3. Double adhesive tape keeps pads in place.

1. Matériel très absorbant qui prévient les fuites et assure que la peau demeure sèche.
2. Doux pour un confort accru.
3. Ruban adhésif double qui garde les coussinets en place.

- **Wash hands with soap and water prior to use.**
- **Designed for a single user.**
- **Laver les mains avec de l'eau et du savon avant d'utiliser.**
- **Conçu pour une seule utilisatrice.**

Contains: 4 disposable individually wrapped nursing pads
Materials: non-woven fabric, fluff pulp, SAP, tissue paper, PE film.

Distributed in the U.S. exclusively by Medela, Inc.
1101 Corporate Drive, McHenry, IL 60050
Phone: (800) 435-8316 or (815) 363-1166
Fax: (815) 363-1246
Email: customer.service@medela.com
www.medela.com

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Medela est une marque de commerce enregistrée de Medela Holding, AG.
Fabriqué, emballé et imprimé en Chine.
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Contient : 4 coussinets d'allaitement jetables emballés individuellement
Matériaux : tissu non tissé, pâte en flocons, polymère super-absorbant, papier tissu, film PE

Distribué au Canada exclusivement par
Medela Canada, Inc.
4160 Sladeview Crescent
Unit #8, Mississauga, Ontario Canada L5L OA1
Téléphone. : (800) 435-8316
Télécopieur. : (800) 995-7867
Email/Courriel :
info@medela.ca

#89982 U.S.
#29982 Canada

1/8" no print area on sides

bottom package fold

4 – pads/ coussinets

1/8" no print area on sides

bottom package fold

- discreet under clothing
- discret sous les vêtements

contre les fuites - le jour ou la nuit

- excellent absorbency & leak protection – day or night
- excellente absorption et protection contre les fuites - le jour ou la nuit

now MORE absorbent maintenant PLUS absorbants

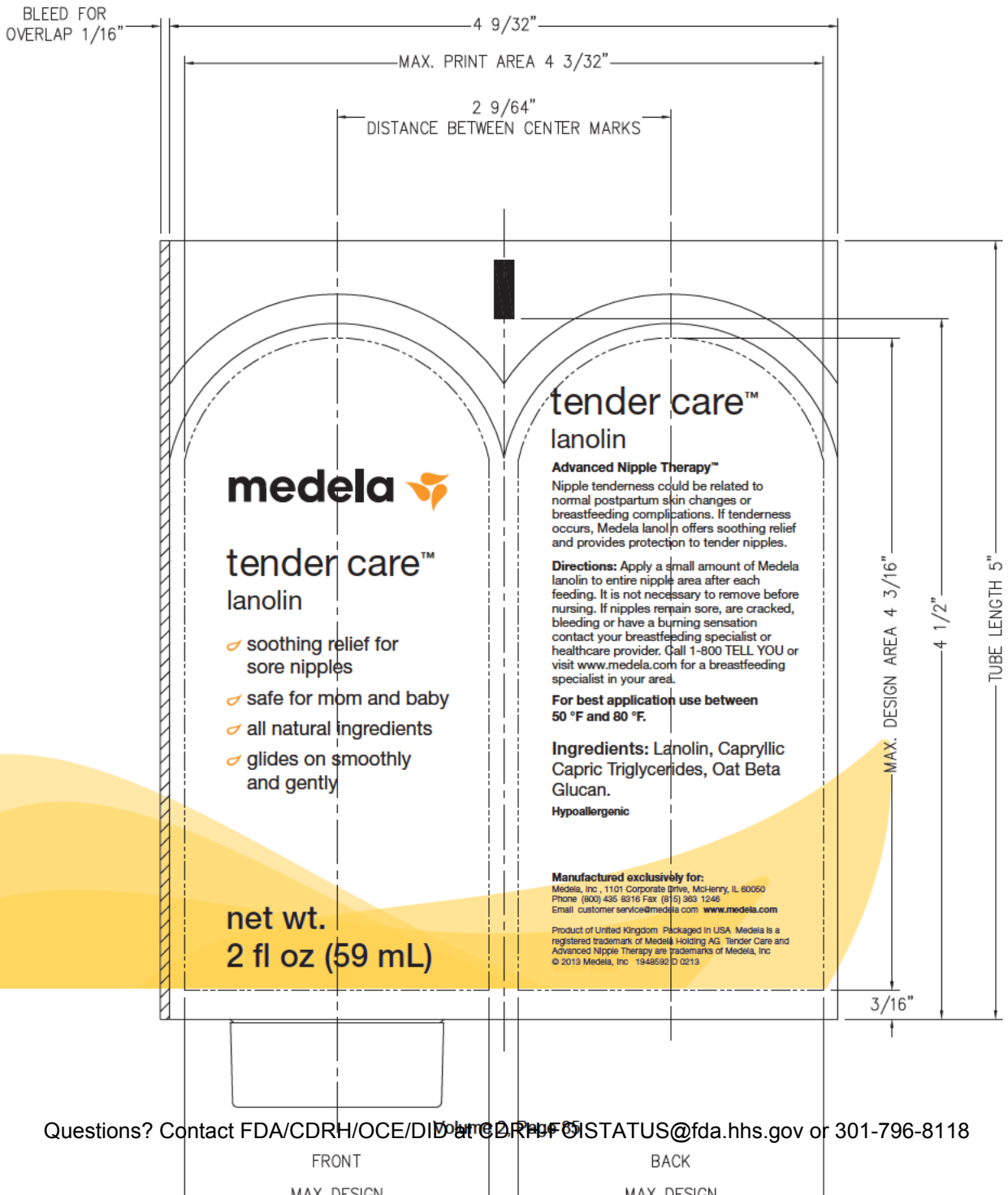
breastfeeding is best

disposable nursing pads
coussinets d'allaitement jetables

medela

1/2" no print area

FRONT OF PACKAGE



SILGAN TUBES CORPORATION
1005 COURTAULDS DR.
WOODSTOCK, ILLINOIS

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DRAWING NUMBER 74PDA-1280

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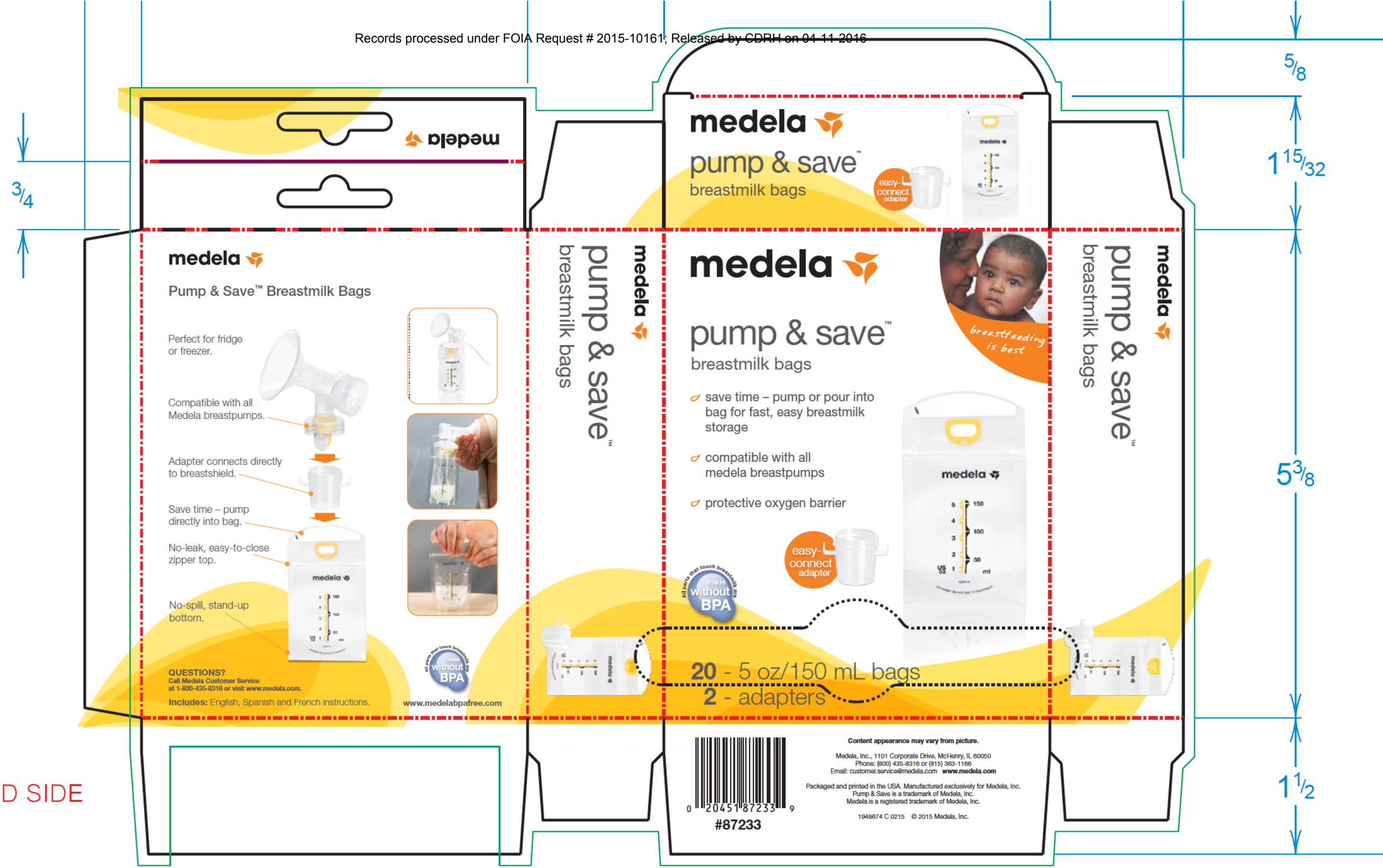

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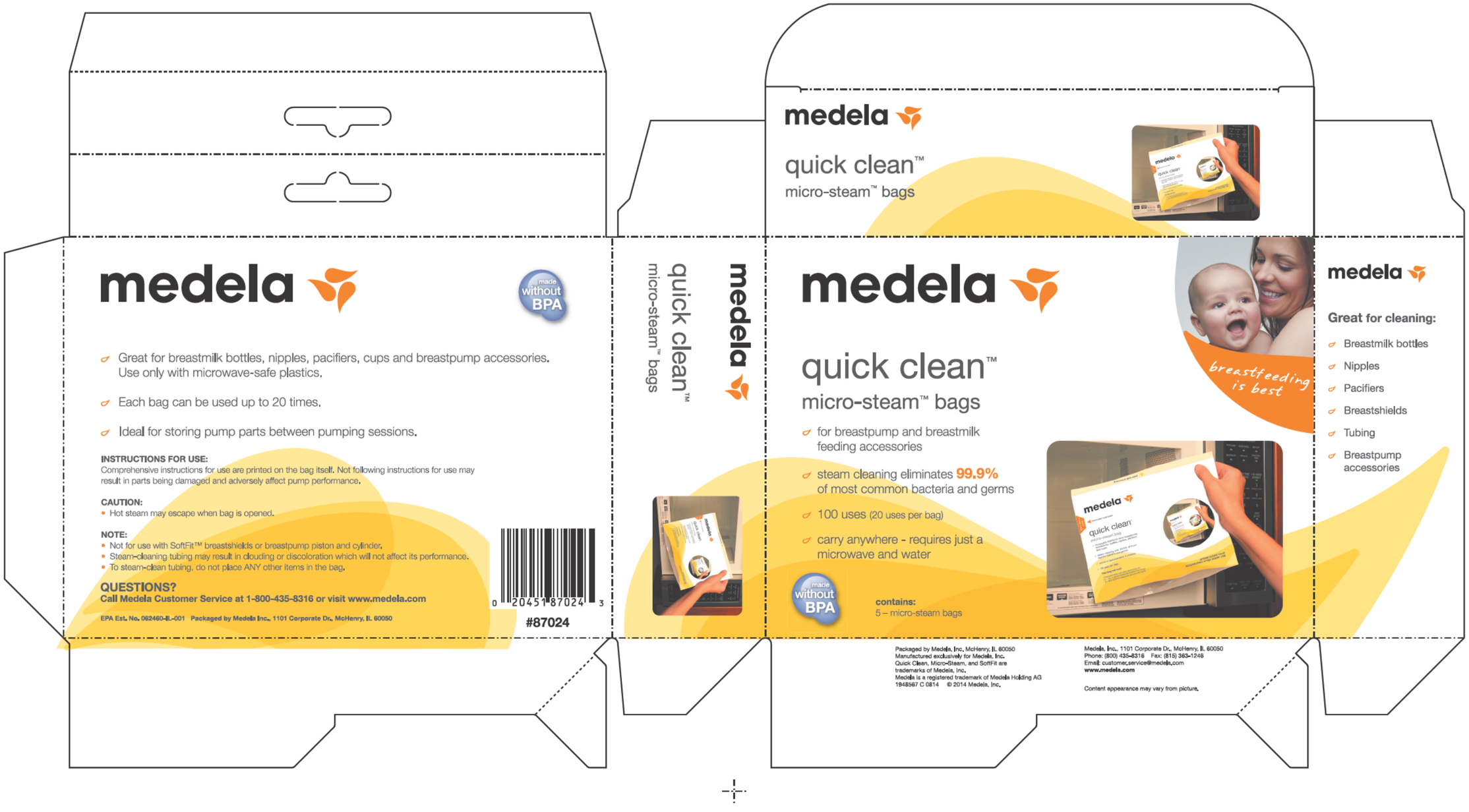


medela

PersonalFit™ breastshields

\# 1 choice of hospitals & mothers™

24 mm breastshields bulk pack

- choose the right size for maximum comfort and pumping efficiency
- breastshields available in 21 mm, 24 mm, 27 mm, 30 mm and 36 mm
- the enclosed breastshields work only with Medela PersonalFit Connectors (#87076), sold separately

Bulk Pack

AUTHENTIC medela spare parts

made without BPA

24 mm

Contains: 12 - (24 mm) breastshields

for assembly and cleaning refer to breastpump kit instructions

0 20451 87087 8

#87087

Medela, Inc. ... McHenry, IL 6005
Phone: (800) 435-8316
Email: customer.service@medela.com
www.medela.com

#1 Choice of Hospitals and Mothers are trademarks of Medela, Inc.
Made in USA. Printed in the USA.
Contents may vary from picture.

M 24 mm

medela

PersonalFit™

24 mm breastshields

M
24 mm

AUTHENTIC medela spare parts

2 – breastshields

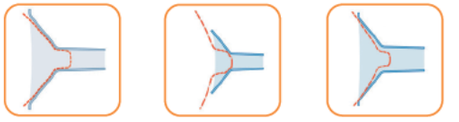
NO TINKER CREATING

2456535-205

medela

Choosing the right size PersonalFit™ breastshield:

1. Determine the size you're currently using. If you're not sure, look for the size embossed on your breastshield.
2. While pumping, compare your fit to the images below as a sizing guideline.



Correct fit | Your breastshield is **too small**; try a larger size | Your breastshield is **too large**; try a smaller size

S 21 mm | M 24 mm (provided with Medela breastpumps) | L 27 mm | XL 30 mm | XXL 36 mm

See a lactation consultant or breastfeeding specialist for assistance in choosing the right size breastshield.

Contains: 2 PersonalFit 24 mm breastshields

medela

PersonalFit™

24 mm breastshields

Why PersonalFit?
Because one size doesn't fit all!

- Personalize your pump.
- Achieve maximum pumping comfort.
- Experience optimal milk removal.
- Compatible with Medela breastpumps including Pump In Style® Advanced and Freestyle®.
- Always have clean parts on-hand!

medela

PersonalFit™

24 mm breastshields

M
24 mm

- choose the right size for maximum comfort & pumping efficiency (see reverse for details)
- compatible with all medela breastpumps

made without BPA

AUTHENTIC medela spare parts

2 – breastshields

medela

Authentic Medela Spare Parts are engineered, tested and approved to work specifically with your Medela breastpump. Non-Medela spare parts can vary significantly in design, materials, and workmanship; all of which may affect the performance of your Medela breastpump.

AUTHENTIC medela spare parts

Quality & performance you can trust

Visit www.medelaaccessories.com for more information.

QUESTIONS?
Call Medela Customer Service at 1-800-435-8316 or visit www.medela.com

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PersonalFit is a trademark of Medela, Inc.
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CAUTION: If you experience discomfort while pumping, contact a breastfeeding specialist. You may need a larger size PersonalFit breastshield to reduce the possibility of nipple irritation or injury. Call 1-800-TELL-YOU to locate a breastfeeding specialist in your area.

NO COAT

medela

PersonalFit™

BREASTSHIELD SYSTEM
JUEGO COPA PARA SENO
ENSEMBLE-TÉTERELLE

Instructions for use

Instrucciones para su uso

Mode d'emploi

Medela, Inc.
P.O. Box 660
McHenry, IL 60051-0660
Phone/Teléfono/Tél.: 1-800-435-8316, 1-815-363-1166
Fax/Téléc.: 1-815-363-1246
Email/Courriel: customer.service@medela.com

Medela Canada Inc.
4090B Sladeview Crescent, Unit 2
Mississauga, Ontario L5L 5Y5
Phone/Teléfono/Tél.: 1-905-608-7272, 1-800-435-8316
Fax/Téléc.: 1-905-608-8720, 1-800-995-7867
Email/Courriel: customer.service@medela.ca

www.medela.com

medela

Instructions for use

Cleaning and Sterilization
Follow these cleaning instructions in the hospital or at home unless you are otherwise instructed by your physician or another medical professional from your hospital.

Home Sanitizing
Prior to first use:

- Disassemble parts.
- Boil for 10 minutes.

After each use:
WASH – Disassemble and wash all parts that come in contact with the breast or milk in soapy water or wash in top-rack of dishwasher.

RINSE – Rinse parts in clear water.

AIR-DRY – Air-dry on clean towel and cover parts when not in use.

Assembly:
- Insert the small end of the Breastshield tightly into the small end of the Connector.
- Assemble and operate per instructions provided with pump.

Hospital Sterilization of Kit (Autoclave)
Prior to first use, follow these cleaning instructions in the hospital unless you are otherwise instructed by your physician or another medical professional from your hospital.

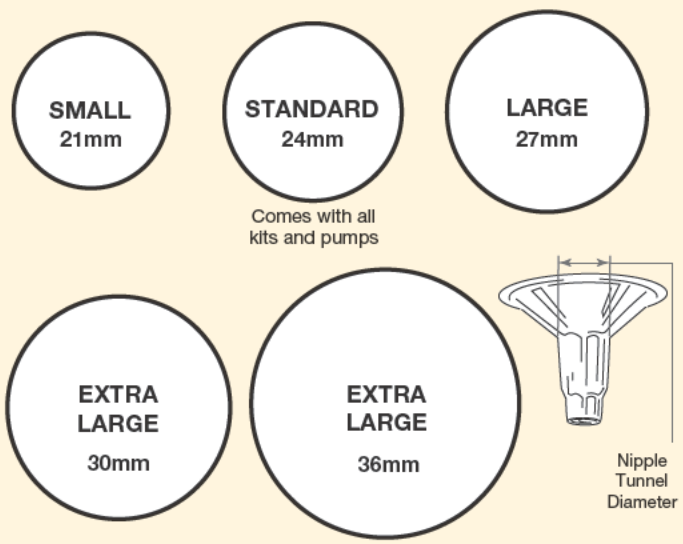
All PersonalFit™ disassembled parts can be autoclaved to a maximum of 272°F for 3 minutes at 29 PSIG or 250° F for 15 minutes at 15 PSIG.

To avoid damage during and immediately after sterilization:

- Sterilize parts without applying external pressure on them.
- Allow parts to cool before applying external pressure.

Note: A white or gray tint may appear on parts after sterilization. This is a normal property of the plastic and will not affect performance.

Nipple Tunnel Diameter



Parts

Connector	87071 (US) / 27071 (Canada)
21mm Breastshield	87072 (US) / 27072 (Canada)
24mm Breastshield	87073 (US) / 27073 (Canada)
27mm Breastshield	87074 (US) / 27074 (Canada)
30mm Breastshield	87075 (US) / 27075 (Canada)
36mm Breastshield	87084 (US) / ***Coming Fall 2006***
SoftFit™ Breastshield (~24mm)	67246 (US) / 27246 (Canada)

Volume 2 Page 20

**See your breastfeeding specialist for proper size breastshields, or if you require a size larger than 36mm.*

Instrucciones de uso

Limpieza y esterilización
Siga estas instrucciones de limpieza en el hospital o en su casa a menos que tenga instrucciones contrarias por parte de su médico o de algún otro profesional médico en su hospital.

Higienización en casa
Antes del primer uso:

- Desarme las piezas.
- Hierva las piezas durante 10 minutos.

Después de cada uso:
LAVADO – Desarme y lave las piezas que tengan contacto con el seno o la leche. Lave las piezas en agua jabonosa o en la parte superior del lavaplatos.

ENJUAGUE – Enjuague las piezas en agua limpia.

SECADO AL AIRE – Permita que las piezas se sequen al aire sobre una toalla limpia y cúbralas cuando no las utilice.

Armado:
- Inserte el extremo pequeño de la copa para seno firmemente en el extremo pequeño del conector.
- Arme y utilice la bomba de acuerdo con el instructivo.

Esterilización del aparato en el hospital (Autoclave)
Antes de usar el aparato por primera vez, siga estas instrucciones de limpieza en el hospital, a menos que tenga instrucciones contrarias por parte de su médico o de algún otro profesional médico del hospital.

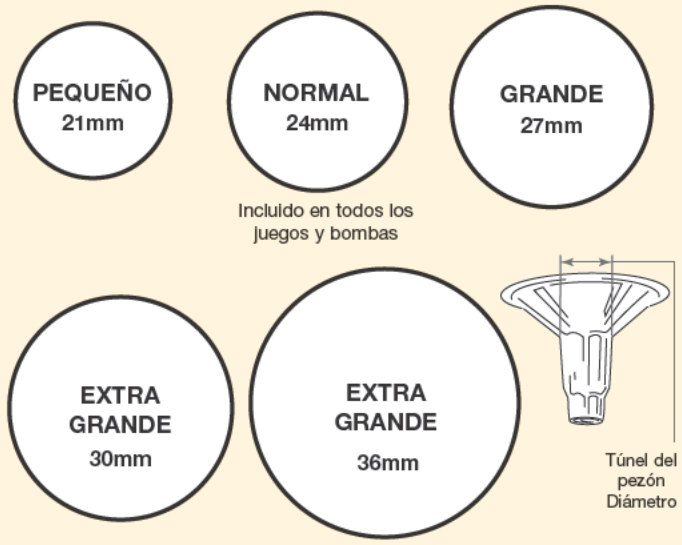
Las piezas desarmadas del juego de copa para seno PersonalFit™ pueden esterilizarse en autoclave durante tres minutos a 2 bar (29 PSIG) y temperatura máxima de 133° C (272° F), o durante 15 minutos a 1 bar (15 PSIG) y temperatura máxima de 121° C (250° F).

Para evitar daños durante e inmediatamente después de la esterilización:

- Esterilice las piezas sin aplicar presión externa sobre ellas.
- Deje que las piezas se enfríen antes de aplicar presión externa.

Nota: Puede aparecer un tinto blancuzco o grisáceo en las piezas después de la esterilización. Ésta es una propiedad normal del plástico y no afecta el funcionamiento.

Túnel del pezón Diámetro



Piezas:

Conector	87071 (E.E.U.U.) /27071 (Canadá)
Copa para seno de 21 mm	87072 (E.E.U.U.) /27072 (Canadá)
Copa para seno de 24 mm	87073 (E.E.U.U.) 27073 (Canadá)
Copa para seno de 27 mm	87074 (E.E.U.U.) /27074 (Canadá)
Copa para seno de 30 mm	87075 (E.E.U.U.) /27075 (Canadá)
Copa para seno de 36 mm	87084 (E.E.U.U.) ***/Entrando Otoño 2006***
Copa para seno SoftFit™ (~24 mm)	67246 (E.E.U.U.) /27246 (Canadá)

**Consulte con un especialista en lactancia para determinar el tamaño correcto de las copas para senos, o si requiere un tamaño mayor que 36 mm.*

Mode d'emploi

Lavage et stérilisation
Que ce soit à l'hôpital ou à la maison, procédez conformément aux instructions suivantes, à moins qu'un médecin ou un autre professionnel de la santé ne vous recommande de procéder autrement.

Stérilisation à domicile
Avant d'utiliser cet ensemble pour la première fois :

- Démontez toutes les pièces.
- Faites bouillir pendant 10 minutes.

Après chaque utilisation :
LAVEZ – Démontez toutes les pièces qui viennent en contact avec le sein ou avec le lait et lavez-les à l'eau et au détergent (ou encore dans le compartiment du haut du lave-vaisselle).

RINCEZ – Rincez les pièces à l'eau claire.

LAISSEZ SÉCHER – Laissez les pièces sécher à l'air sur une serviette propre, et recouvrez-les lorsqu'elles ne servent pas.

Assemblage :
- Introduisez le petit bout de la téterelle choisie dans la petite extrémité du connecteur.
- Assemblez et faites fonctionner conformément aux instructions fournies avec le tire-lait.

Stérilisation à l'hôpital (autoclave)
Avant d'utiliser cet ensemble pour la première fois, suivez ces instructions pour la stérilisation à l'hôpital, à moins d'avoir reçu des instructions différentes d'un médecin ou autre membre du personnel médical de l'hôpital.

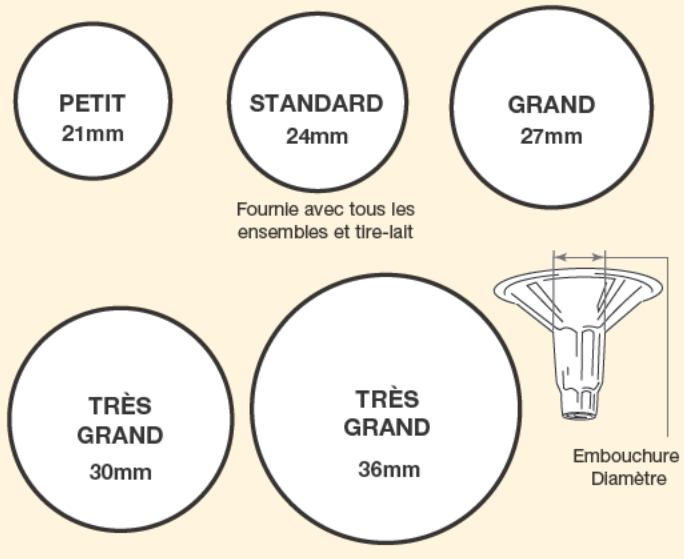
Toutes les pièces démontées de l'ensemble PersonalFit™ peuvent être autoclavées à une température maximale de 133 °C (272 °F) pendant 3 minutes sous une pression de 29 PSIG, ou de 121 °C (250 °F) pendant 15 minutes sous une pression de 15 PSIG.

Pour éviter les dommages pendant et immédiatement après la stérilisation :

- Stérilisez les pièces sans appliquer de pression externe dessus.
- Laissez refroidir les pièces avant d'appliquer une pression externe dessus.

Note : Une fois stérilisées, les pièces peuvent prendre une teinte blanchâtre ou grisâtre. Cela est normal et n'affecte pas leur performance.

Embouchure Diamètre



Pièces:

Connecteur	87071 (É.–U.) / 27071 (Canada)
Téterelle de 21 mm	87072 (É.–U.) / 27072 (Canada)
Téterelle de 24 mm	87073 (É.–U.) / 27073 (Canada)
Téterelle de 27 mm	87074 (É.–U.) / 27074 (Canada)
Téterelle de 30 mm	87075 (É.–U.) / 27075 (Canada)
Téterelle de 36 mm	87084 (É.–U.) / ***Disponible Automne 2006***
Téterelle SoftFit™ (~24 mm)	67246 (É.–U.) / 27246 (Canada)

**Consultez votre spécialiste en lactation pour déterminer quelle est la taille de téterelle qui vous convient, ou si vous avez besoin d'une taille supérieure à 36 mm.*

medela

PersonalFit™ breastshields

1 choice of hospitals & mothers™

27 mm breastshields bulk pack

Bulk Pack

- choose the right size for maximum comfort and pumping efficiency
- breastshields available in 21 mm, 24 mm, 27 mm, 30 mm and 36 mm
- the enclosed breastshields work only with Medela PersonalFit Connectors (#87076), sold separately

AUTHENTIC medela spare parts

made without BPA

27 mm

Contains: 12 - (27 mm) breastshields

for assembly and cleaning refer to breastpump kit instructions

0 20451 87077 9

#87077

Phone: (800) 435-8316
Email: customer.service@medela.com
www.medela.com

XXL
36 mm

medela

PersonalFit™

36 mm breastshields

XXL
36 mm

AUTHENTIC medela spare parts

2 – breastshields

medela

Choosing the right size PersonalFit™ breastshield:

1. Determine the size you're currently using. If you're not sure, look for the size embossed on your breastshield.
2. While pumping, compare your fit to the images below as a sizing guideline.

Correct fit

Your breastshield is **too small**; try a larger size

Your breastshield is **too large**; try a smaller size

S 21 mm
M 24 mm (provided with Medela breastpumps)
L 27 mm
XL 30 mm
XXL 36 mm

See a lactation consultant or breastfeeding specialist for assistance in choosing the right size breastshield.

Contains: 2 PersonalFit 36 mm breastshields

#87084

medela

PersonalFit™

36 mm breastshields

Why PersonalFit?
Because one size doesn't fit all!

- Personalize your pump.
- Achieve maximum pumping comfort.
- Experience optimal milk removal.
- Compatible with Medela breastpumps including Pump In Style® Advanced and Freestyle®.
- Always have clean parts on-hand!

medela

PersonalFit™

36 mm breastshields

- choose the right size for maximum comfort & pumping efficiency (see reverse for details)
- compatible with all medela breastpumps

XXL
36 mm

made without BPA

AUTHENTIC medela spare parts

2 – breastshields

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Email: customer.service@medela.com
www.medela.com

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Manufactured in the USA or Switzerland. Medela, Freestyle and Pump In Style are registered trademarks of Medela Holding AG.
PersonalFit is a trademark of Medela, Inc.
1948554 C 0813

CAUTION: If you experience discomfort while pumping, contact a breastfeeding specialist. You may need a different size PersonalFit breastshield to reduce this discomfort or nipple irritation or injury. Call 1-800-TELL-YOU to locate a breastfeeding specialist in your area.

medela

Authentic Medela Spare Parts are made with the quality materials and workmanship you expect and trust, only from Medela.

Non-Medela spare parts can vary significantly in terms of product design, materials, and workmanship; all of which may affect the performance of your Medela breastpump.

AUTHENTIC medela spare parts

Quality & performance you can trust.

Visit www.medelaaccessories.com for more information.

QUESTIONS?
Call Medela Customer Service at 1-800-435-8316 or visit www.medela.com

medela

PersonalFit™ breastshields

21 mm breastshields bulk pack

- choose the right size for maximum comfort and pumping efficiency
- breastshields available in 21 mm, 24 mm, 27 mm, 30 mm and 36 mm
- the enclosed breastshields work only with Medela PersonalFit Connectors (#87076), sold separately

Bulk Pack

AUTHENTIC medela spare parts

made without BPA

21 mm

Contains: 12 - (21 mm) breastshields

for assembly and cleaning refer to breastpump kit instructions

0 20451 87086 1

#87086

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Email: customer.service@medela.com
www.medela.com

PRINTED SIDE UP

#1060

2 — breastshields

AUTHENTIC medela spare parts

made without BPA

21 mm

S

personalize your breastshield size for better pumping

compatible with all medela breastpumps

choose the right size for maximum comfort and pumping efficiency (see reverse for details)

medela

PersonalFit™

21 mm breastshields

medela

Choosing the right size PersonalFit™ breastshield:

1. Determine the size you're currently using. If you're not sure, look for the size embossed on your breastshield (*see picture*). 24 mm (M) breastshields are provided with Medela breastpumps.

2. While pumping, compare your fit to the images below as a sizing guideline.

Correct fit

Your breastshield is **too small**; try a larger size

Your breastshield is **too large**; try a smaller size

AUTHENTIC medela spare parts

Quality & performance you can trust

Our size range ensures that you'll find the right fit for you:

S	M	L	XL	XXL
21 mm	24 mm *(provided with Medela breastpumps)*	27 mm	30 mm	36 mm

Use with PersonalFit™ connectors (sold separately).

See a lactation consultant or breastfeeding specialist for assistance in choosing the right size breastshield.

CAUTION: If you experience discomfort while pumping, contact a breastfeeding specialist. You may need a larger size PersonalFit™ breastshield to reduce the possibility of nipple irritation or injury. Call 1-800-TELL YOU to locate a breastfeeding specialist in your area.

QUESTIONS?
Call Medela Customer Service at 1-800-435-8316 or visit www.medela.com

Contains:
2 PersonalFit 21 mm breastshields

0 20451 87072 4

#87072

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Email: customer.service@medela.com **www.medela.com**

Manufactured in the USA or Switzerland. Packaged and printed in the USA.

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PersonalFit™ breastshields

30 mm breastshields bulk pack

- choose the right size for maximum comfort and pumping efficiency
- breastshields available in 21 mm, 24 mm, 27 mm, 30 mm and 36 mm
- the enclosed breastshields work only with Medela PersonalFit Connectors (#87076), sold separately

Bulk Pack

AUTHENTIC medela spare parts

made without BPA

30 mm

Contains: 12 - (30 mm) breastshields

for assembly and cleaning refer to breastpump kit instructions

0 20451 87079 3

#87079

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Email: customer.service@medela.com
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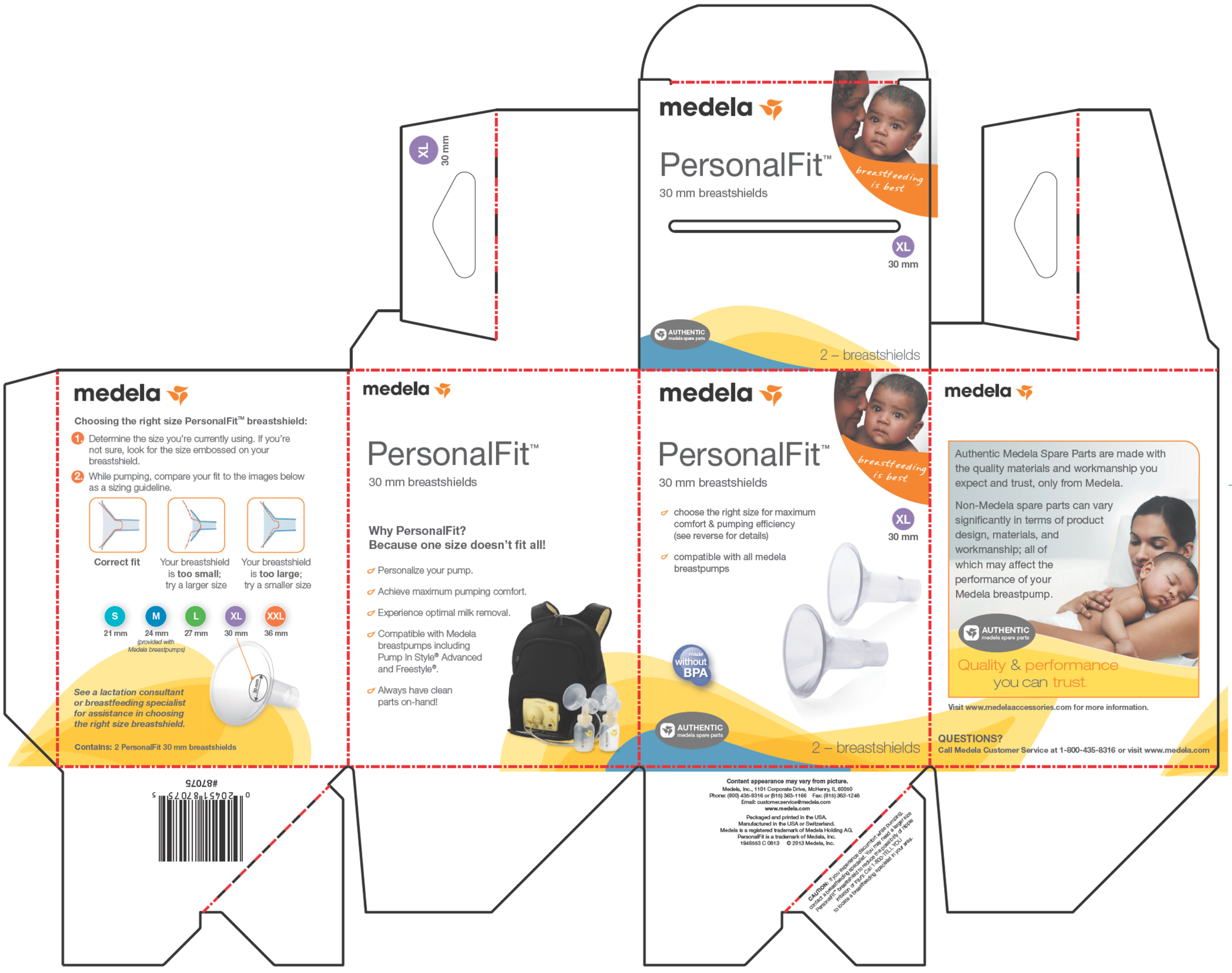

medela

PersonalFit™ breastshields

36 mm breastshields bulk pack

- choose the right size for maximum comfort and pumping efficiency
- breastshields available in 21 mm, 24 mm, 27 mm, 30 mm and 36 mm
- the enclosed breastshields work only with Medela PersonalFit Connectors (#87076), sold separately

Bulk Pack

AUTHENTIC medela spare parts

made without BPA

36 mm

Contains: 12 - (36 mm) breastshields

for assembly and cleaning refer to breastpump kit instructions

0 20451 87094 6

#87094

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www.medela.com

L
27 mm

medela

PersonalFit™
27 mm breastshields

L
27 mm

AUTHENTIC medela spare parts

2 – breastshields

medela

Choosing the right size PersonalFit™ breastshield:

1. Determine the size you're currently using. If you're not sure, look for the size embossed on your breastshield.
2. While pumping, compare your fit to the images below as a sizing guideline.

Correct fit

Your breastshield is **too small**; try a larger size

Your breastshield is **too large**; try a smaller size

S 21 mm
M 24 mm
L 27 mm
XL 30 mm
XXL 36 mm
(provided with Medela breastpumps)

See a lactation consultant or breastfeeding specialist for assistance in choosing the right size breastshield.

Contains: 2 PersonalFit 27 mm breastshields

#87274

medela

PersonalFit™
27 mm breastshields

Why PersonalFit?
Because one size doesn't fit all!

- Personalize your pump.
- Achieve maximum pumping comfort.
- Experience optimal milk removal.
- Compatible with Medela breastpumps including Pump In Style® Advanced and Freestyle®.
- Always have clean parts on-hand!

medela

PersonalFit™
27 mm breastshields

- choose the right size for maximum comfort & pumping efficiency (see reverse for details)
- compatible with all medela breastpumps

L
27 mm

made without BPA

AUTHENTIC medela spare parts

2 – breastshields

medela

Authentic Medela Spare Parts are made with the quality materials and workmanship you expect and trust, only from Medela.

Non-Medela spare parts can vary significantly in terms of product design, materials, and workmanship; all of which may affect the performance of your Medela breastpump.

AUTHENTIC medela spare parts

Quality & performance you can trust.

Visit www.medelaaccessories.com for more information.

QUESTIONS?
Call Medela Customer Service at 1-800-435-8316 or visit www.medela.com

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www.medela.com
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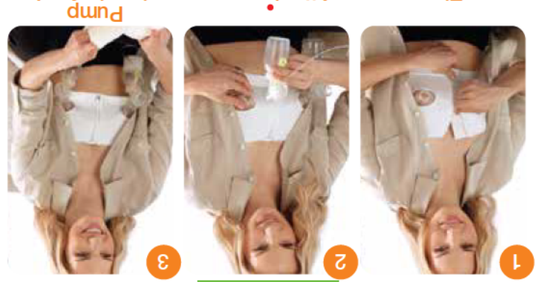
CAUTION: If you experience discomfort while pumping, contact a breastfeeding specialist. You may need a larger size PersonalFit breastshield to reduce the possibility of nipple irritation or injury. Call 1-800-TELL YOU to locate a breastfeeding specialist in your area.

vendor to apply velcro dots



aqueous knockout

medela

vendor to apply velcro dots

medela

easy expression™ bustier

hands-free pumping made easy

- gives you the freedom to do other things while pumping
- compatible with most electric breastpumps
- easy to wear, easy to wash
- cotton/spandex blend is comfortable on its own or over a nursing bra or camisole

Easy Expression™ Hands-Free Pumping Made Easy!

mylar window

AUTHENTIC medela spare parts

1 — bustier

Authentic Medela Spare Parts are made with the quality materials and workmanship you expect and trust, only from Medela.

Non-Medela spare parts can vary significantly in terms of product design, materials, and workmanship; all of which may affect the performance of your Medela breastpump.

AUTHENTIC medela spare parts

Quality & performance you can trust

Visit www.medelaaccessories.com for more information.

Available sizes:

Cup Size	Band Size 32	34	36	38	40	42	44
A	XS	S	M	L	XL	XXL	
B							
C							
D							
DD							
E							
F							
G							
H							

Fiber content: 93% Cotton, 7% Spandex.
Care Instructions: Machine wash, tumble dry.
Contains: one bustier

Compatible with most Medela electric breastpumps including Freestyle® and Pump In Style®.

Contains: 1 — bustier

QUESTIONS? Call Medela at 1-800-435-8316 or visit www.medela.com

Contents may vary from picture.

To locate Medela products or a breastfeeding specialist in your area, call 1-800-TELL YOU.
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portable vehicle adapter

AUTHENTIC medela spare parts

medela

The Portable Vehicle Adaptor is compatible with Medela 12 Volt breastpumps:

Instructions:
Plug small metal end of the portable vehicle adaptor into breastpump and larger end into vehicle outlet.

- 8-foot long cord.
- Not for use with the Symphony®, Single Deluxe™ or 9 Volt Pump In Style breastpumps.
- Use of the vehicle adaptor will slightly alter the pumping speed of Pump In Style breastpumps. Adjust pumping speed for your comfort.

†Including models 57040, 57026, 57060

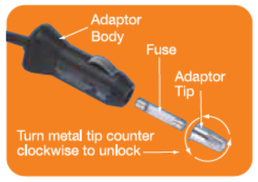
May not work with all vehicle outlets. Please check vehicle owners manual.

Contains: one portable vehicle adaptor

medela

Fuse Replacement:
Your Portable Vehicle Adaptor comes equipped with a 1.5-amp fuse (#9317001).

To check or replace fuse:
1. Unscrew at tip of adaptor.
2. Remove metal tip with fuse and visually inspect fuse element.
3. If blown or if you are unsure, replace fuse.



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#67153

medela

portable vehicle adaptor

12v

- for medela 12 volt breastpumps
  (see reverse for all compatible models)

AUTHENTIC medela spare parts

1 - portable vehicle adaptor

medela

Authentic Medela Spare Parts are made with the quality materials and workmanship you expect and trust, only from Medela.

Non-Medela spare parts can vary significantly in terms of product design, materials, and workmanship; all of which may affect the performance of your Medela breastpump.

AUTHENTIC medela spare parts

Quality & performance you can trust.

Visit www.medelaaccessories.com for more information.

QUESTIONS?
Call Medela Customer Service at 1-800-435-8316 or visit www.medela.com

medela

quick clean™
breastmilk
removal soap

medela

over 25 washes per bottle

Removes stubborn breastmilk residue up to 3 days old.

Quick Clean™ Family of Products

work & travel
end of day sanitizing
quick clean **bags**

home
every time you clean
quick clean **soap**

out & about
portable cleaning
quick clean **wipes**

Scan to learn more about Quick Clean.

medela

Clinically tested under physician supervision not to cause skin irritation.

Not a body wash. As with all soaps, we recommend keeping this product away from small children. Rinse thoroughly if soap gets in eyes. Intended for use with Medela products.

Questions?
Call 1-800-435-8316 or email customer.service@medela.com.
www.medela.com

0 20451 87240 7
#87240

medela

quick clean™
breastmilk
removal soap

- for breastpump parts, bottles, nipples and more
- no added fragrance or taste that might discourage baby from breastfeeding
- safe & hypoallergenic

6 fl oz (180 mL)

Product appearance may vary.
Medela, Inc., 1101 Corporate Drive, McHenry, IL 60050
Phone: (800) 435-8316 Fax: (815) 363-1246
Email: customer.service@medela.com **www.medela.com**

Manufactured for Medela, Inc.
Quick Clean is a trademark of Medela, Inc.
Medela is a registered trademark of Medela Holding AG.

Soap made in the USA, bottle made in Canada.
1998068 B 0812 © 2012 Medela, Inc.

No-scrub soap.

Quick Clean™ Breastmilk Removal Soap

INSTRUCTIONS FOR USE

Breastpump and Feeding Accessories

- Separate and rinse parts briefly before cleaning.
- Fill your sink with just enough lukewarm water to cover everything you are cleaning.
- While sink is filling, add 3 pumps of soap for every gallon of water.
- Submerge all parts in soapy water.
- Let everything soak for 5 minutes then rinse thoroughly with water.
- Air dry and store parts when not in use. Do not store wet or damp parts.

Nursing Apparel

Machine Wash

- Machine wash cold, delicate cycle with like colors.
- Add 2 pumps of soap as machine is filling (ratio is 2 pumps of soap for every 12 gallons of water).
- Dry according to garment cleaning instructions.

Questions?

Call 1-800-435-8316 or email customer.service@medela.com.
www.medela.com

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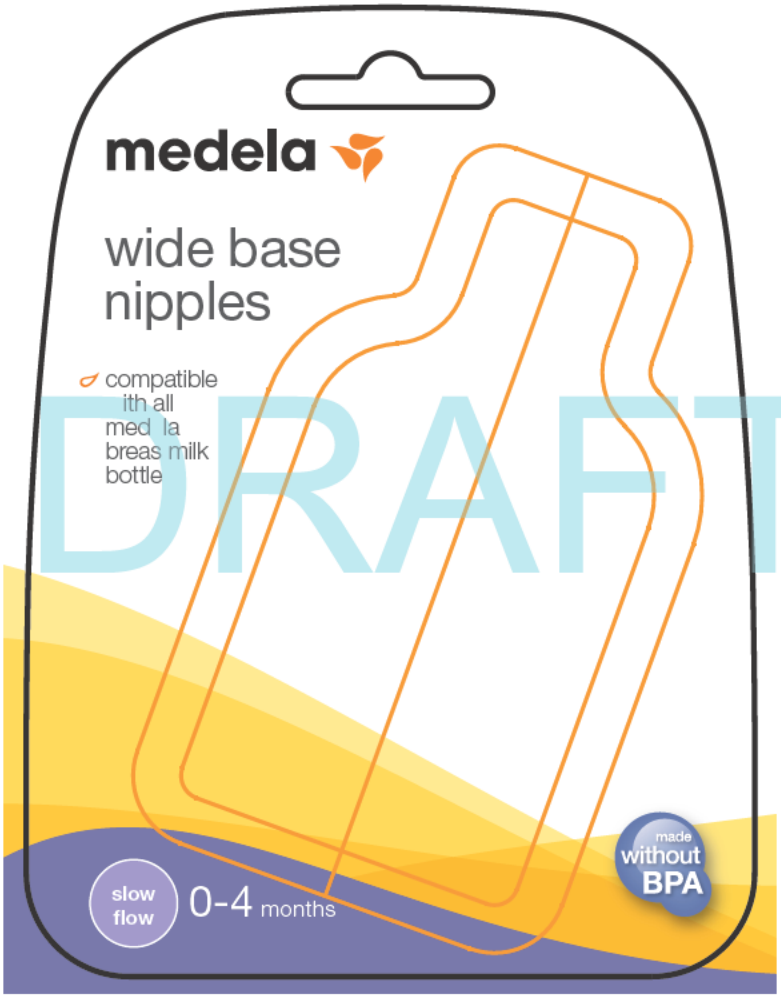
McHenry, IL 60050
Phone: (800) 435-8316 Fax: (815) 363-1246

Email: customer.service@medela.com
www.medela.com

Packaged and printed in the USA.
Manufactured for Medela, Inc. Quick Clean is a trademark of Medela, Inc. Medela is a registered trademark of Medela Holding AG.
1908334 A 0413



Wide Base Nipples

5 oz & 8 o polypr ylene bottles

Co patible wi all Mede breas milk bot s

equires e base co Call Medela at 1-80 5 8316 if y eed a wide e collar.)

Cleaning & are: B ore first use, ace in ling water fo 0 min es. After each use, h th pple in w m soapy wate nd r e with clear wa Do ot turn the nipple inside out during cleaning.

Nipple can also be washed on top rack of dishwasher. In addition to washing, you can sanitize nipples using a Quick Clean™ Micro-Steam™ bag or boiling.

Safety: Always inspect the nipple before and after each use. To prevent possible choking hazard, test strength of nipple by pulling on bulb portion. If nipple appears cracked or torn immediately discontinue use. Infants must not be bottle fed without adult supervision. Do not attempt to enlarge the nipple hole. Nipples should not be used as pacifiers.

Make sure breastfeeding is well established before introducing a nipple.

Contains: 3 wide base nipples

Medela, Inc., 1101 Corporate Drive, McHenry, IL 60050
Phone: (800) 435-8316 or (815) 363-1166
Email: customer.service@medela.com **www.medela.com**
Manufactured in Canada. Packaged in the USA by Medela, Inc.

1948539 D 0215

0 20451 87133 2

#87133

medela

Why Medela?

Medela is dedicated to providing research-based breastfeeding solutions for you and your baby.

Why Calma?

Calma was developed using evidence-based research on babies' natural feeding behavior so you can enjoy your breastfeeding bond longer.

calma®

breastmilk feeding nipple

- switching from bottle to breast has never been easier

baby controls milk flow

made without BPA

1 – all-stage nipple & cap

Scan to learn more about Calma.

Medela AG
Lättichstrasse 4b
6341 Baar / Switzerland
www.medela.com

Medela, Inc.,
1101 Corporate Drive,
McHenry, IL 60050
Phone: (800) 435-8316 or (815) 363-1166
Fax: (815) 363-1246
Email: customer.service@medela.com
www.medela.com

Content appearance may vary from picture.

0 20451 68020 0

#68020

1 PETE

Contains: 1 nipple, cap, instructions
Compatible with all Medela breastmilk bottles.
Breastfeeding must be well established before introducing Calma.

One size/shape nipple for all stages of breastmilk feeding.

Vented nipple designed to help avoid gassiness.

- Flow control valve allows baby to control milk flow.
- Milk only flows when baby creates a vacuum.
- Mimics natural feeding behavior: baby can feed, pause and breathe, similar to breastfeeding.

Flow Control System

calma®
breastmilk feeding nipple

medela

medela

Calma®

Instructions

- The revolutionary new breastmilk feeding system

made without BPA

Dear parents,
Congratulations on your decision to choose Calma. For more than 50 years, Medela has pioneered innovative products which help to enhance babies' health through the life enhancing benefits of breastmilk. With Calma you can trust in a product that has been developed on a well-established research foundation. This research has shown that with Calma, your baby is able to maintain the learned feeding behavior that your baby exhibits when breastfeeding. Your baby will continue to benefit from breastfeeding. However, if you are separated from your baby, Calma provides an excellent alternative that should not interfere with the breastfeeding relationship between you and your baby.

The warning symbol identifies all instructions that are important to safety. Failure to observe these instructions can lead to injury or damage to the breastpump. When used in conjunction with the following words, the warning symbols stand for:

⚠ **WARNING**
Can lead to serious injury or death.

⚠ **CAUTION**
Can lead to minor injury.

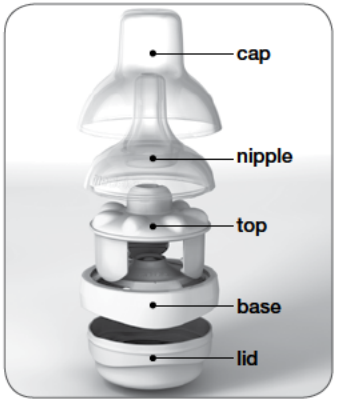
! **NOTE**
Can lead to material damage.

i **INFO**
Useful or important information that is not related to safety.

Prior to First Use: Important Safeguards

- Read all instructions.
- Separate all parts.
- Boil by following the cleaning instructions in this manual.

Calma is intended to be used for feeding breastmilk to healthy term babies. Medela does not recommend using Calma with formula.



⚠ **Caution:**
- Always use this product under adult supervision.
- All parts that are not in use must be kept out of children's reach.
- Never use nipple as a pacifier.
- Continuous and prolonged sucking of fluids can cause tooth decay.
- Inspect for damage before each use. Replace at the first signs of damage or weakness.

IMPORTANT: Plastic bottles and component parts become brittle when frozen and may break when dropped. Also, bottles and component parts may become damaged if mishandled, e.g. dropped, over-tightened, or knocked over. Take appropriate care in handling bottles and components. Do not use the breastmilk if bottles or components become damaged.

To purchase a replacement:
- Locate a Medela retailer at www.breastfeedingnationalnetwork.com.
- Email customer.service@medela.com, or
- Call 1-800-435-8316

Cleaning & Care

Prior to first use and after each use.

Disassembly

1. Remove Calma from [illegible] clockwise.

2. Press base down.

3. Lift nipple from top and remove silicone nipple.

Cleaning

i It is important to clean Calma immediately after every feed.

1. Rinse all separated parts in cool water to remove breastmilk.
2. Wash all separated parts in warm, soapy water.*
3. Rinse all separated parts with clear water.
4. Allow all separated parts to air dry in a clean area.

! **Note:** You can also wash all separated parts on top rack of dishwasher.

*It is not recommended to use a bottle brush with Calma.

⚠ **Caution:** Do not leave feeding parts in direct sunlight or heat, as this may weaken or damage parts.

Sanitizing

In addition to cleaning, Calma can be sanitized once per day by boiling:

1. Separate all parts.
2. Choose a pot that is large enough so parts **DO NOT** rest on the sides or bottom while boiling.
3. Fill the pot with water and bring to a boil.
4. Carefully drop parts into boiling water, and boil for 10 minutes.
5. Gently remove parts from water with tongs and place on a clean surface.
6. Allow all separated parts to air dry in a clean area.

Medela's Quick Clean™ Micro-Steam™ bag can be used as an alternate to boiling. To locate a Medela retailer visit www.breastfeedingnationalnetwork.com.

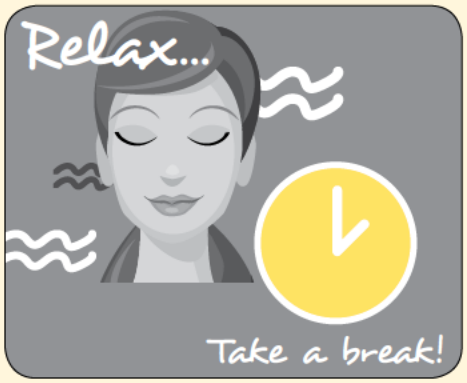
Storing Parts

Make sure all parts are completely dry before storing. When parts are not in use, put in clean plastic bag or store in a container with a lid. Alternatively, the parts can be wrapped in clean paper or cloth towel. Do NOT store wet or damp parts.

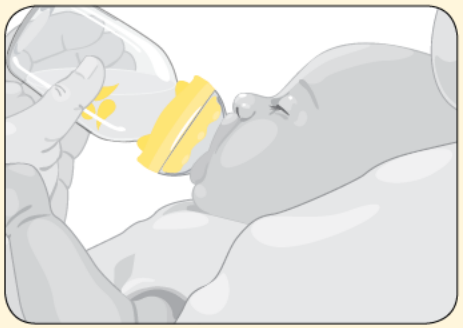
Continued on reverse side.

Quick Card Instructions

Please tear off and keep on hand.



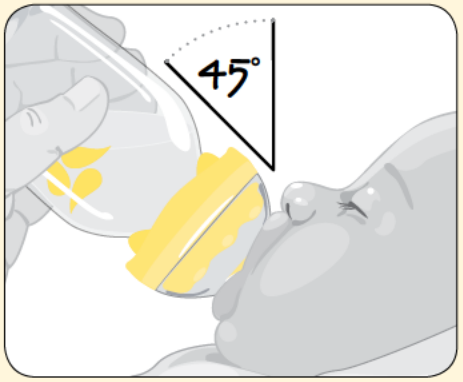
Be calm and patient for a soothing atmosphere.



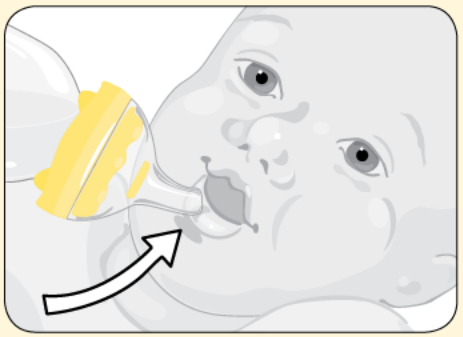
Position the baby in a different way than when breastfeeding. This helps your baby to learn a new way to feed and makes it easier to switch from breast to Calma and back again.

Dip the tip of Calma's nipple into expressed breastmilk before starting to feed.

Quick Card Instructions (continued)



Keep the bottle at a 45° angle. Place Calma on the tip of the baby's tongue. Do not push Calma in. Your baby will take Calma in as far as it needs; just as your baby has learned on the breast with the nipple.



Stimulate your baby's lip with Calma to begin.

It may take **3 or more feedings** for your baby to become succsssful with Calma.

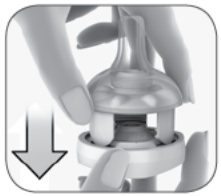
Assembly

Calma can be assembled in a hygienic way.

1. Wash hands with soap and water prior to handling.

2. Place the silicone nipple onto top by turning the bottom edge upwards.

3. Flip the edges of the silicone nipple down.



4. Insert the top onto the base and screw it onto the Medela bottle.

5. Lid can be used on bottom of Calma and on bottle for storage.

Using Calma

Your baby will prefer and benefit from breastfeeding, so breastfeed your baby whenever you are together. For those times you are separated from your baby we recommend you use Calma exclusively and not with other nipples when feeding your baby from a bottle. If your baby has already used another nipple, be aware, that with Calma, the milk flow is controlled by the interaction of your baby's sucking action and the milk-flow control system. This is different than with any other nipple – you may need a bit of patience and persistence.

It may take a little time for Calma to be accepted by your baby. Remember this is the first time that your baby will come in contact with an artificial product instead of the familiar breast. Everything is new for your baby and he or she cannot smell you and your milk as with breastfeeding.

Medela wishes you and your baby all the best!

Breastfeeding must be well established before introducing a nipple.

Storing and Handling Breastmilk

Prior to storing and handling, refer to the Breastmilk Storage Guidelines for Healthy Term Babies (*check with your local WIC agency for specific storage instructions, if needed*).

- Wash hands before pumping milk.
- Use clean pump kit and bottles every time you pump.
- Pumped milk can be stored in a bottle with a solid lid or a disposable breastmilk storage bag.
- If you do not use your pumped milk within 4-6 hours, label bottles with the date the milk was pumped and refrigerate or freeze it.
- Do not store breastmilk in the door of the refrigerator.
- When freezing your milk, only fill containers up to ¾ full because milk expands with freezing.
- Chill your freshly expressed milk before adding it to already frozen milk.
- If you need to transport your breastmilk, for example to the baby's caregiver, use a cooler with three (3) frozen ice packs. This will help keep your milk cold until you reach your destination (up to 24 hours).

Thawing and Warming Breastmilk

Prior to thawing and/or warming, refer to the Breastmilk Storage Guidelines for Healthy Term Babies (*check with your local WIC agency for specific storage instructions, if needed*).

⚠ **Caution:** Never microwave breastmilk either to defrost or warm it. Microwaving milk may create "hot spots." There is always a risk of hot spots, which can burn your baby. Microwaving can also change the composition of your milk.

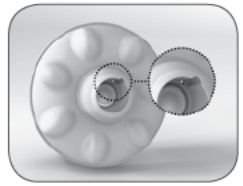
- It is recommended to thaw breastmilk in the refrigerator overnight.
- Milk can be thawed quickly in container of warm water (not over 37° C/98° F), making sure that the water does not touch the lid. Once milk is liquid and still chilled, dry off the container and refrigerate until use. Do not thaw frozen milk in a microwave or in a pan of boiling water.
- You can warm your milk by standing the bottle briefly in warm water or holding under running warm water. Care must be taken to keep the cap dry.
- Thawed milk must be refrigerated after thawing and used within 24 hours. Do not refreeze.
- Prior to feeding, make sure the entire bottle is defrosted and the milk is gently swirled to mix.

Freshly Expressed Breastmilk Storage Guidelines
(For Healthy Term Babies)

Room Temperature	Cooler with 3 Frozen Ice Packs	Refrigerator	Freezer	Thawed Breastmilk
4–6 hours at 66–78 °F (19–26 °C)	24 hours at 59 °F (15 °C) or lower	3–8 days at 39 °F (4 °C) or lower	6–12 months 0 °F (-18 °C) or lower	use within 24 hrs

References: www.BreastmilkGuidelines.com

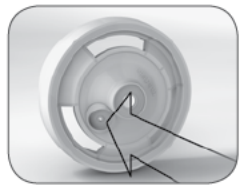
More about Calma



Size is right
You might not believe it, but one size is sufficient. Your nipples stay the same over the course of your lactation. The flow, shape and length of Calma are designed to suit your baby's needs as your baby grows. Calma was designed to meet your baby's needs during the entire breastfeeding experience.

Your baby has time to breathe
Your baby has a unique sucking pattern, including pauses to swallow and breathe. By using Calma, your baby is able to feed and pause naturally according to his/her personal rhythm. This helps to slow down the feed and results in a calm and relaxed baby both during and after the feed.

Can Calma help avoid gassiness?



Calma helps avoid gassiness as the bottle is vented through our unique air control system. Unlike many other vented bottles Calma vents air independent of how it is assembled.

Where does the milk come from?
The milk flows through the small hole at the rate that is controlled by the interaction of your baby's vacuum and the milk-flow control system. Compressing the nipple will not result in any milk flow. You can be confident your baby will be able to get enough milk based on his own nursing pattern.

Why is the hole at the tip of the nipple so wide?

Only the milk that passes through the milk-flow control system will flow into the baby's mouth. The wide hole makes the nipple soft, flexible and adaptable to your baby.

For hygiene reasons, we recommend replacing Calma after 3 months.

medela

www.medela.com

Medela AG
Lättichstrasse 4b
6341 Baar, Switzerland
www.medela.com

Distributed by: Medela, Inc.
1101 Corporate Drive
McHenry, IL 60050, USA
Ph: (800) 435-8316 / (815) 363-1166
Fax: (815) 363-1246
Email: customer.service@medela.com

medela

breastmilk bottle spare parts

- convenient mesh bag for cleaning
- always have clean parts on hand
- for medela wide base nipples and breastmilk bottles

3 - sets of parts

medela

Convenient mesh bag for cleaning bottle parts in the dishwasher – and keeping them together!

Contains:
- Mesh bag
- 3 travel caps
- 3 collars
- 3 discs
- 3 solid lids

www.medela.com

* Only for use with Medela wide base nipples.

made without BPA

#87165

medela

breastm k bott spare par

For use with Me wide ba nipples and breastmilk bo s.

8 oz and 5 oz sets with nipples

5 oz 6 pack bottles

Medela breastmilk bottles are made without BPA from food-grade,polypropylene to retain breastmilk's beneficial properties.*

* Make sure breastfeeding is well established before introducing a nipple.

medela

brea tmilk bott spa e p rts

- c enient mesh b or cleaning
- ays have clean p on hand
- or medela wide base es and breastmilk bottles

made without BPA

3 - sets of parts

Content appearance may vary from picture.

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www.medela.com

medela

Also from Medela

Breastmi eeding & Storage Solutions*

Pump · Store · Feed™

- Breastmilk bottles
- Wide base nipples
- Breastmilk Feeding Gift Set™
- Pump & Save™ breastmilk bags – 20 or 50 pack
- Breastmilk Freezing & Storage Bulk Pack (12) 2.7 oz/80 mL breastmilk bottles

QUESTIONS?

Call Medela Customer Service at 1-800-435-8316 or visit www.medela.com.

* Make sure breastfeeding is wel established before introducing a nipple.

IMPORTANT
Plastic bottles and component parts become brittle when frozen and may break when dropped. Also, bottles and component parts may become damaged if mishandled, e.g. dropped, over-tightened, or knocked over. Take appropriate care in handling bottles and components. Do not use the breastmilk if bottles or components become damaged.

Safety

- Always test temperature of breastmilk before feeding to baby.
- Always inspect the bottle, nipple and other components before and after each use.
- To prevent possible choking hazard, test strength of nipple by pulling on bulb portion. If nipples appear cracked or torn, discontinue use immediately.
- Infants must not be bottle fed without adult supervision.
- Do not allow child to walk or run with bottle.
- Do not let child take bottle to bed or self-feed for long periods of time.
- Do not attempt to enlarge the nipple hole.
- Nipples should not be used as pacifiers.

medela

www.medela.com

QUESTIONS?
Call Medela at 1-800-435-8316 or visit www.medela.com

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Phone: (800) 435-8316 or (815) 363-1166 Fax: (815) 363-1246
Email: customer.service@medela.com

medela

Breastmilk Bottles

Breastmilk Freezing & Storage

BPA free

Instructions for use

NOTE: Breastfeeding should be well-established (approx. 4-6 weeks) before introducing a nipple.

How to Clean

Prior to first Use

Wash

1. Disassemble all parts.
2. Rinse with warm water by hand.
3. Wash with warm soapy water.
4. Rinse with clean water and proceed to boil.

Boil

5. Choose a pot that is large enough so parts do not rest on the sides or bottom while boiling.
6. Place all parts in pot and fill with water.
7. Bring water to a boil and let parts boil for 10 minutes.
8. Allow water to cool and gently remove parts from water with tongs.
9. Place parts on a clean surface and/or towel.
10. Allow all parts to air dry.
11. Store dry parts when not in use. Do NOT store wet or damp parts.

After every use

1. Disassemble all parts.
2. Rinse the bottle, nipple and other parts in cool water.
3. Fill sink with warm soapy water and let parts soak for 5 minutes.
4. Wash parts with clean dish towel or soft brush in warm soapy water.
   Do not turn the nipple inside out during cleaning.
5. Rinse parts with clear water.
6. Place parts on a clean surface and/or towel.
7. Allow all parts to air dry.
8. Store dry parts when not in use. Do NOT store wet or damp parts.

NOTE: Disassembled parts can be cleaned in the top rack of the dishwasher instead of washing by hand.

- In addition to washing, you can sanitize using a Quick Clean™ Micro-Steam™ bag or by boiling.

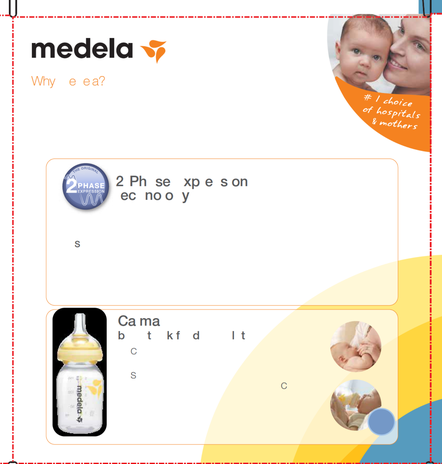


EXHIBIT 13.6

SUBSTANTIATION OF MARKETING CLAIMS

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREAST PUMP

Promotional materials for the Freestyle Breast Pump are presented in **Exhibit 13.8.** Claims made on these and future promotional materials are supported by the following evidence. Additionally, **Section 20** describes these studies and includes reprints in **Exhibit 20.1**.

Number	Claim	Substantiation	Justification
1	Medela's emphasis on research of baby's natural feeding behavior led to the innovation of 2-Phase Expression Technology	**(1)** Wolff,P.H. The serial organization of sucking in the young infant. Pediatrics 42, 943-956 (1968). **(2)** Woolridge,M.W. The 'anatomy' of infant sucking. Midwifery 2, 164-171 (1986). **(3)** Kent,J.C., Ramsay,D.T., Doherty,D., Larsson,M., & Hartmann,P.E. Response of breasts to different stimulation patterns of an electric breast pump. J Hum Lact 19, 179-186 (2003).	(b)(4) [redacted]
2	Through research Medela learned that there are two distinct phases of how babies breastfeed:		
3	Stimulation Phase: when babies first go to breast, they suck faster to start milk flowing		

Number	Claim	Substantiation	Justification
4	Expression Phase: after milk flow or "let-down" starts, babies breastfeed with a slower deeper suck to remove milk		(b)(4) [redacted]
5	Adjustable speed / vacuum combinations provide for a comfortable pump settings	**(4)** Kent,J.C. et al. Importance of vacuum for breastmilk expression. Breastfeed Med 3, 11-19 (2008). **(3)** Kent,J.C., Ramsay,D.T., Doherty,D., Larsson,M., & Hartmann,P.E. Response of breasts to different stimulation patterns of an electric breast pump. J Hum Lact 19, 179-186 (2003). **(5)** Mitoulas,L., Lai,C.T., Gurrin,L.C., Larsson,M., & Hartmann,P.E. Effect of vacuum profile on breast milk expression using an electric breast pump. J Hum Lact 18, 353-360 (2002).	
6	Adjustable speed / vacuum lets you choose the most comfortable setting for you		

Number	Claim	Substantiation	Justification
7	2-phase expression technology, using the one-touch let-down button, produces more milk in less time*. * When pumping at Maximum Comfort Vacuum in the Expression Phase	**(5)** Mitoulas,L., Lai,C.T., Gurrin,L.C., Larsson,M., & Hartmann,P.E. Effect of vacuum profile on breast milk expression using an electric breast pump. J Hum Lact 18, 353-360 (2002). **(6)** Kent,J.C. et al. Volume and frequency of breastfeeds and fat content of breastmilk throughout the day. Pediatrics 117, e387-e395 (2006). **(4)** Kent,J.C. et al. Importance of vacuum for breastmilk expression. Breastfeed Med 3, 11-19 (2008). **(7)** Prime,D.K., Kent,J.C., Hepworth,A.R., Trengove,N.J., & Hartmann,P.E. Dynamics of Milk Removal During Simultaneous Breast	(b)(4) [redacted]
8	2-Phase expression technology has been shown to get more milk in less time		
9	With this technology, Medela breastpumps work more like breastfeeding babies.		

Number	Claim	Substantiation	Justification
10	Research based solutions to support and protect breastmilk feeding	Expression in Women. Breastfeed Med 7, 100-106 (2011) **(3)** Kent,J.C., Ramsay,D.T., Doherty,D., Larsson,M., & Hartmann,P.E. Response of breasts to different stimulation patterns of an electric breast pump. J Hum Lact 19, 179-186 (2003).	(b)(4) [redacted]
11	18% more milk when double pumping with 2 phase technology	**(8)** Prime,D.K., Garbin,C.P., Hartmann,P.E., & Kent,J.C. Simultaneous Breast Expression in Breastfeeding Women Is More Efficacious than Sequential Breast Expression. Breastfeed Med 7, 442-447 (2012).	
12	Drawing out flat or inverted nipples, sore nipples or engorgement, and low milk supply	**(9)** Riordan,J. & Auerbach,K. Breastfeeding and Human Lactation (Jones and Bartlett,1999).	

Number	Claim	Substantiation	Justification
13	#1 choice of hospitals and mothers	2012 Medela Tracker Study	(b)(4) [redacted]
14	Multiple sizes of PersonalFit breastshields For comfortable & efficient pumping -	Paula P. Meier, RN. DNSc, FANN	

Number	Claim	Substantiation	Justification
			(b)(4) [redacted]

EXHIBIT 13.8

PROMOTIONAL MATERIALS

Medela **breastpumps** are the **#1 Choice** of **Moms** & **Hospitals**

Symphony®

Freestyle®

Harmony™

Pump In Style Advanced®
On-the-Go Tote

Swing™

THE ORIGINAL 2 PHASE EXPRESSION

For help with breastfeeding

You can trust Medela breastpumps

Which Medela breastpump is best for you?

	Harmony™ (Manual)	Swing™	Pump in Style® Advanced (backpack or shoulder bag)	Pump in Style® Advanced The Metro Bag™	Freestyle®	Symphony®*
Lifestyle/Situation						
Occasional use (missed feeding, working part-time, etc.)	■	■	■	■	■	■
Daily use			■	■	■	■
Multiple births			■	■	■	■
Pump dependent (medically necessary exclusive pumping)						■
Mobile & Hands-free - pump anywhere and multi-task while pumping					■	
Portable - all-in-one to go with you anywhere	■	■	■	■	■	
Breastpump Features						
Breastmilk Initiation Program						■
2-Phase Expression technology for more milk in less time**	●	●	●	●	●	●
Double pumping option			■	■	■	■
Single pumping option	■	■	■	■	■	■
Adjustable speed / vacuum lets you choose the most comfortable setting for you	■	■	■	■	■	■
Removable motor for pumping, organization & transport options				■	■	
Includes 1 set of PersonalFit breastshields (24 mm)	■	■	■			
Includes 2 sets of PersonalFit breastshields (24 mm & 27 mm)				■	■	
Double pumping kit sold separately						■
Includes breastmilk feeding and storage set with cooler carrier & ice pack			■	■	■	
Microfiber carrying bag holds pump accessories and more for convenient portability, organizaion, setup & storage			■	■	■	
Hard cover case for pump storage						■
Rechargeable battery lets you pump anywhere†					■	■
Digital display					■	■
Backlit display					■	
Memory & timer					■	
Compact & lightweight, weighing less than one pound for pumping mobility					■	
Includes hands-free accessories					■	
Breastfeeding Challenges						
Initiation of breastmilk						■
Drawing out flat or inverted nipples	■	■	■	■	■	■
Sore nipples or engorgement		■	■	■	■	■
Latch on problems			■	■	■	■
Low milk supply			■	■	■	■
Prolonged seperation of mother & baby and/or inability for baby to feed at the breast						■

*Pumps shown with this symbol ● feature 2-Phase Expression® technology, which is the only research-based breastpump technology that mimics a baby's nursing rhythm, delivering more milk in less time (when pumping at Maximum Comfort Vacuum™).

Look in the far left column for the circumstances that apply. Any pump marked with a ■ symbol in that row is recommended. You can narrow your choices by considering whether you have daily or occasional pumping needs and whether you want an electric or manual pump.

Breastpumps are personal hygiene medical devices and may not be returned to store once opened.

If you have any questions regarding your breastpump, please call Medela's Customer Service Team at:
(800) 435-8316 or Email: customer.service@medela.com

medela

Hospital-grade breastpumps are used in hospitals and are available for use at home, on a rental basis. †When pumping at maximum Comfort Vacuum in the expression phase.
*Select Symphony breastpumps include a rechargeable battery. For the location of a Rental Station in your area, call 1-800-TELL YOU (1-800-835-5968). Medela, Inc., 1101 Corporate Dr. McHenry IL 60050
Phone: (800) 435-8316 or (815) 363-1166 Fax: (815) 363-1246 Email: customer.service@medela.com
Harmony, The Metro Bag, PersonalFit, Swing and Maximum Comfort Vacuum are trademarks of Medela, Inc.
Pump In Style, Symphony, 2-Phase Expression, Freestyle and Medela are registered trademarks of Medela Holding AG. 1547598 C 0513

Authentic Medela Spare Parts

Medela Authentic Spare Parts will provide mom with the confidence that she is purchasing parts that are designed, engineered and tested specifically to perform with her Medela breastpump.

Product Lineup

The designation of the Medela Authentic Spare Parts product line was created to support breastpump performance and mom's pumping experience.

Breastpump Kit Spare Parts

Great for extras or replacement.

- PNSA Double Pumping Kits
- PersonalFit™ Breastshields & Connectors
- Valves & Membranes
- Freestyle® Spare Parts Kit

Breastpump Accessories

For comfort and convenience.

- Easy Expression™
- Breastmilk Collection & Storage Containers
- Breastmilk Cooler Set
- Pump Bags

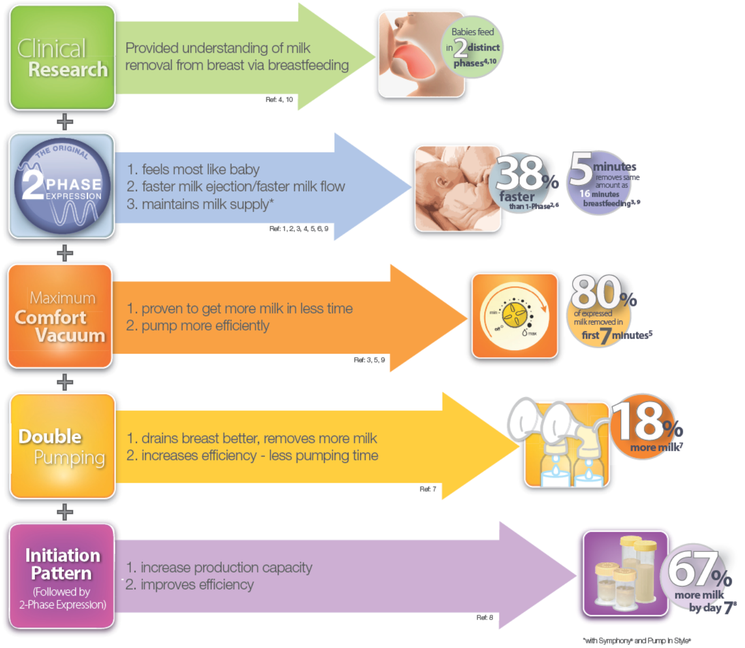
Power Accessories

Flexible power options for every lifestyle.

- Pump In Style® Power Adaptor
- Pump In Style® Battery Pack
- Portable Vehicle Adaptors 9V & 12V

Medela's Innovation Journey

Our commitment to developing innovative, research-based products reinforces our position as a trusted partner for retailers and the #1 choice of moms.



1	Pediatrics Vol. 113 No. 2 February 2004 "Ultrasound Imaging of Milk Ejection in the Breast of Lactating Woman" Donna T. Ramsay, Dip; Jacqueline C. Kent, PhD; Robyn A. Owens, PhD; and Peter E. Hartmann, PhD
2	Journal of Human Lactation 19(2) 2003 "Response of Breasts to Different Stimulation Patterns of an Electric Breast Pump" Jacqueline C. Kent, BSc, PhD; Donna T. Ramsay, DMU, PGDip; Dorota A. Doherty, PhD; Michael Larsson, MBA; Peter E. Hartmann, BRurSci, PhD
3	Journal of Human Lactation 18(4) 2002 "Effect of Vacuum Profile on Breast Milk Expression Using an Electric Breast Pump" Leon R. Mitoulas, PhD; ChingTat Lai, MSc; Lyle C. Gurrin, PhD; Michael Larsson, MBA; Peter E. Hartmann, PhD
4	Midwifery (1986) 2 "The 'Anatomy' of Infant Sucking" Michael W. Woolridge
5	Breastfeeding Medicine Volume 3, November 1 2008 "Importance of Vacuum for Breastmilk Expression" Jacqueline C. Kent, Leon R. Mitoulas, Mark D. Cregan, Donna T. Geddes, Michael Larsson, Dorota A. Doherty, Peter E. Hartmann
6	Breastfeeding Medicine Volume 1, Number 1, 2006 "Milk Flow Rates Can Be Used to Identify and Investigate Milk Ejection in Women Expressing Breast Milk Using an Electric Breast Pump" Donna T. Ramsay; Leon R. Mitoulas; Jacqueline C. Kent; Mark D. Cregan; Dorota A. Doherty; Michael Larsson; and Peter E. Hartmann
7	Breastfeeding Medicine Volume 7, Number 6, 2012 "Simultaneous breast expression in breastfeeding women is more efficacious than sequential breast expression." Danielle K. Prime, Catherine P. Garbin, Peter E. Hartmann and Jacqueline C. Kent;
8	J Perinatol. Vol.31, online version released 2011 "Breast Pump Suction Patterns that Mimic the Human Infant During Breastfeeding: Greater Milk Output in Less Time Spent Pumping for Breast Pump-Dependant Mothers with Premature Infants" Meier, PP., Engstrom, JL., Janes JE., Jegier, BJ., Loera, F.
9	Journal of Human Lactation 18(4) 2002 "Efficacy of Breast Mlk Expression Using an Electric Breast Pump." Leon R. Mitoulas, PhD; ChingTat Lai, MSc; Lyle C. Gurrin, PhD; Michael Larsson, MBA; Peter E. Hartmann, PhD
10	Pediatrics 42(6):943-56 December 1968 "The Serial Organization of Sucking in the Young Infant" Wolff, PH.

Medela, Inc., 1101 Corporate Drive, McHenry, IL 60050
Phone: (800) 435-8316 or (815) 363-1166 Fax: (815) 363-1246 Email: customer.service@medela.com

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Why Medela?

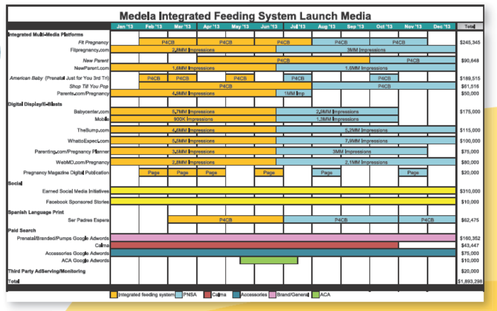
- Leveraging the Medela brand to drive meaningful differentiation and purchase at retail.
- Educating moms on the importance of choosing 2-Phase Expression technology.
- Educating moms to set them up for breastfeeding success.
- Partnering with accounts to be the trusted source and increase sales with the Authentic Spare Parts product line.
- Providing the highest quality, research-based breastpumps and breastfeeding products.

Brand Support – Making an Impression!

Print & Online Advertising

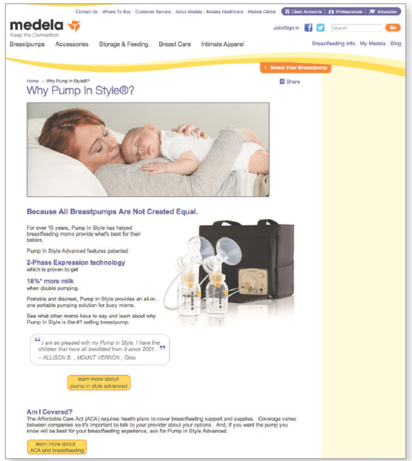
Highlighting the Medela brand as a retail destination.

over 78 million impressions!



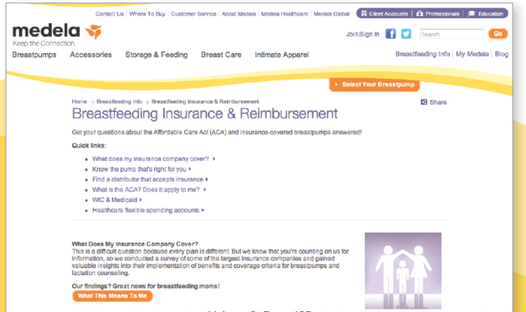
WhyPumpInStyle.com

Destination for print ad with detailed education about Pump In Style and 2-Phase Expression technology.



BreastfeedingInsurance.com

Proactively educating moms on ACA coverage and obtaining the best breastpump.



Introducing:

Medela Breastfeeding University

for Breastfeeding Success

Online breastfeeding education for moms-to-be and new moms. Establishing Medela as the brand destination for breastfeeding education, support and products.

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

TRADITIONAL 510(K)

VOLUME 3

SECTIONS 14-15

TABLE OF CONTENTS

SECTION 14

STERILIZATION AND SHELF LIFE

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

SECTION 14.1: STERILIZATION

Neither the components of, accessories nor the finished pumps are sold or provided sterile or are considered a reprocessed single use device. The device is not sterile when used.

SECTION 14.2: CLEANING AND DISINFECTION

Instructions for cleaning the components of the Freestyle® double electric breastpump were presented in **Exhibit 13.1**. These cleaning methods have been validated and the results of the validation are presented in the following Exhibits.

Exhibit	Title/Description
14.1	(b)(4) [redacted]
14.2	
14.3	
14.4	
14.5	
14.6	
14.7	
14.8	
14.9	

SECTION 14.3: STORAGE AND SHELF LIFE

The Freestyle® pump and its accessories are not provided sterile. There is no shelf life. Storage conditions for components after cleaning are provided in the user manual in **Exhibit 13.1**.

EXHIBIT 14.1

ADOPTION OF THE FREESTYLE BREASTFEEDING PUMP COMPONENTS ONTO THE VALIDATED MEDELA HANDWASHING, DISHWASHER, AND BOILING METHODS

medela

Memo

To: (b)(4) (b)(6)

From: (b)(4) (b)(6) 1-30-2015

Subject: Adoption of the Freestyle Breastfeeding Pump Components onto the Validated Medela Handwashing, Dishwasher, and Boiling Methods

Date: 1/30/2015

Page(s): 2

(b)(4)

[redacted]

medela

Table 1. Freestyle Pump Components Adoption Comparison for the Manual, Dishwashing, and Boiling Cleaning Validations

(b)(4)

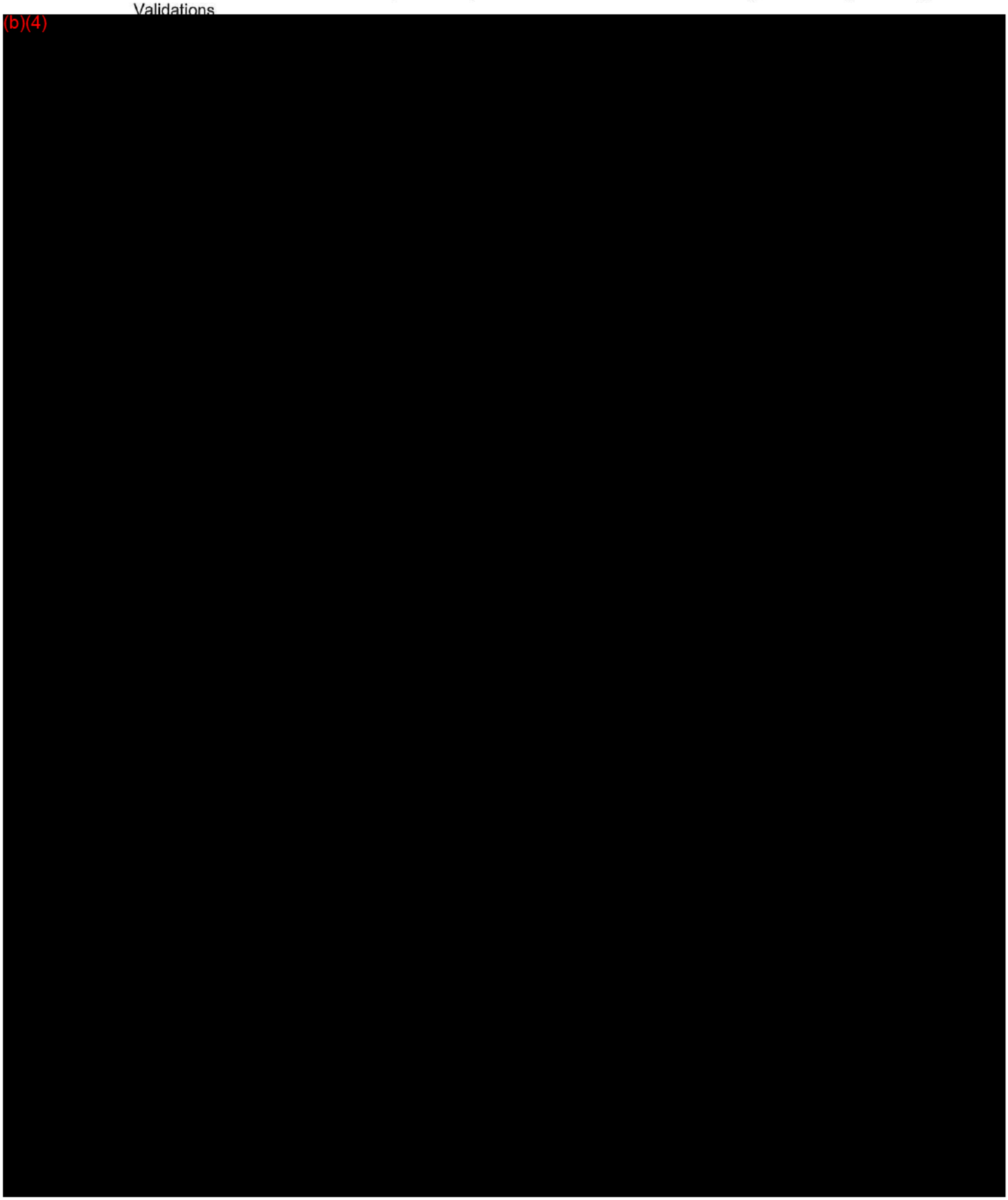


EXHIBIT 14.2

CLEANING VALIDATION FOR MEDELA BREAST PUMP COMPONENTS (b)(4) [redacted]

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EXHIBIT 14.3

CLEANING VALIDATION FOR MEDELA BREAST PUMP COMPONENTS CLEANED IN (b)(4)

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EXHIBIT 14.4

VALIDATION OF LOW LEVEL DISINFECTION OF MEDELA BREAST PUMP COMPONENTS (b)(4)

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EXHIBIT 14.5

ADOPTION OF THE FREESTYLE BREASTFEEDING PUMP COMPONENTS ONTO CLEANING VALIDATION STUDY FOR (b)(4) (b)(4)

medela

Memo

To: Medela (b)(4) Cleaning Validation

From: (b)(6) 1-31-2015

(b)(4)

EXHIBIT 14.6

CLEANING VALIDATION STUDY (b)(4) [redacted]

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EXHIBIT 14.7

(b)(4)

[redacted]

CLEANING VALIDATION STUDY

medela

Memo

To: (b)(4) File

From: (b)(6) 1-31-2015

Subject (4) Cleaning Validation Study

Date: 1/31/15

Page(s): 1

(b)(4)

EXHIBIT 14.8

CLEANING VALIDATION (b)(4) [redacted]

(b)(4) Third Party Testing

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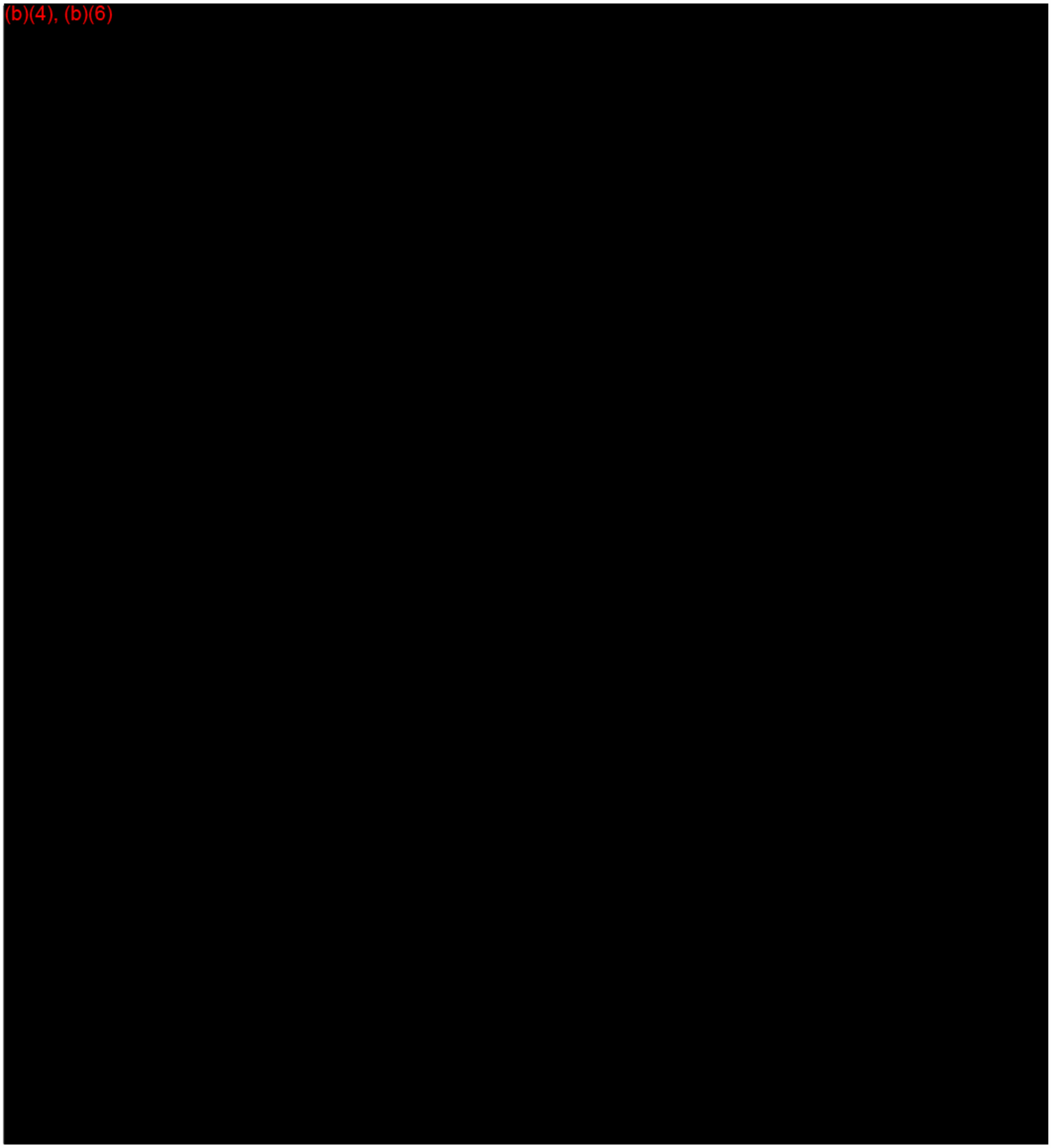
EXHIBIT 14.9

(b)(4) TEST REPORT

medela®

Test Report **Product Development**

(b)(4), (b)(6)



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SECTION 15

BIOCOMPATIBILITY

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

SECTION 15: BIOCOMPATIBILITY

The following parts have direct contact with the user of the Freestyle® breastpump during pumping:

Item Sales #	Description	Material	Contact type and duration
87072	PersonalFit Breastshield Size 21 mm / S	Polypropylene, (b)(4) [redacted]	skin-contacting devices with limited (≤24h) contact duration
87073	PersonalFit Breastshield Size 24 mm / M	Polypropylene, (b)(4) [redacted]	skin-contacting devices with limited (≤24h) contact duration
87274	PersonalFit Breastshield Size 27 mm / L	Polypropylene, (b)(4) [redacted]	skin-contacting devices with limited (≤24h) contact duration
87075	PersonalFit Breastshield Size 30 mm / XL	Polypropylene, (b)(4) [redacted]	skin-contacting devices with limited (≤24h) contact duration
87084	PersonalFit Breastshield Size 36 mm / XXL	Polypropylene, (b)(4) [redacted]	skin-contacting devices with limited (≤24h) contact duration

The (b)(4) [redacted] used with the PersonalFit breast shields is identical to the material used with the Symphony breast shields as it was cleared in K020518, March 7, 2002 in formulation, processing, and sterilization, and other chemicals have not been added (e.g., plasticizer, fillers, color additives, cleaning agents, mold release agents, etc).

As this material is previously cleared for use in a breast shield, additional biocompatibility testing was not required (as described in Section 10 of Draft Guidance for Industry and Food and Drug Administration Staff).

Many components of the Freestyle® pump kit contact breast milk and therefore, all materials used in these components are appropriate for food contact. Refer to **Exhibit 11.4** for additional details of these materials.

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

TRADITIONAL 510(K)

VOLUME 4

SECTION 16

TABLE OF CONTENTS

SECTION 16

SOFTWARE

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

SECTION 16: SOFTWARE

This section has been prepared in accordance with the FDA guidance document titled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005.

This section describes the software of the Medela AG Freestyle® double electric breast pump. The Freestyle® uses software to control the user interface and pump motor. Approved copies of all documents are retained in the Design History File at Medela AG.

TABLE 16.1: SOFTWARE DOCUMENTATION

Reference	Exhibit Number
Software Design Specifications	16.1
Off the Shelf Software Description	16.2
Risk Management	16.3
Software Requirements Specification	16.4
Architecture	16.5
Traceability Analysis	16.6
Software Development Environment Description	16.7
(b)(4) Test Report	16.8
(b)(4) Test Report	16.9
Revision Level History	16.10

16.1 LEVEL OF CONCERN ANALYSIS

The level of concern for the Freestyle® double electric breast pump was determined to be **Moderate** in accordance with the May 11, 2005 Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

The Freestyle® is a powered breastpump to be used by lactating women to express and collect milk from their breasts. Prior to mitigations of hazards, failure of the software could lead to

minor injury, such as pain or engorgement, and therefore the software was classified as moderate level of concern.

Table 16.2 answers to questions in the guidance for determining Level of Concern to support the conclusion of Moderate.

TABLE 16.2: LEVEL OF CONCERN

Level of Concern	
If the answer to any <u>one</u> question below is Yes, the Level of Concern for the Software Device is likely to be Major	
1. Does the Software Device qualify as Blood Establishment Computer Software	No
2. Is the Software Device Intended to be used in combination with a drug or biologic?	No
3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?	No
4. Prior to mitigations of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:	No
a) Does the Software Device control a life supporting or life sustaining function?	No
b) Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?	No
c) Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?	No
d) Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?	No
e) Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	No
If the Software Device is not Major Level of Concern and the answer to any <u>one</u> question below is Yes, the Level of Concern is likely to be Moderate.	
1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?	No

Level of Concern	
2. Prior to mitigations of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?	Yes
3. Could a malfunction of, or latent design flaw in, the Software Device lead to an erroneous diagnosis or delay in delivery of appropriate medical care that would likely lead to Minor Injury?	Yes
If the answer to all of the questions in Tables 1 and 2 above are No, the Level of concern is Minor.	

16.2 SOFTWARE DESCRIPTION

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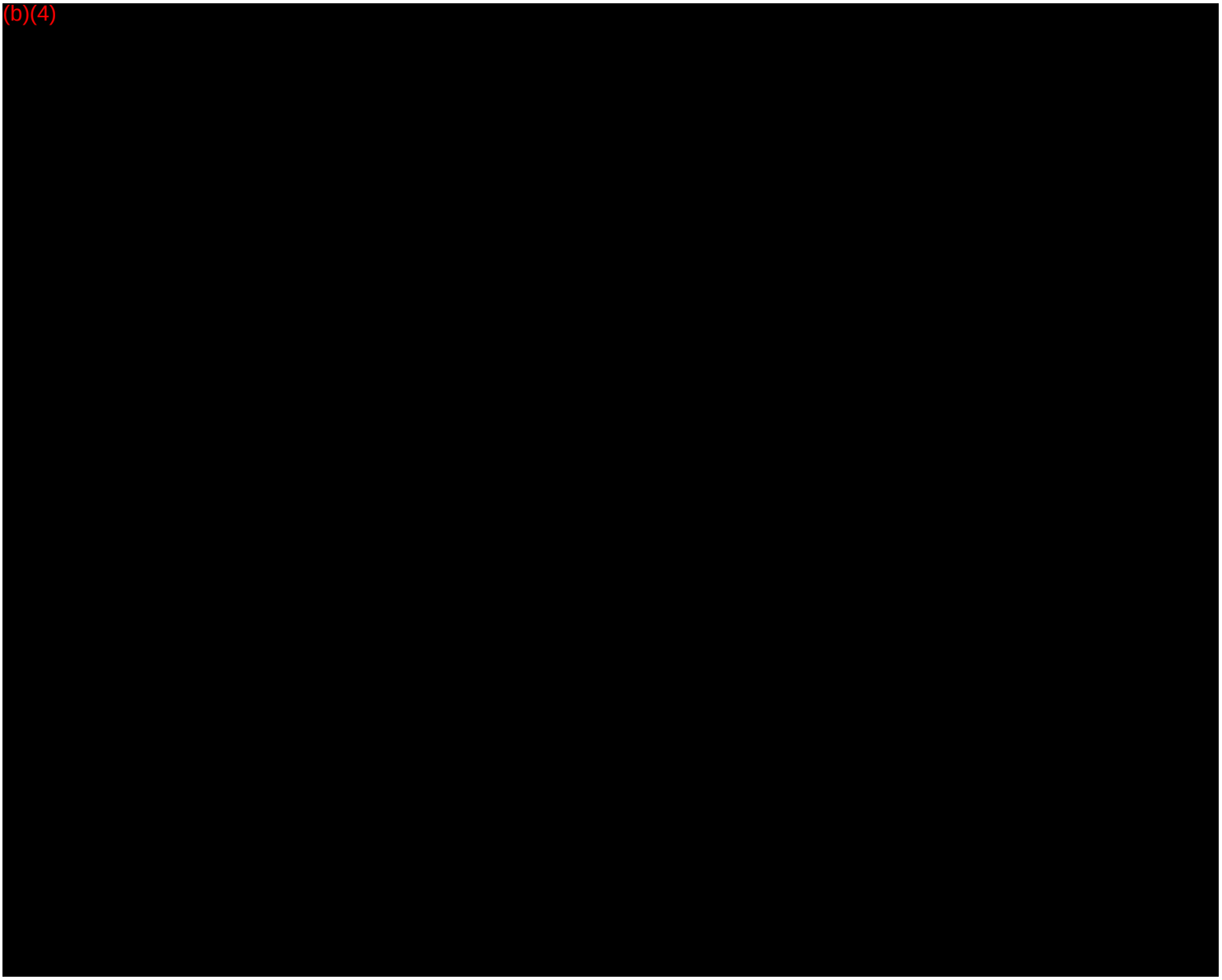

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EXHIBIT 16.1

SOFTWARE DESCRIPTION

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Software Design Specification

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EXHIBIT 16.2

OFF THE SHELF SOFTWARE DESCRIPTION

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Software
Off-The-Shelf Software
Description

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EXHIBIT 16.3

RISK MANAGEMENT

Title:
System/Design Risk Management
Workbook

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EXHIBIT 16.4

SOFTWARE REQUIREMENTS SPECIFICATION

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Software Requirements Specifications

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EXHIBIT 16.5

ARCHITECTURAL DESIGN CHART

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Software Architecture Design Chart

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EXHIBIT 16.6

TRACEABILITY ANALYSIS

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Software/Hardware Traceability Analysis

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EXHIBIT 16.7

SOFTWARE DEVELOPMENT ENVIRONMENT DESCRIPTION

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Software Development Environment Description (SDED)

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EXHIBIT 16.8

(b)(4) TEST REPORT

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Test Reports

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EXHIBIT 16.9

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EXHIBIT 16.10

REVISION LEVEL HISTORY

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Software Revision Level History

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MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

TRADITIONAL 510(K)

VOLUME 5

SECTION 17

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SECTION 17

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

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SECTION 17: ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The Freestyle® double electric breast pump has been tested for compliance to standards for electrical safety, including use in the home, and electromagnetic compatibility. Refer to Section 9 for FDA form 3654 for these standards.

Table 17.1 lists the test reports for electromagnetic compatibility and electrical safety testing.

TABLE 17.1 ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY TEST REPORTS

Test Name	Standard	Result	Exhibit
Electromagnetic Compatibility	IEC 60601-1-2: 2007. Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	Pass	17.1
	Power Supply FCC Certificate	Certified	17.2
Electrical Safety	IEC 60601-1: 2005, Medical Electrical Equipment - Part 1: General Requirements for Safety	Pass	17.3
	IEC 60601-1-11:2010, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	Pass	17.4

FDA's guidance document, Design Considerations for Devices Intended for Home Use, recommends compliance with the fourth edition of IEC 60601-1-2 for electromagnetic compatibility but due to the transition period through April 2, 2017, IEC 60601-1-2:2007 is acceptable during this transition period (per footnote 6). Medela has evaluated the fourth edition of the standard and its impact to the safety and effectiveness of the Freestyle®. A report of this evaluation is presented in **Exhibit 17.5**.

EXHIBIT 17.1

IEC 60601-1-2: 2007. MEDICAL ELECTRICAL EQUIPMENT - PART 1-2: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS

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EXHIBIT 17.2

POWER SUPPLY FCC CERTIFICATE

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EXHIBIT 17.3 (PART 1 OF 2)

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TEST REPORTS FOR:

IEC 60601-1: 2005, MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR SAFETY

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EXHIBIT 17.3 CONTINUED – SECTION 20

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EXHIBIT 17.3 CONTINUED

TEST REPORTS FOR:

IEC 60601-1: 2005, MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR SAFETY

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EXHIBIT 17.4

TEST REPORT FOR:

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EXHIBIT 17.5

IEC60601-1-2: DIFFERENCES BETWEEN 3RD AND 4TH EDITION AND IMPACT ON SAFETY AND EFFECTIVENESS ON THE MEDELA BREASTPUMP "FREESTYLE"

1 Summary

The relevant changes from the IEC 60601-1-2 3rd to the 4th edition concern the testing levels and methods of the immunity.

Many of the new immunity requirements have already been successfully tested with the Freestyle. For the other requirements not tested yet it can be said that even a worst case failure consideration would not lead to situation where safety or effectiveness may be impacted.

The same conclusion can be deduced from the fact that the Freestyle Breastpump has no essential performance (acc. to IEC60601-1 definition, see chapter 2.) which means that in case of absence or degradation of performance there is no unacceptable Risk at all.

2 Definitions

ESSENTIAL PERFORMANCE	Performance of a clinical function, other than that related to BASIC SAFETY, where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable RISK NOTE ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK. *Definition from IEC 60601-1:3rd Edition, 2012*
BASIC SAFETY	BASIC SAFETY relates to a device not resulting in HARM incidental to its operation. *IEC60601-1: 3rd Edition, 2012*
HOME HEALTHCARE EVIRONMENT	Dwelling place in which a PATIENT lives or other places where PATIENTS are present, excluding professional healthcare facility environments where OPERATORS with medical training are continually available when PATIENTS are present *IEC60601-1-11: 1st Edition, 2010*

3 Abbreviations

EMC	Electromagnetic compatibility
IEC	International Electrotechnical Commission

	Name	***Position***	***Date***	***Signature***
***Created*:**	(b)(6)	(b)(4)		
***Approved*:**				
***Approved*:**				
***Released*:**				

4 Introduction

FDA recognizes both the 3rd and the 4th editions of IEC 60601-1-2 EMC standard, with a transition date for acceptance of the 3rd edition until April 1, 2017. In the guidance document for Design Considerations for Devices Intended for Home Use, FDA recommends using the 4th edition of this standard for devices used in the home. The Freestyle breastpump has only been tested to the 3rd edition of the standard and is used in the home. This document will discuss the differences between both editions of the standard and justified why the differences, which haven`t been tested for Freestyle, do not affect safety and effectiveness of the device.

5 Comparison between EMC Standards IEC 60601-1-2 3rd Edition and IEC 60601-1-2 4th Edition

The relevant changes between the 3rd Edition and 4th Edition Standard are listed in the Foreword section of the 4th Edition Standard.

The most significant changes with respect to the previous edition include the following modifications:

- *specification of IMMUNITY TEST LEVELS according to the environments of INTENDED USE, categorized according to locations that are harmonized with IEC 60601-1-11: the professional healthcare facility environment, the HOME HEALTHCARE ENVIRONMENT and SPECIAL ENVIRONMENTS;*
- *specification of tests and test levels to improve the safety of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS when PORTABLE RF communications equipment is used closer to the MEDICAL ELECTRICAL EQUIPMENT than was recommended based on the IMMUNITY TEST LEVELS that were specified in the third edition;*
- *specification of IMMUNITY tests and IMMUNITY TEST LEVELS according to the PORTS of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM;*
- *specification of IMMUNITY TEST LEVELS based on the reasonably foreseeable maximum level of ELECTROMAGNETIC DISTURBANCES in the environments of INTENDED USE, resulting in some IMMUNITY TEST LEVELS that are higher than in the previous edition; and*
- *better harmonization with the RISK concepts of BASIC SAFETY and ESSENTIAL PERFORMANCE, including deletion of the defined term "life-supporting";*

…and the following additions:

- *guidance for determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS;*
- *guidance for adjustment of IMMUNITY TEST LEVELS when special considerations of mitigations or INTENDED USE are applicable;*
- *guidance on RISK MANAGEMENT for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES; and*
- *guidance on identification of IMMUNITY pass/fail criteria.*

(…)"

With regard to the Freestyle breastpump:

- **Environment**
  The Freestyle breastpump belongs into the category of "home healthcare".

- **Emission**
  The tighter "Class B" limits are used for the "home healthcare", which are the same limits already applied for the Freestyle breastpump in the IEC 60601-1-2 3rd edition tests.

- **Immunity**
  Additional and increased requirements are applied for "professional healthcare" as well as for "home healthcare" environments.

In summary, it can be said that the **relevant changes** are **linked to the immunity tests.**

6 Immunitiy

The following table shows in detail the differences in immunity test levels between the IEC 60601-1-2 3rd and 4th edition as well as possible effects on safety or effectiveness and the corresponding justification.

	IEC60601-1-2 3rd Edition	**IEC60601-1-2 4th Edition**	**Effects off 4th edition test conditions on Safety or Effectiveness?**	**Justification**	Comment
IEC 61000-4-2 **Electrostatic Discharges**	6 kV Contact Discharge 8 kV Air Discharge	**8 kV** Contact Discharge **15 kV** Air Discharge	None	1	(b)(4) tested and passed within 3rd Edition CB-Report. (b)(4)
IEC61000-4-3 **Radiated fields and proximity fields**	3 V/m at 80 - 2,500MHz, AM Modulation 10V/m for Life-Support:	3 V/m (**10V/m Home Healthcare**) at 80 - 2,700MHz, AM Modulation. And **9-28V/m at 385-6000MHz, Pulse Mode and other Modulation** (upon Risk Analysis).	None	1 2	(b)(4) tested and passed within 3rd Edition CB-Report. (b)(4)
IEC 61000-4-4 **Electrical Fast Transients / Burst**	2 kV Power Lines, 1 kV Interconnect Lines at 5kHz rate	2 kV Power Lines, 1 kV Interconnect Lines at **100kHz** rate	None	2	(b)(4)
IEC 61000-4-5 **Power Surge**	2kV Power Lines	2kV Power Lines	None	3	(b)(4)
IEC 61000-4-6 **Conducted Radio Frequency Immunity**	3V at 0.15 – 80MHz Additionally for Life-Support: 10V at ISM Frequencies.	3V at 0.15 – 80MHz & **6V at ISM Frequencies.**	None	1	Tested and passed (b)(4) within 3rd Edition CB-Report.
IEC 61000-4-8 **Magnetic Field**	3 A/m, 50/60Hz	**30 A/m**, 50/60Hz	None	1	Tested and passed (b)(4) within 3rd Edition CB-Report.
IEC 61000-4-11 **Voltage Dips and Interruptions**	<5 % Ut for 0.5 cycle; 70% Ut for 25 cycles ; 40% Ut for 5 cycles	**0% Ut for 0.5 at 8 Φangles;** **0% for 1 cycle;** 40% Ut for 5 cycles 70% Ut for 25 cycles;	None	**2**	(b)(4)

Green: Increased or additional requirement already tested and passed with the Freestyle breastpump
Blue: Increased or additional requirement not yet tested with the Freestyle breastpump

Justifications

1) The device already meets the requirements of 60601-1-2 4th edition. The increased requirements were tested within the 60601-1-1 3rd edition tests and have been passed. The results are included in the 60601-1-2 3rd edition test report.
2) The device has not been tested yet with the increased requirements of the 60601-1-2 4th edition. Corresponding tests could in worst case cause the device to switch off. As the device could be turned on again without any performance loss such a failure would have no negative effect on the safety or effectiveness. In the case where the disturbance cannot be avoided, delay in pumping would result. Delay in pumping breastmilk is not a safety concern and in the worst case, milk could be expressed manually to avoid discomfort.
3) The requirements have not changed from the 60601-1-2 3rd to 4th edition.

SECTION 18

PERFORMANCE TESTING - BENCH

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

SECTION 18: PERFORMANCE TESTING – BENCH

Performance of many features of the Freestyle® double electric breastpump is covered in the software testing presented in Section 16. Additional testing for usability and performance are presented in the following exhibits and summarized below:

Test	Exhibit
Usability Validation Plan	18.1
Usability Validation Report	18.2
EN ISO 10079-1: 2009 Particular requirements for the safety of electrically powered suction equipment	18.3
Overflow test report	18.4
Vacuum Performance	18.5
Vacuum Stability	18.6
Vacuum Performance – comparison with predicate	18.7
Freestyle durability	18.8
Pump temperatures during operation	18.9

18.1 USABILITY

(b)(4)

[redacted]

18.2 PERFORMANCE TESTING

(b)(4)

[redacted]

(b)(4) Testing

[redacted]

(b)(4) Testing

EXHIBIT 18.1

USABILITY VALIDATION PLAN

medela

Freestyle Breastpump

Usability Validation Plan

(b)(4), (b)(6)

[redacted]

(b)(4)

[redacted]

(b)(4) Usability Validation Plan

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(b)(4) Usability Validation Plan

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EXHIBIT 18.2

USABILITY VALIDATION REPORT

medela

Freestyle Breastpump

Usability Validation Test Report

(b)(4), (b)(6)

[redacted]

(b)(4)

[redacted]

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EXHIBIT 18.3

TEST REPORT (b)(4) Testing FREESTYLE

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EXHIBIT 18.4

OVERFLOW TEST PROTOCOL AND REPORT

(b)(4) Testing

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EXHIBIT 18.5

VACUUM PERFORMANCE TEST REPORT

(b)(4) Testing

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EXHIBIT 18.6

VACUUM STABILITY TEST REPORT

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EXHIBIT 18.7

VACUUM PERFORMANCE – COMPARSON TO PREDICATE

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EXHIBIT 18.8

FREESTYLE DURABILITY TEST REPORT

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EXHIBIT 18.9

PUMP TEMPERATURE DURING OPERATION TEST REPORT

(b)(4) Testing

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SECTION 19

PERFORMANCE TESTING - ANIMAL

MEDELA AG

FREESTYLE®

DOUBLE ELECTRIC BREASTPUMP

This section is not applicable to this submission for the Medela AG Freestyle® powered breast pump. The subject of this premarket submission did not require animal studies and test results to support substantial equivalence.

SECTION 20

PERFORMANCE TESTING – CLINICAL

MEDELA AG

FREESTYLE® DOUBLE ELECTRIC BREAST PUMP

(b)(4) Studies

(b)(4) Studies

(b)(4) Studies

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(b)(4) Studies

(b)(4) Studies

EXHIBIT 20.1

LITERATURE REPRINTS

THE SERIAL ORGANIZATION OF SUCKING IN THE YOUNG INFANT

Peter H. Wolff, M.D.

Department of Psychiatry, Harvard Medical School; Children's Hospital Medical Center; Judge Baker Guidance Center, and Boston Hospital for Women, Lying-In Division, Boston

ABSTRACT. The sucking rhythms of infants with a benign perinatal course are compared to those of infants with a history of perinatal distress. The ontogenesis of sucking rhythms, and the sucking patterns of children with major congenital malformations of the brain and various metabolic disorders are described. The analysis of rhythms of non-nutritive sucking discriminates to a statistically significant degree between normal infants and infants with a history of perinatal distress who have no gross neurological signs. *Pediatrics*, 42:943, 1968, SUCKING, BIOLOGICAL RHYTHMS, NEUROLOGICAL EXAMINATION, PERINATAL STRESS, NEWBORN INFANTS.

THIS REPORT summarizes current work on the temporal organization of sucking, a simple and rhythmical motor reflex present in all healthy, full-term infants. The rhythmical properties of non-nutritive and nutritive sucking are compared, and some of the effects of organic illness on its temporal organization are explored. The sucking reflex was selected as a system for studying the serial order of behavior because its rhythm is very similar in all normal, full-term, human infants and has species-specific characteristics that distinguish it from the sucking behavior of other infant mammals.[1] Since the temporal organization of sucking is disturbed to various degrees by different disorders affecting the central nervous system and since these can be stated in quantitative terms,[2] the detailed analysis of sucking rhythms may also be useful for correlating abnormal brain function with observable behavior in the young infant.[3-5]

METHODS

Subjects

Control subjects for this study were 40 full-term infants tested on the fourth day after a benign pregnancy and uneventful vaginal delivery. The basic measures of sucking behavior in these infants were extracted from polygraph records and compared with the sucking rhythms of other populations. Non-nutritive sucking was tested during light and restful sleep, drowsiness, alert inactivity and waking activity. Nutritive sucking was always recorded while the infant was awake before a meal. However, most comparisons, except those between nutritive and non-nutritive sucking, are based on data obtained while the infants were asleep or drowsy.* Only infants with a history of a normal gestation and labor and an Apgar score of 8 or better at 1, 3, and 5 minutes after birth were used as normal controls.[6] Nutritive and non-nutritive sucking were compared in 10 infants randomly selected from this normal group of neonates, 15 normal older infants, and 3 premature infants.

Other subjects tested in the study were neonates and infants with a history of perinatal distress but no gross neurological signs, infants and children with obvious congenital or acquired neurological lesions, selected children with treatable metabolic disorders, and a few adult patients with chronic degenerative disease of the central

* Since sucking tends to inhibit gross motility, the records were usually free from movement artifact as long as the infant was sucking actively.[7,8]

(Received February 12; accepted for publication May 16, 1968.)

Work for this report was completed while the author was supported in full by a Career Development Award of the U.S. Public Health Service, N.I.M.H., KMH-3461, and a research grant of the U.S. Public Health Service, MH-06034.

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nervous system. The basic clinical information about these subjects will be summarized in appropriate sections.

Recordings

Non-nutritive sucking was defined as any repetitive mouthing activity on a blind nipple other than biting. It was recorded from a commercial pacifier connected to a pressure transducer and visually displayed by a DC polygraph writer. The parameters selected for analysis were based on the changes in positive pressure as the lips and tongue alternately compressed and released the air in the rubber bulb. Therefore, the final tabulations do not account for all important elements of sucking (intra-oral negative pressure, sucking amplitude, and so forth), although the stripping action of the tongue and compression of the nipple by the lips are as essential to successful nursing as sucking proper and are phase related to the latter.[9-11]

Nutritive sucking was defined as any repetitive mouthing on a nursing nipple associated with negative intra-oral pressure sufficient to deliver a potable liquid (e.g., milk, 5% glucose solution) from that nipple. Nutritive sucking was recorded in the same way as non-nutritive sucking, except that the pressure changes were recorded from a modified nursing nipple which would deliver fluid by a thin ethylene tube through its tip at the same time as it measured changes in the bulb of the nipple. The milk flow was controlled by a valve which could be opened and closed so that the nutritive and non-nutritive modes of sucking could be compared on the same nipple during one feeding.[12]

TABLE I

NON-NUTRITIVE SUCKING PATTERNS OF 40 FULL-TERM 4-DAY OLD INFANTS

Data	*Mean*	*Range*	*S.D.*	*Range*
Frequency of sucks per second per burst	2.13	1.9–2.4	0.20	0.07–0.43
Number of sucks per burst	7.76	4.3–13.2	1.31	0.48–2.38
Duration of rest-periods (seconds)	6.61	3.0–10.6	1.50	0.94–2.41

While the valve was open, the infant had to create suction in order to obtain a regular supply of fluid. A standard hospital milk formula was used for all tests of nutritive sucking, after pilot experiments indicated that the nutritional value of the fluid did not significantly affect the temporal organization of nutritive sucking as long as the fluid did not have a noxious taste.

The effect of the nipple's physical properties on the sucking rhythm was tested by comparing the sucking response on seven different types of pacifiers and three nursing nipples of different shape and stiffness for each of five infants. The rhythmical features were not influenced by the variations in shape of the nipples, although the amplitude of sucking varied somewhat with the stiffness of the nipple. One common type of pacifier and one standard type of nursing nipple were therefore used on all except premature infants.

Data Analysis

All data of mouthing activity (nutritive and non-nutritive sucking) were taken from records like those reproduced in Figure 1 and the following information was extracted:

1. The rate was tabulated as mean frequency of sucks per second (i.e., per second per burst for non-nutritive sucking; per second for each 10-second segment of the record for nutritive sucking); and as peak interval time (PIT) to measure the absolute duration of individual sucks (Fig. 2). The peak interval time between successive sucks, rather than the duration from the start to the end of every suck, was chosen as a measure of absolute rate because the polygraph record did not discriminate clearly between the end of one suck and the start of the next, whereas the peak intervals could be identified precisely.

2. The stability of the sucking rhythm was determined by calculating the variance in mean rate per second per burst per 10 second episode.

3. The characteristic alternation of bursts of mouthing and rest periods during non-nutritive sucking (Figs. 2 and 3) was

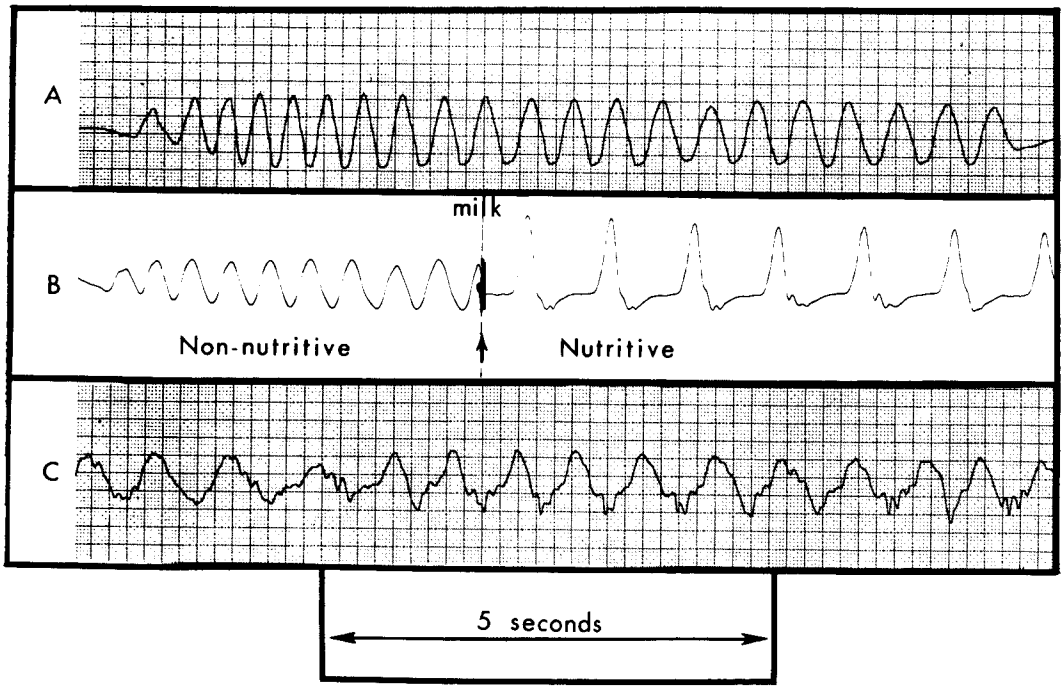

FIG. 1. Sucking patterns of 4-day old infants. *A*, non-nutritive sucking, normal waking infant (long burst illustrates rise in peak interval time). *B*, shift from non-nutritive to nutritive sucking with onset of milk flow, normal waking neonate. *C*, non-nutritive sucking of infant with repeated spells of hypoglycemia. Note long peak interval time and tremors superimposed on sucks.

tabulated as the mean duration of bursts and rest periods with corresponding standard deviations. The end of a burst was defined as any segment of the record when the polygraph writer remained in the baseline position for one second or longer.

4. Rapid tongue and jaw tremors, or "Q-waves"[13] appeared in the sucking records of many infants either between bursts of sucking or superimposed on the sucking curve. Their frequency varied from 6 to 10 per-second, with a mean rate of 7 to 8 per second. Since infants with a history of perinatal distress had sucking records with more tremors than normal infants, tremors were counted for the first 20 bursts of every record, and it was noted whether the tremors occurred between bursts or as part of the burst of sucking itself (as in Fig. 1c).

RESULTS

Basic Data

The non-nutritive sucking data of 40 normal, full-term infants are summarized in Table I as (a) mean rate per second per burst; (b) mean number of sucks per burst or duration of bursts; (c) mean duration of rest periods; and as standard deviations for (a), (b), and (c) respectively.

The mean rate of sucks per second per burst was nearly the same for all healthy, 4-day-old infants (i.e., the range of frequencies was narrow) and relatively invariant from burst to burst for any one infant (i.e., the standard deviation was small). The mean rate per second and its standard deviation were therefore used for comparing normal and pathological infants. Although the mean number of sucks per burst was also constant as long as the baby's state did not change, slight changes of state produced considerable variations in the length of bursts so that the alternation of bursts and rest periods was not considered a reliable index of comparison.

Despite the stability of mean rate from burst to burst, the absolute duration of individual sucks in any burst varied systemat-

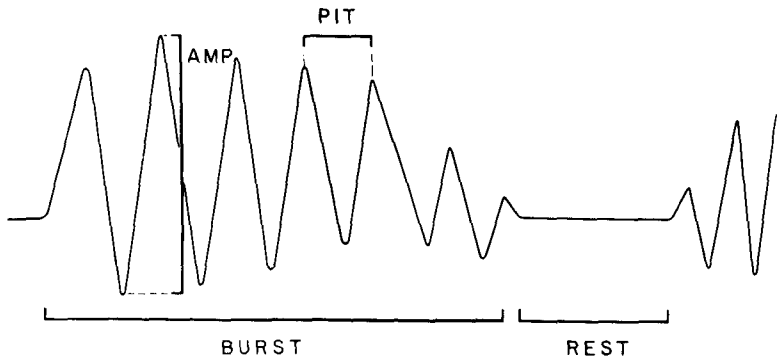

FIG. 2. Diagram of non-nutritive sucking pattern representing burst (number of sucks per burst), rest period, and peak interval time (PIT).

ically around the mean value for that burst. The non-nutritive sucking records of 20 infants randomly selected from the control population were analyzed so that each of the first 20 bursts in every sleep record was divided into three equal parts regardless of their length, and the mean sucking rates of the first, second, and third segments were compared. The rates in the first and second segment were invariably faster than that of the third segment (mean duration per suck in the first segment, 0.42 second; in the second segment, 0.46 second; in the third segment, 0.53 second), and the differences were statistically significant ($p < .001$ by Friedman 2-way analysis of variance). The same rise of peak interval time within the burst was observed in normal waking neonates, premature infants above 35 weeks' gestation, older normal infants up to at least 6 months of age, and in many infants with severe neurological disturbances.[5] The rise was not observed in nutritive sucking, even towards the end of a feeding when the continuous stream of sucks broke up into irregular episodes.

The simplest explanation for the systematic intra-burst rise in peak time would invoke peripheral muscular fatigue with a corresponding recovery during rest periods as the causal mechanism. However, clinical evidence summarized previously[5] indicated, that the peak time did not rise progressively from the beginning to the end of a burst but increased shortly before the end of a burst, even when bursts of non-nutritive sucking were exceedingly long (100 or more sucks per burst). Thus, the rise in peak time was associated with the termination of a burst and not with the actual number of sucks in the burst already elapsed. Furthermore, the intraburst rise in peak time was no greater after 30 minutes of continuous recording than just after the infant had begun to suck. Since one would expect peripheral fatigue to have a cumulative effect during an unusually long burst or over an extended period of intermittent sucking, the fatigue factor was not an adequate explanation for the rise in peak interval time.

The clinical evidence[5] is at least compatible with the assumption that the intraburst rise in peak time reflects a central mechanism which is analogous to a negatively dampened oscillator.[14] Even the simplest explanation for the temporal organization of non-nutritive mouthing as alternating bursts and rest periods would require the assumption that both "on" (excitatory) and "off" (inhibitory) mechanisms as well as a basic pacemaker or oscillator regulate the non-nutritive mode, and that the "on" and "off" mechanisms operate in a fixed reciprocal relation to each other similar to the central regulation of breathing.[15] It may be fruitful to postulate that, in the intact nervous system, the basic pacemaker which activates repetitive mouthing movements begins by recycling itself at a fixed and rela-

tively high rate, but gradually recycles at a lower frequency in response to a hypothetical damping mechanism. When the damping effect exceeds a threshold value, the recycling mechanism is interrupted and a burst of non-nutritive sucking ends. In some pathological instances, the damping mechanism may be damaged without impairing the basic pacemaker so that one observes unusually long bursts of sucking at a normal rate. In the normal infant who sucks in significantly longer bursts when he is highly aroused, the damping effects may be blocked transiently by physiological factors.

Spontaneous Mouthing

Within 3 days after birth, many full-term infants begin to make spontaneous mouthing movements during sleep that are similar in temporal organization to non-nutritive pacifier sucking. By counting the mouthing movements in each burst and timing the bursts for the first minute of an observation, timing the duration of rest periods in the second minute, and counting the mouthing movements and timing the bursts for the third minute, and so forth, it was shown that the mouthing rhythms with and without the pacifier are almost identical. Although the pacifier did not alter the basic rhythm, it had a facilitating effect on the total amount of non-nutritive mouthing. Of the 200 normal infants below 1 month tested to date, all but 2 have sucked on a pacifier, while only half of the 40 normal infants in the control population (above) made spontaneous mouthing movements in sleep. Moreover, spontaneous rhythmical mouthing was observed only in restful sleep, whereas pacifier sucking can be elicited in all states except profound sleep and extreme agitation.[16,17] The fact that "spontaneous" and pacifier-induced non-nutritive mouthing have the same temporal organization is of theoretical interest because it suggests that the mouthing rhythm is regulated by central nervous system mechanisms which can instigate well coordinated action independent of peripheral stimuli. In this sense rhythmical mouthing may be classified among the spontaneous motor actions observed in deafferented experimental preparations by Weiss,[18] and von Holst[19] who referred to them as "Erb-Koordinationen." (Table II.)

Nutritive Sucking

The temporal organization of nutritive sucking differs from non-nutritive mouthing rhythms in at least two important aspects:

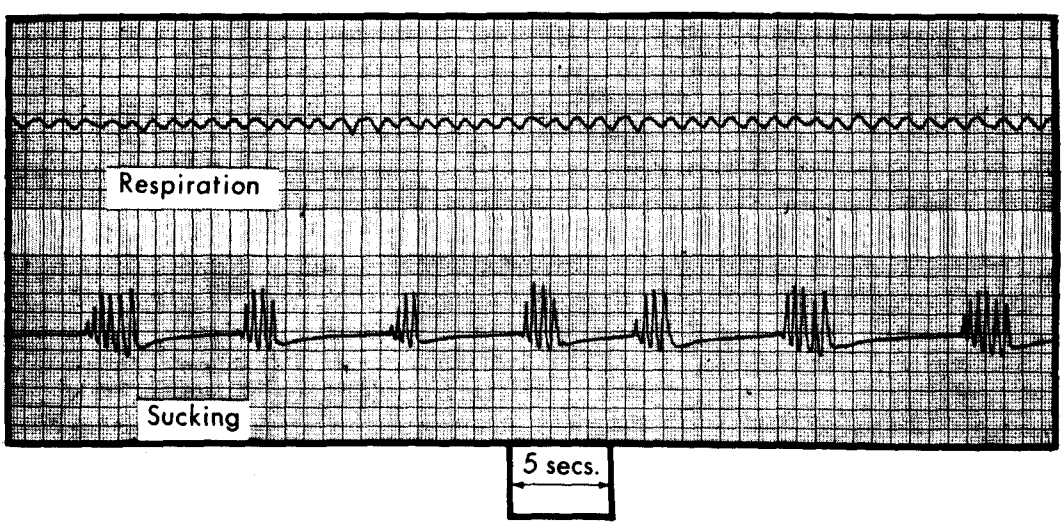

FIG. 3. Non-nutritive sucking during restful sleep; 4-day-old full-term healthy infant. Note rhythmical alternation of bursts and rest periods.

TABLE II

NON-NUTRITIVE AND SPONTANEOUS MOUTHING IN SLEEP—10 INFANTS

	Mean Frequency		*Sucks per Burst*		*Seconds of Rest Between Bursts*	
	Pacifier	*Spontaneous*	*Pacifier*	*Spontaneous*	*Pacifier*	*Spontaneous*
Rate	2.1	2.1	7.9	6.8	6.0	8.2
Range	2.0–2.3	1.9–2.4	5.9–13.2	4.3–10.1	4.6–9.8	4.1–13.1

nutritive sucking is organized as a continuous stream rather than an alternation of bursts and rest periods; and, its mean rate per second is slower and usually about half that of non-nutritive mouthing.

Ten full-term, normal neonates randomly selected from the normal control group, 15 older normal infants, and 3 premature infants were tested on the modified nursing nipple for both nutritive and non-nutritive sucking by alternately opening and closing the valve which controlled the flow of milk. They were all tested 3½ hours after a feeding while they were awake and presumably hungry.

Each infant sucked in two distinct modes that were directly correlated with two distinct rates, depending on the presence or absence of milk in the nursing nipple. As long as the nipple delivered milk, the infant sucked at a steady rate of about one suck per second with no regular segmentation of sucks into bursts and rest periods. Five seconds after the milk flow was blocked, the mean rate per second increased to about twice the nutritive rate, and the continuous stream of sucks was segmented into discrete bursts and rest periods, with a relative rise in peak time for each burst. When the flow of milk was restored, the rate dropped by about half and the alternation of bursts and rest periods was replaced by a continuous stream of equally spaced sucks (Fig. 1 and Table III).

Towards the end of the feeding, the continuous stream of nutritive sucking also broke up into shorter segments separated by rest periods, but the alternation of bursts and rest periods was variable and sensitive to changes of state and environmental conditions. These segments of nutritive sucking also demonstrated no systematic rise in peak intervals as in the case of non-nutritive sucking. Yet, when milk flow was blocked toward the end of the feeding the non-nutritive mode reappeared with a definite alternation of bursts and rest periods and the intraburst rise in peak time.

The rate variance of nutritive sucking was calculated as mean rate per second for each 10-second episode. For the most part, however, nutritive sucking rhythms were quite sensitive to environmental distractions, changes in the baby's state, and the like. Therefore, the mean rate of nutritive sucking and the variance in nutritive sucking rate will not be used as an index of neurological function until extraneous factors such as the effects of changes in state on mean rate have been studied systematically.

Ontogenesis of Non-nutritive Sucking Patterns

PREMATURE INFANTS—Many 29 to 30-week-old premature infants sucked in some fashion in the first week after birth, although they usually failed to suck in a recognizable pattern until they had been in the nursery for 2 to 3 weeks. The earliest perinatal records (i.e., records taken in the first week after birth) that were suitable for comparison with records of full-term infants were obtained from premature infants born after a 33 to 34 week gestation. Table IV summarizes the non-nutritive sucking rates of premature infants born at various gestational ages and tested during the first week after delivery. Only clinically healthy premature infants without respiratory distress or obvious neurological signs have been in-

cluded. The pattern of sucking in 33 to 36-week-old premature infants was grossly the same as that of full-term infants, but the mean rate per second per burst was lower and the interburst variance of rate was greater in the less mature infants. Differences between 34-week and 40-week-old neonates were statistically significant ($p < .01$ by Mann-Whitney U-test), while infants tested in the first week after a 37-week gestation generally sucked at the same mean rate as full-term infants.

FULL-TERM INFANTS AT BIRTH—Ten full-term infants not included in the control sample were tested in the first 3 hours after delivery, and once every 24 hours thereafter until discharge from hospital. According to their medical history and physical examination on the fourth day, they were normal. Yet, only four of them sucked in the same stable pattern and at the same rate on the first day as on the fourth day. The other six sucked in abnormal patterns with lower mean rates per second per burst and greater variances in mean rate until the fourth day, when their sucking records became statistically indistinguishable from the normal controls. Neither estimated gestational age, nor duration or quality of labor, nor Apgar score, nor amount of medication given to the mother during labor gave any indication why some apparently normal infants sucked normally when tested right after birth and others did not until the fourth day. The sample of infants tested repeatedly over the first 4 days was small, so that any one or any combination of the foregoing perinatal factors cannot be ruled out as contributing to the reported differences.

Since there were no significant changes in the overall rhythm or the mean rate per second per burst of non-nutritive sucking from the fourth to the seventh day after birth (Table V), the fourth day was taken as the earliest occasion after birth when a stable and repeatable sucking pattern could be obtained.

YOUNG INFANTS AFTER THE NEONATAL PERIOD—After the neonatal period the temporal organization of non-nutritive sucking showed no qualitative changes, but there was a steady rise in the mean rate per second per burst from 1 to 6 months. Differences in the rates of 1 and 3-month-old infants, or of 3 and 6-month-old infants were statistically significant ($p < .01$, Wilcoxon rank order test; Table V).

Twenty-two of the 40 infants tested when they were 6 months or older, refused to accept any sort of pacifier, while those who accepted a pacifier continued to suck in the same non-nutritive mode well into the second year. Those who refused a pacifier had either been weaned from it by their parents, had given it up on their own, or had never been given or accepted a pacifier. Two of the normal infants who refused the test pacifier, as well as four older children (4 to 7 years) with neurological diseases who refused it, nevertheless sucked rhythmically on their thumb or fingers, but in the nutritive mode. While the shape of

TABLE III

COMPARISON OF NON-NUTRITIVE AND NUTRITIVE SUCKING RATES

Age	*Number of Infants*	*Mean Frequency per Second*			
		Non-nutritive		*Nutritive*	
		Mean	*Range*	*Mean*	*Range*
37–38 wk prematures	3	1.7	1.7–1.8	0.92	0.86–0.96
4–6 da	10	2.1	1.9–2.3	1.0	0.8–1.2
14–60 da	10	2.2	2.0–2.6	1.3	1.1–1.5
7–9 mo	5	2.7	2.4–2.7	1.5	1.3–1.6

TABLE IV

NON-NUTRITIVE SUCKING RATES OF PREMATURE INFANTS TESTED IN FIRST WEEK AFTER BIRTH

Gestational Age	*Number of Infants*	*Mean Frequency per Second*		*Standard Deviation*	
		Mean	*Range*	*S.D.*	*Range*
33–35 wk	16	1.67†	1.4–2.0	.42†	.22–.51
36–38 wk	19	1.87†	1.5–2.3	.19*	.11–.35

Significance of difference from normal full-term infants. As tested by Mann Whitney U-test.
* $p > .10$.
† $p < .01$.

the sucking curve, the mean rate per second per burst, the intraburst rise in peak time, and the average duration of bursts of non-nutritive sucking remain relatively constant during early development, the non-nutritive mode is apparently inhibited at some time in the second half of the first year unless it is continually exercised.

ADULTS—Normal young adults were unable to reproduce a stable non-nutritive sucking pattern when asked to perform as control subjects. Even those who helped in the analysis of the sucking records and therefore knew what was "expected" could not produce a stable alternation of bursts and rest periods. Even in the best records the variability of mean rate per second per burst was at least five times as great as that of all but the most seriously damaged infants. Normal adults were also not able to suck for more than 1 or 2 minutes before getting tired. In contrast to normal adults, some adult neurological patients, who had lost all voluntary motor control, sucked in about the same pattern as neonates, with the same variance in mean rate per second per burst and without any evidence of fatigue. A 56-year-old woman with chronic encephalitis, for instance, sucked on a pacifier in the characteristic non-nutritive mode at the same rate as young infants and for 5 minutes or longer without signs of fatigue. A 68-year-old patient with senile dementia who responded to simple verbal commands, sucked in the characteristic non-nutritive mode and at the usual mean rate but became irritable and uncooperative after 5 minutes. Four other senile patients between the ages of 75 to 85 also accepted the pacifier, but either sucked in the nutritive mode or so erratically that the record could not be analyzed by the criteria outlined above. Most adult patients with severe neurological disease, however, failed to respond to a pacifier with any sucking movements.

Non-nutritive Sucking and Organic Pathology

Since the parameters of non-nutritive sucking rhythms can be stated in quantitative terms, the analysis of the sucking rhythm as an objective clinical tool for assessing the effects of congenital abnormalities and perinatal stress on the brain function of the young infant was explored in a series of comparative studies.

CHROMOSOME DEFECTS—Fifteen full-term infants with cytologically demonstrated Down's syndrome (trisomy 21) were tested under the usual conditions on the fourth or fifth day after birth. They sucked on the pacifier in the same general pattern of alternating bursts and rest periods as normal infants, but consistently at a lower mean rate per second per burst (1.6 sucks per second per burst; range 1.1 to 1.9). Differences of rate between the two groups of neonates were statistically significant ($p < .001$ level), although the variance in mean rate per second per burst was no greater than in the normal population (Table VI). Apparently these differences of rate were not related to

a specific chromosome defect but represented a developmental lag. By the time they were 3 months old, mongoloid infants began to suck at the same rates as their normal age peers and by then differences in rate between normal infants and mongoloid infants were no longer statistically significant ($p > .05$).

Three infants with a 13 to 15 trisomy syndrome sucked in patterns that were so abnormal they could not be analyzed by our criteria. In contrast, two infants with a 17 to 18 trisomy syndrome, and four infants with a chromosomally demonstrated Turner syndrome, all sucked in normal patterns and at the expected rate.

Peri-natal Anoxia—Twenty full-term infants with a history of hypoxia following perinatal complications (e.g., repeated fetal cardiac deceleration during the third stage of labor, delayed onset of spontaneous breathing, cyanotic spells during the first 48 hours, and so forth) were tested on the fourth day after delivery. Neurological examination of these children on the fourth day revealed no abnormalities, but their non-nutritive sucking patterns differed from the normal in several respects. The mean rate per second per burst was lower, the interburst variance of mean rate was greater in the hypoxic than in the normal group, and the differences were statistically significant. Furthermore, the range of mean rates per second in the pathological group was wider, and the incidence of tongue and jaw tremors ("Q-waves") superimposed on the sucking curve was greater than in normal infants (Table VII). Quantitative differences in sucking patterns of normal and pathological infants, although statistically significant, are small when considered in absolute terms. There was also some overlap between normal and presumably pathological values. Since the statistical techniques used in this study were nonparametric[20] and are based on group comparisons (rank order correlations) in keeping with the small size of the samples, it would have been impossible to "diagnose" the neurological status of any single infant from his sucking record. At the present stage of its development, the analysis of non-nutritive sucking patterns should therefore not be construed as a simple test of neurological function in the newborn.

Hyperbilirubinemia—Twenty full-term infants with an Rh incompatibility and transient hyperbilirubinemia were tested either on the fourth day after delivery (when no exchange transfusion was required) or before and after an exchange transfusion in the first 10 days after delivery. The mean rate of sucks per second per burst was lower, the interburst variance of mean rate was greater, and the incidence of rapid tremors ("Q" waves) superimposed on the sucking curve was higher than in the normal population (Table VII). When the jaundiced infants were rank-ordered according to their highest indirect serum bilirubin level, the more icteric infants sucked at lower mean rates and with a greater interburst variance than the less icteric infants ($p < .01$ by

TABLE V

Ontogenesis of Non-Nutritive Sucking Frequencies in Normal Infants

Age	*Number of Infants*	*Mean Frequency per Second*		*Range*
0–3 da	10	1.7		1.4–2.2
4–7 da	10*	2.1		1.9–2.3
4 da	40	2.1		1.9–2.3
1 mo	10	2.2	†	2.0–2.6
3 mo	10	2.4	†	2.2–2.6
6 mo	8	2.6	n.s.	2.1–2.8
12–14 mo	10	2.6		2.3–2.8

* Same group as at 0–3 days; other data refer to cross-sectional samples

† $p < .01$; Kruskall-Wallis one-way analysis of variance.

n.s.—not significant at $p = .05$.

TABLE VI

NON-NUTRITIVE SUCKING OF INFANTS WITH DOWN'S SYNDROME

Age	*Number of Infants*	*Mean Frequency per Second*	*Range*	*Mean S.D.*
4–6 da	15	1.64†	1.1–1.9	.22
4–12 wk	16	1.95*	1.6–2.4	.34

Significance of difference in rate from normal neonate. As tested by Mann Whitney U-test.
* $p > .10$.
† $p < .01$.

Mann-Whitney U-test). Exchange transfusion had no detectable influence on mean rate or interburst variance.

DYSMATURITY—Twelve infants with low birth weights after a 40 to 42-week gestation and the clinical signs of dysmaturity, but no specific neurological disturbance, showed the same kinds of disturbances in sucking records as infants with hypoxia and hyperbilirubinemia (Table VII).

NEONATAL SEIZURES—Lower mean rates per second per burst, greater interburst variability of rate, and a higher incidence of rapid tremors were also found in 20 infants with infantile seizures of unknown origin (Table VII).

METABOLIC DISORDERS—In a few infants the effect of metabolic disorders on the sucking patterns was demonstrated "experimentally." A 1-month-old infant with hyperphospotemia showed a dramatic clinical improvement when treated by calcium infusions and parathormone. The improvement was paralleled by a rise in mean sucking rate from 1.3 to 2.2 sucks per second, and a reduction of rapid tremors of the jaw and tongue.

An 18-month-old infant with hypsarrhythmia was tested serially during her ACTH therapy. In this instance clinical improvement was not paralleled by a change in mean rate since it was normal throughout, but there was a dramatic reduction in the incidence of tongue and jaw tremors ("Q" waves) which at first permeated every burst and were present in only 10% of bursts at the end of treatment.

Three infants with recurrent episodes of severe hypoglycemia during the first 2 weeks (blood sugar levels repeatedly below 10 mg/100 ml) who were not infants of diabetic mothers, showed a rise in mean sucking rate per second per burst from 1.3 to 2.0 sucks per second per burst after the blood glucose levels had stabilized at normal values; the rapid tongue tremors remained for at least another month.

Thus, many of the infants with a history of mild and presumably diffuse insults to the central nervous system but no other neurological signs sucked in abnormal patterns. In contrast, selected infants with major brain malformations affecting primarily the "higher centers" sucked in a perfectly normal pattern. One infant with an arhinencephaly (holotelencephaly)—the only subject with such a malformation tested to date—sucked on the pacifier at the mean normal rate of 2.0 to 2.4 per second and in the characteristic non-nutritive mode as long as she was asleep. Whenever she opened her eyes, her sucking changed to the nutritive mode and the uninterrupted stream of sucks had a mean rate of 0.98 per second. Two infants with a diagnosis of anencephaly—the only two infants with this malformation tested to date—sucked at a lower than normal rate but in the familiar non-nutritive pattern with a characteristic intraburst rise of peak time. Three microcephalic children between 3 and 12 months sucked at a mean rate of 1.8 per second (range 1.7 to 2.3), with no specific abnormalities in rate or serial organization.

Eight children from 3 to 5 years, with advanced obstructive hydrocephalus and tested at a point in their clinical course when they were socially apathetic but still responsive to environmental events, sucked in a pattern that was indistinguishable from the normal. The mean rate per second per burst was 1.8 sucks (range 1.6 to 2.2) and the variance in mean rate was no greater than in normal infants less than 1 month. Seven moribund children in the same age

range from the same institution with a more advanced form of the same disease did not suck at all, while eight alert and socially responsive children with a mild form of the disease refused the pacifier or chewed on it in a disorganized pattern like their normal age mates. Older children, whose non-nutritive mode of sucking is usually inhibited by the time they are 3 years old, can apparently regress to a more primitive level of neurological function and resume sucking in the archaic pattern during certain stages of neurological dedifferentiation, but they will stop sucking altogether when their disease reduces them to a state of total apathy.

COMMENT

The three major findings of this report are the following.

1. The rhythm of sucking is nearly the same in all normal newborn infants and may be considered as a species-specific mechanism for the temporal regulation of motor behavior.

2. The sucking reflex subsumes at least two modes or rhythms of sucking—a nutritive mode organized as an uninterrupted sequence of sucks and cycled at a relatively slow mean rate, and a non-nutritive mode organized as an alternation of bursts and rest periods and cycled at a relatively fast mean rate.

3. Neurological disease deranges patterns of non-nutritive sucking to different degrees and along different parameters, depending on the nature and severity of the disease. To date, no correlation has been found between a particular diagnosis and specific abnormalities of the sucking rhythms.

In earlier studies sucking activity has been recorded in a variety of ways and for a variety of purposes. Halverson[21] and Balint[13] found that the rate of nutritive sucking per second was a stable value with little intraindividual but considerable interindividual variations. Kaye[22] reports that rates of non-nutritive sucking are sufficiently stable over time to make one minute samples a reliable basis of interindividual comparisons. For the most part, however, studies of sucking behavior have focused on the relation between motivational state or experience on one hand and total amount

TABLE VII

NON-NUTRITIVE SUCKING IN FULL-TERM INFANTS WITH PERINATAL DISTRESS

Diagnosis	*Age*	*Number of Infants*	*Mean Frequency per Second*		*Standard Deviation*		*Incidence of Rapid Tremors*	
			Rate	*Range*	*S.D.*	*Range*	*Total*	*On Burst*
Normal	Full term 4 da	20	2.1	1.9–2.4	0.02	0.07–0.38	24.4%	15.6%
Perinatal anoxia	Full term 4–7 da	20	1.8‡	1.6–2.4	0.30†	0.16–0.46	57.0%†	53.3%†
Hyperbilirubinemia (Rh)	Full term 4–10 da	20	1.9†	1.5–2.6	0.43‡	0.13–1.56	58.2%†	27.3%
Dysmaturity	40–42 wk 4–5 da	12	1.7†	1.5–2.1	0.26*	0.18–0.43	76.6%†	76.6%†
Infantile seizures	Full term 4–5 da	10	1.8†	1.7–2.0	0.31†	0.13–0.61	83.2%†	42.3%†

Significance of difference from corresponding value for normal full term infants. As tested by Mann Whitney U-test.

* $p > .10$.

† $p < .01$.

‡ $p < .001$.

of sucking on the other, so that the "microstructure" or rhythm of sucking has not been analyzed in any detail.

The theoretical focus of this study was the temporal organization of behavior, and sucking rhythms were used chiefly as a "system" for investigating one aspect of the central question of serial order in behavior and development, which has remained among the problems most resistant to empirical investigation.[23] The rapid sequential arrangement of motor units is a fundamental property of all behavioral adaptations.[18,19,23] The investigation of central mechanisms regulating the temporal organization of behavior is essential for understanding the basic relationship between cerebral activity and behavior and by inference also the relation between abnormal brain function and abnormal behavior.[24-26]

Aside from its potential contributions to the study of brain behavior relationship, the analysis of sucking rhythms was found to have clinical implications to the extent that it discriminated between infants with a history of perinatal distress but no neurological signs and infants with a benign perinatal history by a simple and objective test. Except in extreme cases, it was until now not possible to establish reliable criteria for diagnosing the neuropsychological status of an individual infant from his sucking record, since the reported differences between normal and abnormal infants were all based on rank order effects. The predictive value of the sucking record for later psychological development has also not been demonstrated since the prognostic significance of irregularities in sucking rhythms during early infancy will depend on follow-up studies which have only been started.

Nevertheless, the close association between central nervous system functions and rapid motor rhythms that has been demonstrated in animal experiments[18,19,27] justifies the expectation of a correlation between minor disturbances in central nervous system regulation and disorders in the sucking rhythm of young infants. Whether infants with abnormal sucking rhythms will later have more difficulties in sensory-motor integration and specific perceptual and cognitive skills, or whether the abnormal rhythm merely reflects a transient instability in function, depends on the outcome of longitudinal follow-up studies. Of particular interest in such follow-up studies will be the correlation between disturbances of sucking rhythm in the neonatal period and subsequent disturbances in voluntary rhythmical actions such as speech, gait, preferred tapping rate, and the like.[5,23-26]

SPECULATIONS

Biological clocks or mechanisms for temporal regulation of physiological processes have been described for various species of animals and man.[27] Except for refined experiments on the central regulation of respiratory rhythms[15] and the analysis of brain waves; however, these descriptions in mammals have focused mostly on "macrorhythms" or temporal sequences with basic periodicities of hours, days, and seasons. The regulative functions of "microrhythms" in cycles of seconds and fractions of seconds have been explored only in isolated instances.

Neuro-physiological evidence points to the central nervous system as the most likely source of high frequency clocks, and demonstrates that these clocks can function independently of sensory feedback.[18,19] In articulating the problem of serial order in behavior, Lashley[23] implicated the central nervous system as the most likely source of such high frequency clocks and specifically proposed autonomous central nervous system oscillators as the primary mechanisms for the temporal regulation of rhythmical motor sequence. By implication this report has suggested that the central mechanism which controls the rate and temporal organization of sucking in the young infant is one such central oscillator. In the intact organism the central oscillators are neither independent of, nor immune to, peripheral

stimulus factors. The rapid shift from non-nutritive to nutritive sucking with milk, for example, indicates that peripheral feedback can have a profound influence on the basic rate of sucking. Whatever the central mechanism controlling the serial order of sucking, it is probably modulated by a variety of stimuli from the internal milieu and from the environment, so that the closest approximation to a "spontaneous" central rhythm is observed during restful sleep.[17]

SUMMARY

Normal newborn infants suck in two distinct rhythms: (1) a non-nutritive mode which is characteristically segmented into alternating bursts of sucking and rest periods, which has a basic frequency in the range of two sucks per second, and which can be elicited in all arousal states except sleep and great excitement; and (2) a nutritive mode which usually depends on a flow of milk from the nipple, is organized as a continuous sequence of sucks, and has a basic frequency of about one suck per second.

In the course of development, these patterns undergo some quantitative but no qualitative changes. The non-nutritive sucking pattern of infants who have suffered various kinds of perinatal stress and may show no definite neurological signs differ from the normal pattern in one or more parameters. These differences are statistically significant. Yet, infants with major brain malformations may show perfectly normal sucking patterns. The predictive significance of abnormalities in the sucking rhythm for later development has so far not been established. The analysis of sucking rhythm has relevance for psychological theory as one species-specific mechanism for the regulation of serial order in behavior.

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Midwifery 1986, 2, 164–171
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INFANT FEEDING

The 'anatomy' of infant sucking

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This paper aims to present a simple account of the mechanisms by which a baby removes milk from the breast, gleaned from past and current literature, to counter the tendency for inaccurate descriptions of the mechanics of infant sucking to be reproduced. The process is described by which milk is expressed from the lactiferous sinuses within the nipple and breast, by compression of the nipple against the palate by rhythmical pulsations of the surface of the tongue. Active in the process of milk transfer are the roles played by negative suction pressure by the infant, and positive ductal pressure due to action of the mother's milk ejection reflex, which interact in making milk available for removal. The reflexes which the newborn possesses to aid feeding are described and suggestions offered as how best to utilise these reflexes in order to fix a baby successfully on the breast. The intention is that armed with an appropriate understanding of the underlying processes by which milk is transferred from mother to baby a midwife is best equipped to advise a mother regarding the correct technique for achieving trouble-free breast-feeding.

INTRODUCTION

It is clear from recent lay and professional texts that there is much confusion as to the precise nature of infant sucking, in particular over both the dynamic changes in anatomy and the physiological mechanisms involved in the process by which the infant obtains milk from the breast. Although the description in many of these texts is substantially correct, the accompanying illustrations often contain inaccuracies which may themselves lead to a misunderstanding of the anatomical mechanisms involved. An incomplete or imprecise knowledge of these mechanisms can be a hindrance to offering adequate advice to the breast-feeding mother.

This article tries to give a clear description of the processes involved in the infant sucking at the breast, and in the transfer of milk. A companion article, based upon this description, considers the theoretical basis of some common complications of breast feeding, and offers some suggestions as to the possible causes of nipple lesions (Woolridge, 1986).

The description of the dynamic anatomy of *normal* sucking is drawn both from older and from more recent studies of infants feeding at the breast. Previous descriptions, derived from direct scientific observations, are impressive for their simplicity and logic, but they have not received the critical attention they deserve in practical guides to breast-feeding and the lactation literature generally.

The studies of Ardran, Kemp and Lind (1958a and b), receive relatively little consideration in

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Manuscript accepted 10 July 1986

textbooks of infant feeding, despite being the most important analyses undertaken. In contrast, the description supplied by Applebaum (1970) has been the most influential, being widely cited, and the one from which illustrations are most frequently reproduced. Applebaum's description, however, contains a number of statements which are inconsistent with the findings of Ardran *et al.*, (1958b). Despite a flawed description of the mechanics of milk transfer Applebaum's work has much to recommend it.

Earlier studies have since been substantiated by Smith *et al.* (1985), and by the observations on the dynamic relationships of sucking using ultrasound scanner techniques for imaging events in the baby's mouth (Weber, Woolridge and Baum, 1986). The following is an attempt at an economical but complete description of the physical events taking place in the baby's mouth during breast feeding.

The mechanics of sucking

The nipple, with surrounding and underlying breast tissue, is drawn out into a teat by suction created within the baby's mouth. This 'teat' is about three times as long as the nipple at rest, and extends back as far as the junction between the hard and soft palates (Ardran *et al.*, 1958b). At its base it is held between the upper gum and the tongue which covers the lower gum.

The lateral margins of the tongue cup around the teat forming a central trough in which the nipple lies. Milk is expressed from the ampullae (widening of the ducts prior to their exit at the nipple surface, also called lacteal or lactiferous sinuses), and propelled towards the back of the mouth by a posteriorly directed, roller-like peristaltic wave along the surface of the tongue (Ardran *et al.*, 1958b). The sucking cycle is initiated by an upward curving of the anterior rim of the tongue, closely followed by pressure from the lower gum, caused by elevation of the lower jaw (this action may serve to trap a pool of milk in the nipple sinuses preventing its reverse flow back into the alveolar duct system). The wave of compression moves backwards progressively occluding the central furrow in which the teat lies, thereby expressing milk from the lactiferous sinuses (Gwynne-Evans, 1951). Compression by the tongue causes the nipple to be indented on its lower surface, and this indentation is preceded by an area of slight expansion (see Fig. 1 [after Weber *et al.*, 1985]). A view in medial section, as provided by ultrasound, would give the impression that the nipple is distended at its tip the oft-cited 'cherry-on-a-stalk' analogy [Evans & MacKeith, 1954]), although it has also become broader at the point of compression. As the point of compression moves back past the end of the nipple, the teat becomes shorter and slightly tapered.

Tongue elevation continues beyond the tip of the nipple moving the milk bolus into the pharynx. If the volume of milk taken is sufficient to trigger swallowing* the soft palate rises and closes off the nasal cavity. The larynx, separating the trachea from the oesophagus, moves up and forward to close the trachea. This is aided by a downward movement of the epiglottis, resulting from pressure from the rear portion of the tongue and the fluid bolus. The pharyngeal space is progressively reduced and ultimately obliterated, propelling the milk bolus into the oesophagus (Logan & Bosma, 1967).

The larynx then returns to its normal position, closing off the oesophagus behind the swallowed milk, and leaving the upper airways patent. Meanwhile a fresh cycle of compression by the tongue has been initiated from its front margin. The complete process is typified by peristaltic expulsion of milk from the nipple to the back of the pharynx, and on into the oesophagus: pulsatile progress typical of the rest of the alimentary tract.

It should be remembered that sucking is a dynamic process, and that pictorial representations freeze in time brief moments of the cycle for scrutiny. Visualising antecedent and subsequent changes, and events away from the

* It is not clear what initiates swallowing – whether it is a neurally elicited response due to specific sensory stimulation (tactile or chemical), or whether the fluid in the oral cavity has reached a specified volume, physically displacing the tip of the palate from its niche behind the epiglottis. Laitman *et al.* (1977), claim that in the human newborn, as in other mammals, this 'locking' mechanism ensures continuity of the larynx and nasopharynx, and swallowing causes only a momentary separation.

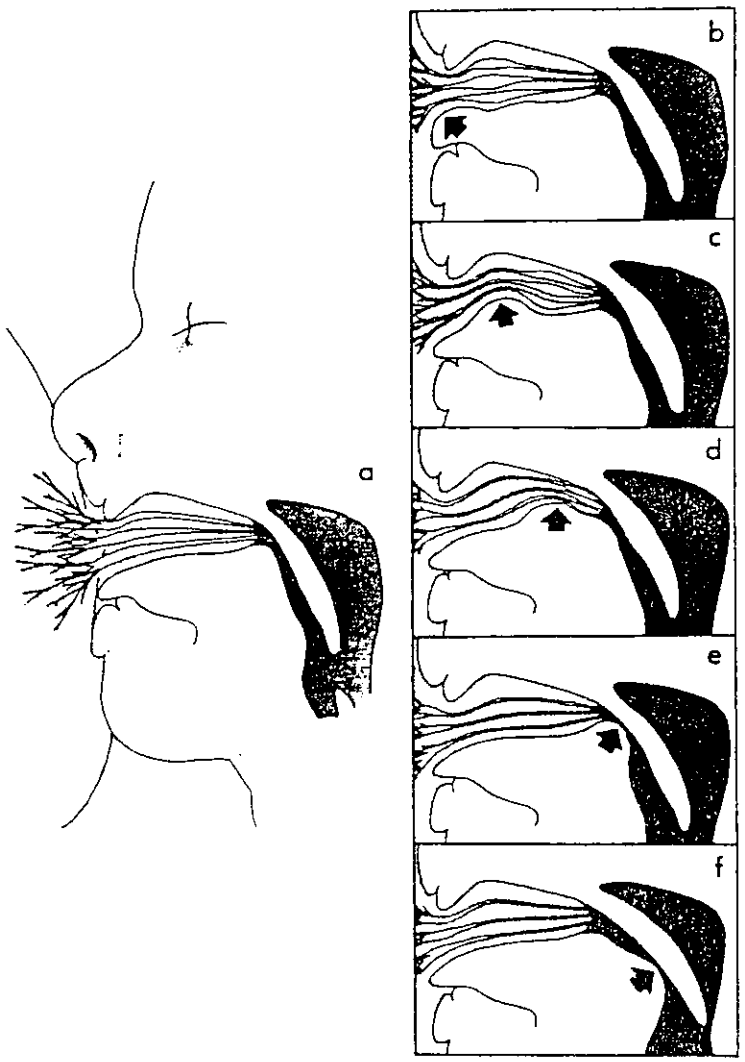

Fig. 1. Shows a complete 'suck' cycle; the baby is shown in median section. The baby exhibits good feeding technique with the nipple drawn well into the mouth, extending back to the junction of the hard and soft palate (the lactiferous sinuses are depicted within the teat though these cannot be visualised on scans).

a. 'Teat' is formed from the nipple and much of the areola, with the lacteal sinuses, which lie behind the nipple, being drawn into the mouth with the breast tissue. The soft palate is relaxed and the nasopharynx is open for breathing. The shape of the tongue at the back represents its position at rest, cupped around the tip of the nipple
b. The suck cycle is initiated by a welling up of the anterior tip of the tongue. At the same time, the lower jaw, which had been momentarily relaxed (not shown), is raised to constrict the base of the nipple, thereby 'pinching off' milk within the ducts of the teat (these movements are inferred as they lie outside the sector viewed in ultrasound scans).
c. The wave of compression by the tongue, moves along the underside of the nipple in a posterior direction, pushing against the hard palate. This roller-like action squeezes milk from the nipple. The posterior portion of the tongue may be depressed as milk collects in the oropharynx.
d & e. The wave of compression passes back past the tip of the nipple and pushes against the soft palate. As the tongue impinges on the soft palate the levator muscles of the palate contract raising it to seal off the nasal cavity Milk is pushed into the oropharynx and is swallowed if sufficient has collected.
f. The cycle of compression continues and ends at the posterior base of the tongue. Depression of the back portion of the tongue creates negative pressure drawing the nipple and its milk contents once more into the mouth. This is accompanied by a lowering of the jaw which allows milk to flow back into the nipple.

In ultrasound scans it appears that compression by the tongue, and negative pressure within the mouth, maintain the tongue in close conformation to the nipple and palate. Events are portrayed here rather more loosely to aid clarity

midline, help to complete a dynamic 3-dimensional picture.

Ramifications of description

Two features of this description deserve closer inspection both as general qualities of normal sucking, and because their disturbance may be of relevance to the aetiology of sore nipples. The first is a descriptive feature, that normal sucking is essentially free from frictional movement. If sufficient breast tissue has been formed into a 'teat' then there should be little movement of this teat in and out of the baby's mouth, simply unidirectional exchange of milk from the breast into the body of the teat, and on into the baby's mouth. Friction from the tongue and gums against the skin of the breast should be minimal. This picture is very different from that which is commonly depicted, whereby the nipple is stripped by the tip of the tongue moving back along the underside of the nipple, and apparently creating friction along its entire length. Such a picture is not consistent with reports made by cineradiographic and ultrasound observation (Ardran *et al.*, 1958b; Smith *et al.*, 1985; Weber *et al.*, 1986).

The second feature is that, as described above, the application of positive pressure on the nipple by the surface of the tongue is the primary force in evacuating milk from the nipple, and despatching it down the oesophagus. No such role is suggested for the negative pressure, which the baby clearly generates in his mouth, during the process of milk removal (Hytten, 1951).

The role of negative pressure

The role of negative suction pressure has not been categorically determined, but the two most likely functions are (i) to retain the nipple and breast in position within the mouth (i.e. to counter the naturally retractile nature of this tissue), thus maintaining the 'teat' shape from the nipple and breast tissue; and (ii) to aid refilling of the nipple by milk from the ducts and sinuses entering it.

Evidence for the former suggestion is provided in the cineradiographic films of Ardran, Kemp and Lind (1958a) (generously made available for viewing by Dr G. Ardran). One film depicts a baby at the moment of becoming detached from the breast. This is preceded by the sudden appearance of an air pocket in the oro-pharyngeal space (back of the mouth), with an equally sudden and *marked retraction* of the nipple in the mouth, and the general relaxation of the tissues of the mouth (tongue, soft palate). Following a momentary pause, the nipple is released by the infant.

The second suggestion is the natural inference given that milk is maintained under positive pressure in the breast, which, via the duct system, is confluent with the sinuses of the teat, and which, during sucking, projects into that part of the breast taken into the baby's mouth.

The border of the mouth (lips, gums and tongue) form an effective seal against the breast allowing negative pressure to be created. As the cycle of compression is completed the back of the tongue is lowered creating negative pressure in the pharyngeal space. The jaw is also lowered thereby releasing the base of the nipple. The nipple is drawn afresh into the oral cavity, occupying as much of the space available as there is free teat tissue to fill it. The shape of the nipple is thereby dictated by the internal geometry of the mouth (certain erroneous illustrations depict the nipple assuming its own shape surrounded by free space [e.g. Ebrahim 1978, Golbfarb and Tibbets 1980, Helsing and Savage King 1982]. The views obtained by Smith *et al.* (1985) clearly show lateral movements of the buccal masses with shifts in pressure within the mouth. The pressure differential between the breast and the baby's mouth naturally causes expansion of the teat, and its refilling with milk from the lactiferous sinuses. At the point of maximum expansion of the teat the lower jaw is raised against the base of the nipple, thereby capturing a pool of milk within the teat.

In this respect breast feeding concurs with descriptions of bottle feeding, where, if the latex rubber from which the bottle teat is made is suitably compliant, the baby can constrict the neck of the teat and squeeze the milk out (Ardran *et al.*, 1958a). If the material is too stiff the neck cannot be constricted, so when it is compressed milk flows back into the bottle reducing the efficiency of feeding (Ardran *et al.*, 1958a). Under these circumstances, suction pressure generated by the baby will be more effective in milk removal and is likely to become the predominant mecha-

nism (Colley & Creamer, 1958). One must remain cautious about assuming, by analogy, that negative pressure is of equal importance in removing milk from the breast.

For a long while an understanding of the mechanisms of milk transfer from mother to baby was bedevilled by the rather sterile controversy as to what acted as the propulsive force in milk removal from the breast. Intuitively, by analogy with dairy animals, 'hand milking' relies exclusively on *stripping* of the teat, which removes milk efficiently. This effect can be duplicated by manual palpation of the sinuses behind the human nipple to remove milk with similar efficiency. Antagonists of this viewpoint could rely on the simple demonstration that placing one's finger in a baby's mouth verified that intense suction was being exerted, while hand suction pumps were capable of removing significant amounts of milk. As with all apparently straightforward dichotomies, it is rarely the case that there is a sole determinant: rather the dual involvement of the mechanisms of both stripping and sucking are necessary for the removal of milk with maximal efficiency. Despite the semantic error in referring to the process of milk removal as 'sucking', when 'stripping' would be physiologically more correct, the term is in such common usage that there would be little to be gained from trying to change it.

The suction generated within the baby's mouth has been implicated as a major cause of nipple lesions, and so variations in negative pressure during the feed will be examined in more detail later.

The milk ejection reflex

The one significant force in milk transfer with which I have not dealt is the mother's milk ejection or 'let-down' reflex (Waller, 1943; Isbister, 1964). This reflex causes the active expulsion of milk into the infant, with little or no involvement on the part of the infant. Waller (1943) considered this to be the predominant process in milk transfer from mother to infant. My conviction, based on the evidence from flow profiles obtained with an ultrasound flow transducer (Woolridge *et al.*, 1982), is that reflex milk ejection, as the term implies, will initially cause the active expulsion of milk from mother to infant, but for a relatively short while. This will soon subside, whereupon the reflex will maintain positive pressure within the sinuses and duct system, ensuring the continued passage of milk into the teat sinuses where it will be available for removal by stripping.

Evidence, largely by analogy from comparative animal studies, suggests that spiked release of oxytocin from the posterior pituitary causes its level in the blood to pass a threshold at which it acts upon its target organ—the breasts—triggering the myo-epithelial cells to contract. The myo-epithelial cells form a loose basket arrangement around each milk-storing alveolus, and are oriented longitudinally along the milk ducts. Their contraction causes simultaneous contraction of the alveoli, driving out the stored products, and shortening of the milk ducts, leading to their dilation. This latter effect reduces resistance to the flow of milk along the ducts (Vorherr, 1974). The milk ejection reflex is bilateral causing equal contraction of the tissue in both breasts. However, the loss of significant amounts of milk from the non-suckled breast is prevented, theoretically at least, by sphincters at the distal end of the ducts (Cross, 1977). A demonstration of the effect of the relaxation of these sphincters is seen when the baby comes off the suckled breast early in the feed, when 1–3 jets of milk may project a foot or more from the nipple. On the unsuckled breast milk simply drips out (albeit at a reasonably profuse rate).

It may be inferred that effective milk removal by the infant's stripping of the teat must take place during the period over which the myo-epithelial cells are maintained in a state of contraction under the influence of oxytocin. It is probable that once these cells relax any milk remaining in the duct system will flow back into alveoli. Here it will be effectively 'sealed off' from the infant in the absence of the positive pressure needed to maintain its transport to the sinuses of the nipple. This implies that the effective period of milk removal from the breast is limited to the time for which the myo-epithelial cells are maintained in a state of contraction by circulating oxytocin. No experimental evidence exists to show how long

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this might be, or how it may vary between mothers.

It should be apparent that these two opposite forces—positive pressure in the alveoli and ducts, and negative suction pressure at the nipple surface—will act synergistically, maintaining a pressure gradient in the duct system. It is this pressure differential which ensures transport of milk to the ampullae or sinuses of the nipple.

The newborn's natural reflexes

Missing from the initial description, which was principally of the process of sucking, was an explanation of how the infant becomes attached on the breast. Whilst the mother has to develop the essential skills for breast feeding the human newborn comes equipped with two specific innate reflexes to help him obtain the nutrients essential for survival. In preparation for the act of suckling the first of these—the 'rooting reflex'—is elicited by the mother. This reflex has two components:

(i) tactile stimulation of the skin around the mouth causes the infant to turn his head towards that source of stimulation, and
(ii) his mouth gapes in preparation to accept the nipple. The former component is described often to the exclusion of the latter. Practically, for the breast feeding mother, the latter component is more crucial as she must learn to mould this response for it to operate to her best advantage.

When the baby's mouth gapes the mother must take the initiative to bring breast and baby together, so that a second reflex—the 'sucking reflex'—can be elicited. The baby gapes only briefly at first in the early days of post-natal life, but with correct reinforcement by the mother this develops into a reliable part of the overall sequence. In contrast to the neonate, the fully competent older infant (6–12 months) locates the breast visually and gapes from when the nipple is first made available to when it is satisfactorily located. The mother must learn how to effectively 'tap' her infant's natural reflexes, and develop them to work *for* her. Contrary to popular belief, attaching the baby on the breast is not an ability with which a mother is innately endowed; rather it is a learned skill which she must acquire by observation and experience. In the absence of the 'extended family' it is the midwife who must pass on these essential skills.

The 'sucking reflex' is elicited by stimulation (tactile/chemical) of the *palate* by the nipple. It may seem improbable that while the tongue is so well endowed with taste receptors it should be the relatively insensitive palate which is the link in the chain leading to functional feeding. However, this may be viewed as being highly adaptive. As the *tongue* and *lower jaw* provide the necessary motive force in milk expulsion by the baby, the breast tissue overlying the milk ducts should be apposed to these structures. This can be ensured by the part of the mouth *opposing* them being the target for stimulation by the nipple. Both traditionally, and in more recent texts (Marmet & Shell, 1984), it has been stressed that the mother should get 'as much of the areola in as possible'. This advice misses the point that the amount of areola visible to the mother above the baby's mouth is not directly relevant to the efficiency of feeding (perversely, the less that is showing above, the more may be exposed below, if, as is often the case, the nipple is taken in asymmetrically). So, for his part, the baby would appear adapted to the task of grasping an adequate teat by possession of the sucking reflex which is stimulated by contact between the nipple and palate. The mother, on her part, must strive to ensure that when breast tissue is grasped by the baby, along with the nipple, most lies adjacent to the tongue and lower jaw. In order to achieve this when attaching her baby, the mother must first 'plant' the lower rim of the baby's mouth well *below* the nipple, and then almost 'fold' the breast into the baby's gaping mouth. Once again, the mother should learn how this natural reflex operates, and develop her skills to make it work for her.

Failure to adequately stimulate the palate early on, through unsatisfactory attempts at fixing, may be a common source of breast-feeding problems. In particular, it can lead to subsequent refusal and rejection of the breast in favour of objects capable of providing the stimulation necessary to elicit sucking (e.g. artificial teats on bottles). Delaying this process for too long after birth may lead, through ineffective milk removal,

to engorgement, which will further compound the problem and may prolong it unacceptably.

Variation in negative pressure with sucking rate

Negative pressure is not applied uniformly with the same intensity at every suck, but rather varies with the baby's sucking pattern. Studies of babies feeding on an artificial teat (Brown, 1973; Wolff, 1968) have shown that the human newborn has two distinct patterns of sucking—'nutritive' and 'non-nutritive' sucking—operationally defined by the presence or absence of fluid, respectively. On the breast these patterns are not so distinct (Drewett & Woolridge, 1979; Bowen-Jones, Thompson & Drewett, 1982), although as early as 1948, they were discriminated into 'basic (N1)' and 'secondary (N2)' frequencies (Balint, 1948). I will use the more recent terms as they are more descriptive, but without meaning to imply a factual knowledge of milk flow other than by inference. I raise the issue of these two types of pattern because the level of negative pressure generated differs between the two.

Non-nutritive sucking occurs in short, fast bursts at a rate of up to two sucks per second. This would appear homologous to Balint's 'Secondary frequency', and sucking on the breast most closely resembling this pattern is seen when the baby first goes onto the breast, and little or no milk is available prior to reflex milk ejection. Gunther (pers comm) uses the expression 'call-up' sucking to refer to this pattern, which implies a functional role in the elicitation of the reflex release of milk (this is plausible, but is, as yet, unsubstantiated). *Nutritive* sucking, in contrast, occurs at a slower pace (one per sec), and early in the feed, once milk has started to flow, sucks appear in a continuous stream. As the feed progresses sucking becomes fragmented into bursts now separated by pauses of longer duration than are typically seen during 'non-nutritive' sucking. At the start of each burst there may be 2–3 fast sucks typical of the previous class of sucking (termed 'restart frequency' by Balint [1948]). In addition to reflecting low milk flow, these sucks may serve to draw the nipple out, filling the oral cavity and reversing any loss of grasp during the pause; once again forming an adequate teat for the expression of milk.

At the slow rate of sucking each cycle lasts approximately 1 second, and the effective period over which negative pressure is applied is roughly half of this (0.5s). During this time the baby exerts maximum intra-oral suction, *but* as milk issues from the nipple it fills the oral cavity relieving the negative pressure, and resulting in the need to re-apply suction in a repetitive manner. Thus, the expansion of the teat in the oral cavity, and its filling with milk from the nipple, both act to reduce the peak negative pressure exerted on the nipple. It should be apparent that either an inadequate 'mouthful' of breast tissue by the baby or impaired milk flow will mean that the nipple is likely to be subjected to unrelieved negative pressure.

At the faster rate the total cycle time is only half a second, with a reduction in the effective suction phase to 0.25s. As a result suction does not reach peak pressure when milk flow is absent. This phenomenon can be seen in published records of suction pressure (Halverson, 1938; Hytten, 1951). One possible inference is that physiological variability in sucking pattern may act as a natural protective mechanism preventing exposure of the nipples to maximum pressure in the absence of milk flow. The significance of these suppositions will become apparent during discussion of the possible causes of nipple lesions.

Gunther (1945) investigated the level of basal resting pressure during the rests between bursts of sucking for its possible involvement in causing nipple lesions, and little can be added to her analysis. It is plausible, however, that the exertion of high resting pressures by the infant may be an adaptation to prevent the nipple retracting from the mouth whilst resting. Highly retractile breast tissue or an inadequate teat may *cause* individual infants to adopt this strategy to prevent loss of the teat from the mouth.

CONCLUSION

A sound understanding of the mechanisms of milk removal from the breast is essential if one is to advise mothers correctly on feed management. As arbitrary rules about management, set up some

decades ago, are found to be of little value (if not positively harmful) and are discarded, greater emphasis must be placed on the development of the essential practical skills necessary to ensure the correct attachment of the baby on the breast, in order to allow natural, unhampered breast-feeding to be undertaken.

Acknowledgement

The author wishes to express his thanks to Lewis Woolf Griptight Ltd. who generously made funds available during their centenary year for the preparation of this manuscript.

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Journal of Human Lactation
http://jhl.sagepub.com

Response of Breasts to Different Stimulation Patterns of an Electric Breast Pump

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J Hum Lact 2003; 19; 179
DOI: 10.1177/0890334403252473

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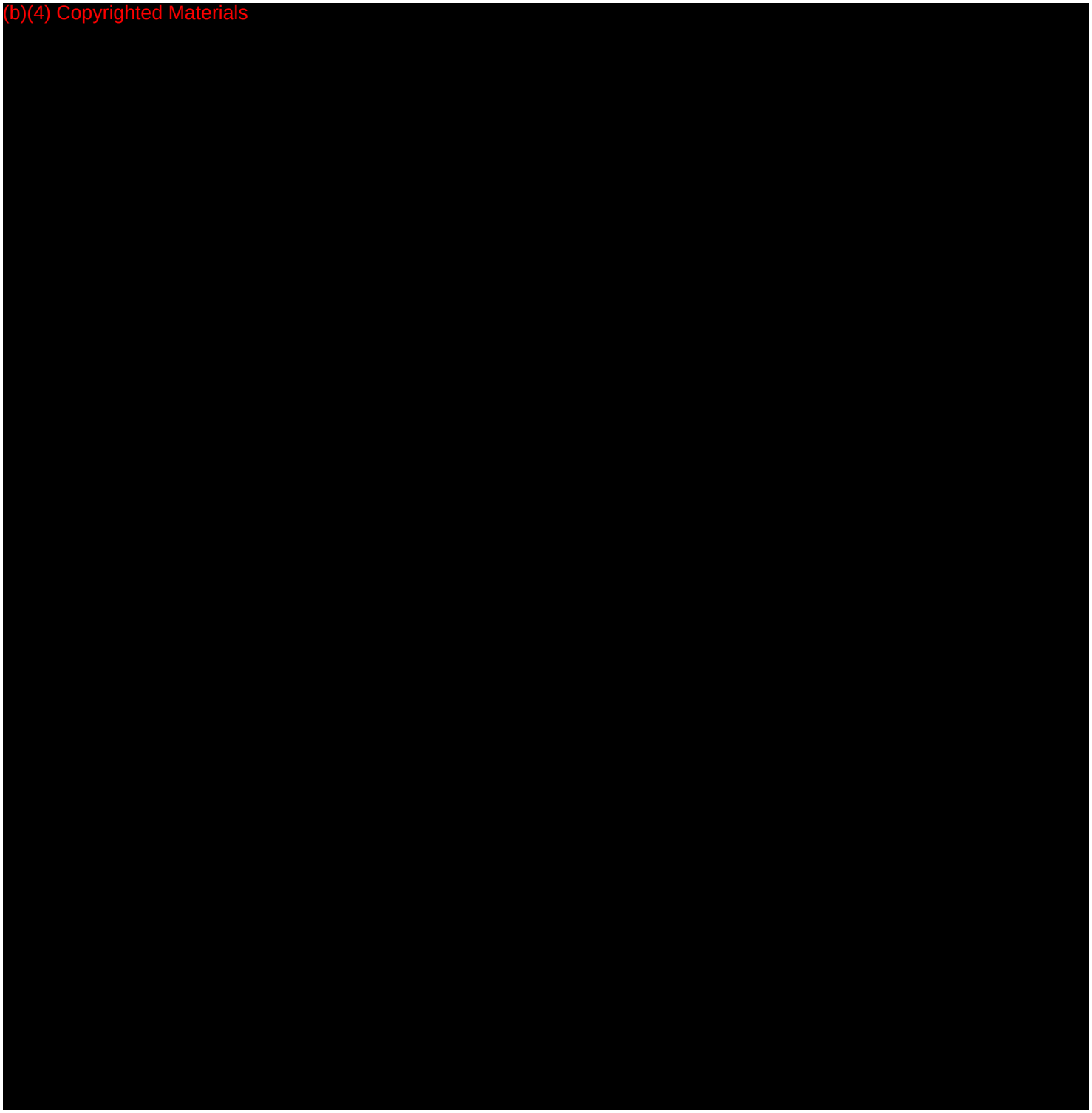

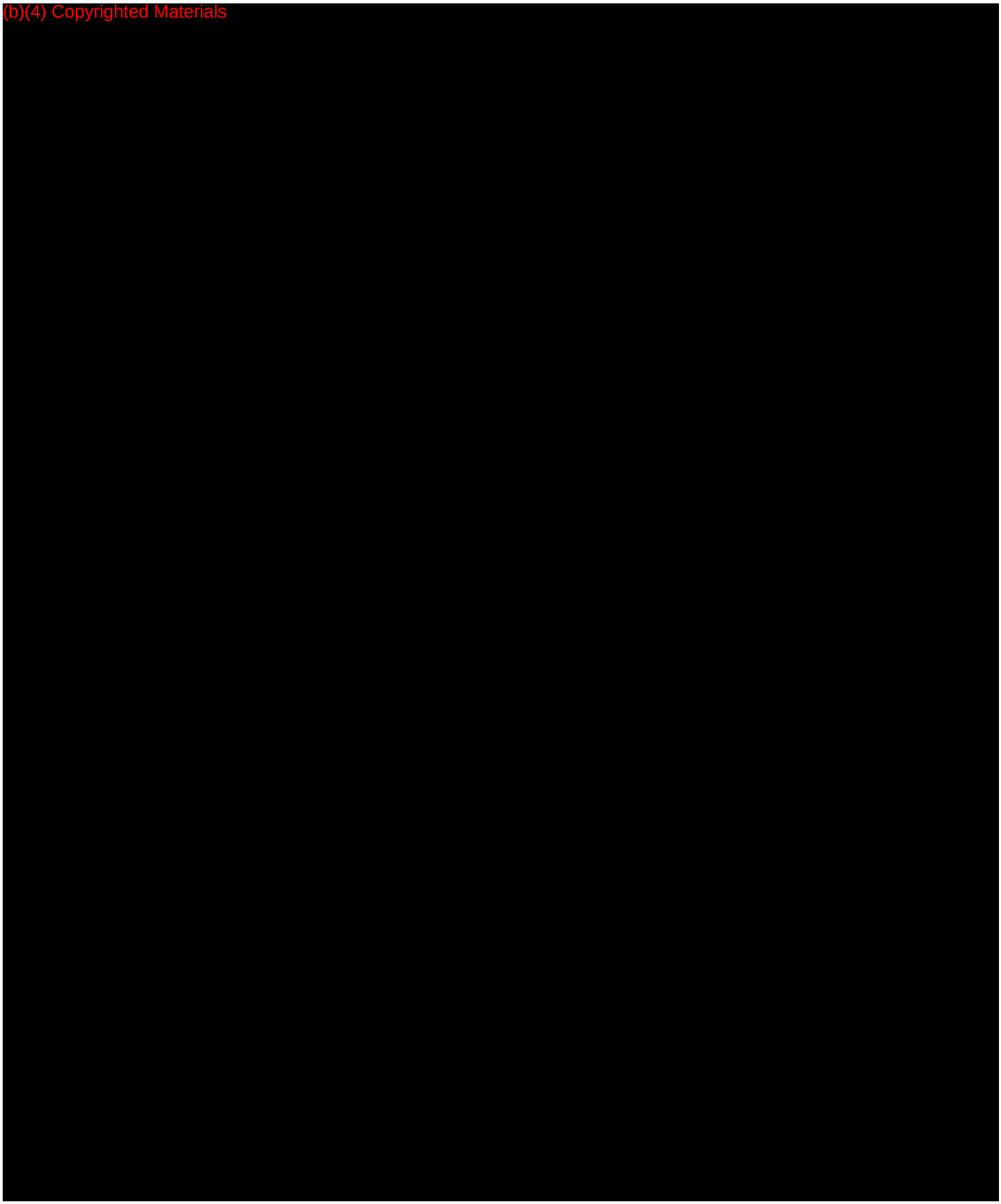

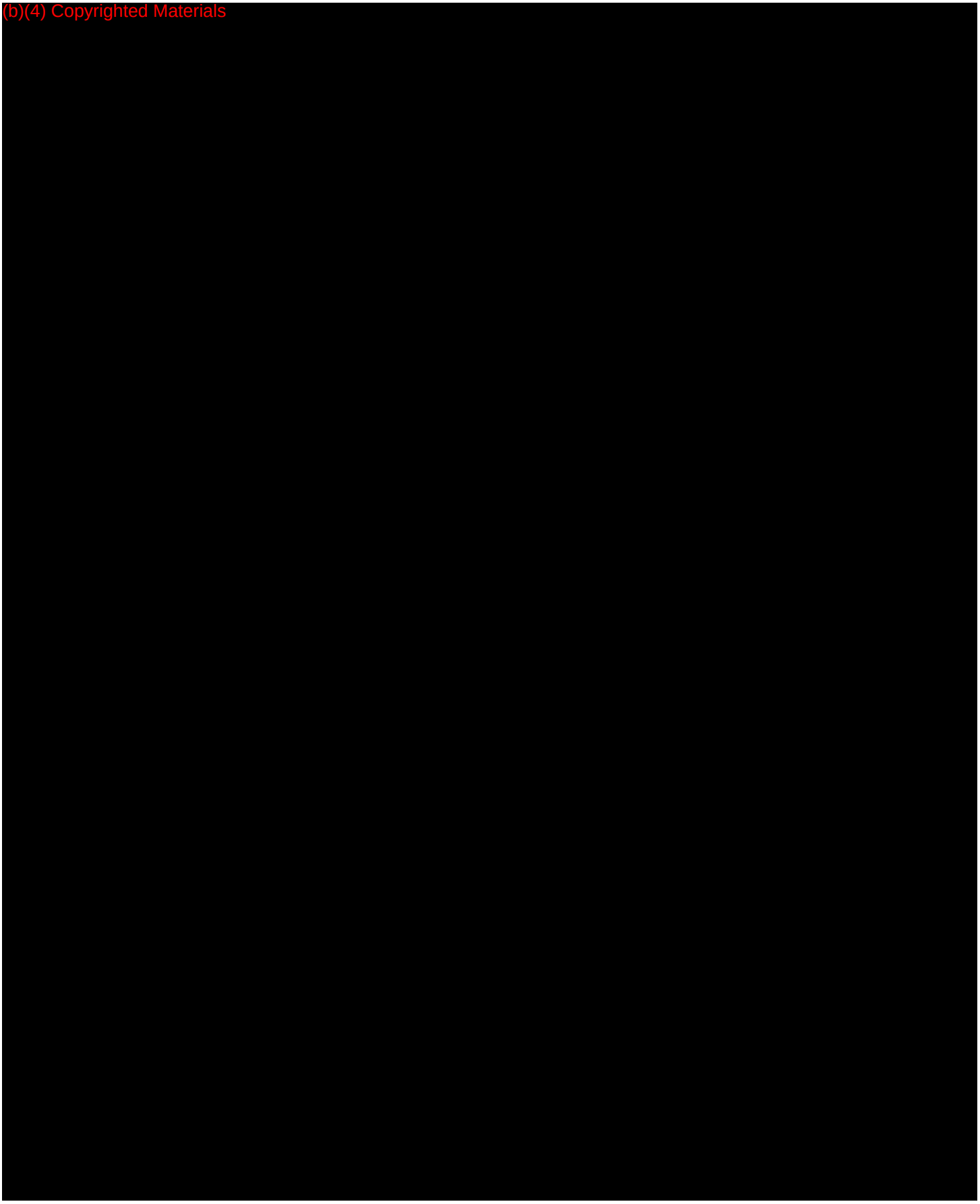

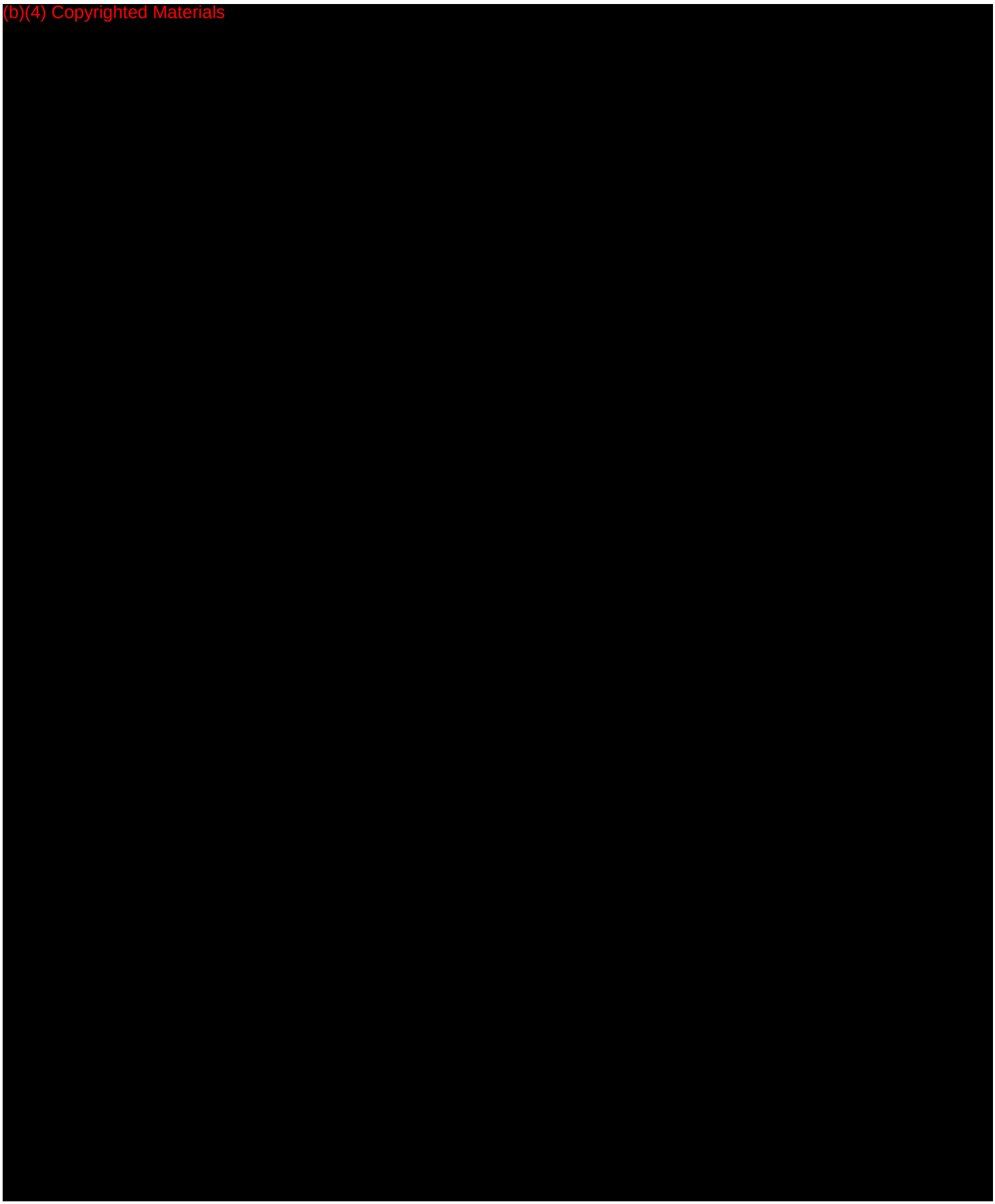

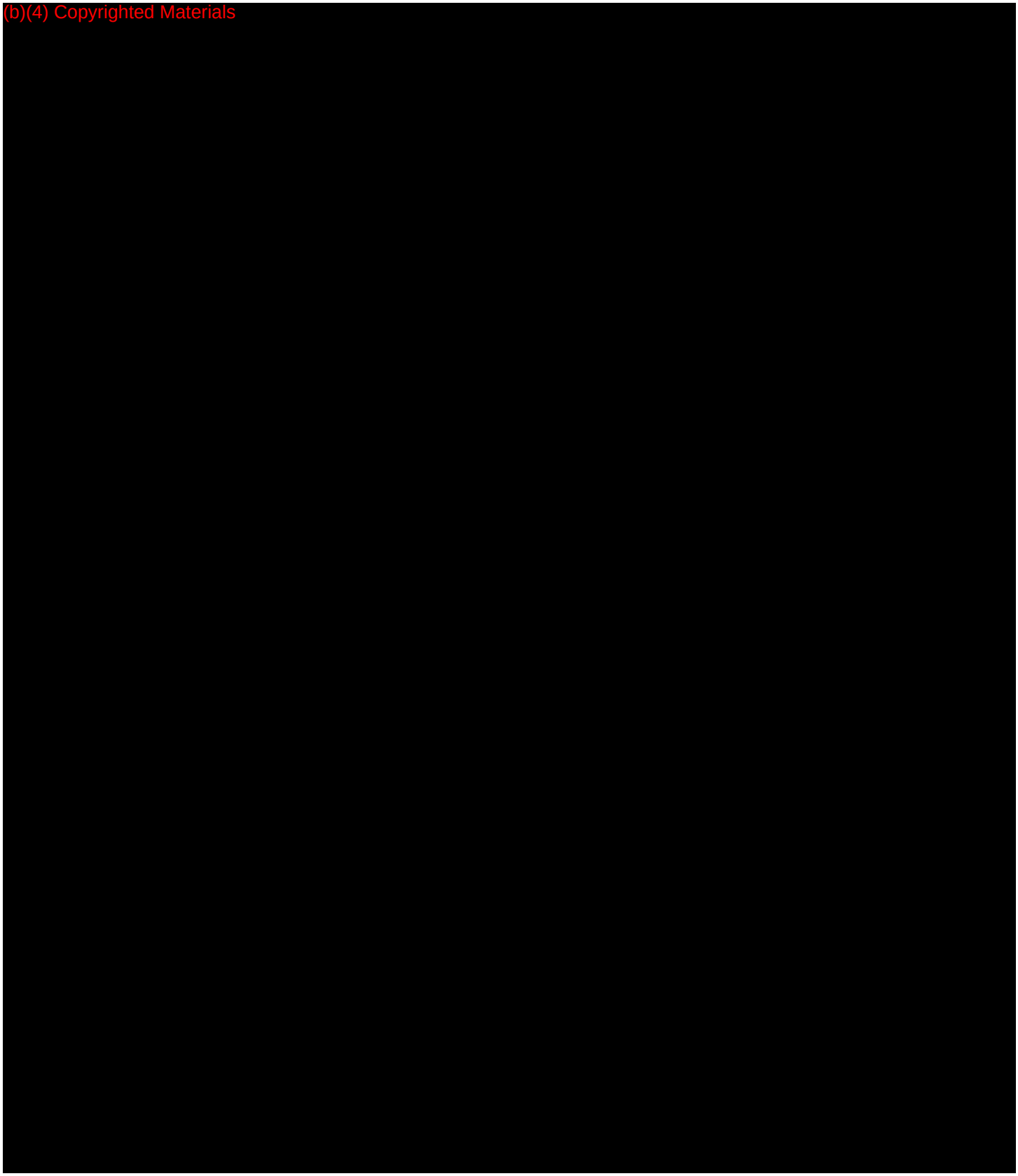

BREASTFEEDING MEDICINE
Volume 3, Number 1, 2008

DOI: 10.1089/bfm.2007.0028

Importance of Vacuum for Breastmilk Expression

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ABSTRACT

Objective: **To determine the effect of the strength of applied vacuum on the flow rate and yield of breastmilk using an electric breast pump.**

Study Design: **Twenty-one breastfeeding mothers and two expressing mothers expressed their breastmilk for 15 minutes using an electric breast pump set at their own maximum comfortable vacuum, and at one to three softer vacuums. Milk yield and flow rate were measured.**

Results: **At the maximum comfortable vacuum (−190.7 ± 8.8 mm Hg) 4.3 ± 0.4 milk ejections occurred during 15 minutes of expression and yielded 118.5 ± 11.4 mL of milk (65.5 ± 4.1% of the available milk). Softer vacuums yielded less milk volume ($p < 0.05$) and less of the available milk ($p < 0.01$). Milk flow rate was greater during the first milk ejection than the third or subsequent milk ejections ($p < 0.001$). Cream content of the milk was highest after expressing for 15 minutes using the mother's maximum comfortable vacuum.**

Conclusions: **Use of the mother's maximum comfortable vacuum enhances milk flow rate and milk yield. The cream content of the milk at the end of the expression period was an indicator of how effectively the breast had been drained.**

INTRODUCTION

BREASTMILK IS THE OPTIMAL NUTRITION for babies. However, because of prematurity, illness, attachment difficulties, or separation, babies are not always able to breastfeed. UNICEF states that the best food for a baby who cannot breastfeed is milk expressed from the mother's breast.[1] Therefore, it is important for many mothers to express their breastmilk. In Western Australia the proportion of mothers of full-term infants who express breastmilk has doubled in the past decade.[2] Breastmilk expression can be done by hand, or with manual or electric breast pumps, but the proportion of mothers using electric pumps has increased threefold to nearly 20% in the past decade.[2] Therefore, mothers and health professionals require evidence-based advice to optimize the use of electric breast pumps. Simultaneous expression of both breasts can save time and has been shown to yield more milk than sequential expression, although the percentage of available milk expressed was not assessed.[3] Recent research on electric breast pumps has focused on evaluating vacuum patterns to stimulate

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milk ejection, and the efficacy of expression patterns,[4,5] but the strength of the applied vacuum was not controlled during these studies. There is evidence in cows that the strength of vacuum has an effect on milk flow rate and the time spent milking.[6] However, the optimal vacuum for milk expression for lactating women has not been investigated.

The aim of this study was to determine the effect of the strength of vacuum on the total yield and rate of flow of milk from the breast, and provide evidence for health professionals advising mothers who are expressing breastmilk for their babies.

MATERIALS AND METHODS

Twenty-three lactating mothers provided written informed consent to participate in the study, which was approved by the Human Research Ethics Committee at The University of Western Australia and the Human Ethics Committee of King Edward Memorial Hospital for Women (Subiaco, WA, Australia). Nineteen of the mothers were exclusively breastfeeding babies less than 6 months old, and two were partially breastfeeding babies aged 7 and 8 months. Two mothers were expressing breastmilk to satisfy all the needs of their babies. One of these mothers was expressing for her 20-week-old full-term baby, and the other mother was expressing for her 6-week-old baby who was born at 24 weeks of gestation. The studies were carried out in the mothers' homes and at the Breast Feeding Centre at King Edward Memorial Hospital for Women.

The 21 breastfeeding mothers measured their 24-hour milk production in their own homes by test-weighing their babies on a Medela Electronic Baby Weigh Scale (Medela AG, Baar, Switzerland) before and after each breastfeeding from each breast for a period of 24 hours plus one breastfeeding. The two mothers who were expressing all their breastmilk for their babies weighed the collection bottle on a balance before and after every expression from each breast for a period of 24 hours plus one expression. The corrected 24-hour milk production was calculated by the method of Arthur et al.[7]; however, no correction for infant-insensible water loss was made, and therefore milk production may be underestimated by 10 ± 12% (mean ± SD). During this period, the mothers hand-expressed small milk samples (<1 mL) into 5-mL polypropylene plastic vials (Disposable Products, Adelaide, SA, Australia), immediately before and after each breastfeeding or expression from each breast. Samples were frozen as soon as possible and kept at −15°C until analyzed. The cream content of all these samples was measured by the creamatocrit method.[8] Because there is a relationship between the cream content of the milk and the degree of fullness of the breast,[9] measuring the cream content of the samples allows the calculation of the change in degree of fullness of the breast from before to after each breastfeeding. These changes, combined with the volumes of the breastfeedings, are used to calculate the breastfeeding storage capacity of the breast for milk.[4] For example, if a change in degree of fullness of 0.5 occurred when 50 mL of milk was removed from the breast, the breastfeeding storage capacity would be calculated to be 100 mL. In addition, small milk samples were similarly collected before and after each experimental expression session at the Breast Feeding Centre. The cream contents of these milk samples and the volumes of the expressions, in combination with the data used to calculate the breastfeeding storage capacity, were used to calculate the potential storage capacity of the breasts of each mother[10] (Fig. 1). The initial degree of fullness of the breast for each expression was calculated from the cream content of the milk collected before the expression,[11] and the volume of available milk in the breast was calculated as the initial degree of fullness of the breast multiplied by the potential storage capacity of the breast.

During the first visit to the Breast Feeding Centre, the maximum comfortable vacuum was determined for the left breast of each mother. An experimental electric breast pump (B2000, Medela AG) equipped with standard breastshield and bottle was used. The pump was computer-driven, and the stimulation pattern (125 cycles per minute) and the expression pattern (54–78 cycles per minute) were similar to those used by the Medela Symphony breast pump. The vacuums were adjustable (0–100%),

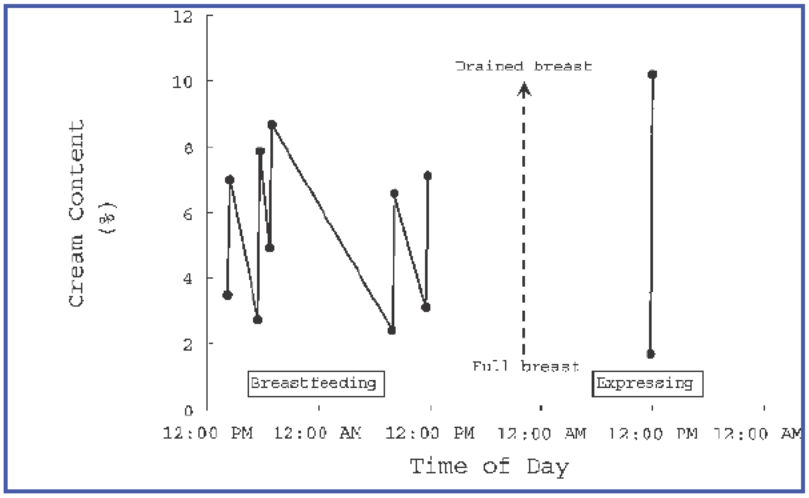

FIG. 1. Example of data used to calculate breastfeeding and potential storage capacity of the breast. Small milk samples were collected before and after each breastfeeding during a 24-hour period of breastfeeding, and before and after one expression session after a prolonged interval without removal of milk from the breast. These breastfeeding data and volumes of breastfeedings were used for calculation of breastfeeding storage capacity. Calculation of potential storage capacity included cream and volume data for both breastfeeding and expressing.

and the vacuum measured at the breast when the pump was set at 100% was −270 mm Hg. The breastshield was applied to the left breast, the pump was turned on using the stimulation pattern, and the vacuum was adjusted to the comfort of the mother. A milk duct in the right breast was monitored using ultrasound with a linear array transducer (5–10 MHz) (Acuson XP10; Siemens, Mountain View, CA) until milk ejection was detected as described by Ramsay et al.[12] All ultrasound scans were videotaped for later analysis. Parker (Fairfield, NJ) Ultrasonic Gel was used for the scans.

After milk ejection was detected, the pump pattern was changed to the expression pattern, and the vacuum rapidly decreased to 24% of maximum vacuum. The vacuum was then increased over the following 30 seconds until the mother started to feel uncomfortable. The vacuum was then decreased by 10 mm Hg, and this vacuum recorded as the maximum comfortable vacuum for that mother. For subsequent visits, this vacuum was used as the 100% vacuum for the individual mother (vacuum A). Expression at 75% of this vacuum was also tested (vacuum B), and the order of testing vacuums A and B was randomized. When vacuum A was stronger than −173 mm Hg (i.e., vacuum B was stronger than −130 mm Hg), expression at −125 mm Hg (vacuum C) and at −75 mm Hg (vacuum D) was also tested. When vacuum A was softer than −173 mm Hg but stronger than −125 mm Hg, testing at vacuum C was omitted. When vacuum A was softer than −125 mm Hg, testing at vacuums C and D were omitted.

An adapter with an 80-cm-long polyvinyl chloride tube was connected to the breastshield. The tube conveyed the milk to sample collection tubes placed on a balance (Scout Pro SP401, OHAUS Corp., Pinebrook, NJ) connected to a computer that recorded the cumulative weight of the milk collected every 5 seconds. During the entire expression period a milk duct in the right breast of the mother was monitored continuously using ultrasound to detect milk ejections.[10,12]

The stimulation pattern was applied by the pump at a vacuum chosen by the mother until milk ejection was detected. The pump was then changed to the expression pattern, and the vacuum was adjusted to the vacuum being tested. Expression continued for 15 minutes after the first milk ejection was detected. The milk removed during application of the stimulation pattern was collected into the first collection tube. After milk ejection, the milk expressed was collected during 30-second intervals. The cream content of each fraction collected was measured.

Continuous data were summarized using means and their standard errors (SEM) or medians and interquartile ranges, as appropriate. Comparisons between the outcomes achieved for each vacuum were carried out using regression modeling with generalized estimating equations methods suitable for analysis of repeated measures (PROC MIXED), where vacuums were modeled as fixed factors and individuals were modeled as random factors. Transformations to achieve normality were used when required, and model assessments

were performed via analysis of regression residuals. SAS statistical software (SAS Institute Inc., Cary, NC) was used for data analysis. Values of $p < 0.05$ were considered statistically significant, and pairwise contrast testing was conducted at an overall significance level of 0.05.

RESULTS

The mothers (previously described[10]) were 33.1 ± 3.5 years old, feeding babies 16.4 ± 7.2 weeks old. During their normal breastfeeding or expressing the mothers were producing between 213 and 925 mL of milk per day from the left breast, and the mean amount of milk taken at a breastfeeding from the left breast was 75 ± 30 mL.

The longest interval between breastfeedings or expressions during the day the 24-hour milk production was measured was 8 hours 52 minutes ± 40 minutes for the left breast (range 3 hours 40 minutes to 15 hours 30 minutes). Before all test sessions, the mothers were asked to refrain from feeding from the left breast long enough for the breast to be more than half full. In some mothers who did not breastfeed or express from the left breast for an extended interval (up to 17 hours), the breast felt very full, and the fat content of the foremilk was lower than the lowest measurement on the day the 24-hour milk production was measured. Since there is an association between the fat content of the milk and the degree of fullness of the breast, this is an indication that the breast was filled to a greater degree compared to before any one breastfeeding on the day the 24-hour production was measured. In addition, at the end of some of the expression periods the breast was more drained than after breastfeeding, and the fat content of the milk was higher than the highest measurement on the day the 24-hour production was measured (Fig. 1). This is an indication that the breast was drained to a greater degree when compared to after any one breastfeeding on the day the 24-hour production was measured. Therefore, for those mothers who had an unusually low cream content of the breastmilk before expression and/or for whom breast expression left minimal residual milk with an unusually high cream content, an estimation could be made of the potential storage capacity of the breast. The potential storage capacity calculated for the left breast (243 ± 21 mL) was greater than the breastfeeding storage capacity (179 ± 13 mL) ($p < 0.001$). Just as the vital capacity of the lungs is the largest amount of air that can be exhaled after taking a deep breath, so the potential storage capacity of the breast is the amount of milk in a distended breast that is available for removal.

The maximum comfortable vacuum measured during expression was −190.7 ± 8.0 mm Hg (range −98 to −270 mm Hg). Therefore vacuum B was −143.0 ± 8.8 mm Hg (range −75 to −203 mm Hg). Eleven mothers tested vacuums A, B, C, and D, seven mothers tested vacuums A, B, and D, and five mothers tested only vacuums A and B.

No milk was expressed during the stimulation phase for 64 of the study sessions. For the other 11 study sessions the median amount of milk expressed before milk ejection was 2.7 mL (interquartile range 1.3–6.8; range 0.4–10.3 mL). There was no relationship between the volume expressed during stimulation and the stimulation vacuum applied ($p = 0.559$). The data for the expression sessions are shown in Table 1.

After 15 minutes of expression, within mothers there were differences between the vacuums in the total yield of milk, the time taken to express 50% and 80% of that volume, and the proportion of the available milk expressed (Table 1). The initial degree of fullness of the breast affected the total yield of milk ($p = 0.05$), but not the time taken to reach 50% or 80% of the total yield of milk or the proportion of available milk expressed. There were no significant differences between the four vacuums in the initial degree of fullness of the breasts, the stimulation vacuum chosen by the mothers, the time taken until the first milk ejection occurred, or the number of milk ejections that occurred during the 15-minute expression period.

When the vacuums tested were reclassified according to absolute vacuum applied (less than or equal to −200 mm Hg, −151 to −200 mm Hg, −101 to −150 mm Hg, greater than or equal to −100 mm Hg) there was a difference between the total yield of milk using the

Table 1. Expression of Milk from the Left Breast

	Vacuum (mm Hg)			
	A (190.7 ± 8.0)	*B (143.0 ± 8.8)*	*C (−125)*	*D (−75)*
n	23	23	11	18
Initial cream content (%)	1.98 ± 0.27	2.71 ± 0.46	1.59 ± 0.31	2.05 ± 0.29
Initial degree of fullness	0.78 ± 0.04	0.72 ± 0.04	0.86 ± 0.03	0.81 ± 0.04
Potential storage capacity (mL)	249 ± 21	249 ± 21	242 ± 29	258 ± 25
Stimulation vacuum (mm Hg)	−80.9 ± 4.8	−84.3 ± 2.2	−89.3 ± 11.2	−88.5 ± 7.4
Time to first milk ejection (seconds)	91.6 ± 12.9	90.0 ± 14.0	86.7 ± 21.5	73.9 ± 9.9
Number of milk ejections	4.3 ± 0.4	4.8 ± 0.6	4.5 ± 0.5	4.4 ± 0.5
Total milk volume (mL)	118.5 ± 11.4	90.7 ± 9.4*	81.2 ± 11.2*	73.2 ± 11.0**
Time to 50% total (minutes)	3.6 ± 0.4	4.1 ± 0.5	4.9 ± 0.8**	11.0 ± 0.6**
Time to 80% total (minutes)	6.7 ± 0.6	7.6 ± 0.8	8.3 ± 1.1*	12.9 ± 0.6**
% available milk expressed	65.5 ± 4.1	55.3 ± 5.3	42.5 ± 5.7**	36.4 ± 4.1**

Data are mean ± SEM values.
Significantly different from vacuum A: *$p < 0.05$, **$p < 0.01$.

strongest vacuum (less than or equal to −200 mm Hg) and all the other vacuums ($p = 0.03$, $p = 0.04$, and $p < 0.0001$, respectively). Using this classification, the initial degree of fullness also affected the total yield of milk ($p = 0.029$).

For the breastfeeding mothers, the ratio of the volume of breastmilk expressed during the study sessions to the average breastfeeding of the baby was calculated. When this ratio was <0.5, 0.5–1, or >1 the mothers have been classified as low-ratio, medium-ratio, or high-ratio mothers, respectively.[5] When the 21 mothers who were breastfeeding expressed using vacuum A, one was a low-ratio, four were medium-ratio, and 16 were high-ratio mothers. Five of the high-ratio mothers changed to medium-ratio when they expressed using vacuum B.

The number of milk ejections that occurred during the 15-minute expression period, detected by ultrasound, was variable (range one to 12) with a mean of 4.3 and was independent of the vacuum applied. The duration of each milk ejection was 228 ± 10 seconds (range 100–8,005 seconds) and was independent of milk ejection number and vacuum. The amount of milk expressed from the first to the seventh milk ejection in the 15-minute expression period is shown in Table 2. The amount of milk expressed during each milk ejection related to applied vacuum ($p < 0.001$) was directly proportional to the degree of fullness ($p < 0.001$) and to the duration of milk ejection ($p < 0.001$) and was inversely proportional to the number of milk ejections that had already occurred during the expression ($p < 0.001$). Pairwise comparisons of the amount of milk expressed during the consecutive milk ejections showed no difference between the volumes expressed during the first and second milk ejection ($p = 0.101$). Compared to the volume expressed during the first milk ejection, significantly lower volumes were expressed for successive milk ejections from the third milk ejection onwards (all $p < 0.001$) (Table 2).

The percentage of the total yield of milk during each milk ejection using different vacuums is shown in Figure 2. Using vacuum A, 45% of the total milk yield was expressed during the first milk ejection, with a further 31% during the second milk ejection, i.e., 76% of the milk that was expressed was removed during the first two milk ejections.

The cream content of the milk was initially 2.33 ± 0.22% and increased during expression. When expressing using vacuums A and B, the cream content of the milk had increased when 50% of the total yield had been expressed ($p = 0.002$ and $p = 0.001$, respectively); however, when expressing using vacuums C and D the cream content of the milk did not increase until 80% of the total yield had been expressed ($p = 0.001$ and $p = 0.010$, respectively). When expressing using vacuums A, B, and C, the cream content of the milk increased further from when 50% to when 80% of the total yield had been expressed ($p \leq 0.001$, $p = 0.004$, and $p = 0.050$, respectively). Only when using vac-

Table 2. Milk Expressed During Milk Ejections

	Milk expressed (mL) at milk ejection number						
	1	*2*	*3*	*4*	*5*	*6*	*7*
Vacuum A	53.5 ± 10.5 (23)	37.1 ± 6.1 (23)	15.8 ± 2.8 (19)*	13.4 ± 3.1 (14)*	6.9 ± 2.6 (11)*	6.8 ± 3.2 (7)*	2.4 ± 0.8 (4)*
Vacuum B	26.1 ± 4.1 (23)	30.0 ± 4.2 (23)	15.5 ± 3.0 (21)*	13.3 ± 2.4 (16)*	10.3 ± 2.9 (10)*	7.3 ± 2.5 (6)*	2.4 ± 0.6 (5)*
Vacuum C	22.1 ± 7.2 (11)	16.2 ± 2.7 (11)	10.8 ± 1.9 (10)*	20.1 ± 7.4 (9)*	17.5 ± 6.5 (6)*	4.4 ± 2.5 (2)	7.7 (1)
Vacuum D	31.3 ± 8.0 (18)	23.6 ± 8.4 (18)	9.7 ± 2.6 (11)*	8.2 ± 2.8 (11)*	7.4 ± 1.8 (11)*	6.5 ± 1.9 (5)*	5.6 ± 3.4 (3)*

Data are mean ± SEM values (numbers of observations).
*Significantly different from milk ejection 1, $p < 0.001$.

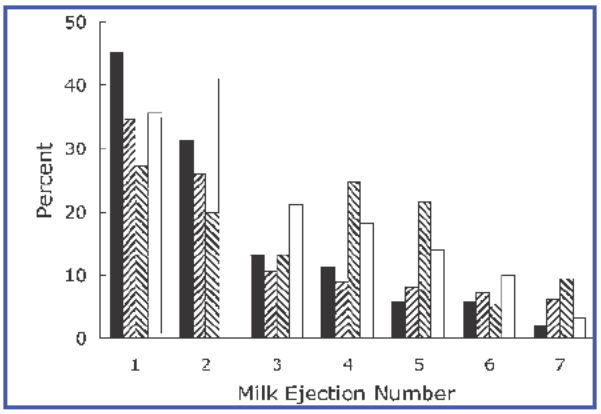

FIG. 2. Percentage of total milk yield expressed during each milk ejection using vacuum A (maximum comfortable vacuum, ■), vacuum B (75% of vacuum A, ▨), vacuum C (−125 mm Hg, ▧), or vacuum D (−75 mm Hg, □).

uum A was there a further change in the cream content from when 80% of the total yield had been expressed to the end of the expression period ($p = 0.005$). The cream at the end of the expression period using vacuum A was 9.48 ± 0.74%, which was higher than at the end of the expression period using vacuums C (6.64 ± 1.38%) and D (5.50 ± 0.87%) ($p = 0.012$ and $p < 0.001$, respectively). The maximum cream contents of the hindmilk for individual mothers were 18%, 18%, 17%, and 12% for vacuums A, B, C, and D, respectively.

DISCUSSION

The milk production characteristics of the participating mothers were variable, but the milk production of all mothers of babies who were exclusively breastmilk-fed was within the normal range,[13] and the mothers of the partially breastfed babies were producing more than 580 mL per day. The maximum comfortable vacuum chosen by the mothers was also variable. Half of the mothers were comfortable using a vacuum stronger than −200 mm Hg, but one mother could not tolerate a vacuum stronger than −98 mm Hg. Therefore, clinicians should advise mothers not to expect to use the maximum vacuum able to be applied by the breast pump and encourage them to determine their own maxima.

Expressing breastmilk for 15 minutes using the mother's maximum comfortable vacuum yielded more milk, and more of the available milk, than using softer vacuums. In addition, the time taken to express 50% and 80% of the total milk yield was shorter using maximum comfortable vacuum than using vacuums of −125 mm Hg or −75 mm Hg. This is a consequence of high milk flow rates resulting in a high volume of milk being expressed (76% of the total) during the first two milk ejections. These occur on average within the first 8 minutes after the beginning of the initial milk ejection when the pump was changed from the stimulation pattern to the expression pattern.[10]

In this study use of the stimulation pattern resulted in a milk ejection after approximately 90 seconds, and little or no milk was expressed during the stimulation phase. Therefore, health professionals can advise mothers that they can maximize their milk yield and minimize their expression time by using the maximum comfortable vacuum of the expression pattern as soon as the milk ejection is detected, by either the mother's sensation or the observation of jets of milk from the openings of the ducts in the nipple. Mothers should also be aware that the initial degree of fullness of the breasts will affect the total yield of milk that will be expressed, but will have no effect on the time taken to express 50% or 80% of that volume.

After the first two milk ejections, as many as 10 more milk ejections were detected, but these subsequent milk ejections made only a minor contribution to the total yield of milk. If a mother is expressing to leave breastmilk with a temporary carer, expression using maximum comfortable vacuum for 8 minutes may be sufficient.

Comparing expressing using maximum comfortable vacuum to breastfeeding, 76% of the breastfeeding mothers were high-ratio, indicating that these mothers were able to effectively express milk from the breast. The reason for some mothers remaining in the medium-ratio or low-ratio categories is not clear. A positive association between milk flow rate and duct diameter in women has been previously demonstrated.[10] Furthermore, comparative analysis with the dairy industry shows that the milk flow rate in cows is associated with both the teat canal length and vacuum.[14] Therefore,

it is possible that the ductal characteristics of the breast contribute to the effectiveness of breast expression. This is an area that requires further investigation.

The cream content of the foremilk collected in this study was lower than that measured by Meier et al.[15] in the milk of preterm mothers (mean 8.1%, SD 1.8%), perhaps reflecting a different composition of milk of preterm mothers, or suggesting a higher starting degree of fullness of the breasts in the current study. Significant increases in the cream content of the milk when 50% of the total yield of milk had been expressed using vacuums A and B reflect the higher yields of milk using these vacuums leading to larger changes in the degree of fullness of the breasts. The maximum cream contents of the hindmilk of individual mothers in the current study were similar to the 17.5% measured by Meier et al.[15] However, the mean cream content of the milk collected at the end of the expression period in this study was lower than that measured by Meier et al.[15] (mean 12.4%, SD 2.7%), but similar to the cream content of the hindmilk collected after breastfeedings of term infants (mean 9.3%, SD 2.4% [J.C.K., unpublished data]). Since the cream content of the milk is related to the degree of fullness of the breast, these results are consistent with breastfeeding babies taking 67.3% of the available milk during a breastfeeding[13] and breast expression using the mother's maximum comfortable vacuum removing 65.5% of the available milk. The lower cream contents of the milk collected at the end of the expression period using vacuums C and D are consistent with less of the available milk being expressed using these vacuums. Therefore the cream content of the milk at the end of expression can be used as a gauge of the effectiveness of the breast pump in draining the breast.

CONCLUSION

When mothers are expressing breastmilk using an electric breast pump the yield of milk and the milk flow rate are maximized if they use their own maximum comfortable vacuum. Since most of the milk is removed during the first two milk ejections mothers should use their maximum comfortable vacuum of the expression pattern and as soon as milk ejection occurs take advantage of the high milk flow rate. A high cream content of milk at the end of expression indicates effective drainage of the breast.

ACKNOWLEDGMENTS

The authors thank the breastfeeding mothers and babies who participated for their time, the Australian Breastfeeding Association for recruiting volunteers, and Tracey Williams for technical assistance. The support of a grant from Medela AG is gratefully acknowledged.

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Volume and Frequency of Breastfeedings and Fat Content of Breast Milk Throughout the Day

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Pediatrics 2006;117;387-395
DOI: 10.1542/peds.2005-1417

ARTICLE

Volume and Frequency of Breastfeedings and Fat Content of Breast Milk Throughout the Day

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The authors have indicated they have no financial relationships relevant to this article to disclose.

ABSTRACT

OBJECTIVE. We aimed to provide information that can be used as a guide to clinicians when advising breastfeeding mothers on normal lactation with regard to the frequency and volume of breastfeedings and the fat content of breast milk.

METHODS. Mothers (71) of infants who were 1 to 6 months of age and exclusively breastfeeding on demand test-weighed their infants before and after every breastfeeding from each breast for 24 to 26 hours and collected small milk samples from each breast each time the infant was weighed.

RESULTS. Infants breastfed 11 ± 3 times in 24 hours (range: 6–18), and a breastfeeding was 76.0 ± 12.6 g (range: 0–240 g), which was 67.3 ± 7.8% (range: 0–100%) of the volume of milk that was available in the breast at the beginning of the breastfeeding. Left and right breasts rarely produced the same volume of milk. The volume of milk consumed by the infant at each breastfeeding depended on whether the breast that was being suckled was the more or less productive breast, whether the breastfeeding was unpaired, or whether it was the first or second breast of paired breastfeedings; the time of day; and whether the infant breastfed during the night or not. Night breastfeedings were common and made an important contribution to the total milk intake. The fat content of the milk was 41.1 ± 7.8 g/L (range: 22.3–61.6 g/L) and was independent of breastfeeding frequency. There was no relationship between the number of breastfeedings per day and the 24-hour milk production of the mothers.

CONCLUSIONS. Breastfed infants should be encouraged to feed on demand, day and night, rather than conform to an average that may not be appropriate for the mother-infant dyad.

www.pediatrics.org/cgi/doi/10.1542/peds.2005-1417

doi:10.1542/peds.2005-1417

Key Words
breastfeeding, feeding behavior, feeding volumes, infant feeding, breast milk

Abbreviation
IQR—interquartile range

Accepted for publication Sep 19, 2005

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BREASTFEEDING MOTHERS SHOULD be made aware of the variability of milk volumes per breastfeeding, the frequencies of breastfeedings, and the distribution of milk intake by day and by night of healthy breastfed infants.[1]

Mothers among the !Kung hunter-gatherers have been observed to breastfeed 4 times every hour during the day and at least once at night.[2] In contrast, Cadogan,[3] in his essay to the Governors of the Foundling Hospital (London, United Kingdom) in 1748 recommended that infants be suckled only 4 times a day and not at night, because he considered the night feeding to result in breastfed infants' becoming "over fat and bloated." Relaxation of the concept of scheduled breastfeeding was first strongly promoted by Wickes[4] in 1953 and subsequently advocated by community support groups such as La Leche League and the Australian Breastfeeding Association that were at the vanguard of the movement back to breastfeeding in the early 1970s in Western societies. As a result, infants were breastfed more frequently both by day and by night. It now is recognized that breast milk provides the optimal nutrition for infants, and current recommendations to mothers are that infants be breastfed "on demand" (according to their appetite) exclusively for the first 6 months of life.[5,6]

Bangladeshi infants have been found to consume half their daily milk intake between 6 AM and 6 PM.[7] Matheny and Picciano[8] in the United States investigated whether measurement of milk production over a 12-hour period could be doubled to determine the 24-milk production. Studying 4-week-old infants, they found that more milk was consumed between 6 AM and 6 PM and less was consumed between 2 PM and 2 AM. Doubling of either of these 12-hour intakes resulted in significant inaccuracies in estimation of 24-hour milk consumption. The product of the volume of 1 or 2 consecutive breastfeedings and the number of breastfeedings in the period also has been found to be inaccurate.[9] The data of Cregan et al[10] showing variation in the volume and the frequency of breastfeedings over 24 hours for Australian infants also suggest that these calculations would be inaccurate. However, for accurate assessment of milk production, the necessity of a full 24-hour period of measurement of milk intake in our society for infants between 4 and 26 weeks has not been determined.

A wide variation in the frequency of breastfeeding has been recorded in the United States and Sweden in exclusively breastfed infants.[11,12] These authors collected longitudinal records of the number, time of day, and duration of breastfeedings of infants between 2 and 26 weeks of age, but no information was provided on the volume of milk consumed at each breastfeeding by these infants. Previously, interest has focused on the nutrient intake of the infant, and the total consumption has been quoted with no information provided on the volume of milk consumed from each breast.[13,14] Therefore, it was not possible to assess how the infant feeds to appetite in relation to the volume of milk available in the mother's breasts. Furthermore, the literature on the frequency of breastfeeding generally fails to define what constitutes a breastfeeding. Although Hörnell et al[11] defined "one breastfeeding episode" as the "duration of suckling 2 minutes or longer and separated from previous breastfeed by at least 30 minutes," this does not consider whether the infant fed from 1 breast or both during that episode.

In this article, we investigate the volume and the pattern of milk intake in a cross-sectional study of 1- to 6-month-old infants who were being exclusively breastfed on demand, and we examine the contribution of each breast. This is the first article to describe the variation in the volume of milk consumed from each breast at each breastfeeding, the degree of fullness of each breast before and after each breastfeeding, and the fat content of the milk consumed from each breast throughout the day and night. This will provide a normal reference range to enhance clinicians' support for breastfeeding mothers.

METHODS

Data were collected from 71 mothers who were exclusively breastfeeding on demand healthy, term infants who were aged between 1 and 6 months. These mothers were participants in studies that were conducted in this laboratory from 2000 to 2004.[15–17] These studies were approved by the Human Research Ethics Committee of The University of Western Australia.

The mothers test-weighed their infants before and after each breastfeeding from each breast on a Medela electronic Baby Weigh Scale (Medela AG, Baar, Switzerland) for a period of 24 hours plus 1 breastfeeding. A corrected 24-hour production for each breast then was determined using these data, but no correction for infant insensible water loss was made; therefore, milk production may be underestimated by 3% to 10%.[18–20] All measurements of breastfeed amounts, storage capacity, and milk production are expressed in grams that can be considered to be nearly equivalent to mL because the density of milk is 1.03 g mL^{-1}.[21] For each mother, the breast that had the higher 24-hour production was termed "more productive" and the breast that had the lower 24-hour production was termed "less productive." In addition, milk samples ($\leq$1 mL) were collected by hand expression into 5-mL polypropylene plastic vials (Disposable Products, Adelaide, Australia), immediately before and after each breastfeeding from each breast. Samples were frozen as soon as possible and kept at −15°C for analysis. The cream content of the milk samples was measured by the creamatocrit method,[22] and the fat content of each sample, in grams per liter, was calculated as 5.37 × creamatocrit + 5.28.[15]

The original estimation of fat content as a function of

degree of breast emptying was introduced by Daly et al,[23] whereby fat content was best predicted using a quadratic function with degree of emptying as a predictor. Although time since last breastfeeding and individual breast had a small effect, the best predictor of fat content was degree of emptying. This accounted for 68% of variation, which was deemed satisfactory given the physiologic process being measured. Degree of fullness was calculated as 1 − degree of emptying, and it was obtained via inverse calculation of degree of emptying using the equation fat = 21.50 + 9.38 × (degree of emptying) + 70.99 × (degree of emptying)^2.[23] This relationship between degree of emptying and fat content was individualized, whereby for each woman, minimal, median, and maximal fat content over 24 hours was set to correspond to degree of fullness of 1, 0.6892, and 0, respectively, that protected against physiologically impossible estimates (ie, degree of fullness exceeding 1 or becoming negative). The storage capacity (the amount of milk available to the infant when the breast is full) was determined using a regression line relating change in degree of fullness at each feeding to the amount of milk removed from the breast at that feeding. Assuming that a change in degree of fullness of 0 corresponds to a feeding amount of 0, the regression line was forced to pass through the origin. Storage capacity then could be calculated as the amount of milk that corresponds to a change in degree of fullness of 1. The volume of available milk in the breast before each breastfeeding was calculated as the degree of fullness multiplied by the storage capacity of the breast.

We defined a breastfeeding as an infant's taking milk from 1 breast. When the next breastfeeding was >30 minutes after the end of the first, the breastfeeding was considered to be unpaired. When the infant took milk from the other breast within 30 minutes of finishing on the first breast, the breastfeedings were considered to be paired. When the infant fed again from the first breast within 30 minutes of finishing on the second breast, the breastfeedings were considered to be clustered. A meal was defined as an unpaired breastfeeding, or 2 paired breastfeedings, or 3 clustered breastfeedings. This definition of a "meal" is equivalent to "1 breastfeeding episode" as defined by Hörnell et al.[11] Four breastfeedings were 0 g when the infant went to the breast and apparently suckled but there was no difference between the infant's weight from before to after the breastfeeding.

For this study, the day was divided into 4 intervals. Morning was considered to be from 4:01 AM to 10:00 AM, day was 10:01 AM to 4:00 PM, evening was 4:01 PM to 10:00 PM, and night was 10:01 PM to 4:00 AM.

Descriptive summaries of continuous data used means and SDs or medians and interquartile ranges (IQRs), depending on data normality. Inference was based on summary data averaged over 24 hours (n = 71), overall summaries for individual breasts (n = 142), and all individual breastfeedings recorded over 24 hours (n = 775). Analyses of individual breastfeedings were weighted according to the number of breastfeedings recorded per woman. Paired and unpaired univariate comparisons of summary data were performed using t tests or their nonparametric equivalents depending on data normality. Multivariate analysis was based on analysis of variance with repeated measures performed using Proc GLM (SAS 8.02; SAS Institute Inc, Cary, NC), and goodness of fit was assessed via analysis of residuals. Linear and polynomial regression analyses were used to assess relationships. Two-sided P values are quoted, and $P < .05$ was regarded as statistically significant.

RESULTS

The characteristics of the mothers are presented in Table 1. There were 41 male and 30 female infants. There was no significant difference either between the mean age of the male and female infants or in the age and parity of their mothers.

Frequency and Volume of Breastfeedings

A total of 775 breastfeedings were monitored. Each infant had 11 ± 3 breastfeedings per day (range: 6–18). The interval between breastfeedings was 2 hours 18 minutes ± 43 minutes (range: 4 minutes to 10 hours 58 minutes). Of these breastfeedings, 345 (44.5%) were unpaired (182 from the more productive breast and 163 from the less productive breast), with an interval of >1 hour until the next breastfeeding for 90% of these breastfeedings. A total of 412 (53.2%) breastfeedings were paired, and 18 (2.3%) were clustered. That is, there were 7.9 ± 1.8 meals per day (range: 4–13), and the interval between meals was 3 hours 2 minutes ± 41

TABLE 1 **Subject Characteristics**

	Mean ± SD	Range
Mother		
Age, y	31.8 ± 4.3	23–42
Parity	1.7 ± 0.8	1–4
Infant		
Age, wk	15.3 ± 5.9	4–26
24-h breast milk intake, g		
Total	788 ± 169	478–1356
More productive breast	459 ± 106	253–769
Less productive breast	339 ± 90	161–553
Breast storage capacity, g		
More productive breast	193 ± 60	76–382
Less productive breast	164 ± 53	74–320
Average breastfeed volume, g		
More productive breast	84 ± 28	32–131
Less productive breast	67 ± 26	27–147
Breastfeed frequency, feeds per day		
More productive breast	5.6 ± 1.6	3–9
Less productive breast	5.4 ± 1.5	3–9
Fat content of milk, g/L		
More productive breast	41.3 ± 8.4	22.5–60.8
Less productive breast	40.9 ± 8.4	22.3–61.6

minutes (range: 40 minutes to 10 hours 58 minutes). Thirteen percent of infants always had paired breastfeedings ($n = 9$), 30% of infants always had unpaired breastfeedings ($n = 21$), and the remaining 57% of infants had a mixture of paired and unpaired breastfeedings ($n = 41$).

There were no changes in the breastfeeding frequency with age of the infant and no significant difference in breastfeeding frequency between girls and boys. The more productive breast was fed from as frequently as the less productive breast, and when the breastfeedings were paired, the more productive breast was offered first as frequently as the less productive breast. There was no relationship between the number of breastfeedings per day and the 24-hour milk production of the mothers.

The infants took 76.0 ± 12.6 g (range: 0–240 g) at each breastfeeding. There was an inverse relationship between the number of breastfeedings per day and the average breastfeeding volume ($r^2 = 0.442$; $P < .001$; $n = 142$ breasts). The average meal was 101.4 ± 15.6 g (range: 0–350 g). The average breastfeeding volume was unrelated to the age of the infant ($P = .421$), but there was an increase in the maximum breastfeeding volume with advancing age between 4 and 26 weeks ($r^2 = 0.09$; $P < .010$). The maximum breastfeeding volume of boys was greater than that of girls (154.6 ± 54.8 g for boys vs 129.8 ± 29.0 g for girls; $P = .029$), but there was no significant difference in the average breastfeeding (79.3 ± 26.9 g for boys vs 73.0 ± 22.4 g for girls; $P = .299$). The average breastfeeding from the more productive breast was higher than that from the less productive breast ($P < .001$; Table 1), and individual breastfeedings from the more productive breast were larger than from the less productive breast ($P < .001$; Fig 1).

Breastfeeding volumes were significantly associated with breastfeedings' being unpaired, paired, or clustered. For an unpaired breastfeeding, the infants consumed 90 ± 26 g (range: 0–240 g). When the breastfeedings were paired, the infants consumed 73 ± 11 g (range: 5–185 g) for the first breast and 54 ± 9 g (range: 0–176 g) from the second. For the clustered breastfeedings, the infant took a median of 42 g (IQR: 31–103 g) from the first breast, a median of 20 g (IQR: 8–44 g) from the second breast, and a median of 31 g (IQR: 6–73 g) from the third breast. For the paired breastfeedings, when the more productive breast was fed from first, the infant took more ($P < .0001$) from the first breast than from the second breast (Fig 1). When the less productive breast was fed from first, the infant took similar volumes from each breast (Fig 1).

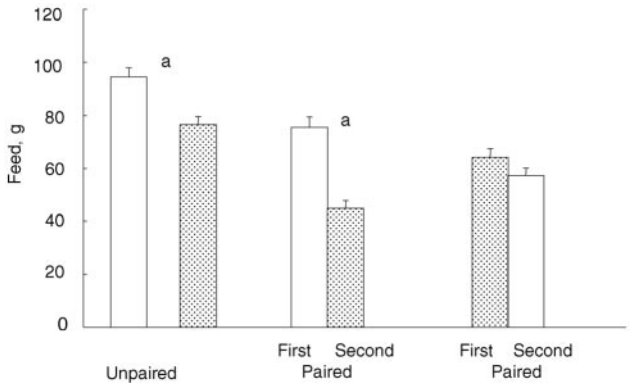

FIGURE 1
Volume of milk consumed at a breastfeeding from the more productive breast (□) and the less productive breast (▨) when the breastfeedings were unpaired or paired. Values are means with SEM represented by vertical bars. [a] More productive and less productive breasts are different ($P < .0001$).

Storage Capacity, Degree of Fullness, and Available Milk

The storage capacity of each breast was 179 ± 59 g (range: 74–382 g). There was no association between the storage capacity and time after birth ($r^2 = 0.015$; $P = .155$; $n = 142$ breasts). There was a positive relationship between the storage capacity and the 24-hour milk production ($r^2 = 0.393$; $P < .001$; $n = 142$ breasts), the maximum breastfeeding ($r^2 = 0.460$; $P < .001$; $n = 142$ breasts), and the average breastfeeding ($r^2 = 0.297$; $P < .001$; $n = 142$ breasts) from each breast. There was a significant difference ($P = .013$) between the total breast storage capacity for mothers who were breastfeeding boys (394 ± 126 g) compared with those who were breastfeeding girls (333 ± 71 g). There was a significant difference ($P = .003$; Table 1) between the storage capacity of the more productive breast (193 ± 60 g; range: 76–382 g) and the less productive breast (164 ± 53 g; range: 74–320 g).

For unpaired breastfeedings, there was no significant difference between the more and less productive breasts in the degree of fullness of the breast at the beginning of the feed (prefeed; 0.69 ± 0.10). This was significantly higher ($P = .032$) than the prefeed degree of fullness of the first breast of a paired breastfeeding. For paired breastfeedings, there was a significant difference ($P = .001$) between the prefeed degree of fullness for the breasts (0.63 ± 0.08 and 0.52 ± 0.07 for the first and second breasts, respectively) regardless of whether the breast was the more or less productive. When the breastfeedings were clustered, the "third" breast had a prefeed degree of fullness of 0.26 ± 0.07. For the 0-g feeds, the mean difference in the cream content of the samples that were collected before and after the breastfeeding was 1.4%, and the prefeed degree of fullness ranged from 0.21 to 0.58. There was a significant relationship between the volume of milk available in the breast and the volume of milk consumed at each breastfeeding ($r^2 = 0.358$; $P < .001$; $n = 775$ breastfeedings).

For unpaired breastfeedings, the available milk was different between the more productive breast and the less productive breast ($P = .003$; Fig 2), but a similar percentage of the available milk was removed (72 ± 7%

and 69 ± 8% from the more and less productive breasts, respectively). The degree of fullness of the breast at the end of the breastfeeding (postfeed) was 0.19 ± 0.06 for both the more and the less productive breasts.

When the breastfeedings were paired and the more productive breast was fed from first, there was a significant difference in the available milk (118 ± 19 g and 80 ± 14 g for the more and less productive breasts, respectively; $P < .0001$; Fig 2), whereas when the less productive breast was fed from first, there was no significant difference between the breasts in the available milk (Fig 2). The percentage of available milk that was removed during paired breastfeedings was significantly less than during an unpaired breastfeeding ($P < .0001$), but a similar percentage of the available milk was removed (63 ± 8%), regardless of the order from which the breasts were fed. There was a significant difference ($P = .003$) between the postfeeding degree of fullness for the breasts (0.20 ± 0.05 and 0.26 ± 0.05 for the first and second breasts, respectively) regardless of whether the more or less productive breast was first. For the clustered breastfeedings, 47 ± 13 g was available in the "third" breast, 47% of the available milk was removed, and the postfeeding degree of fullness was 0.19 ± 0.05 ($n = 4$).

Total 24-Hour Milk Production

The overall 24-hour milk production for both breasts combined was 788 ± 169 g (range: 478–1356 g; Table 1). A significant difference in the 24-hour milk production between the more productive and less productive breasts was evident ($P < .001$; Table 1), with an absolute median difference between the breasts of 106 g (IQR: 39–173 g; range: 5–441 g). For the majority of the mothers (76%), the right breast was the more productive, resulting in a significant difference between the right and the left breasts (426 ± 116 g [range: 161–769 g] and 372 ± 109 g [range: 177–601 g], respectively; $P = .003$).

There was a significant difference in milk production ($P = .036$) between mothers of boys (831 ± 187 g) and those of girls (755 ± 151 g). No significant effects on milk production were associated with time after birth ($r^2 = 0.037$, $n = 71$), parity ($r^2 = 0.051$, $n = 71$), or maternal age ($r^2 = 0.028$, $n = 71$). There was no relationship between the "cold" and "warm" months of the year and the 24-hour milk production ($r^2 = 0.010$; $P = .413$).

Overall, infants consumed 64% of their 24-hour intake (497 ± 17 g) in 6.8 ± 0.3 feedings between 6 AM and 6 PM and 275 ± 13 g in 4.0 ± 0.2 feedings between 6 PM and 6 AM. Between 2 PM and 2 AM, they consumed 322 ± 12 g (42% of their 24-hour intake) in 5.1 ± 0.2 feedings and 450 ± 16 g in 5.7 ± 0.2 feedings between 2 AM and 2 PM. Younger infants, up to 9 weeks of age, consumed 443 ± 32 g (61% of their 24-h intake) in 7.0 ± 0.7 feedings between 6 AM and 6 PM and 275 ± 15 g in 4.7 ± 0.4 feedings between 6 PM and 6 AM. Between 2 PM and 2 AM, they consumed 328 ± 15 g (45% of their 24-hour intake) in 5.8 ± 0.6 feedings and 390 ± 29 g in 5.6 ± 0.7 feedings between 2 AM and 2 PM.

Night Feedings

The majority (64%) of infants breastfed between 1 and 3 times at night (10 PM to 4 AM), and the number of nighttime breastfeedings did not change between 4 and 26 weeks. Only 36% of infants did not feed during the night.

There was no significant difference in the total 24-hour milk production for infants who did and did not breastfeed at night. Mothers of infants who breastfed at night had a total breast storage capacity of 342 ± 95 g, which was not significantly different ($P = .078$) from that of mothers of infants who did not breastfeed at night (386 ± 108 g). There was no significant difference in the total number of breastfeedings per 24 hours between infants who did and did not breastfeed at night, with the median numbers of 11 breastfeedings (IQR: 8–13; range: 6–18) and 10 breastfeedings (IQR: 10–12; range: 6–17), respectively ($P = .890$). Infants who breastfed at night had fewer breastfeedings at night (median: 1; IQR: 1–2) than during any other interval ($P < .001$). There was a median of 3 breastfeedings (IQR: 3–4; range: 1–6) during all other intervals, irrespective of whether the infants breastfed at night.

Statistically different volumes were measured at different intervals of the day ($P = .019$; Fig 3), with the night breastfeedings being the largest and increasing with both age and degree of fullness of the breast ($r^2 = 0.255$; $P < .001$; $n = 81$). Infants who breastfed at night had significantly larger breastfeedings during the night compared with the morning ($P = .012$), the day ($P = .002$), and the evening ($r^2 = 0.294$; $P = .001$; $n = 496$

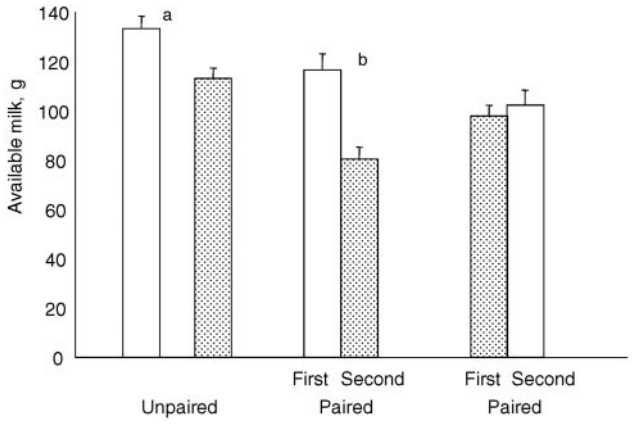

FIGURE 2
Volume of milk available before each breastfeeding from the more productive (□) and the less productive (▨) breasts when the breastfeedings were unpaired or paired. Values are means with SEM represented by vertical bars. More productive and less productive breasts are different ([a] $P = .003$; [b] $P < .0001$).

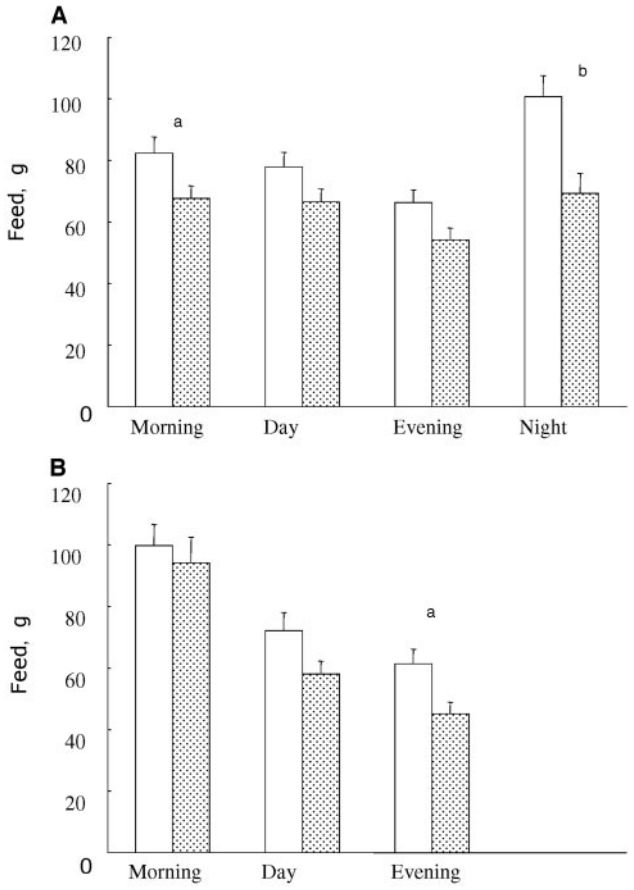

FIGURE 3
Volume of milk consumed at a breastfeeding from the more productive breast (□) and the less productive breast (▨) during the morning (4:01 AM to 10:00 AM), day (10:01 AM to 4:00 PM), evening (4:01 PM to 10:00 PM), and night (10:01 PM to 4:00 AM) by infants who breastfed at night (A) or did not breastfeed at night (B). Values are means with SEM represented by vertical bars. More productive and less productive breasts are different ([a] $P < .05$; [b] $P < .0001$).

breastfeedings; Fig 3A). From the less productive breast, the infants had smaller breastfeedings in the evening than during the night and the morning ($P < .05$). Although the night breastfeedings were larger from the more productive breast, because the night breastfeedings were less frequent than during the rest of the day, 20 ± 7% of the total 24-hour milk production was consumed at night, which was significantly less ($P < .008$) than that taken during the morning (28 ± 9%), the afternoon (28 ± 8%), and the evening (24 ± 8%).

Infants who did not breastfeed at night had significantly larger breastfeedings during the morning than during the day and the evening ($P < .001$) from both the more and the less productive breasts (Fig 3B). These infants took more of the 24-hour milk production (40 ± 12%) during the morning than during the day (29 ± 10%) and during the evening (25 ± 9%; $P < .001$).

The volume of milk that was available at the beginning of a breastfeeding in the breasts of mothers who breastfed at night ranged from 88.9 g for the less productive breast in the evening to 125.8 g for the more productive breast at night. For mothers who breastfed only during the day, the volume of milk that was available at the beginning of a breastfeeding ranged from 83.7 g in the evening for the less productive breast to 156.0 g in the morning for the more productive breast.

For mothers who breastfed at night, more milk remained in the breast at the end of breastfeedings in the morning and the night (degree of fullness: 0.27 and 0.24, respectively) than during the day or the evening (degree of fullness: 0.17 and 0.18, respectively; $P < .001$). For mothers who breastfed only during the day, more milk remained in the breast at the end of breastfeedings in the morning (degree of fullness: 0.31) than during the day or the evening (degree of fullness: 0.18 and 0.20, respectively; $P < .001$).

Fat Content of Breast Milk

The average fat content of the milk was 41.1 ± 7.8 g/L and ranged from 22.3 to 61.6 g/L. The average fat content was not associated with either the time after birth ($r^2 = 0.036$, $n = 71$) or the number of breastfeedings during the day ($r^2 = 0.013$, $n = 775$). There was an inverse relationship between the mean fat content of the milk and the 24-hour milk intake from that breast ($P = .007$, $r^2 = 0.089$, $n = 142$). The average 24-hour fat intake of the infants was 32.0 ± 7.7 g (range: 15.4–49.5 g) and was not related to the frequency of breastfeedings.

Analysis of the individual breastfeedings showed that there was no effect on the average milk fat content as a result of the gender of the infant ($P = .160$); more or less productive breast ($P = .332$); unpaired, paired, or clustered breastfeedings ($P = .339$); or whether the infant breastfed at night or not ($P = .830$). The mean fat content of the milk was significantly related to time of day ($P < .001$) and was higher ($P < .008$) during the day and the evening (42.8 ± 9.1 and 43.2 ± 9.1 g/L, respectively) compared with the morning and the night (37.1 ± 10.1 and 37.2 ± 10.3 g/L, respectively).

The interval between meals was independent of the volume of the previous meal (paired or unpaired breastfeeding). The interval was also independent of the average fat content of the milk consumed in that meal or the amount of fat in the meal.

DISCUSSION

Frequency and Volume of Breastfeedings

The spectrum of breastfeeding behavior of normal infants who were exclusively breastfed ranged between having a few large breastfeedings and having frequent small breastfeedings during 24-hour periods, and the infants distributed the number of breastfeedings evenly when comparing morning with afternoon and evening, with fewer breastfeedings at night. The wide range in

frequency of "meals" that we observed was very similar to that described by Butte et al,[24] Cregan et al,[10] and Hörnell et al.[11] The inverse relationship between the number of breastfeedings per day and the average breastfeeding volume is consistent with the lack of a relationship between the number of breastfeedings per day and the 24-hour milk production of the mothers. The volume of milk consumed during a breastfeeding depended on (1) whether the breast was the more or less productive breast, (2) whether the breastfeeding was unpaired or paired, (3) whether it was the first or the second breast of paired breastfeedings, and (4) the time of day (Figs 1 and 3).

For 53% of the meals, 1 breast was sufficient to satisfy the infant for at least 1 hour. This is consistent with the unpaired breastfeedings, particularly from the more productive breast, being larger than the average breastfeeding (Fig 1) and supports the advice of Riordan and Aurbach[25(p247)] that after breastfeeding becomes established, it may not be necessary to use both breasts at each meal, and also the recommendation of the National Health and Medical Research Council[6] that both breasts be offered at each meal, but the infant may or may not feed from the second breast. For the 44% of the breastfeedings that were paired, if the second breast was the less productive breast, then the breastfeeding volume could be considered to be a "top up." However, if the second breast was the more productive breast, then the infant took an equal volume to the first breast. Therefore, the milk yield from the second breast, when the infant chooses to feed from it, may provide a significant volume of milk.

The larger breastfeedings in the morning compared with the evening were also observed by Butte et al.[24] For infants who breastfed at night, although there were fewer breastfeedings during this time, those from the more productive breast were the largest of the 24-hour period, and the nighttime intake composed 20% of the total 24-hour intake. For the infants who did not breastfeed at night, the morning breastfeedings were the largest (Fig 3B).

Some mothers are concerned about the frequency of breastfeeding and wish to extend the interval between breastfeedings. We found that some infants would breastfeed again within 1 hour after breastfeedings of up to 175 g, and others would not breastfeed for >8 hours after a breastfeeding of as little as 35 g. In fact, the interval after the largest meal of 350 g was only 3 hours 35 minutes. Infants of the 5 mothers with total storage capacity of <235 mL all breastfed at night. However, most of the infants of mothers with larger storage capacities chose to breastfeed at night. Infants may need to feed at night if they have a relatively small stomach capacity and/or a rapid gastric emptying time.

Storage Capacity, Degree of Fullness, and Available Milk

The storage capacity that was calculated in this study is similar to that calculated by Kent et al[26] for the first 6 months of lactation (196 ± 57 g). It is smaller than that measured by Daly et al[27] (242 mL; SD: 129) by Computerized Breast Measurement; however, that study included 1 breast with an unusually large storage capacity of 606 mL. The relationship between storage capacity of the breast and the 24-hour milk production is similar to that found by Kent et al.[26] In the current cross-sectional study, there was no relationship between the storage capacity of the breast and the age of the infant. However, in a longitudinal study, the mean storage capacity at 1 month (179.9 ± 20.2 g) increased to 234.6 ± 17.5 g at 6 months (mean ± SEM), indicating that the storage capacity of the breast can change during lactation.[26] Because the maximum breastfeeding increased between 4 and 26 weeks and there was a relationship between the storage capacity and the maximum breastfeeding, it is likely that the storage capacity of the breast is able to change to meet an increase in demand for milk.

Anecdotally, mothers usually first offer the breast that feels more full. The data on the prefeeding degree of fullness of the breast confirm this subjective choice of the mothers. The prefeeding degree of fullness and the storage capacity allow calculation of the volume of available milk in the breast. The volume of milk that is available accounted for most of the differences in volume of milk consumed at each breastfeeding (Figs 1 and 2). For unpaired breastfeedings, not only was there more milk available in the more productive breast, but also the infants took a higher percentage of that available milk than during a paired breastfeeding.

The observation that the breasts are rarely drained at the end of a breastfeeding was also noted by Dewey et al,[20] who found that an extra 12% of milk could be expressed after a breastfeeding. Because breast expression is not always effective in removing all of the available milk,[15] this finding is consistent with the infants' removing 63% to 72% of the available milk during a breastfeeding. This suggests that the breasts do not need to be drained at every feeding to maintain adequate milk production.

Total 24-Hour Milk Production

The 24-hour milk production was within the normal range of 440 to 1220 g,[26] except for 2 mothers, who produced 1298 g and 1356 g. The average of 798 g is similar to the data presented by Dewey and Lönnerdal.[14] It is important to note the wide SD and bear in mind that the variation in milk production is related to the variation in the growth rates of the infants.[12,26,28] In addition, the higher milk intake of male infants was also noted by Butte et al[29] and is consistent with their higher growth rate.[30] The lack of effect of either maternal age or parity

on milk production is in agreement with the findings of Dewey and Lönnerdal.[14]

Consistent milk intake from 1 to 6 months supports previous findings.[26] This is not surprising considering 2 factors. First, younger infants (1–3 months of age) grow more rapidly than older infants (4–6 months of age).[30] Second, smaller infants have a larger surface area to volume ratio and therefore have a relatively higher metabolic rate per kilogram of body weight[31] and use relatively more of their nutrient intake for maintenance of body temperature than do older, heavier infants.

Differences in milk production of right and left breasts have been noted previously. Mitoulas et al[32] found a significant difference between breasts, with the right breast being more productive (443 vs 356 g/24 hours). In addition, Cox et al[33] showed that the right breast was often more productive than the left. In this context, it is interesting to note that when we measured the milk production of 4 mothers who were exclusively expressing their milk for their infants (>660 g/day), there was a significant difference ($P = .03$) between the left and the right breasts (unpublished results). Three of these mothers, who were double pumping and therefore submitting both of their breasts to equivalent vacuums and times of expression, had the largest differences between the breasts. This leads us to suggest that the difference in milk production between the breasts may be attributable to differences in intrinsic milk production rather than the infant's preference. The 24-hour milk production of mothers of infants who breastfed at night was the same as for those who did not breastfeed at night, similar to the observations of Butte et al.[24]

The current data for infants up to 26 weeks of age confirm the findings of Matheny and Picciano[8] for 4-week-old infants that more milk is consumed between 6 AM and 6 PM and less is consumed between 2 PM and 2 AM. The uneven distribution of the volumes of breastfeedings of both infants who breastfeed at night and those who do not breastfeed at night (Fig 3) explains why doubling of either of these 12-hour intakes will result in significant inaccuracies in estimation of 24-hour milk consumption. Therefore, our measurements confirm that in our society, a full 24-hour period of measurement of milk intake is necessary for accuracy.

Fat Content of Breast Milk

The fat content of the milk that we measured was similar to that measured by Dewey and Lönnerdal,[14] and the 24-hour fat intake of the infants was similar to that measured previously.[12,14] Fat content of the milk at different times of day reflects the higher degree of milk removal during the day and evening and the higher degree of fullness in the morning and night. The changes in fat content of milk from the beginning to the end of the first and second breasts of a paired breastfeeding described by Woodward et al[34] can be explained by the degrees of fullness that we have calculated. The lower fat content of milk from the first breast at the beginning of the breastfeeding that they measured reflects the mother's starting to feed her infant on the fuller breast, and the higher fat content of milk from the first breast at the end of the breastfeeding reflects the higher degree of milk removal from the first breast.

Because the breast was not full at the beginning of each breastfeeding for the whole day, the fat content of the fore-milk was not always low. Because the fat intake of the infants was not related to the frequency of breastfeedings, mothers can be reassured that infants who take frequent small breastfeedings have the same daily fat intake as infants who take infrequent large breastfeedings.

An understanding of the patterns of milk intake by the breastfed infant has implications for mothers who need to express their milk either fully for a preterm infant or when they return to the paid workforce. Given the variability in breastfeeding patterns, it may be unreasonable to expect all breasts to yield the same volume of milk at the same rate when the mother is using an electric breast pump, and the breast may not need to be totally drained at every expression to maintain an adequate supply of milk. Breast pump settings and regimens may need to be customized for each mother.

CONCLUSIONS

Healthy, exclusively breastfed 1- to 6-month-old infants consume 0 to 240 g of milk between 6 and 18 times during 24 hours, with 64% of infants breastfeeding 1 to 3 times at night. The right breast usually produces significantly more milk than the left, and the volume of milk consumed at each breastfeeding is related to the volume of milk available in the breast, whether the breastfeeding is unpaired or paired, and the time of day. On average, 67% of the available milk is consumed at each breastfeeding. The fat content of breast milk varies between mothers (22.3–61.6 g/L) and within and between breastfeedings, but the amount of fat consumed by the infant is independent of the frequency of breastfeeding.

ACKNOWLEDGMENTS

The research described in this article was funded by Medela AG, which is gratefully acknowledged.

We thank the participating breastfeeding mothers and infants for their time, the Australian Breastfeeding Association for recruiting volunteers, and Tracey Williams for technical assistance.

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Volume and Frequency of Breastfeedings and Fat Content of Breast Milk Throughout the Day

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Pediatrics 2006;117;387-395
DOI: 10.1542/peds.2005-1417

BREASTFEEDING MEDICINE
Volume 0, Number 0, 2011

DOI: 10.1089/bfm.2011.0013

Original Article

Dynamics of Milk Removal During Simultaneous Breast Expression in Women

Danielle K. Prime, Jacqueline C. Kent, Anna R. Hepworth, Naomi J. Trengove, and Peter E. Hartmann

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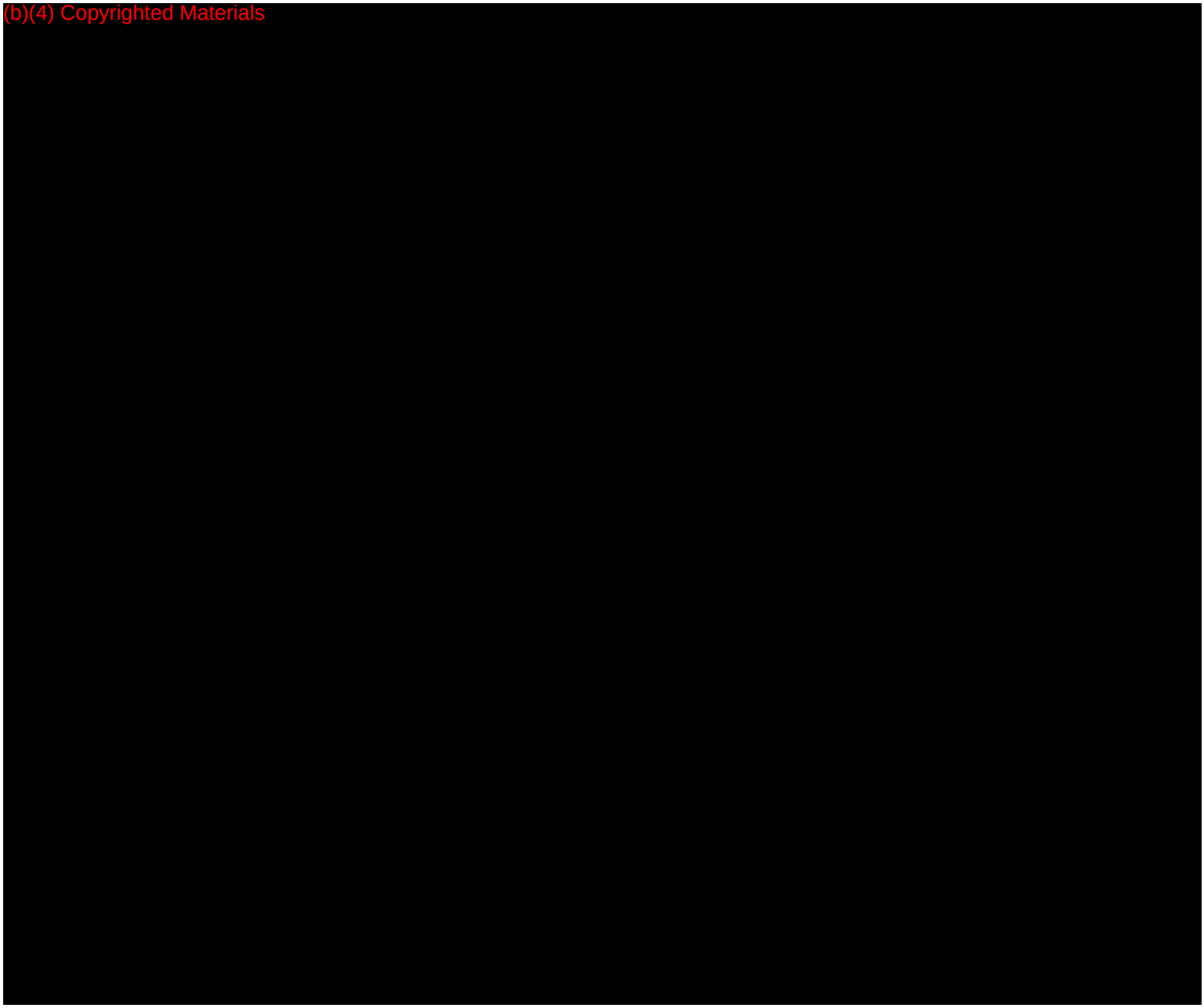

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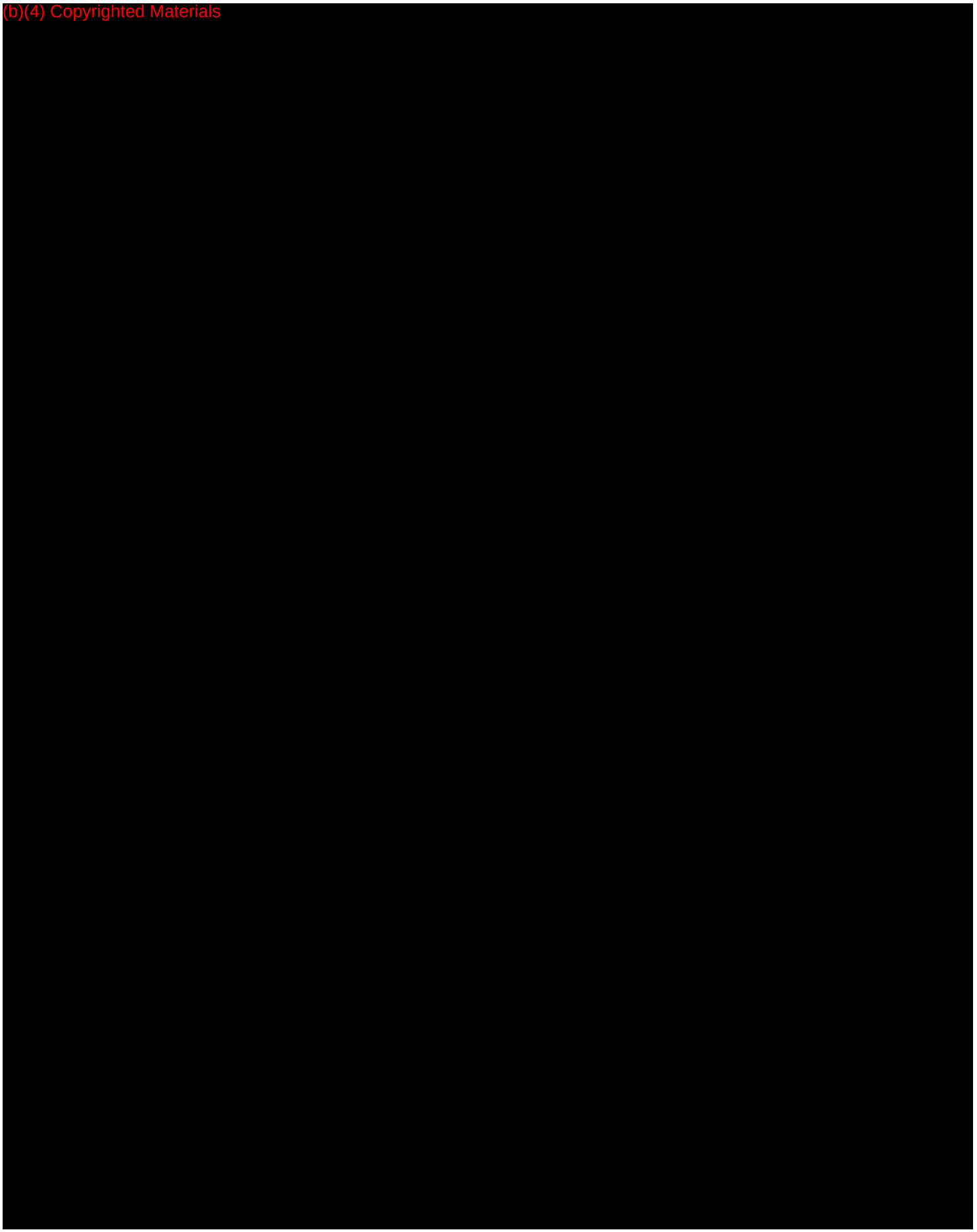
BREASTFEEDING MEDICINE
Volume 7, Number 6, 2012

DOI: 10.1089/bfm.2011.0139

Simultaneous Breast Expression in Breastfeeding Women Is More Efficacious Than Sequential Breast Expression

Danielle K. Prime, Catherine P. Garbin, Peter E. Hartmann, and Jacqueline C. Kent



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