

# 2-Phase Expression® Pumping Technology

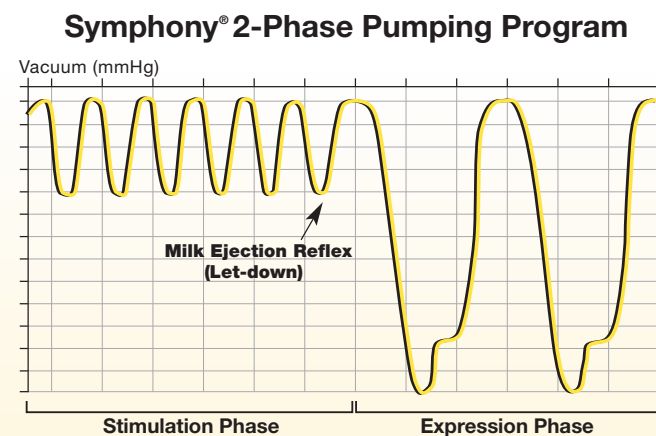
**Making Medela breastpumps more like baby than any other pumps**

When it comes to breastfeeding, babies are the gold standard and they instinctively know how to breastfeed. For mothers, breastfeeding and breastpumping is learned through trial and error. Medela's 2-Phase Expression® technology helps moms take the guesswork out of pumping.



2-Phase Expression technology is based upon an in-depth study by leading lactation researcher, Dr. Peter Hartmann. Hartmann's research showed that a breastfeeding baby naturally nurses in a characteristic sucking pattern. It begins with a rapid, rhythmic pattern and then changes at the time of milk ejection to a slower suck/swallow pattern. Hartmann's research also demonstrated that a breastpump using a two-phase approach, which most closely resembles a baby's nursing rhythm, is more effective in breastmilk removal than single-cycling breastpumps.

2-Phase Expression uses two pumping patterns to mimic a baby's nursing rhythm more effectively than ever before. Specifically, Dr. Hartmann compared different pumping patterns and found that a multi-phase combination of a high frequency "stimulation" pattern followed by a low frequency "expression" pattern is the most effective means of expressing milk. Most effective high frequency is defined as a minimum of 100 CPM (cycles per minute). Low frequency pumping is defined as approximately 45-78 CPM<sup>®</sup>. During the "stimulation" phase, the pump mimics a breastfeeding baby's rapid nursing action that stimulates the milk ejection reflex (MER), or "let-down," and quickly begins milk flow. Once milk begins to flow, moms switch to the second phase, called "expression," which mimics the infant's longer feeding cycle in which slower, deeper suckling helps to maximize milk flow in less time.



2-Phase Expression pumping pattern creates a comfortable and authentic pumping experience that is more like a baby than any other pump. The combination of stimulation and expression, found only in 2-Phase Expression, is proven to achieve faster milk ejection and milk flow, delivering more milk in less time when pumping at Maximum Comfort Vacuum™.

*2-Phase Expression technology is available exclusively in a variety of Medela breastpumps to fit moms' needs:*



**Symphony® Breastpump**  
A hospital-grade, multi-user pump ideal for long-term and daily pumping needs.



**Pump In Style® Advanced The Metro Bag™**  
A double-electric, personal-use pump ideal for daily use. Available in a variety of styles to fit moms' needs.



**Swing™ Breastpump**  
A single-electric, personal-use pump designed for daily use.



**Harmony™ Breastpump**  
A manual pump ideal for occasional use.



[www.medela.com](http://www.medela.com)

Medela, Inc., 1101 Corporate Dr., McHenry, IL 60050  
Phone: 815-363-1166 or 1-800-435-8316 Fax: 815-363-1246

CSF, Supplemental Nursing System, SpringExpress, Pumping Free, PersonalFit, SpecialNeeds, Maximum Comfort Vacuum, The Metro Bag, Pump & Save, Swing, Harmony, Classic, DoubleEase, ManualEase, Advanced Collection, MiniElectric, Ease Collection, Traveler, Companion and Quick Clean are trademarks and Symphony, Lactina, Pump In Style, 2-Phase Expression and Medela are registered trademarks of Medela, Inc. Hazelbaker is a trademark of Alison Hazelbaker.

1547474 C 1007 ©2007 Medela, Inc.



*First in*  
**Breastpump  
Innovation,  
Safety, &  
Effectiveness**



# Safeguarding the benefits of breastfeeding

*There are no concerns more important than safeguarding the process by which today's mothers provide their infants the optimal nutrition – breastmilk.*

*For Medela, this responsibility is the driving force behind ensuring the safety and excellence of every product we develop, every advancement we make.*

The majority of the **10** largest U.S. hospitals by birth volumes have chosen Medela breastpumps for their facilities<sup>1</sup>

All **46** freestanding U.S. children's hospitals choose Medela<sup>2</sup>

WIC agencies in all **50** states choose Medela<sup>3</sup>

## Breastfeeding . . . the very heart of our business.

Medela's primary focus in business has been and remains breastfeeding...by helping mothers to successfully breastfeed their babies, and to do so for as long as they choose. Meeting this goal responsibly is at the heart of everything we do as a company and of our ongoing commitment to the well-being of the mothers who use our products.

## Medela is the industry leader in breastpump hygiene, safety and effectiveness.

For over 25 years, Medela has set the standards of excellence in our field and by doing so, raises the bar for the rest of the industry. Our dedication to excellence in quality and safety, improving knowledge through research, and appropriate use of technological developments confirms our leadership position and is what enables us to offer the highest quality products available.

Our commitment to quality and safety is why most of the 10 largest U.S. hospitals,<sup>1</sup> based on annual births, and the majority of NICUs across the nation have chosen Medela breastpumps for their facilities. Significantly, Medela is also the choice of all of the freestanding children's hospitals in the country.<sup>2</sup> At these facilities, situations involving babies with life-threatening illnesses or birth circumstances call for stringent safety and hygiene standards. Medela also services WIC agencies in all 50 states.

## At Medela, safety comes first.

Since the inception of Medela in the U.S., Medela breastpumps and kits have received market clearance by the U.S. Food & Drug Administration (FDA) prior to their introduction into the market. Internally, our quality-directed ISO 13485 organization also builds standards into our quality assurance programs *that meet and exceed FDA regulations.*

The safety and effectiveness of each Medela breastpump is ensured through a number of exclusive design and technological developments:

- All of Medela's hospital-grade pumps such as the Lactina® and Symphony® breastpumps utilize systems that offer unique and unparalleled safety and hygiene
- The Lactina's system provides each mother with her own "kit" that is the single and sole source of suction, eliminating the possibility of any cross-contamination. The piston/cylinder assembly in each kit prevents pump contamination
- The Symphony Breastpump utilizes an effective system to support multiple users. A unique membrane cap and protective membrane, designed to protect the pump from contamination, are components of each mother's personal kit, thus preventing cross-contamination
- Medela's kits and collection containers are made of 100% safe plastic for the health of mom and baby (Bisphenol-A Free)

**Bisphenol-A Free\***  
Chosen for you & your baby  
\*All Medela bottles & breastpump kits are 100% Bisphenol-A (BPA) Free

## Research . . . not mere claims . . . supports the safety of Medela breastpumps.

Multiple independent laboratory studies have been conducted through the years to demonstrate the safety of Medela breastpumps.

- Two studies, in 1987 and in 1998, confirmed that even when bacteria is introduced into the tubing of a Classic or Lactina double pumping kit, the bacteria is not transferred to any location in the accessories tested or milk collected,<sup>3,4</sup> eliminating the argument that self-contamination is a safety issue. An independent study was also performed in 1994, using a Lactina breastpump, to demonstrate that when milk is collected in an aerosol contaminated atmosphere with 4 strains of bacteria, no contamination of the collected breastmilk took place<sup>5</sup>
- A similar 2002 independent study of the Symphony Breastpump again proved there was no transfer of bacteria to accessories or collected breastmilk<sup>6</sup>

Medela regularly funds research studies that help expand our knowledge of breastfeeding infants and mothers. Breastpump comparisons, microbiological research on safety and efficacy issues, premature infant studies and, most recently, breast capacity and breastmilk production<sup>7</sup> have increased our knowledge and our development of evermore sophisticated and effective products.

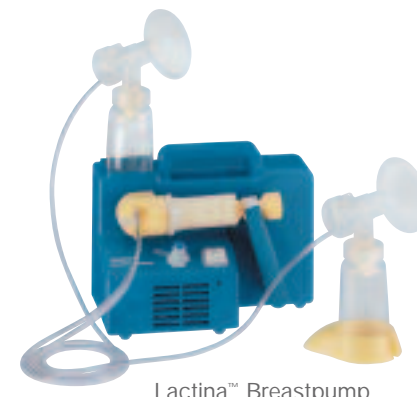
## Medela is at the forefront of groundbreaking discoveries.

Medela recently announced the results of research that overturns 160 years of perceived wisdom concerning the female breast, which has important implications for women. Dr. Peter Hartmann, Dr. Donna Geddes and their team, working collaboratively with Medela at the University of Western Australia's Human Lactation Research Group, investigated the lactating breast using sophisticated ultrasound technology.

What has changed?

- Ducts branch closer to the nipple
- The conventionally described lactiferous sinuses do not exist
- Glandular tissue is found closer to the nipple
- Subcutaneous fat is minimal at the base of the nipple

The findings overturn a number of commonly accepted conclusions regarding the anatomy of the breast. They will help breastfeeding mothers and lactation consultant professionals gain a better understanding of the way breasts work, to the benefit of mothers' and babies' health.



Lactina™ Breastpump



Symphony® Breastpump



# Medela breastpumps and kits meet and exceed FDA and other safety standards

## Medela . . . first in breastpump and breastfeeding accessory innovations.

The majority of unique developments in both breastpumps and breastfeeding products has been and continues to be pioneered by Medela:

- 1980 Medela Inc. founded in the USA and **Classic™ Breastpump** launched in US hospitals.
- 1986 **Supplemental Nursing System™** first specialty feeding device from Medela.
- 1987 First **Lactina®** Breastpumps introduced in U.S.
- 1989 **Universal Pumping System** kits allow use with Classic or Lactina.
- 1990 **SpecialNeeds™ Feeder** introduced in U.S.
- 1991 **MiniElectric™** – the first retail, battery powered autocycling breastpump introduced.
- 1992 **CSF™ Bags** add a safe, hygienic alternative for collecting & storing breastmilk.
- 1994 **Lactina Select** featuring adjustable pumping speed & **SpringExpress™** Manual Pump launched in market.
- 1995 Lactina Select Adapter and reduced parts for easy assembly/cleaning found in new **Advanced™ Collection Kits** for Medela pumps.
- 1996 The first launch of the phenomenally successful **Pump In Style®** retail breastpump with professional performance.
- 1996 **Medela Maternity/Nursing Bras & Pumping Free™ Kit**, for hands-free pumping revolutionizes the way the retail market will evaluate the fit and function of maternity/nursing intimate apparel.
- 1997 **Hazebaker™ FingerFeeder**, a unique device designed to assist feeding special-needs babies.
- 1999 The **Ease Collection™** – DoubleEase™ tabletop double-pumping and ManualEase™ breastpumps. In answer to customers' requests, two new versions of the Pump In Style introduced: the **Pump In Style Traveler™** and the **Pump In Style Companion™ Breastpumps**.
- 2001 **PersonalFit™ Breastshields** introduced to address the need that one size shield does not fit all.
- 2002 New **Symphony® Breastpump** launched in the U.S., utilizing totally new micro-chip technology to create a revolutionary 2-Phase Expression® breastpump. The first of its kind on the market, this technology changes the way breastpumps will be judged in the future.
- 2003 The **Symphony Breastpump** wins the **Medical Design Excellence Award** for Over-The-Counter and Self-Care Products. The Medical Design Excellence Awards (MDEA) competition is the premier awards program for the medical technology community, recognizing the achievements of medical product manufacturers and the many people behind the scenes — engineers, scientists, designers, and clinicians — who are responsible for the groundbreaking innovations that are changing the face of healthcare.
- 2003 New **Pump In Style Advanced** breastpump launched the only electric retail pump with the breakthrough 2-Phase Expression technology.
- 2003 **Harmony™ Breastpump** introduced – the first manual breastpump to feature 2-Phase Expression technology.
- 2004 **Quick Clean™ bags and wipes** are introduced, designed and tested for disinfecting breastpump parts and feeding accessories, eliminating harmful bacteria and germs by 99.9%.
- 2006 New **Swing™ Breastpump** introduced. The first single-electric, personal-use pump featuring 2-Phase Expression. Designed with advanced technology and portability. The Swing Breastpump wins the Medical Design Excellence Award for Over-The-Counter and Self-Care Products.
- 2006 The Symphony Breastpump makes another technological advancement with the release of the **Symphony 2.0 program card**, continuing to be the premier hospital-grade breastpump on the market and meeting the expanding needs of mothers. The 2.0 card delivers on the promise of the Symphony breastpump's ability to be upgraded and offer flexible programming.
- 2006 **Pump & Save™ Bags** added to the Medela breastmilk collection and storage line. Designed with mom in mind featuring no-leak, easy-to-close zipper top and no-spill stand-up bottom.
- 2007 Medela, Inc. announces that all of its breastpump kits and collection/storage devices are **Bisphenol-A/DEHP-free** for the safety and health of mom and baby.

<sup>1</sup> Source: Based on 2005 AHA data on U.S. Hospitals – General

<sup>2</sup> Source: Based on 2006 NACHRI data on U.S. freestanding children's hospitals

<sup>3</sup> Independent research: Silliker Laboratories Group, Inc. Nov. 1987 "Analysis of electric breastpump challenged with selected organisms"

<sup>4</sup> Independent research: Silliker Laboratories Group, Inc. Aug. 1998 "Analysis of Medela advanced double breastpump system used in conjunction with Classic and Lactina Plus breastpumps challenged with escherichia coli and aspergillus niger"

<sup>5</sup> Independent study: Hygiene Mikrobiologie Labor, Lucerne, Switzerland, April 1994

<sup>6</sup> Independent research: Silliker Laboratories Group, Inc. July 2002 "Analysis of Medela Symphony Breastpump system challenged with escherichia coli and aspergillus niger"

<sup>7</sup> Research: Hartmann, PE, et al, Research presentations: "Efficacy of milk removal using an electric breast pump,"

Society for Reproductive Biology, 32nd Annual Conference, Sept. 2001; and "Breast pump efficacy: comparison of two pumping patterns,"

Combined Biological Sciences Meeting, Perth, Australia, 2001

<sup>8</sup> 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.

<sup>9</sup> Medela Annual Sales Report 2006