

Introducing Medela's NEW Pump in Style®

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Introduction

In 1994 Medela introduced the first single-user, portable, double-electric breast pump. It was designed specifically for mothers dedicated to sustaining breast- and breast milk feeding while juggling additional commitments outside the home. Since its launch, Medela Pump in Style® has become the gold standard for busy moms, recognized nationally as the breast pump moms trust most.²⁴ Over the years the Pump in Style® was modified to incorporate two-phase pumping, however, the pump collection kit and inner mechanics have essentially remained the same. That is, until now.

This year Medela introduces the NEW Pump in Style® with MaxFlow™, a breast pump that builds on our ever-growing understanding of lactation science. Outwardly, the changes are obvious; the housing is elegant, remarkably smaller, lightweight with 4 simple control buttons. Notably the NEW Pump in Style® has fewer individual parts for easier set-up, cleaning and transport. Also, the oval-shaped PersonalFit™ PLUS and PersonalFit Flex™ breast shields with a wider opening angle allow mothers to customize shield placement for better milk expression. Indeed, a recent clinical study reports this new breast shield allows mothers to express 11.8% more milk.¹

Although not visible, the inner workings of the NEW Pump in Style® embody state-of-the-art breakthroughs in breast pump technology. The New Pump in Style® incorporates MaxFlow™ technology which combines the known benefits of 2-Phase Expression® technology with the new discovery of micro-vibrations, in order to optimize milk expression performance. Clinical research suggests that MaxFlow™ vibration technology alters milk flow dynamics, yielding a higher percentage of available milk removed (PAMR) in less time than previous pump designs.²

Advances in the NEW Pump in Style® speak to the needs of committed mothers: a smaller, simpler model that is more effective, more efficient and more comfortable. The following discussion details some of these new features, incorporating relevant findings from science and research.

Interior Innovations

Overview

At the heart of the NEW Pump in Style® is an innovative and advanced pumping motor that generates vacuum with micro-vibrations for more effective milk removal. This new pump design augments 2-Phase Expression® technology (milk stimulation

and milk expression)³⁻⁵ resulting in removal of higher percentages of available milk than the previous Pump in Style®. It is well established that optimal milk removal is key to long-term breastfeeding success; the more the breast is drained, the greater it is stimulated to make more milk.⁶ Mothers have different capacities for production and storage, thus efficacy of milk removal is best reflected by percentage of available milk removal (PAMR) rather than milk volume removed.⁷⁻⁹

Inspiration

Inspiration for MaxFlow™ technology began when researchers intuited similarities between breast and lung anatomy; both of these organs have systems of alveolar structures connected to an increasingly consolidated branched system of channels leading to the body's exterior. Side-by-side pictures of both organ systems highlighting colorful sections of lobular networks make this insightful analogy apparent. With that image in mind, researchers working with Medela investigated the dynamics of improved air exchange in the lungs and how those strategies might inform milk flow in the breast. This trail of thought led first to an examination of therapeutic effects of vibration.



Vibration technology

General benefits of whole body and localized high frequency vibration are related to improved tissue function and healing. In a variety of studies vibration has been associated with accelerated bone healing, decreased perception of muscle soreness, and reduction of lymphedema.¹⁰⁻¹³ These effects are most often attributed to enhanced localized blood and fluid flow and nitrous oxide release.¹⁴⁻¹⁶ Vibration therapy with ultrasound is also reported in chiropractic care to treat blocked mammary ducts.¹⁷

In pulmonary science, vibration is integral to high-frequency oscillatory ventilation (HFOV), designed to augment gas transport and dispersion in the lungs. In the NICU, high frequency oscillatory ventilators are used over conventional ventilators because they provide better gas exchange while keeping airways and alveoli open with less pressure and tissue damage.¹⁸ It is, in part, the unique application of controlled vibration of gases, or oscillation that makes HFOV the preferred modality for fragile babies.

Lastly, investigations into the effects of vibration led to consideration of its effects on the physical properties of human milk and its removal through the ductal structures of the breast. Although a thorough explanation is beyond the scope of this discussion, it is worthwhile to mention that research suggests that the flow of human milk through narrow channels (i.e., milk ducts) under pressure (milk ejection) can be enhanced by vibration.^{19,20} When considered as a whole, scientific evidence suggests there are at least 2 plausible rationales for the positive effects of vibration on milk flow: 1) enhanced blood and fluid flow in the breast in order to decrease congestion and 2) improved milk flow through ductal structures.

Evidence to support MaxFlow™ technology

The NEW Pump in Style® motor creates vacuum plus high frequency vibrations of 5-35 Hz throughout pumping, in both stimulation and expression phases. The pump has 10 vacuum settings.

Recent clinical research compared MaxFlow™ to standard pump technology. Findings of this pilot study were as follows:²

Efficacy

- MaxFlow™ removed on average a higher percentage of available milk.
- PAMR: 80% with MaxFlow™ vs. 55% with standard pump. Results statistically significant, p=0.019

Efficiency

- MaxFlow™ expressed milk faster. PAMR in first 2 milk ejections: 53% vs. 34% with standard pump. Results trending towards statistical significance, p=0.08.

To put these performance characteristics into context, previous studies have established that the percentage of available milk removed by pumping or breastfeeding averages between 62 - 71%, with a standard average ~65%.^{1,7} ⁸ Since optimal milk removal is critical to sustaining lactation, the average PAMR of 80% with MaxFlow™ technology implies this new technology is highly effective. It is hypothesized that the micro-vibrations produced by the new Pump in Style® enhance and sustain milk flow over the course of the pumping session.

Comfort

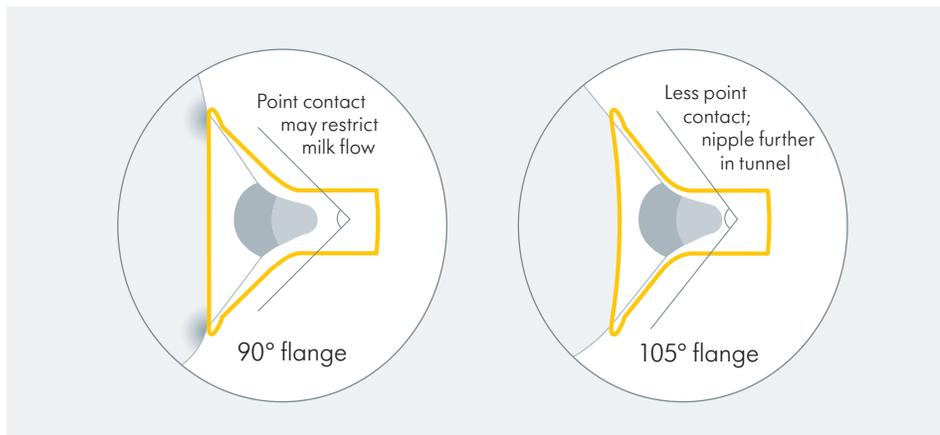
Mothers found the pumping experience to be very comfortable, providing an average comfort rating of 1.3 for the pumping session (1 very comfortable - 5 very uncomfortable). Although present throughout, vibration was perceptible to mothers mostly only during the expression phase. All subjects used standard breast shields, so the comfort rating is attributed to the pump. PersonalFit™ PLUS and PersonalFit Flex™ breast shields add yet another level of comfort.

Exterior Innovations

Breast shields

Breast shields are critical points of contact between mothers and the pump. As milk ejection occurs, milk ducts expand by up to 68% to accommodate milk flow to the nipple.²¹ In response, nipple diameter increases by 2-3 mm.²² With a well-fitted shield, the nipple moves freely, milk flow is unrestricted and pumping is comfortable. If the tunnel is too small, milk ducts closest to the surface of the nipple may be compressed; if it is too large, ducts closest to the areola may be compromised. Likewise, a flange that is too narrow may restrict milk flow through ducts and breast tissue. Therefore, the breast shield flange and tunnel must accommodate differences between moms and individual changes during milk expression. As for all Medela pumps, several compatible breast shield sizes (based on nipple diameter) are available and content included may vary by model.

Since publication of ultrasound studies of breast anatomy in 2005, we have known that within a 30-mm radius of the base of the nipple a large amount of glandular and ductal tissue lies very superficial to the skin with less cushioning by adipose tissue. This suggests pressure on these areas during



milk expression might restrict milk flow.²³ PersonalFit™ PLUS and PersonalFit Flex™ shields are oval shaped with a wider flange opening (105° compared to traditional 90°) to reduce the risk of compression. Mothers using these oval flanges can rotate them in such a manner to avoid compression, creating a more personalized, comfortable fit.

Evidence to support PersonalFit™ PLUS and PersonalFit Flex™ breast shields

In a single-center, crossover, randomized-controlled trial, Sakalidis et al¹ demonstrate this new design improves milk flow and drainage when compared to 90° flanges.

Results of the new design include:

- **Greater efficacy** – 4.54% increase in percentage of available milk removed (PAMR) with revised breast shields: 63.45% vs. 58.91%
- **Increased efficiency**
- An average of 9 mL more milk was obtained per pumping session with revised breast shields
- 11.8% more milk volume obtained
- **More comfort**
- 88% of participants using the wider shield strongly agreed that the shield fits/ adapts well to the breast compared to 50% of women using 90° flange
- 88% of participants strongly agreed the wider shield feels comfortable on the skin compared to 48% of women using 90° flange

All of these results are statistically significant. Therefore, the authors recommend 105° breast shields in combination with double pumping and use of maximum comfort vacuum to achieve best milk expression results.

Pump controls

The simplified pump control panel, located on the top of the NEW Pump in Style®, is comprised of 4 drop-shaped buttons for the following functions:

- Power on/off
- Letdown button to toggle back and forth stimulation and expression phases
- Vacuum up +
- Vacuum down -

The new system of vacuum control encourages mothers to find their personal Maximum Comfort Vacuum™ level by increasing or decreasing suction based solely on their pumping experience and comfort. Research-based speed and vacuum settings are pre-programmed in the pump motor to ensure effective expression and ease of use. Thus, the minimalist appearance disguises sophisticated internal complexity.

Concluding remarks

The NEW Pump in Style® will undoubtedly become a new standard of excellence for personal-use pumps. Changes to the exterior extend beyond its more modern design; the pump is easier to assemble, use and clean as well as more compact and portable. PersonalFit™ PLUS and PersonalFit Flex™ breast-shields are more comfortable and effective in facilitating milk flow from the breast. Lastly, MaxFlow™ vibration technology is an exceptionally intuitive concept to integrate into the science of human milk expression. The combination of pioneering innovations will maximize the expression of available milk while maintaining a simple and comfortable pumping experience.

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