

Proving the positive impact of PersonalFit™ PLUS for Symphony® on the dynamics of milk removal

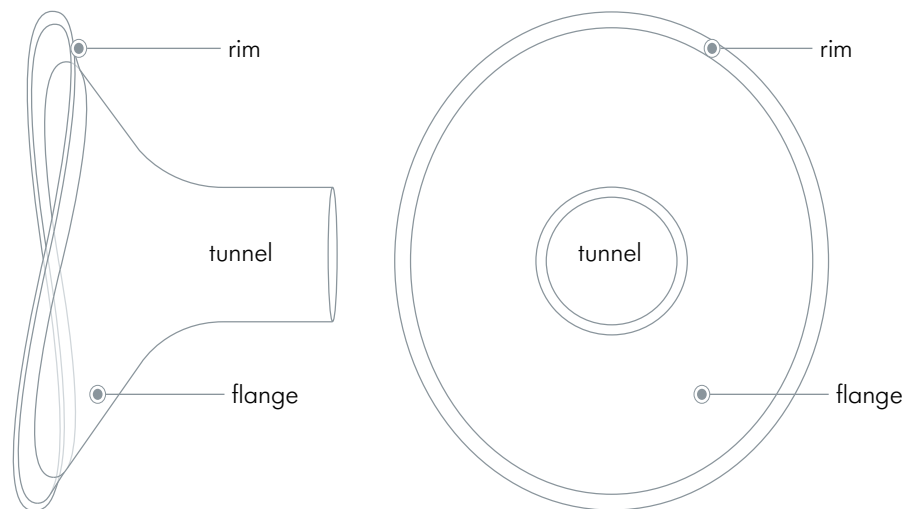
Mother's milk is irreplaceable: it meets the nutritional needs of the infant, supporting optimal growth and development. It also reduces the rate of some of the most serious complications in newborns, and significantly improves both short-term and future health,¹ with positive long-term implications for infants, mothers, healthcare professionals, hospitals, and society as a whole.²

All these factors mean that ensuring mothers can initiate and build adequate milk volumes and feed their infants an exclusive human milk diet, as early as possible and for as long as possible, is crucial. Healthcare professionals are at the frontline of this process, but can require support to facilitate it effectively and efficiently. Applying evidence-based solutions can help.

This is why Medela is committed to optimising expression when breastfeeding is impaired, by investigating all aspects of human milk removal. This includes researching the important role of the pump set, and in particular the breast shield, which is the interface between mother and breast pump.

Previous work established that correct breast shield fit³ is essential: because nipple diameter increases temporarily by 2 to 3 mm (0.07 to 0.11 in) when applying vacuum to the nipple,⁴ the breast shield tunnel needs careful sizing to allow free movement within it. However, the relationship between the breast shield flange and superficial breast anatomy had not been widely explored. This was the starting point for the development of the PersonalFit™ PLUS pump set for Symphony®.

The PersonalFit™ PLUS breast shield has a unique oval shape



Anatomy of the lactating breast redefined

The knowledge that influenced the development of the PersonalFit™ PLUS breast shield originated from the 2005 work of Ramsay et al., supported by Medela.⁵ This study used ultrasound imaging to reinvestigate the anatomy of the lactating breast. It established that 65% of the breast's glandular tissue is found within a 30 mm (1.18 in) radius of the nipple base. The milk ducts in this area are superficial and, therefore, easily compressed. As milk ducts can temporarily increase in size by 68% during milk ejection, these ducts are particularly at risk from compression.⁵

PersonalFit™ PLUS pump sets for Symphony®

More milk. More comfort. More efficiency.



Research and development

PersonalFit™ PLUS is the result of five successive studies: two into the feasibility of developing a new type of breast shield, and three clinical trials into the efficiency and effectiveness of a new pump set that included the same breast shield.

The two initial studies were based on images of the breasts of 44 lactating women, made using a laser scanner.

The research team selected the 13 scans that gave a most representative range of breast and nipple sizes, which were then imported into modelling software.^{6,7}

The first study⁶ focused on the existing PersonalFit™ breast shield, which had a flange angle of 90°, typical of the majority of breast shields currently available. A 'virtual' version of this breast shield was created so it could be placed on the scans. Lateral views enabled the team to measure the contact points between breast tissue and the inner surface of the flange, as well as the degree to which the nipple reached into the tunnel. The team found that:

- The upper surface contact point was usually close to the outer rim of the breast shield. This contact may result in localised breast tissue compression and potential reduced milk flow.
- In nearly one-third (eight out of 13) of the scans the tip of the nipple did not reach the tunnel, making centring of the nipple clinically difficult.

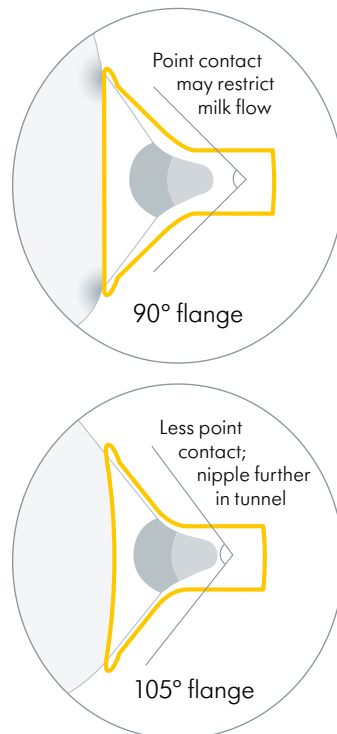
In addition, it was thought that the vacuum applied when pumping could result in a large amount of breast and nipple tissue deformation within the breast shield in some cases. The researchers concluded this method could be used to determine whether or not breast shields with angles greater than 90° would better fit lactating breasts.

In the second study,⁷ the team compared the fit of the 90° breast shield to breast shields with flange angles of 105° and 120°, using the same set of scans.

They found that, on average:

- The nipple reached 3 mm (0.11 in) further into the tunnel at 105°, and 4 mm (0.15 in) further at 120°.
- At 120°, the outer edge of the flange often lost contact with the breast. This could potentially interfere with the seal of the breast shield.
- The 105° breast shield maintained contact towards the rim and allowed gentle contact of the breast's surface.

The researchers concluded that an opening flange angle of 105° may better match lactating breast anatomy.



The next step was to evaluate the 105° breast shield with mothers. For these tests, the breast shield shape was altered from a circle to an oval that could be rotated 360°, with the aim of offering more flexible positioning. In addition, the pump set as a whole was simplified, with fewer parts to assemble, disassemble and clean. The parts were also enlarged to aid handling.

Clinical trials

Three research teams, coordinated by Medela Medical Research Associate Dr Danielle Prime, assessed the performance of the 105° breast shield in clinical and home settings.

ESP I: Reliability and usability of PersonalFit™ PLUS pump set in a hospital setting

A study comparing PersonalFit™ PLUS to a standard pump set after five days of usage. It was conducted with 25 healthcare professionals observing seven lactating women performing a total of 51 pumping sessions in different hospitals. The healthcare professionals assessed the pump sets and all data was analysed by an independent statistician.⁸ In addition, the mothers provided general feedback about each pumping session and were asked to describe their experiences.

ESP II: Reliability and usability of PersonalFit™ PLUS pump set in a home setting

A prospective cohort study comparing PersonalFit™ PLUS to a standard pump set. It was conducted with 22 lactating women with previous pumping experience. They performed a total of 308 sessions with PersonalFit™ PLUS and 307 with the standard design. Participants assessed the pump sets after seven days and then again after 14 days, and all data was analysed by an independent statistician.⁹

BDM: PersonalFit™ PLUS influence on milk removal dynamics

A randomised controlled trial (RCT) to assess the volume of milk expressed (efficiency) and breast drainage (effectiveness) of the PersonalFit™ PLUS pump set compared to a standard design. This was conducted with 49 mothers in established lactation, who performed a total of 196 breast expressions with the two pump sets. The study also assessed comfort, through a questionnaire.¹⁰

Results

More milk in the same expression time

The BDM trial¹⁰ found PersonalFit™ PLUS obtained 11% more milk after 15 minutes compared to the standard design. It also showed a 4% improvement in breast drainage – significant, as a key principle of maintaining milk production is to drain the breast well.¹¹ This represents the first evidence that breast shield design can significantly impact expression outcomes.

11%

more milk after 15 min

4%

more breast drainage

Breast drainage: An additional critical factor

Strategies to optimise outcomes when expressing include pumping with the maximum comfortable vacuum compared to a lower vacuum,¹² and double pumping rather than single pumping each breast in turn.¹³ The effectiveness of the new breast shield appears to be a new critical factor that could be used to further improve expression.

Easier to use and clean

ESP I⁸ graded user experience of cleaning PersonalFit™ PLUS and the standard pump set. The new pump set rated significantly higher for both cleaning and overall usability ($p < 0.05$). It also scored numerically higher for assembly and disassembly (though not statistically significant). ESP II⁹ conducted a similar grading and found that cleaning was also

significantly easier with PersonalFit™ PLUS. Easier use and cleaning suggests mothers will need less support when pumping at hospital and at home. These results also mean PersonalFit™ PLUS can deliver more streamlined hospital processes.

ESP I results

■ Standard pump set

■ PersonalFit™ PLUS

70% 100%

Cleaning 83%

Cleaning 90%*

Overall usability 82%

Overall usability 89%*

Healthcare professional feedback scores of the usability experience (ESP I, n=25). Experience was graded 1 to 7, where 7 is highest achievable score. The asterisk (*) denotes results were statistically significant ($p < 0.05$).

ESP II results

■ Standard pump set

■ PersonalFit™ PLUS

70% 100%

Cleaning 82%

Cleaning 87%*

Overall usability 83%

Overall usability 89%*

Mother feedback scores of the usability experience (ESP II, n=22). Experience was graded 1 to 7, where 7 is highest achievable score. The asterisk (*) denotes results were statistically significant ($p < 0.05$).

More comfortable expression

Mothers taking part in ESP II reported significant improvements in comfort and fit, with 100% citing that they experienced minimal or no skin pressure marks when using PersonalFit™ PLUS.⁹

The same cohort's feedback after every pumping session confirmed the new breast shield was a better fit than the standard design. They also rated PersonalFit™ PLUS as offering significantly better nipple suction and movement, and reported milk expression felt more natural, compared to the standard pump set.⁹

In addition, the participants in BDM rated the 105° breast shield as significantly more comfortable ($p < .001$) and as having an improved fit to the breast ($p < .001$) than the 90° breast shield.¹⁰

It is important to note that the integrated overflow protection in the PersonalFit™ PLUS connector allows mothers to express in a more comfortable reclined position, and being relaxed helps them to express more milk.¹⁴

This is particularly beneficial for mothers who have had a c-section or traumatic delivery, for whom sitting upright may be difficult. Both the healthcare professionals in a hospital setting and mothers at home reported that the new pump set could be used in a variety of pumping positions.^{8,9}

The mothers also reported that the oval shape of the PersonalFit™ PLUS breast shield gave them the flexibility to place it vertically (32% of mothers), horizontally (59%), and obliquely (9%) on the breast, depending on how they felt.⁹

Additional benefits

Lowers dependency on formula and donor human milk

The greater breast milk output¹⁰ that PersonalFit™ PLUS provides indicates more own mother's milk will be made available in the hospitals where it is used. This subsequently lowers the need for infants to be fed donor milk or formula.

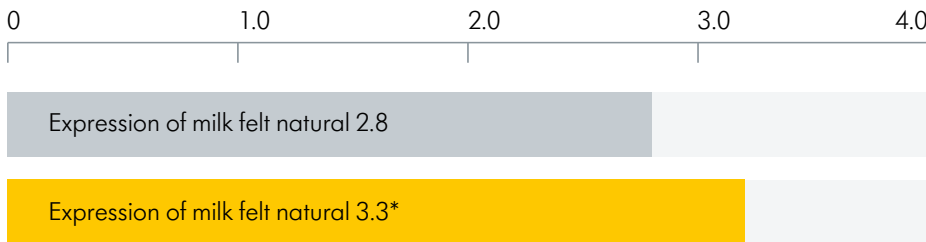
Increased chance of infants receiving an exclusive human milk diet

The increased efficiency and effectiveness¹⁰ of PersonalFit™ PLUS, combined with the improvements in pump set usability and cleaning,^{8,9} means healthcare professionals can support mothers with human milk expression in the NICU and maternity ward, and at home, more easily.

And when paired with the Symphony® breast pump, PersonalFit™ PLUS also helps all pumping mothers initiate, build and maintain an adequate¹⁵ milk supply for the future, so their infants can reap the benefits of an exclusive human milk diet for longer.

ESP II results

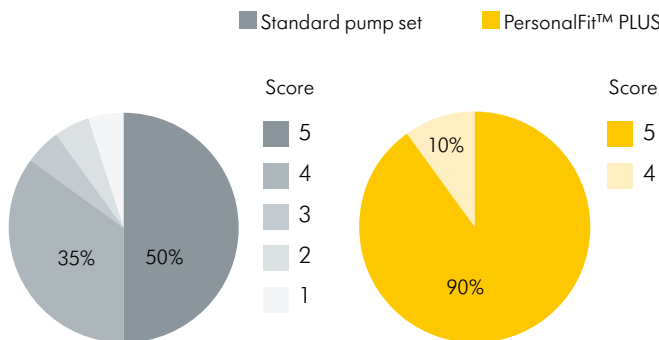
Score (Grade 1–4)



Mother feedback scores of pumping experience from ESP II. Pumping sessions were graded 1 to 4 (1=disagree; 4=agree). The asterisk (*) denotes that the results were statistically significant ($p < 0.05$).

BDM results on comfort

Pumping felt very comfortable:
5 = strongly agree
1 = strongly disagree



Mother feedback scores of comfort during pumping (BDM, $n=49$). Comfort was graded 1 to 5 (1 = strongly disagree; 5 = strongly agree). Results were statistically significant ($p < 0.001$).

References

1 Victora CG et al. *The Lancet*. 2016; 387(10017):475–490. 2 Mahon J et al. *Health Econ Rev*. 2016; 6(1):54. 3 Jones E, Hilton S. *J Neonatal Nurs*. 2009; 15(1):14–17. 4 Geddes DT et al. *Early Hum Dev*. 2008; 84:471–477. 5 Ramsay DT et al. *J Anat*. 2005; 206(6):525–534. 6 Muther M et al. *Breastfeed Med*. 2016; 11(2):A28. 7 Schlienger A et al. *Breastfeed Med*. 2016; 11(2):A28–A29. 8 Clinical study. [NCT02496429]. 2015. 9 Clinical study. [NCT02492139]. 2016. 10 Prime DK et al. 6th ABM Europe Conference, Rotterdam, NL; 2018. 11 Kent JC et al. *J Obstet Gynecol Neonatal Nurs*. 2012; 41(1):114–121. 12 Kent JC et al. *Breastfeed Med*. 2008; 3(1):11–19. 13 Prime DK et al. *Breastfeed Med*. 2012; 7(2):100–106. 14 Newton M, Newton N. *J Pediatr*. 1948; 33(6):698–704. 15 Meier PP et al. *J Perinatol*. 2012; 32(2):103–110.

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