

New Study Proves:

Ameda HygieniKit Protects Breast Milk from Bacteria and Viruses*



Ameda

Choose Purity. Choose Ameda.

FDA Clears Product Claim:

Ameda HygieniKit with Patented Diaphragm Protects Breast Milk from Bacteria and Viruses*

The Food and Drug Administration (FDA) has reviewed and cleared the claim that the patented silicone diaphragm used in the Ameda HygieniKit milk collection system creates a barrier that protects both:

- A. collected breast milk from potential contaminants such as viruses and bacteria that may be present in the pump and kit tubing, and
- B. pump and kit tubing from potential contaminants such as viruses and bacteria that may be present in collected breast milk.

The new claim states:

★ “The Ameda HygieniKit has a patented silicone diaphragm that creates a barrier protecting the pump and tubing from penetration of bacteria^{1,2} and viruses (Hepatitis B and C and Human Immunodeficiency Virus HIV)^{1,2} from contaminated liquids inside the collection bottle system.

The diaphragm in this product creates a barrier protecting liquids collected in the collection bottle system from penetration of bacteria^{1,2} and viruses (Hepatitis B and C and Human Immunodeficiency Virus HIV)^{1,2} from the pump and tubing in the event of contamination of these components during a prior use or by a prior user.

Note that the Ameda HygieniKit neither removes bacteria and viruses (Hepatitis B and C and Human Immunodeficiency Virus HIV)^{1,2} from the breast milk being collected into the collection bottle nor does the Ameda HygieniKit make it safe for infected mothers to feed their infants with milk collected using this device.”

1. Testing performed in situ using actual HygieniKits and SMB Piston Breast Pump with suspension of Phi-X174 bacteriophage and Escherichia coli, Staphylococcus pneumoniae and Pseudomonas aeruginosa. Procedure was adapted from ASTM 1671-97b “Standard Test method Resistance of materials Used in Protective Clothing to Penetration by Blood-borne Pathogens Using Phi-X174 Bacteriophage as a test System.”
2. The use of this product neither guarantees or warrants against the transmission of Hepatitis B and C and Human Immunodeficiency Virus HIV.



The Ameda Diaphragm

One small part,

many big advantages!

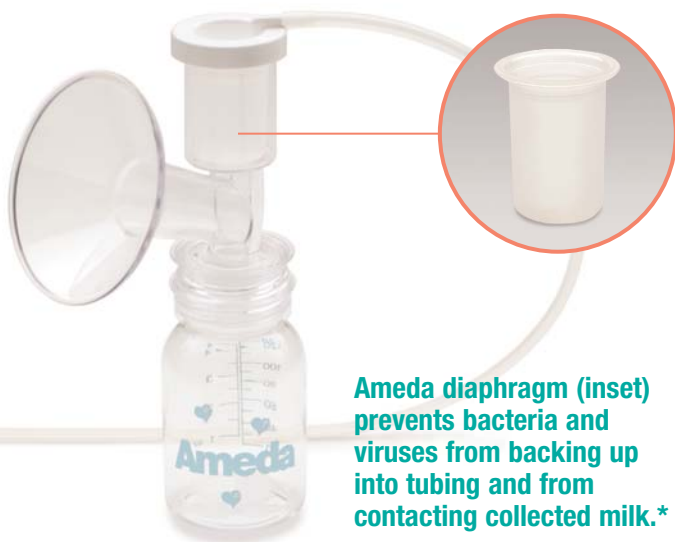
(Ameda diaphragm shown larger than actual size)

“Breast Pumps...carry the same inherent risk of infection as other shared durable medical equipment.”

“Medical Grade Breast Pumps are no different than other patient care medical devices and should be treated as cautiously as IV pumps, PCA pumps or ventilators. They carry the same inherent risk of infection as other shared durable medical equipment. Because breast milk is a bodily fluid – an ideal host for bacteria and virus transmission – precautions should be followed to use breast pump equipment safely and effectively.

While contaminated and cross-contaminated breast milk have not been researched extensively, a number of journal articles cite breast pumps as the contamination source for infected breast milk and/or infection outbreak in the neonatal nursery of hospitals.¹ This reinforces the need for strict adherence to precautions and creates an opportunity for a well-designed product that protects a mother and her collected breast milk from risk of contamination when using breast pump equipment.”

Janet S. Kinney, M.D., Neonatologist, Dallas, Texas



“Mothers pumping for their own premature or ill infants who cannot breastfeed need to use extra caution in expressing, handling, and storing of milk to assure optimal nutrition and immunologic protection with minimal chance of contamination.”

Human Milk Banking Association of North America, Inc.

Study Results

An independent laboratory study was conducted testing the Ameda HygieniKit and the ability of its patented silicone diaphragm to act as a two way barrier to viral and bacterial contamination.³

Simulating severe use conditions, the Ameda diaphragm was tested for its ability to act as a barrier to bacterial and viral penetration. Representative bacteria and virus selected to challenge the barrier properties of the diaphragm included:

Bacteria	Virus
Staphylococcus aureus	Phi-X174 (25-27 nm)
Streptococcus pneumoniae	
Pseudomonas aeruginosa	
Escherichia coli	

*Virus Phi-X174, was selected for viral testing as it is one of the smallest known viruses and simulates larger size viruses, for example, Hepatitis C, Hepatitis B, HIV, CMV. See chart below.

Virus	Size
Phi-X174 – smallest known virus	25-27 nm
Hepatitis C (HCV)	27-30 nm
Hepatitis B (HBV)	42-47 nm
Human Immunodeficiency Virus (HIV)	70-110 nm
Cytomegalovirus (CMV)	150-200 nm

The challenge suspension was placed on either side of the Ameda HygieniKit silicone diaphragm to simulate contamination either from vacuum pump or tubing, or from liquids inside the collection kit itself. The HygieniKit was then attached to the pump and vacuum was applied.

Test Conditions	
Breast Pump	Ameda SMB
Suction Level	>= 230mmHg
Pumping Time	One hour
Pumping Cycle	Continuous at 48 cpm
Flow Rate	20 liters/min
Replications	2 sets of 16, on each side of the diaphragm (64)
Test Method	Adapted from: ASTM 1671-97b ³

After one hour, the sides of the diaphragm opposite the challenge suspensions were rinsed with a nutrient broth which was cultured for penetration. Positive and negative controls were used.

Results

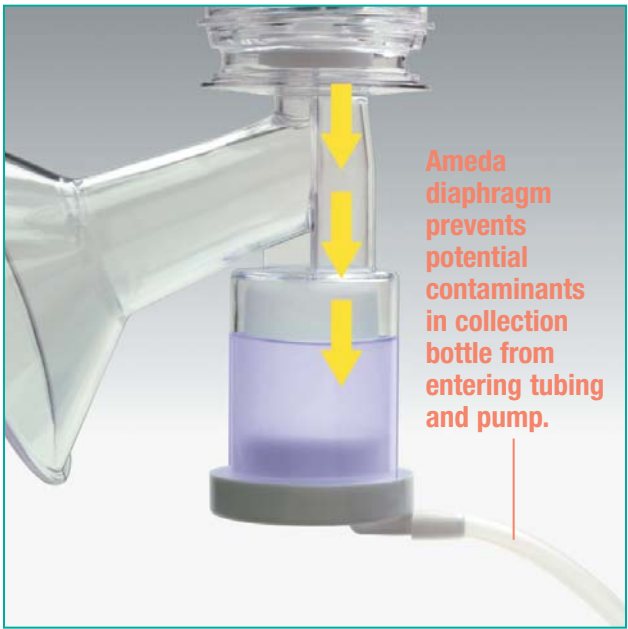
In all replications, bacteria and viral penetration through the diaphragm was not detected in either direction.

Conclusion

► The diaphragm in the Ameda HygieniKit system functions as a protective barrier defending against contamination.

Independent study proves patented silicone diaphragm acts as a two-way barrier.

(Purple coloration represents bacterial and viral contamination.)



References

1. Bacterial contaminants of collected and frozen human milk used in an intensive care nursery, El-Mohandes, Schatz, Keiser, Jackson, American Journal of Infection Control AJIC, Volume 21 Number 5, October 1993.
Infection risks from electrically operated breast pumps, J. Ian Blenkarn, Journal of Hospital Infection (1989) 13, 27-31.
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An outbreak of *Serratia marcescens* transmitted by contaminated breast pumps in a special care baby unit, Gransden, Webster, French, Phillips, Journal of Hospital Infection 1986 Marc:7 (2): 149-54.
2. Recommendations for Collection, Storage and Handling of a Mother's Milk for Her Own Infant in the Hospital Setting, Third Edition, Human Milk Banking Association of North America, Inc. 1999, p iii.
3. ASTM 1671-97b "Standard Test method Resistance of materials Used in Protective Clothing to Penetration by Blood-borne Pathogens Using Phi-X174 Bacteriophage as a test System" American Society for Testing and Materials. West Conshohocken, PA

Latex Statement

The specifications for all Ameda breastfeeding products and packaging do not contain natural rubber latex as a component, and our component suppliers do not add natural rubber latex as part of their production process. As we are sure is the case with other responsible manufacturers, Hollister has instructed its component suppliers that they must eliminate even incidental contact with natural rubber latex materials which may occur during processing.

Ordering information

To order any of the fine Ameda products, including the various Ameda HygieniKit Milk Collection Systems with patented Ameda diaphragm, call 1-877-99-AMEDA.

Ameda Breastfeeding Products with HygieniKit®	
17121	One-Hand Breast Pump/Dual HygieniKit
17126	One-Hand Breast Pump/Dual HygieniKit with Flexishield
17131	Dual HygieniKit
17101	One-Hand Breast Pump/Single HygieniKit
17111	Single HygieniKit
17141	One-Hand Pump HygieniKit Collection System Adapter
17128	Elite Pump Rental Tote
17070	Purely Yours without Tote
17072	Purely Yours with Tote

For additional information on the study, visit www.ameda.com or call 1-877-99-ameda



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Libertyville, Illinois, 60048 USA
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