Ameda HygieniKit with *Patented Diaphragm Barrier* to Bacterial and Viral Penetration

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INTRODUCTION

Breast pumping systems are widely used today in the hospital, at home and at work. Like any medical device that handles body fluids, with use of a breast pumping system there is the potential for contamination from bacteria or virus. While the topic of breast pumping systems and contamination has not been extensively researched, reports among clinicians have considered the breast pump as a potential source for contamination.

One breast pumping system, the Ameda HygieniKit, addresses these concerns. The design of the Ameda HygieniKit reduces risks of potential contamination by the incorporation of a unique silicone diaphragm. A study has been conducted to demonstrate the effectiveness of the diaphragm in the Ameda HygieniKit to function as a barrier to both bacteria and virus.

STUDY DESIGN

In order to demonstrate that the silicone diaphragm does function as a barrier to both bacteria and virus, a standard test procedure developed by the American Society for Testing and Materials (ASTM) was chosen as a starting point. 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," was developed to assess the effectiveness of materials used in protective clothing to protect the wearer against contact with blood-borne pathogens.

While the ASTM procedure was established to test individual materials in a static test fixture, simply testing the silicone diaphragm material would not clearly demonstrate its effectiveness as a moving dynamic system. Revisions were made to better examine the effect of actual use of the Ameda HygieniKit.

In order to best challenge the silicone diaphragm, the test procedure was set up to mimic use conditions. Since the Ameda HygieniKit can be used under a wide variety of conditions, severe simulated use conditions were selected to test the diaphragm for its ability to act as a barrier to bacterial and viral penetration.

Many different microorganisms can pose significant risks to life and health. Therefore, representative microorganisms were selected to function as surrogate microbes for this testing. Two groupings of representative microbes were selected: bacteria and virus.

TEST CONDITIONS	
Breast Pump	AmedaSMB
Suction Level	>= 230mmHg
Pumping Time	One hour
Pumping Cycle	Continuous at 48 cpm
Flow Rate	20 liters/min
Replications	2 sets of I6, on each side of the diaphragm (64)
Test Method	Adapted from: ASTM 1671-97b

Bacterial Selection

Since a wide variety of bacteria may cause contamination in breast milk, input from lactation consultants was solicited to select representative bacteria. In addition, an independent microbiological testing laboratory was contacted for input concerning the viability of mixing the various suggested bacteria strains. The following bacteria were selected to be mixed together as a challenge suspension:

BACTERIA	VIRUS
Staphylococcus aureus	Phi-XI 74 (25-27 nm)
Streptococcus pneumoniae	
Pseudomonas aeruginosa	
Escherichia coli	

Virus Ph1-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.

The challenge suspension of these bacteria was prepared by inoculating sterile soybean casein digest broth with a stock solution of the microorganisms. Aliquots of the stock suspension were transferred to nutrient broth with 0.01 % Tween® 80 to achieve an approximate liter of 1.0^{7} x 101 colony forming units (CFU) per milliliter.

Viral Selection

Viral pathogens of major concern are hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV) and cytomegalovirus (CMV). Phi-X174 bacteriophage, one of the smallest known viruses, a nonenveloped, icosahedral virus (as is HCV), was selected as a representative pathogenic virus to form a challenge suspension.

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

TEST PROCEDURE

The challenge suspension of Phi-X174 bacteriophage was maintained at a concentration of at least 1.0×10^{8} plaque forming units (PFU) per milliliter.

General

Bacterial and viral challenges were performed by placing the appropriate challenge suspension on either side of the Ameda HygieniKit silicone diaphragm. The Ameda HygieniKit was then attached to a medical grade, piston-driven electric vacuum pump. The maximum vacuum was applied for one hour. The sides of the diaphragm opposite of the challenge suspensions were flushed with nutrient broth with 0.01 % Tween® 80 to extract any organisms which may have penetrated the diaphragm. Positive and negative controls were used to validate the test procedure.

Bacterial Penetration from Inside of Diaphragm

Representing bacterial contamination from a vacuum line or pump, 0.1 milliliter of the bacterial challenge suspension was introduced into the inside of the diaphragm. The nipple tunnel of the Ameda HygieniKit (designed to fit on the breast) was plugged with a rubber stopper. The pump was attached and a vacuum applied for one hour. At twenty (20) minute intervals, the pump was turned off momentarily and the collection bottle was inverted momentarily so that the challenge suspension came in contact with the seal of the diaphragm. After the test period, the outside of the diaphragm was rinsed with nutrient broth. This broth was then cultured for any bacteria that may have penetrated.

This procedure was performed with a total of sixteen (16) new Ameda HygieniKits.

Bacterial Penetration from Outside of Diaphram

Representing bacterial contamination from mother's milk inside the Ameda HygieniKit bottle, the experiment was repeated using sixteen (16) new Ameda HygieniKits, with 0.1 milliliter of the identical bacterial challenge suspension introduced into the **outside** of the diaphragm. To produce the most challenging environment, the Ameda HygieniKit system was inverted during the entire one-hour testing period to ensure intimate contact between the diaphragm and the bacterial challenge suspension.

After the test period, the inside of the diaphragm was rinsed with nutrient broth. This broth was then cultured to look for any bacteria that may have penetrated.

TEST RESULTS

Viral Penetration from Inside and Outside of Diaphram

Following the same format as the bacterial challenge, testing for viral penetration was done with new Ameda HygieniKits. A set of sixteen (16) was used to examine the potential for penetration from the inside of the diaphragm and a second set of sixteen (16) for penetration from the outside of the diaphragm.

In two (2) sets of sixteen (16) replicates, bacteria and viral penetration were not detected through the outside of the diaphragm.

In two sets of sixteen (16) replicates, bacteria and viral penetration were not detected through the inside of the diaphragm.

CONCLUSION

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

DISCUSSION

The Ameda HygieniKit addresses concerns about contamination of expressed mother's milk due to contaminated pump or tubing. Use of the Ameda HygieniKit will provide some assurance of a sound milk supply where the status of the pump and tubing with respect to pathogens is uncertain.

Likewise, the Ameda HygieniKit addresses issues about contamination of breast pumps and tubing from use by infected mothers. This is of special concern in cases where breast pumps are used by multiple users; e.g., breast pump rental or hospital NICU use.

This does not imply that the Ameda HygieniKit sterilizes or removes bacteria or viruses from infected milk. The configuration of the Ameda HygieniKit diaphragm is to function as a barrier preventing contamination from either side of diaphragm. The Ameda HygieniKit diaphragm is not intended to filter or sterilize mother's milk.

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