



23 January, 2019

RE: KIMIE: The New Human Breast Milk Pasteurizer

Hi Everyone,

Season's Greetings from the Tinsel town. Trust you and your family are doing well.

While baby's own mother's breast milk (MBM) still remains the Rolls Royce of all feeding options, own MBM is not always available, is insufficient or at times not suitable to meet baby's nutritional needs. Under these circumstances it is a common practice to use pasteurized donor breast milk (DBM) purchased / obtained from a Donor Breast Milk Bank (DBMB). While existing DBMB do serve the purpose, all the machines used for pasteurization are not automated, very expensive, take a lot of space, are cumbersome, require special ongoing extensive training (lactation consultant or a nutritionist, therefore not available 24/7), need lot of water which is not recycled. In addition, DBM is frozen and thawed several times thus losing some of it's important nutritional value.

There are limited number of DBMB in a particular part of the country or none at all. For example, there is only one DBMB in the entire state of California. They charge US \$ 5-6/oz. There are only ~ 30 DBMB all over USA. There are very few DBMB in India mostly in big hospitals in metropolitan cities. Thus there is a tremendous need for every hospital who has a Neonatal Intensive Care Unit and normal nursery to have it's own DBMB which is user friendly, time and cost effective.

I did an extensive search regarding the evolution of pasteurization and DBMB. Folks from the DBMB request women who had a baby at full term gestation several days or weeks ago to donate BM. They are screened for the use of medications, tobacco, alcohol and illicit drugs. They are then tested when indicated for HIV, Hep-B, syphilis and rubella. The donation is voluntary with no cash rewards.

At present most of the DBMB all over the world use "Holder" technique. Pooled DBM is warmed to 62.5 * C (10 min), held at 62.5* C (30 min) and then cooled to 4-10 * C (5-10 min). The existing technology is antiquated and needs to be revamped using present day technology especially the cooling system, recycling of water and digital display of time and temperature in real time.

In November of 2017, I designed a prototype of the pasteurizer named **Kimie**. I contacted Mr. Sudhir Waghmare in Pune. He was very receptive of my idea of developing a small pasteurizer using present day technology. Mrs Vishakha Haridas (Lactation consultant, in charge of DBMB at Deenanath Mangeshkar Hospital, Pune, where I work), and I met with Mr. Waghmare and his team of two other talented Engineers in December, 2017. Present **Kimie** is indeed the genesis of that meeting. Sudhir and his team deserve a lot of credit for developing the first, second and now the third and final model of Kimie (Fig 2).

It is user friendly, fully automated, & is controlled by intelligent micro controllers for pin point accuracy of the milk temperature. It is Servo controlled for accuracy and reliability. Provided Digital display that indicates the elapsed time and temperature in real time. A special milk temperature sensor is incorporated to ensure accuracy of milk temperature.

The machine comprises of three modes: A-Heating, B-Holding and C: Cooling. An inbuilt heating system ensures milk is warmed to $62.5 \text{ }^{\circ}\text{C} \pm 0.5 \text{ }^{\circ}\text{C}$. Once warmed, the microprocessor ensures that the temperature is maintained at $62.5 \text{ }^{\circ}\text{C}$ (30 min). Digital display indicates elapsed time and temperature. Inbuilt Cooling system ensures that the milk is rapidly cooled to $4 \text{ }^{\circ}\text{C} \pm 0.5 \text{ }^{\circ}\text{C}$ (20 min.). Once the hold time is over, the cooling system automatically takes over the cycle and starts rapid cooling. Inbuilt alarms provide real time information to the operator. UN like the existing pasteurizers, Kimie does not require special plumbing or water connections. **Water is recycled and therefore required water is much less. This is an important feature where there is scarcity of water.**

Kimie has 5 cylinders, each with a capacity of 100 ml. Thus five different samples (10-100 ml) can be pasteurized during each cycle. In addition, the DBM does not need to be frozen and thawed several times since it can be used 24/7.

Kimie has been extensively tested for engineering performance. Sudhir will be happy to provide more information. In addition, an extensive bacteriological sterility testing has been performed at DMH and KEM hospital in Pune under the supervision of Dr. Sampada Patwardhan and Dr. Umesh Vaidya. Attached please find the detailed report from both these hospitals. Based on these results I believe routine bacteriological testing after every pasteurization is not mandated. However, it should be done under special clinical situations (e.g. h/o mastitis or BM is foul smelling) or as a Quality control measure. Nonetheless, you are at liberty to perform bacteriological culture after every pasteurization. It will only increase the cost, may need freezing / thawing and will delay the use of DBM.

I am totally convinced **Kimie** meets all world milk bank guidelines / requirements. It is safe, user friendly and cost effective. It is ready for clinical use worldwide.

The overall objective is to increase the use of pasteurized DHM as indicated and try to decrease the use of formulas mostly derived from the cow milk, in premature and full term babies alike. There are many medical problems, short and long term, associated with the use of formulas in the newborn period. It is beyond the scope of this letter to describe them.

Use of Kimie is indicated whenever a Pediatrician / Neonatologist decides that the BM milk should be pasteurized before it is used. The typical situations we face as pediatricians / neonatologists are as follows.

1) Newly born premature baby admitted to the NICU while waiting for the biological mother's BM becomes available.

No matter how hard they try, new mothers, generally take 2-3 days or longer before enough colostrum / BM is available. However, in most NICUs there are > 3 mothers who had delivered a baby > 7 days ago. They are able to produce more BM than what their baby needs. Mom's always want to help any other baby. These days most hospitals have medical information including HIV, Hepatitis B or Rubella status and pertinent social history. Besides, in addition to the bacteria, pasteurization eliminates all these pathogens. The NICU staff can easily decide which mothers are high BM producers and should be approached.

2) Newly born full term baby admitted in the normal nursery.

Very similar situation. Mothers are unable to produce enough milk for 1-3 days. During this period we end up using formula. This is not a good situation as mentioned earlier. Use of the formula even for 1-3

days seems to have long lasting problems in these patients. Nursery staff can easily contact mothers who have been discharged from the hospital and now are several days or weeks post-partum. They are able to produce enough BM than what their baby needs. Nursery staff can easily call and request them to donate BM. Such a system already exists at DMH and Sasoon hospital in Pune. With the use of Kimie DBM can be easily pasteurized. Thus every normal newborn nursery should be able to have a stock of pasteurized DBM to be used as a bridge during the first 1-3 days.

3) Unfortunate situation when baby's mother has died.

This is really a sad situation but not so rare in poor countries like India.

4) Mother has other medical illness, mastitis, cancer etc or is on medications.

Many times mother has other medical illness like pneumonia, heart failure, mastitis or even cancer. Chances are very good she is on several medications. Due to her illness it is not easy to express BM or is not suitable for the baby because of her medication.

In summary, Kimie is automated, less expensive (almost 1/3rd the price), takes 1/3rd the space, user friendly needing minimum training (idiot proof), can pasteurize from 10 to 500 ml at a time, can be used many times and any time of the day (24/7), consumes less water and electricity (10 cents per cycle). It requires minimum freezing and thawing.

Every Pediatrician / Neonatologist I have talked to in India and USA agree it will be a game changer in the field of DBMB pasteurization. And it will help in improving the health of the newborn babies all over the world.

If you are interested in starting a Donor Breast Milk bank using Kimie instead of the existing technology, please contact Sudhir for quotation and how to set up the entire DBMB operation. Kimie is made in Pune, Sudhir owns the patent and it comes with a 100 % returnable warranty for one year. Sudhir promises me that you can run ~ 25,000 cycles and there will be no problems.

I have no vested interest regarding the use of Kimie except that it will improve the health of the newborn babies, premature and full term alike.

Please feel free to contact me at 310-435-4086 or Sudhir at 9822375996 if you have any questions.

I thank you for your attention and consideration.

With warm regards,

Sincerely,

Dr. Uday Devaskar