KIMIE: New Human Breast Milk Pasteurizer-Fully Automated, User Friendly, Cost-Effective Device for Universal Application

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Abstract

Natural mother's breast milk (MBM) is the best food for all newborns especially the preterm. However, when natural MBM is not available or insufficient donor breast milk (DBM) is the second-best option. Sterifeed or HSC human milk pasteurizers have been commonly used for several decades. While these devices have served the purpose, they are relatively large, expensive, require special electrical and water connections, need a large amount of water which is not recycled and an ongoing supply of disposable plastic bottles. In addition, the use of these machines requires special training. Here we describe the development of a compact, automated, user-friendly human breast milk pasteurizer (HBMP) named Kimie capable of pasteurizing small volumes of DBM. This device does not require special water plumbing, recycles water, is inexpensive and does not require FDA approval.

Introduction

Natural mother's breast milk (MBM) is the best of all feeding options for all newborns, especially preterm infants (1-6). However, natural MBM is not always available, can be insufficient to provide an adequate amount (soon after delivery, maternal refusal or death) or is contraindicated (maternal illness, use of illicit drugs or medications, or unsatisfactory collection practices). Under these circumstances, pasteurized donor breast milk (PDBM) is considered the second-best option compared to formulas derived from cow's milk (1-7). Therefore, PDBM is commonly used in neonatal intensive care units (NICUs) worldwide. Many bodies, such as the WHO, the United States Breastfeeding Committee, the American Academy of Pediatrics, the European Society for Pediatric Gastroenterology, Hepatology and Nutrition, and the Indian Academy of Pediatrics, have emphasized the importance of donor breast milk (DBM) and acknowledged that donor breast milk banks (DBMB) play an important role in the well-being of preterm babies (1, 8-14).

Traditional DBMBs are operated independently and are not hospital-based. They sell PDBM to NICUs within their region (15-17). However, there are an increasing number of in-hospital DBMBs (1, 18-19). In the traditional DBMB, Sterifeed or HSC HBMP has been used for many decades. During the process of Holder pasteurization, most of the viruses and bacteria are killed while preserving most of the nutritional and immunologic properties of MBM (1, 15, 20-23). These devices are large, expensive, require special electrical and water connections, require a large amount of water that is not recycled and require an ongoing supply of disposable plastic bottles. In addition, the use of these devices requires special training. To be cost effective, they require a large volume of DBM to be pasteurized during each cycle. Therefore, the use of these devices is limited to DBMB in developed countries or larger hospitals in large cities in countries such as India. Here, we describe the development of a compact, automated, user-friendly HBMP capable of pasteurizing small volumes of DBM. This device does not require special water plumbing, recycles water and is inexpensive. It is designed mostly for the in-hospital installed DBMB.

Materials And Methods

In December 2017, health care providers and both engineers met and decided to develop an HBMP using the principle of the widely used Holder technology (Fig. 1).

It was discovered that current pasteurizers are connected to a water source for filling the chamber and that separate plumbing is needed to drain the water. It uses a submersible water heater of very high wattage. To distribute heat evenly, it incorporates a water stirrer. The use of a submersible water heater is concerning due to a risk of electrical shock. In addition, the waste of large amounts, ~ 80 liters, of water after each cycle was considered problematic.

Various options to manufacture a compact, portable, user-and eco-friendly, cost-effective device using modern technology were discussed. It was decided to use two separate water tanks, one for heating and one for cooling. Two different water pumps were connected to the respective tanks. In this closed loop system, each pump propels water in the chamber, which warms or cools the DBM, and water returns to its respective tank. The capacities of the heating and cooling tanks were arbitrarily decided to be 1,750 and 2,750 ml, respectively. Thus, only 4,500 ml of water would be used and recycled. Other discussions included the technical and tubing design, the method of water circulation around the milk containers, the components required and their placement, the type of water pumps for heating and cooling, the required flow rate, its durability, the type of heaters and their wattage, the type of cooling mechanism (chiller) and their capacity, the size and shape of DBM containers. To be eco-friendly, easy cleaning and cost-effective, grade 304 stainless-steel cylinders were used instead of disposable plastic bottles (24). Eventually, we developed a closed loop system for circulating hot and cold water around milk containers by using submersible water pumps, a sandwich heater mechanism, solenoid valves, a water tight steel container and a microprocessor-based temperature indicator and controller with a timer mechanism. The electronic temperature indicator and controller were used with a sensor to measure the milk temperature in real time. Technology to separately display the milk temperature and the duration of the cycle in real time in digital form was also devised.

In this device, Perplex, a better material compared to plastic, is used. The pasteurization chamber is designed in molded plastic with a cavity in between the walls of the chamber to avoid energy losses. This air gap acts as thermal protection, ensuring that heating or cooling energy is conserved. The water inlet is on one side, while the water outlet is on the opposite side to ensure laminar flow. An auto-drain facility utilized after hold or cool mode and completion of cycle were implemented. The main chamber is fitted with a separate water draining facility at the bottom of the chamber. A separate small compartment is provided to collect and then drain the overflowed water. This chamber has a separate outlet to drain hot or cold water to their respective reservoirs during the respective cycle. The pasteurization chamber is fitted with a properly fitting lid on the top.

A stainless-steel cage holds six cylinders, one for water and the other for DBM. The cage is provided with a water temperature sensor. The height of the cage is maintained from 0.3 to 1 cm, ensuring that the cylinders are submerged to the desired level during both cycles. It is fitted with a special mechanism that ensures that the cylinders do not float in water even if the milk volume is small. This ensures that the cylinders are fully submerged in water to 2.5 cm during the entire cycle. A separate stainless-steel cylinder numbered one was built to measure the temperature of the water using a sensor in real time. In addition, five different stainless-steel cylinders, numbered two to five, with a maximum capacity of 100 ml each, were introduced. Thus, a maximum of 500 ml of DBM can be pasteurized during each cycle. A special ring is used to ensure that water does not leak into the cylinder.

A water recirculating pump (model BLDC, Iwaki, Japan) that can withstand a temperature of 80 $^{\circ}C$ and has a longer shelf life is used. It can also operate on 24 volts DC, has a potentiometer to adjust the flow of water electronically, and comes with a lifetime warranty of 25,000 hours. Since we needed less flow, we incorporated a flow control valve towards the heater and the chiller. A water reservoir has a separate drain valve to drain the water after each cycle. It also has an overflow outlet to ensure that the water level in the tank is always maintained at the desired level. The reservoir also has a water inlet to refill the tank. Two sensors are placed in the pasteurization chamber to measure the temperature of the circulating water around the milk containers and the temperature of the water inside the cylinder. The level of water was maintained in the chamber 0.2 cm above the milk level to ensure effective treatment. Once the water level reaches 0.2 cm above the milk container, it starts flowing above the specially constructed restriction wall. It is then collected in the retraction chamber from where it is drained through a sol valve and is returned back to the hot water reservoir. Seven sol valves are used in the system, with diameters varying from 0.8 to 1.2 cm.

A separate flat brass heater of 600 watts is placed in an aluminum enclosure. It has 2 parts: male and female. Special grooves are made in the enclosures with a width of 6 mm and a depth of 4 mm, through which the water passes. This is the female compartment. The heater is placed pressed on both sides of the enclosures for even heating of water. Heavy insulation is used to avoid radiative heat loss. The male part is then fixed on the female part.

After the hold cycle is completed after 30 minutes, the microcontroller indicates DRN 1. Simultaneously, the drain valve for the heating mechanism activates and drains the hot water in the compartment within 20 to 30 seconds. Then, drain valve 1 is switched off. The hot water tank consists of one water inlet, one water outlet, one overflow outlet and one drain outlet. A separate filter is incorporated at the water inlet to ensure that foreign particles do not enter the system. The hot water tank has a separate outlet that supplies water to the pump, which is pumped in the system and then returns back to the reservoir tank via a separate inlet.

We found a chiller to decrease the milk temperature to 4 °C within 25 minutes. A separate sensor mechanism was instituted for more accuracy and faster warming. When the system is switched on, the heating cycle starts. Simultaneously, the cooling system is also switched on. Sol valves S2 and S5 are switched on. The pump sucks the water from the reservoir tank and pushes it to the chiller via sol valve S2 and then returns to the tank via solve valve S5. A separate water sensor is placed in the reservoir tank that shuts off the chiller when the tank water temperature reaches 1.5^0 C. Once the temperature rises to 2.5 ^{0} C, the chiller is switched on again. This process continues throughout the entire cycle, ensuring that cold water is readily available when the cooling process starts. A specially developed chiller is able to cool the water from room temperature to 1.5 ^{0} C in 30 to 35 minutes. When the cycle is over, the microcontroller indicates DRN 2, and the drain valve is activated to drain the cold water within 20 to 30 seconds. After 30 seconds, drain valve number 2 is switched off.

A waterproof stainless-steel sensor is fitted inside the water cylinder number one. It measures the water temperature in real time and servo controls the heater output via a microprocessor. If the water temperature exceeds 63.5 ^{0} C. in heating mode, it shuts off the heater. During the hold mode, the water temperature sensor cuts off the heater if the water temperature exceeds 63.5 ^{0} C. This dual control ensures that the milk temperature never exceeds 63.5 ^{0} C. Another sensor is fitted in the pasteurization chamber that measures the water temperature. This water sensor is fitted to the steel cage that holds the milk cylinders. Another sensor measures the temperature in the cooling system.

The LED displays indicate the elapsed time and temperature of water (^{0} C) in real time.

We performed a comparative study for bacteriologic testing of DBM before and after pasteurization using HSC (control group) or Kimie (study group). This study was approved by the IRB at DMH. Prior to pasteurization, 1-3 ml of DBM in a sterile container (n=100) was sent to the microbiology laboratory. The remaining DBM was divided into two equal portions. The volume ranged from 20 to 60 ml. They were pasteurized separately using HSC or Kimie. Subsequently, 1-3 ml of PDBM was subjected to bacteriological testing using sheep blood agar plates or McKonkey medium (25). Incubation was performed for 48-72 hours at 37 $^{˚C}$ [25]. A qualitative and semi-quantitative analysis of bacterial growth was performed. We did not attempt to subclassify the species of bacterial growth.

Results

We performed trials by placing six steel containers filled with water and submerged two sensors in two different containers to measure and compare the temperatures during the cycle. Two different temperature indicators and controllers were used. All the containers depicted the same temperature during the entire cycle. More than 100 satisfactory trials were conducted to verify and ensure the accuracy of the milk temperature during the hold or cooling mode. We placed two sensors in two different milk containers that were in opposite directions. We noted the temperature indicated by the master sensor and the temperature displayed by the second (slave) sensor. The slave sensor showed a difference of 1.5 ^{0} C before the start of the cycle and continued to show that temperature during the entire cycle. We recorded the difference. In cooling mode, the same things occurred. This confirmed that the heat transfer during the entire pasteurization process was equal and effective in all six compartments of the pasteurization chambers. The average difference shown by the temperature sensors was 1.4 to 1.6 ^{0} C and was constant during all the trials.

All of the DBM samples before pasteurization grew Gram-positive (n=34, colony count 3 x 10^{2} to 1 x 10^{5}), Gram-negative (n=36, colony count 1 x 10^{2} to 1 x 10^{5}) or both (n=30) bacteria. However, all of the DBM samples except one were sterile in both groups after pasteurization. The colony count did decrease in both the positive growth samples, suggesting partial pasteurization. We concluded that Kimie was equally effective in killing bacteria when compared to HSCs.

After washing the cylinders and the plastic lids with a detergent, rinse them thoroughly with water to remove the detergent. The cylinder and the plastic lids can be sterilized by using any suitable sterilization method for stainless steel and plastic. These include but are not limited to Sterrad hydrogen peroxide plasma-based low temperature or any other low temperature gas sterilization system. One may also use a dishwasher or submerge the cylinders and the plastic lids in a large container with boiling hot water for ten minutes. Then, the samples were carefully removed and placed on a clean surface until completely dry.

Kimie has received the European Certificate of compliance (no 1810170911101) for a Human Milk Pasteurizer and met Standards EN 6060-1, EN 60601-1-2, and EN 60601-1-6 to demonstrate conformity. In the USA, any BM pasteurizer does not require federal drug administration approval since it is considered a catering device. Kimie was imported to the USA from India under commodity code number 84198998.

We have developed an operating instructions manual for the easy use of Kimie (not included).

Discussion

We describe the development of a portable, fully automated, user friendly, cost-effective HBM that uses modern technology, requires less space, no special plumbing, and can recycle water. Digital screens display time and temperature in real time. Heating or cooling is controlled by intelligent microcontrollers ensuring temperature accuracy. The device is capable of pasteurizing 10-500 ml of EBM. It has been used successfully in four hospital-installed DBMB in India for more than a year and a half and at Centinela Hospital Medical Centre, Inglewood, California for more than wo months.

In the food industry worldwide, regulating agencies prefer to use stainless steel for heating, cooling or drying food because it prevents any chemical reaction between the food and the container (24). The Food and Drug Association's rule states that materials used in the construction of utensils and food contact surfaces may not allow the migration of deleterious substances or impart color, odor, or tastes to food. Such material needs to be safe, durable, corrosion-resistant to many chemicals, non-absorbent, sufficient in weight and thickness to withstand repeated washing, have a smooth, easy-to-clean surface, resistant to pitting, chipping, crazing, scratching and scoring. Therefore, we chose stainless-steel grade 304 rather than plastic bottles. This type of stainless steel is most commonly used as an alloy in a variety of industries since it can resist corrosion caused by several chemicals and can be electropolished to a smooth, shiny and easy-to-clean surface.

In this device, the water level during heating or cooling mode is above the milk level, ensuring that the BM is evenly treated with the provided energy. During heating or cooling, it is an unsteady state of energy transfer, meaning the temperature difference between the DBM and water is high. However, as the temperature difference between the water and DBM decreases, the energy transfer is slow. Therefore, as per the law of thermodynamics, it is called an unsteady state. We conducted several experiments to determine the optimum rate of heat transfer so that the desired milk temperature can be reached in the shortest time, which will be cost effective regarding power consumption and time. To accomplish this goal, we varied the flow of water entering the pasteurization chamber, its effects on warming and cooling and the time taken. Then, we varied the heater wattage and heater output power via microcontrollers to achieve fast warming without overshooting it. In these trials, we ensured that the milk temperature never exceeded 63 °C. Lastly, we invented a sandwich heating mechanism that ensures that each drop of water entering the heating body is evenly heated to the same temperature during the entire travel time. We manufactured the heater body in stainless steel for better heat transfer compared to aluminium.

There is always a gap between the milk and the lid of the milk container. During the heating process, heat transfer will only occur when there is a temperature difference between milk and air. As the milk temperature starts rising, the air temperature will also start rising due to convective heat transfer. As the temperature difference is high, the rate of heat transfer will also be very high, but as the temperature difference between air and milk decreases, there will be no heat transfer to the air. This state is defined as equilibrium.

We measured the milk and air temperature using two different probes, and the temperature difference was recorded. When the milk temperature was 62.7 ^{0} C, the air temperature was 62.3 ^{0} C. This did not change even when we increased the time of heating because the system reached the stage of equilibrium. In the heating mode, equilibrium is achieved in 25 minutes.

There are concerns with fully submerging plastic bottle containers under water during heating. As used in other pasteurizers. plastic is an insulation material; therefore, heat conduction is poor. As a result, it is necessary to stir the water for better heat transfer. In Kimie, stirring milk is not necessary because the conductive property of steel is 100 times faster than that of plastic (24). Submerging the plastic bottles under water increases the time for heating, consumes more energy and needs more water and is not eco-friendly. Even if recycled, plastic bottles will need to be discarded after a few cycles. Stainless-steel containers can be reused indefinitely.

Debate continues regarding early postnatal readiness for enteral feeding in premature appropriate for gestational age (AGA) or intrauterine growth restricted (IUGR) neonates (25-38). Early enteral feeding has been associated with improved survival and postnatal growth, decreased incidence of sepsis and necrotizing enterocolitis (NEC) and fewer days of total parenteral nutrition (25, 26, 29, 34-36). Therefore, there is an increasing trend to initiate at least minimal enteral nutrition (trophic feedings) as early as 6 hours of life and for early aggresive enteral nutrition (25-29). A baby’s own mother’s expressed breast milk (EBM), including colostrum, is the best feeding option. The overarching goal is to reach full enteral EBM feeding in the shortest possible time (25-38). However, when mother's EBM milk is not available, insufficient or not suitable, supplementation with PDBM or specially designed preterm formulas is a common practice (1-6). PDBM is considered to be a better option than the preterm formula (1-6).

The detailed operation of traditional DBMBs has been described (15-17, 39-49). These banks rely on a donor breast-feeding population to ensure an adequate supply of DBM (15-17, 39-45). In general, donor mothers have delivered a baby at full-term gestation and have been lactating for several weeks or months (15-17, 36-39). These women, under prescription from a physician, donate their extra BM for vulnerable babies (15-17). These mothers are screened for medical and lifestyle risk factors, serum for syphilis, HIV, hepatitis B and C, and human T-cell leukemia virus (HTLV) (15-17). Staff members of the traditional DBMB instruct women to properly collect and store milk at home in hygienic conditions (15-17). Subsequently, they are instructed to transfer stored frozen DBM to the DBMB in a suitable insulated container on ice or ice packs. In this model, it is assumed that the donor mother has a refrigerator at home that they may not. At these banks, collected DBM milk is stored frozen until pasteurized and then frozen again until shipped to the regional NICU. DBM is frozen and thawed up to three times before it is consumed by the baby. In general, DBM from four to six mothers is pooled for pasteurization. On the other hand, in the in-hospital installed DBMB setting, a physician, nurse or both approach all mothers who deliver premature babies in the immediate postpartum period. Information regarding their medical and lifestyle risk factors and prenatal serum syphilis, HIV, hepatitis B and C, and HTLV is readily available from prenatal records, even in developing countries such as India. No additional testing or an order for donation by a physician is needed. The NICU staff educate these women regarding the need for expressing milk, the importance of breast hygiene, and the proper collection and storage of EBM. Several times BM is expressed in the hospital under supervision of a nurse or a lactation specialist. These mothers are requested, when needed, to express milk more than what their baby requires. The extra fresh EBM can be easily pasteurized shortly and stored at 4^0 °C in small aliquots to be used within the next 24 hours or stored frozen at -18^0 °C for use after 24 hours.

In any NICU, the following is a common scenario: A premature baby gets admitted to the NICU, needing assisted ventilation or not, and is ready for enteral feedings as early as 6 hours of age. It is common that the baby's natural mother is unable to produce enough colostrum or BM for at least 2-3 days or even longer. During the interim, the baby receives TPN, premature formula, DBM obtained from the traditional DBMB or a combination of these. With the availability of Kimie, it will be easy to give PDBM obtained from another mother who had a premature baby a few days or weeks ago and is now able to produce extra milk than what her baby requires. The DBM from the preterm mother can be collected, pasteurized and stored frozen or pasteurized soon after expressing and used immediately. In the later scenario, PDBM can be stored at 40°C in small aliquots to be used within the next 24 hours. This approach will decrease the need for TPN and eliminate the use of premature formula or DBM obtained from mothers who had a baby at full-term gestation. The use of preterm milk is better since it has a higher content of protein, fat, amino acids, lysozymes, calcium and sodium (50-53). Clinical studies to establish the validity of the above stated approach using Kimie seem warranted.

In summary, we have developed a human breast milk pasteurizer better suited for in-hospital installed DBMB that should help improve the health of premature babies worldwide.

Declarations

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Abbreviations:

AGA-Appropriate for gestational age, **BM:** Breast milk, **DBM-**Donor breast milk, **DBMB-**Donor breast milk bank, **EBM-** Expressed breast milk, **HTLV**-human T-cell leukemia virus, **HBMP-**Human breast milk pasteurizer, **IUGR-** Intrauterine growth restriction, **MBM-**Mother's breast milk, **NEC-**Necrotizing enterocolitis, **NICU-**Neonatal intensive care unit, **PDBM-**Pasteurized donor breast milk, **TPN-**Total parenteral nutrition

Author contributions:

Uday Devaskar, Shilpa Kalane and Mrs Vishakha Haridas had several discussions regarding the limitations of existing human breast milk pasteurizers. It was concluded that there was a need for a new pasteurizer that would be user friendly, cost effective and capable of pasteurizing a relatively small volume of milk. Devaskar developed the design of such a pasteurizer. Then, they met with Mr Sudhir Waghmare and Mr Ashay Kharche several times. Kharche developed first and then the second prototype of the pasteurizer named Kimie. Their design, mode of operation, utility and limitations were discussed by the group that led to the genesis of the present (third) prototype. Kalane obtained IRB approval, while M. Haridas obtained consent from lactating mothers to perform bacteriologic testing of the expressed breast milk before and after pasteurizer using Kimie or HSC. Sampada Patwardhan performed the bacteriologic cultures and analyzed all the results. While M. Waghmare and M. Kharche wrote the engineering part, D. Devaskar and D. Kalane wrote the medical portion.

Conflicts of interest : None

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Figures

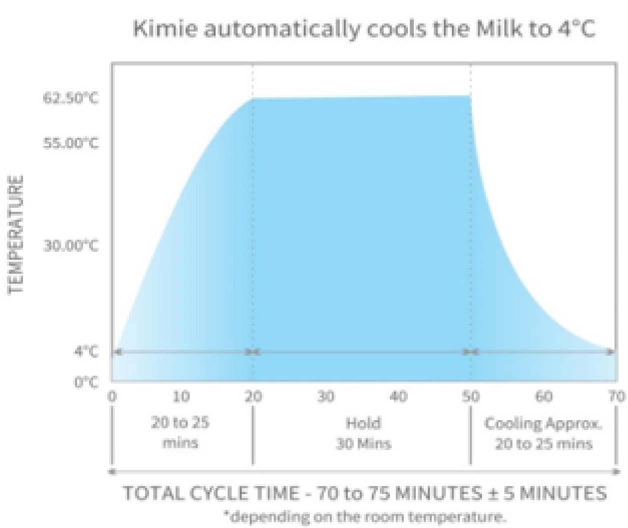

Figure 1

Graphical presentation of Holder Technology

Figure 2

Kimie: The Bird’s Eye Views

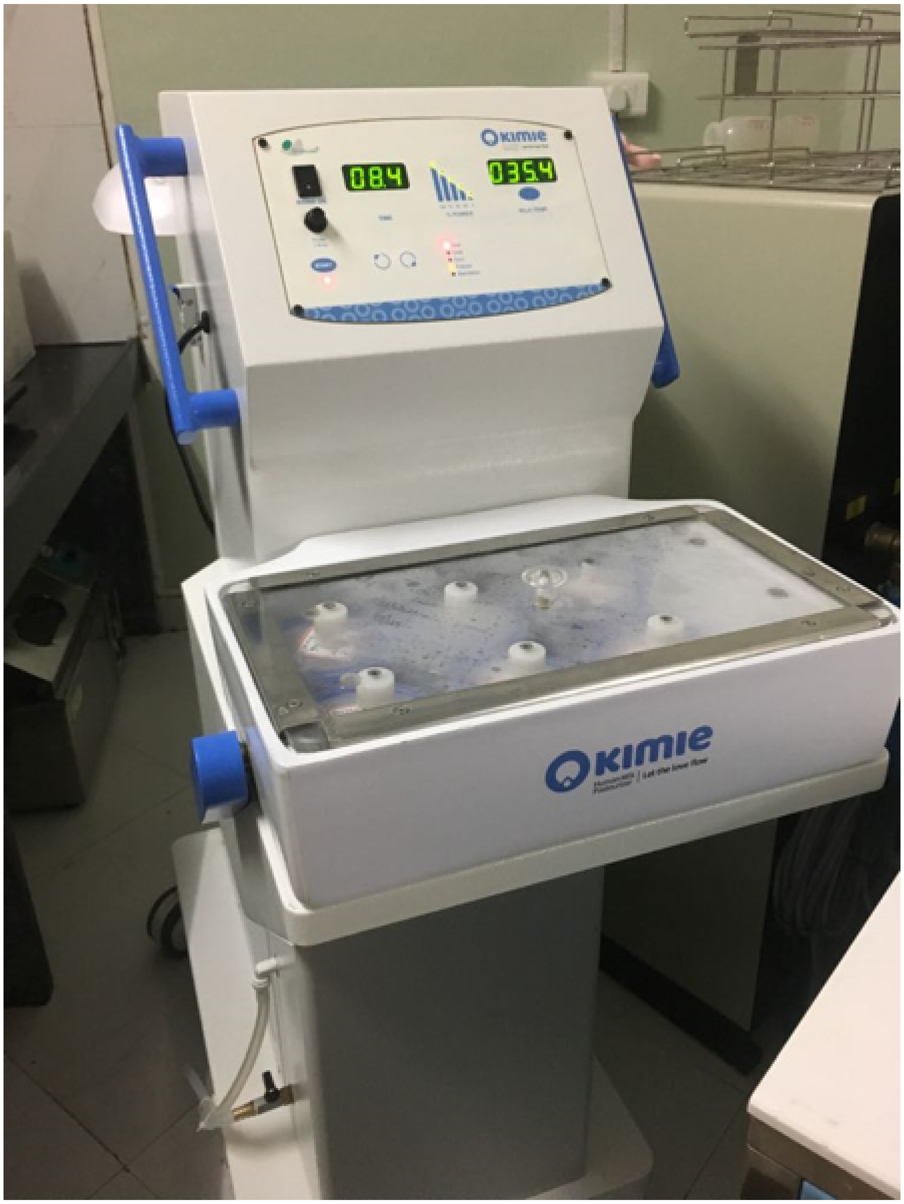

Figure 3

Kimie: The Bird’s Eye Views