Boekel Scientific

Platelet Incubator and Agitator New Regulated Equipment Evaluation

San Diego Blood Bank (SDBB) Thoroughly Examines and Assesses New Equipment for Platelet Storage

Background

Alternative equipment suppliers for Blood Banks are limited and new equipment technology requires a thorough vetting before adoption. The purpose of the study was to review and qualify new technology for Platelet Storage.

New equipment may incorporate novel design features that are not available through current suppliers. Some of the new features incorporated into the Boekel equipment include Refrigerant-less and Compressor-less "non-mechanical" Solid State Peltier Heating and Cooling, a Patent Pending Inventory Management System, Onboard Inkless Printer, Large Color Touch Screen, and a USB Downloadable Event Log. These features should be tested for usefulness and robustness.

An installation qualification (IQ), operational qualification (OQ) product or process qualification (PQ) and process flow integration, will be evaluated. The evaluation team will observe and report on critical performance items including system alarms, calibration process, and temperature mapping. The items will be considered in approving the product for use in the blood banking laboratory.

San Diego Blood Bank

The purpose of the equipment we evaluated is solely for the storage of fresh platelets to be used for clinical transfusion.

SDBB was founded in December, 1950 and has been serving the San Diego community for 66 years.

SDBB is a community blood center which also caters to the needs of researchers in the southern California region. We have approximately 350 staff across all areas from donor recruitment, collection, component manufacturing, quality control, and immunohematology reference laboratory.

We collect and process approximately 1,600-1,800 units of whole blood and 500-600 units of single donor platelets per week. We currently have 8 larger incubators with 15 large agitators in our QC laboratory and our Hospital Services (distribution) department.

Our blood bank has a total capacity to hold 640 single donor platelet products.

The incubators in our QC Laboratory are used to store the collected platelet units while they are processed to determine platelet yield, leukoreduction is confirmed and bacterial testing is performed.

Our customer hospitals are in San Diego County, Orange County and LA County.

We have many years of running history with the equipment obtained from our current vendors, and we are fully aware of their strong points and weaknesses.

As a progressive minded blood center, we are always open to new technologies, especially if there are new features which bring additional benefits and value.

As the need arises to grow platelet storage capacity or replace older or failed units, we need alternatives that bring new benefits that will, in effect, pay for themselves with a good return on investment.

Smaller Boekel units also have a unique possibility for use on our mobile units that do platelet collections, with two significant benefits of lighter weight and much less power draw.

The Boekel technology should demonstrate an obvious electrical power savings. We would like to suggest the use of power monitors to do a direct comparison over time, to get a better estimate of power consumption. It is completely logical that these solid state, Peltier heating and cooling systems, minus the usual less efficient mechanical systems, should be more energy efficient.

Blood centers today, are much more likely to have reduced funds for capital equipment purchases, and may need to rely more on financing purchases or leasing options. Also, this is all the more reason that it is likely to be required by senior management to show a good return on investment (data not available).

Materials and Methods

There are currently two sizes of Platelet Incubator and Agitators available from the potential new supplier. The Small Incubator and Agitator has 6 shelves and can accommodate 6-12 apheresis or 18 random donor bags. The Large Incubator and Agitator has 8 shelves and can accommodate 8 – 16 apheresis or 48 random donor bags. We decided to evaluate the Larger Incubator as the size is better suited our operations.

The equipment was validated by our Equipment Management department Biomedical Engineer, a Laboratory Technologist and our Development and Research Services Manager, who have decades of experience working with blood banking equipment.

In addition to Equipment Management/Biomedical Engineering and Laboratory resources, the Regulatory and Quality Assurance department, Chief Medical Officer or Medical Director, and CEO are also involved in the reviews and approvals the validation plan both prior to execution of the validation and after the validation tasks have been completed.

Our Manager of Equipment Management is a Mechanical Engineer. Our Development and Research Services Manager is a certified Medical Laboratory Scientist and MBA. Our Lab Techs are California licensed Clinical Laboratory Scientists and Techs with various degrees in related sciences such as Biology, Chemistry, Physics and Microbiology, etc.

The equipment needed to validate incubators and agitators:

- NIST calibrated-traceable timer/stopwatch
- NIST calibrated-traceable digital thermometer
- NIST calibrated-traceable digital data loggers with thermocouples

The processes used are approved cGMP Validation plans, for which the plan templates are pre-approved, and the executed completed plans are reviewed and approved by our Director of Laboratories, VP of Regulatory/Quality, Chief Medical Officer, and Chief Executive Officer.

Platelet Agitator Manufacturers Model Number 301300

Electrical	115V, 1 Phase, 50/60Hz
Operating Range	±10% of rated voltage
Speed	60rpm
Capacity	8 Shelves / 8 - 16 Apheresis
Alarm	Yes
Shelves	15" W x 14.25" D x 1.25" H (between shelves)
Product Dimensions	18.5" W x 16.5" D x 17.5" H
Shipping Weight	45 lbs

Product Details

Platelet Incubator Manufacturers Model Number 301650

Electrical	115V, 1 Phase, 50/60Hz
Temperature Range	20°C - 24°C
Alarms	Door, Printer, Inventory, Low Temperature, High Temperature, Agitator
Printer	50mm thermal printer
Temperature Control Method	Thermoelectric
Inventory Management System	Time Based
Operation Temperature Range	16°C - 28°C Ambient
Temperature Accuracy	±0.5°C between 20°C and 24°C
Temperature Setting	20°C - 24°C (22.0°C default temperature)
Connectivity	USB, Ethernet, RS485
Product Dimensions	25.3" W x 26.5" D x 30.0" H
Interior Dimensions	20.75" W x 17.25" D x 19.5" H
Interior Light	Yes, 6" LED strip
Shipping Weight	67 lbs

Discussion Section

Installation was performed primarily by a Boekel representative. Laboratory and/or Facilities Management should plan accordingly to have an adequate sized space, electrical power, placement determined with lean process flow in mind, no interference with air flow or other devices, opening doors, cabinets, etc.

Qualification is performed via cGMP, per an approved Validation Plan including an Installation Qualification (IQ), Operational Qualification (OQ) and a Products/Process Validation (PQ), followed by multiple senior management and regulatory reviews.

Operation is simple and user friendly. End user must determine what features are needed and ultimately to be used in their unique processes.

We found it was necessary to first calibrate the on-board temperature monitoring sensor prior to temperature mapping. This was a relatively simple but important task to perform.

Temperature Mapping should be performed using a 10 point mapping process with all areas top, bottom, front, back, left, right and center being represented plus a probe placed nearest to the on-board monitoring system probe. All probes must be NIST certified traceable.

Temperature regulation inside the incubator, with the agitator in operation, is a function of the heat output of the agitator. We found that the variation between coldest and warmest spots, was less than 1.5 ° C which allowed us to place the Rees external temperature monitoring probe anywhere inside the incubator based on ease of installation while avoiding interfering with access to place products. Otherwise the Rees probe would have been mounted closest to the warmest identified location.

Real World Performance will of course, depend upon the end user's physical facility in the area used for installation, their unique process flow and capacity limitations, including possible room HVAC limitations and availability of electrical power.

In addition to room or laboratory installations, we foresee possible mobile unit use, where the incubators and agitators could be installed on a bus or truck chassis based vehicle used for mobile blood collections.

Shelving Configuration appears to be optimal, but we would like to see larger/ longer incubators and agitators to allow for an increase in the number of platelet units that can be stored.

We appreciate having an optimally sized unit. Too large places too many platelet products at risk in case of failure, and too small creates limitations based upon room layout, counter top space, electrical power outlets and contributions to heat output and tasking of HVAC systems.

We found that Boekel incubators and agitators offer a number of novel features which may lend themselves well to an end users specific needs, whether it's just space utilization, protecting products from failures due to temperature excursions and power outages, improved process flow and product access, and improved point-of-use inventory management. The features lend themselves well to both larger and smaller operations. Hence, also the potential for use in mobile operations.

System Alarming Capability appears to be competitive and has many useful features which may or may not be utilized by the end user. Whether or not a feature is used may be determined by its impact on time utilization, process flow, access activity level, and use of external temperature and inventory monitoring systems which may already be in place, which is the case with our laboratories.

The Boekel Heating/Cooling Method, using solid state Peltier technology, is quite novel and in fact, addresses some of our most common points of failure, such as, frequency of failure, and operational costs and risk of product loss, by eliminating the most common mechanical components that are central to other incubator technologies currently available. Gone are evaporator coils, condenser coils, compressors, and environmentally unfriendly refrigeration system gases.

Integration - Process/System Changes that would be required to use the system would include facilities and space planning, addressing the potential impact on HVAC and electrical power, the ability to stack the units to make comparable use of the available space as is currently done by other vendor's technologies. Being smaller units would require additional electrical outlets and external centralized temperature monitoring cables and probes, and easy installation of these probes inside the incubator. A port for this purpose would be very helpful.

Due to the larger number of incubator units needed to gain comparable storage capacity, a larger number of device calibrations and validations, would have to be done. This would include an increased number of cables, and probes to be certified.

Energy Savings could be significant over time and an attempt to measure actual comparative electrical power usage should be made to allow for this factor to play a role in a return on investment calculation.

Pricing needs to be competitive, and needs to take into consideration any significant factor which can positively or negatively impact the ROI. Features and benefits add value and smaller units to achieve the same capacity detracts from the ROI

Service requirements such as lack of refrigeration maintenance is a major contributing factor to a positive return on investment calculation. Reduced energy consumption, maintenance costs, and service/repairs related costs, will pay a role in offsetting additional costs associated with need to purchase more devices to gain a comparable storage capacity.

It may be useful to develop one free-standing inventory management system that would

In comparison to competitor's systems, the obvious differences (features with benefits) are identified as relating to the fact that competitor's systems are "mechanical" in nature, requiring compressor, evaporator coils, and condenser coils, as components of traditional refrigeration systems. The Boekel does not utilize any of these components, which are often linked to the primary causes of failures and down time, as well as preventive maintenance.

communicate with and cover all of the incubators in a physical area or department in place of each incubator having its own system.

Incubators with traditional mechanical refrigeration systems, tend to begin to fail as soon as just after the 1st year. Mean Time Between Failures (MTBF) and overall reliability of these traditional mechanical systems has not been favorable.

With regard to other electronic inventory management related features, we feel the Boekel system is comparable and competitive overall.

The agitator with its elliptical-like movement pattern, we feel provides a superior mixing capability, and may prove to be more reliable over time, with less wear related failures and maintenance.

Recommendation Summary

As a blood center that manufactures a large number of platelet products for transfusion, and given the relatively large number of incubators and agitators used, the features and benefits that address the most "pain points" from an end user's perspective, is the vastly different mechanisms of traditional mechanical refrigeration vs Peltier based systems.

Our facilities / plant operations and equipment management teams are excited that we finally have a way to address / prevent the refrigeration system and maintenance related issues and associated costs. We feel there is a significant reduction in risk of product loss with the Boekel system.

We would always acquire the Boekel incubator together with the agitator, as this is the best combination to have, and validate together, as is the intention of the engineers that developed the devices.