PATH

STRENGTHENING HUMAN MILK BANKING:

A Resource Toolkit for Establishing & Integrating Human Milk Bank Programs

Establishing Quality Assurance: An Audit Template

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Starting every life with mothers' milk

STRENGTHENING HUMAN MILK BANKING:
A Resource Toolkit for Establishing & Integrating Human Milk Bank Programs

This toolkit was developed as a comprehensive set of templates, standards, and tools to guide critical steps for establishing human milk banking as an integrated component within breastfeeding support and neonatal care, with in-depth focus on readiness, quality assurance, operations, auditing, training, monitoring and evaluation, and communications. These resources are freely available, globally accessible, and should be adapted to the local context to maximize effectiveness.

PHOTOS: *Cover (left to right): Northwest Mothers Milk Bank; Brazilian National Network of Human Milk Banks; Laerdal Global Health; Back cover (left to right): United States Breastfeeding Committee; Mothers' Milk Bank Austin, Texas; Northwest Mothers Milk Bank.*

PATH CONTACT:
Kiersten Israel-Ballard, DrPH
Associate Director, Maternal, Newborn, and Child Health and Nutrition
Kisrael-ballard@path.org; info@path.org. 1.206.285.3500

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ABBREVIATIONS

CAPA *corrective and preventative actions*

CFU *colony forming unit*

DHM *donor human milk*

HACCP *hazard analysis and critical control points*

HBV *hepatitis B*

HCV *hepatitis C*

HIV *human immunodeficiency virus*

HMB *human milk bank*

HTLV *human T-lymphotropic virus*

HTST *high-temperature short-time*

LTLT *low-temperature long-time*

MOM *mother's own milk*

SOP *standard operating procedure*

Contents

Photo: Northwest Mothers Milk Bank

OBJECTIVES OF THIS TEMPLATE

Use of this template will enable HMBs:

- To increase their understanding of differences and similarities in standard operating procedures (SOPs) present in many human milk banks (HMBs) around the world.
- To increase their awareness of the need for both internal and external auditing.
- To self-evaluate their HMB's quality control systems and SOPs.
- To recognize potential gaps in their HMB's SOPs.
- To identify areas to improve upon site-specific guidelines to ensure the safety and quality of donor human milk.

ABOUT THIS TEMPLATE

This template was developed to help human milk banks (HMBs) self-evaluate their standard operating procedures (SOPs), staffing, equipment, and infrastructure. This quality assurance template covers SOPs present in HMBs and can be utilized by all developing and existing HMBs.

This template covers the entire milk banking process from donor recruitment, donor screening, milk expression, milk handling, milk processing, and allocation to recipient prioritization and staff training. Staffing, infrastructure, equipment, record keeping, and documentation recommendations are also presented.

Every HMB carries out numerous and complex processes. HMBs must align with the resources and needs of their community, and each country should decide how to best utilize available resources to help guarantee the safety and quality of their donor human milk (DHM). Accordingly, specific protocols in HMBs can vary due to the diversity of resources, disease risks, and cultures. International human milk banking guidelines that outline precise operating processes and requirements present in every milk bank are thus neither feasible nor appropriate. The guidelines presented in this template are based on SOPs from many milk banks globally.

This template was developed to help HMBs identify differences and possible gaps in their SOPs, with the ultimate goal of improving and protecting the quality and safety of the DHM they produce. This template creates a starting point for HMBs to evaluate their own procedures and raises awareness that milk banks need to evaluate their procedures and facility, requiring both internal and external auditing. As such, HMBs must have written SOPs

and facility manuals, formal training on SOPs, and record keeping instructions, based on established quality and management systems, in place to properly utilize this template and perform an audit. There is currently no international organization, and often countries do not have national organizations, to enforce external or internal audits. External audits are more feasible in countries with the resources for enforcement, such as in countries where HMBs are authorized and monitored by the ministry of health. Ideally, both external and internal audits are conducted on a regular basis to identify problems before milk safety and quality is affected.

This template can be used to help guide changes in SOPs, but it does not provide a specific or step-by-step prescription on how to improve SOPs as there can be many reasons for variations. If your HMB's process steps do not align with the SOPs presented, we recommend using your national guidelines on human milk banking and the resources listed in PATH's *Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Global Implementation Framework* to help improve and protect the quality and safety of the DHM your facility produces.

This template **WILL**:

- Provide a starting point for HMBs to self-evaluate their operating procedures.
- Guide HMBs in self-evaluating their SOPs.
- Help HMBs identify gaps in their SOPs.
- Help outline SOPs present in many HMBs.

This template **WILL NOT**:

- Provide mandatory international guidelines for SOPs.
- Provide a comprehensive list of guidelines for every HMB.
- Evaluate the compliance or grade the performance of HMBs based on specific requirements.
- Provide specific instructions on how to improve upon site-specific guidelines.

AN AUDIT TEMPLATE

Photo: Cheshire and North Wales Human Milk Bank

Photo: Brazilian National Network of Human Milk Banks

HOW TO USE THIS TEMPLATE

An audit is a series of simple and direct questions which, when answered, confirm if an HMB is correctly carrying out SOPs, activities, and policies. An audit is a means of continuous assessment and improvement by evaluating facility performance, and triggering and prioritizing an improvement process.

Audits may be performed internally and voluntarily or forced upon facilities through legally required external audits and inspections.[1] Regular audits should be conducted following an established procedure to ensure compliance and implementation of quality management systems.[2] Audits must be conducted by trained individuals and should cover all parts of the milk banking operation, including record keeping. Audits must be performed according to a formally approved system that evaluates compliance with internal regulations and guidelines as well as applicable regional requirements.[2] To secure resources and facilitate learning of HMB staff and lasting change throughout departments, audits must address and involve senior managers.[1]

INSTRUCTIONS

1 WHO COMPLETES THIS TEMPLATE?

Two or more individuals who are knowledgeable about the SOPs and processes in the HMBs should complete this audit template. Challenges in auditing can arise where the ministry of health or quality control staff in local governments are not knowledgeable in HMB practices, and staff within the milk bank do not have the time or motivation to complete an internal audit where it is not enforced. Qualifications of internal and external auditors are determined by local, regional, and national guidelines.

⏩ *Internal audit:* Separating the audit process into HMB sections will decrease the time commitment required for each person completing the audit and will help ensure an individual knowledgeable about the activities of the section completes the audit. Individual departments can then submit the internal audit of their section to an HMB manager. Official inspections conducted by national authorities checking for compliance with national standards cannot be substituted with internal audits.[2]

⏩ *External audit:* An independent assessor who is knowledgeable about HMB processes must conduct external audits. External audits may be under the responsibility of the local ministry of health, which checks compliance with national regulations. Ministries of health can support the formation of a committee of HMB experts or contract an independent agency to perform external auditing.

2 HOW OFTEN SHOULD THIS TEMPLATE BE COMPLETED?

To properly monitor compliance with a quality management system, regular audits should be conducted following an established procedure and quality management system.

⏩ *Internal audit:* Internal auditing should be a continuous process where corrective and preventive actions are taken. Frequency of internal auditing depends on the results of a risk assessment. Newer HMBs or those with identified quality and safety failures must conduct internal audits more frequently and must repeat audits when corrective and preventive actions are taken. Formal recording of internal auditing should occur as a minimum on a quarterly basis but may be more frequent.

⏩ *External audit:* External audits should be conducted on an annual basis or as required by the ministry of health.

3 HOW SHOULD THIS TEMPLATE BE COMPLETED?

This template is intended to be as comprehensive as possible; however the diversity of resources, disease risks, and cultures, and absence of universal human milk banking guidelines, do not make it feasible to include procedures

and processes present in every HMB. This template is thus intended to be customizable and adaptable, and space is provided for HMBs to list guidelines appropriate for their country. Facilities are encouraged to adapt this template throughout the auditing process to meet the needs of their HMB.

MODIFY

- Text highlighted in **blue** is provided for your instruction and will prompt you to insert additional information specific to your HMB and regional policies and guidelines. This text must be altered to finalize the audit template.

- The presence or absence of the listed staff, infrastructure, procedures, and processes should be designated with a "yes," "no," or "not applicable" in the column labeled *Aligns*.

- In the column labeled *Deviations*, each recommendation that does not align with the practices of the HMB should be designated with a "C" if it is a critical deviation or "NC" if it is a non-critical deviation. Immediate action must be taken on deviations labeled as critical.
    - As part of a comprehensive corrective and preventative actions (CAPA) system, once a deviation from the recommendations is detected, the non-conformance must be evaluated to determine its root cause and potential impact on the DHM recipient. CAPA is a system for applying corrective and preventative actions to prevent the reoccurrence or possible occurrence of non-conformities found during audits and other investigations of product quality. Deviations can be labeled as critical or non-critical. *Critical* deviations are those that have a significant risk of creating a product that is harmful. A deviation should be designated as critical if it frequency occurs or significantly deviates from the recommendation and has a high impact on patient safety. *Non-critical* deviations may affect a quality attribute, a process parameter, or equipment critical for processing, but are unlikely to impact the DHM recipient and create a risk.

- The root cause of the deviation and the designated CAPA plan should be described in the column labeled *Actions Items*.
    - After assessing the risk of each deviation, all possible causes of the non-alignment must be investigated to determine the root cause of the issue. Once the root cause of the deviation is determined, the CAPA plan is developed. As appropriate, a CAPA plan should include: all action items needed to correct the deviation, time plan for the completion of each action, detailed revisions to the facility's procedural documents explaining how to correctly carry out procedures and what to expect when procedures are completed, staff training of revised SOPs, and appropriate monitoring procedures.

- The resources, tools, and information provided in PATH's *Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Global Implementation Framework* can assist your HMB in the process of implementing action items and provide information to help increase the safety and quality of your DHM.

4 AFTER CORRECTIVE AND PREVENTATIVE ACTION IS TAKEN:

Verification of corrective and preventative actions must be documented in the *Verification* column of the table.

- Once corrective and preventative actions are implemented, your facility must verify the effectiveness of the action taken. This verification should determine if the root cause of the deviation is corrected. Your facility should also verify that proper controls are in place, all defined actions are fully implemented, no adverse effects have resulted from the action taken, staff have been properly trained in carrying out new procedures, and all actions and changes to SOPs are documented.

- All results of internal and external audits must be documented and reported for safety and quality management.

Photo: Cheshire and North Wales Human Milk Bank

SECTION A:
STAFF, FACILITY, AND EQUIPMENT QUALITY ASSURANCE

Establishing a solid foundation of personnel, facilities, and equipment is critical for ensuring a properly functioning human milk bank (HMB) system. The items listed below are recommendations for ensuring a robust and effective HMB foundation. Some items are listed as optional as they are not commonly found in HMB guidelines or are not critical to the safety of producing donor human milk (DHM).

Staff and Infrastructure	Aligns (Y/N/S) (Yes/No/Not applicable)	Deviation (C/NC) (Critical/ Non-critical)	Action Items	Verification
Staff				
▸ The HMB has a dedicated leader or champion who can promote the HMB and breastfeeding while also providing clinical and operational expertise .				
▸ The HMB has an adequate amount of dedicated staff time to operate effectively—including maintenance of space and equipment.				
▸ The HMB team consists of representatives from a range of disciplines including microbiology, lactation and nutrition support, medicine/neonatology/pediatrics, infection control, management/ administration, and community relations.				
Facility				
▸ The facility provides sufficient space for equipment and storage of materials to ensure milk can be processed in a sanitary environment.				
▸ The facility has clear demarcation of zones and access control to ensure movement of storage items and non-designated personnel do not impact the hygiene levels within the milk-handling areas.				
▸ The facility is free from pests, and there are effective preventative measures taken to prevent contamination by pests.				
▸ The facility floors, walls, and ceilings are constructed to withstand external pollution and facilitate adequate and easy cleaning.				
▸ The water supply is in compliance with local ordinances for potable water.				

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Staff and Infrastructure	Aligns (Y/N/S) (Yes/No/Not applicable)	Deviation (C/NC) (Critical/ Non-critical)	Action Items	Verification
▸ The facility has adequate air ventilation. The facility room for milk processing has room temperature control (18–22°C).				
Equipment				
▸ Inspection/servicing of equipment used in DHM handling and processing occurs at least annually.				
▸ The equipment used in DHM handling and processing is cleaned, sterilized, and calibrated according to manufacturers' instructions. Frequency of cleaning can depend on type of equipment and external factors such as water quality.				
▸ All equipment that affects temperature levels has a sensor and alarm.				
▸ The following pieces of equipment owned by the HMB and are used in accordance with manufacturers' instructions and cleaning and maintenance records are kept.				
• Milk expression equipment:				
o Food-grade milk storage containers: can be reusable or single-use containers made from plastic, glass, or stainless steel.				
o Cleaning manual and logbook.				
• Microbial screening equipment:				
o Microscope.				
o Inspection manual.				
o Inspection logbook.				
o Incubator.				
o Autoclave.				
o Refrigerator.				
o Bio-safety cabinet.				
o Bunsen burner.				

Staff and Infrastructure	Aligns (Y/N/S) (Yes/No/Not applicable)	Deviation (C/NC) (Critical/ Non-critical)	Action Items	Verification
o Counter for culture.				
• Processing and treatment equipment:				
o For Holder method pasteurizer: pasteurizer, power connection, water connection and pipes, baskets, and drainage.				
o For high-temperature short-time pasteurization (HTST): HTST pasteurizer, power connection, water connection and pipes, baskets, and drainage.				
o For flash heating pasteurizer: stove, pot, stand, FoneAstra, phone, water basin, thermometer, and frozen packs. **NOTE:** *Equipment for pasteurization can vary.* List necessary equipment according to manufacturers' instructions.				
o Cleaning manual and logbook.				
o Water bath.				
o Autoclave.				
• Storage equipment:				
o Refrigerator with thermometer with automatic temperature tracing.				
o Freezer with thermometer with automatic temperature tracing.				
o Refrigerator and freezer connected to emergency generator.				
o Food-grade milk storage containers: can be reusable or single-use containers made from plastic, glass, or stainless steel.				
o Traceable milk labels that distinguish between different stages of DHM processing.				

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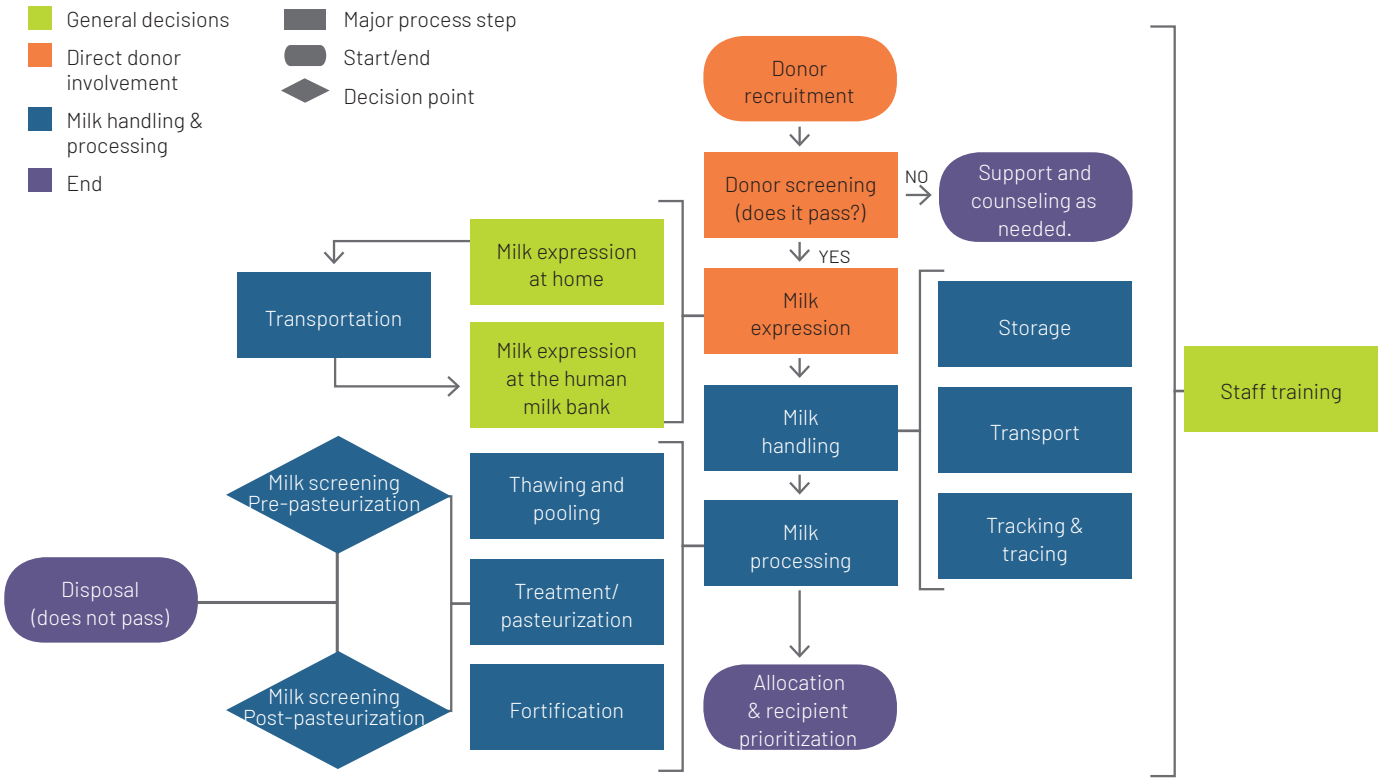
Staff and Infrastructure	Aligns (Y/N/S) (Yes/No/Not applicable)	Deviation (C/NC) (Critical/ Non-critical)	Action Items	Verification
o Calibrated temperature recorder to check the temperatures used in the freezers, fridges, and pasteurizer.				
• Administrative equipment:				
o Communications equipment (computer and/or phone).				
o Printer.				
o Storage equipment for quality control records.				
• Equipment for maintaining a hygienic environment:				
o Separate sinks with clean, running water that meets local standards for handwashing and cleaning equipment.				
o Handwash soap/disinfectant and disposable towels for use in hospitals.				
o Disposable hand towels or sterilized towels.				
o Pedal trash cans.				
o Hairnets, masks, and protective garments for body and shoes.				
o Powder-free gloves.				
• Optional equipment:				
o Breast pumps (electrical or manual) including disposable or re-sterilizable personal expressing sets.				
o Milk analyzer.				
o Homogenizer.				
o Laminar hood cabinet.				
o Dishwasher.				
o Clothes washer.				

SECTION B:
PROCESS STEP QUALITY ASSURANCE

Numerous operational processes are required to provide safe and high quality DHM. These standards of practice must be determined by each HMB to appropriately meet the local context. The process steps listed in the following quality assessment are recommendations for ensuring safe and high quality DHM. Figure 1 represents a flow chart of these processes. Some processes are listed as optional as they are not commonly found in HMB guidelines or are not critical to the safety of producing DHM.

Figure 1. Flow diagram of process practices in human milk banking.



Process step 1. Donor recruitment

Key objectives:

- A variety of promotional methods are utilized to recruit as many potential milk donors as necessary to meet the area's DHM needs.
- Promotional methods target suitable sources of DHM.
- Nontechnical language is used in the promotion of DHM and activities.
- Promotional methods can target the facility and the community.

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
▸ There is ongoing breastfeeding education and motivation during antenatal care.				
▸ There is ongoing breastfeeding education and motivation during postnatal care to ensure mother is expressing sufficient milk for her infant.				
MODIFY ▸ Active recruitment programs are needed to maintain DHM supplies by providing a continuous supply of new milk donors. Local guidelines, culture, and resources dictate the channels used to recruit donors, including:				
• Pamphlets and flyers to be left in antenatal clinics and postnatal wards; maternity and childbirth centers; children's and maternity shops; childcare centers; and organized community events for infants and their caregivers.				
• Direct referrals and recommendations from current and previous donors; staff at neonatal units; pediatricians; healthcare professionals providing postpartum care; childbirth educators; organizers and attendees of prenatal and postnatal classes; breastfeeding mothers support groups and organizations; and high-visibility advocates.				
• Media (e.g., TV, radio, newspapers, magazine articles, and social media).				
▸ Recruitment materials include step 1 screening questions to permit self-screening by interested milk donors.				
▸ All recruitment materials and messages are clear, easy to read, and suitable for all reading levels, avoiding technical language.				
▸ All recruitment materials emphasize the importance of breastfeeding.				
▸ All recruitment materials provide information on lactation support services.				

Process step 2a. Donor screening and selection

Key objectives:

- Follow an HMB-approved and guided screening process when recruiting donors involving oral and written screening and a serologic blood test for infectious disease.
- An HMB's decision to screen for an infectious disease is based on several different areas including local prevalence, national screening recommendations, and availability of effective treatment, testing, and prevention programs.

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
▸ The reasons for screening and testing are explained to all interested donor.				
▸ Interested donors are advised that, depending on their answers to any of these questions, they may not be eligible to donate milk, but her own milk is still safe for her own infant and they should continue to breastfeed.				
▸ If a potential donor is donating previously expressed breast milk, she is asked to answer the screening questions for the period when the milk was expressed.				
▸ A telephone, email, or in-person screening interview is conducted at a mutually acceptable time and place.				
• Stage 1 interview questions exclude an interested donors if: **Note:** *Guidelines for stage 1 screening questions can vary according to local resources, disease risks, and cultures.*				
o She is a smoker, using nicotine replacement therapy, or exposed to sustained levels of passive smoke.				
MODIFY o Local guidelines dictate limits for alcohol intake. The American Academy of Pediatrics recommends limiting alcohol intake to 0.5 g per kg body weight (for a 60 kg mother this is approximately 2 oz liquor, 8 oz wine, or 2 beers).[3]				

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Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
MODIFY o Local guidelines dictate limits for recreational or habit-forming drugs. (HMB guidelines for the France, Italy, North America, Norway, Sweden, and the United Kingdom recommend excluding donors for recreational drug use).[4-8]				
o She has previously tested positive for HIV, hepatitis B (HBV) or C (HCV), human T-lymphotropic virus (HTLV) type I or II, or syphilis.				
o She is at increased risk of Creutzfeldt-Jakob disease.				
o She has had a sexual partner in the past 12 months who is suffering from/at risk for HBV, HCV, HIV and venereal diseases or she has high-risk behavior for contracting these diseases.				
• If YES is answered to any of these questions, the interested donor is advised that she is not eligible to donate milk.				
• Women who are ineligible to donate milk are counseled and provided support services to ensure they continue breastfeeding their own infants.				
• If NO is answered to all these questions, a stage 2 interview and serological testing is conducted. Information obtained from stage 2 interview questions is used to make a balanced decision about the interested donor's eligibility to donate based on possible risks to recipients and/or the results of subsequent serological testing. Stage 2 interview questions determine the health of the potential donor and her infant.				
• Stage 2 interview questions are used to temporarily defer interested donors if: **Note:** *Guidelines for stage 2 screening questions can vary according to local resources, disease risks, and cultures.*				

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
• She has a localized breast disease such as infective or non-infective mastitis or candida.				
• Donation would compromise the satiety of her own infant.				
• She has poor nutritional intake.				
• She is receiving medication or a medical intervention that is contraindicated during breastfeeding, including antidepressants, cytotoxic medication, pharmacologically active herbal products, and exposure to diagnostic radioactive isotopes.				
• She has had a significant environmental or chemical exposure (for example, heavy metal contamination of the local water supply or chemical exposure) that can be expressed in breast milk.				
• She has received recent vaccination with live attenuated virus, such as rubella, measles, or mumps.				
MODIFY o Local guidelines dictate the need to temporarily exclude potential donors on vegetarian/vegan diets (without supplementation of vitamin B12).				
MODIFY o Local resources and disease risks dictate the amount of time a woman must abstain from donation if she has high risk behavior including: recent tattoo or body piercing, acupuncture, IV drug use, recipient of organ or tissue transplant, recipient of blood transfusion, and accidental needle sticks occurring in the medical field. (HMB guidelines for India recommend abstaining from donation for 12 months).				

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Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
MODIFY o Local resources, stock levels, and guidelines dictate the maximum age of an infant before a mother is asked to stop donating. (HMB guidelines in the United Kingdom recommend asking mothers to stop donation when their infant is 12 months old).				
• The following optional tests or screening tools can also be used when evaluating and selecting potential donors: **Note:** *Guidelines for tests and screening tools can vary according to local resources, disease risks, and cultures.*				
o Physical examination.				
o Medical records.				
o Visit to potential donor's home.				
MODIFY o Local disease risk for tuberculosis dictates the need for chest radiograph, purified protein derivative, or tine test for tuberculosis.				
MODIFY o Local guidelines dictate the need to conduct all serological testing upon enrollment. (HMB guidelines in Brazil permit the use of antenatal testing as a substitute for additional testing upon enrollment.)[4]				
• Serological testing is conducted for: **Note:** *Guidelines for serological screening can vary according to local resources, disease risks, and cultures.*				
o HIV 1 and 2.				
o Hepatitis B and C.				
o HTLV I and II.				
o Syphilis.				

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
o A positive test during serological screening excludes donation. All tests are undertaken in laboratories with appropriate accreditation.				
o Serological test results are given to potential donor either in person or by telephone.				
MODIFY o If a woman continues to donate, local resources and disease risk dictate the frequency of repeated blood testing.				
• All screening results from donors are archived.				

Process step 2b. Donor consent

Key objectives:

- HMB obtains written informed consent from each donor.

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
▸ Consent is obtained from all potential donors for both serological testing and the process of handling donor's milk.				
▸ Consent forms are stored to provide proof of the donor's agreement to donate.				
▸ Consent is obtained from all potential donors for intended use of the donated milk.				
MODIFY ▸ Local guidelines determine the need for consent from the donor's physician or the physician of the baby. (HMB guidelines for North America require a statement of health from donor's physician and by donor's child's physician).[5]				

Process step 2c. Donor education

Key objectives:

- Provide all donors with lactation support and education about the expression of milk, including how to hygienically use and clean a manual or automatic breast pump and accessories.

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
MODIFY - Local resources dictate the level of education provided to donors. Education is optimally performed face-to-face, but is also provided to the donor by telephone and in writing. Education is conducted at a time and place suitable for both donor and trainer.				
- Donor education includes:				
• Support on breastfeeding infant and/or maintaining milk supply.				
• Emotional support for all mothers, including those who have recently lost an infant.				
• Support on meeting HMB requirements for donor's diet, including food safety and alcohol limitation.				
• Facility ensures that the donor understands the responsibility to maintain the safety and quality of the milk she donates.				
• All educational materials and messages are clear, easy to read, and suitable for all reading levels, avoiding technical language.				
- Additional support and education on milk collection is provided to donors whose milk has significant or repeated microbial contamination.				
- Donors are advised to contact the HMB for discussion of suspension or discontinuation of milk donation if:				
• Donor develops a fever or comes in contact with a viral disease.				
• Donor begins taking a new medication.				
• Donor develops an infection or lesion on the breast (including herpes or mastitis).				
• Donor is accidentally stuck with a needle.				

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
MODIFY ▸ Based on local protocols and resources, additional assistance and support is offered, including information on counseling and local support groups to all potential donors.				
▸ Based on individual needs, all donors are provided with ongoing support and assistance.				

Process step 2d. Donor approval

Key objectives:

- There are no current international standards for the screening and approval of human milk donors.
- The aim of donor selection and approval is to minimize infection risk, and bacterial contamination of the milk and, therefore, relative risk for the baby.

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
▸ Donor selection and approval is contingent on answers to interview questions, serological screening, and other screening tools and tests.				
▸ Donor approval is contingent upon donor consent and donor education and training.				
▸ There is suspension or discontinuation of milk from donors who, after further education and support, consistently supply milk that does not meet microbiological criteria, or supply small amounts of milk.				

Process step 3a. Milk expression at home and HMB/health facility

Key objectives:

- Expression requires a temperature-controlled supply chain during storage and transportation.
- Donor and staff education must be ongoing to maintain the highest level of quality control at all stages of milk handling and storage.

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
MODIFY Guidelines for maintaining the highest level of quality control at all stages of milk handling at home include ongoing donor and staff education on:				
• Maintaining hygiene and handwashing prior to milk expression.				
• Avoiding skin products unsuitable for ingestion that may contaminate the milk.				
• Collecting expressed milk rather than drip milk.				
• Using a breast pump and containers that are disinfected/ cleaned and stored dry after use.				
• Preventing foreign body contamination.				
MODIFY Local guidelines dictate policies and procedures for adding freshly expressed milk into containers with already frozen milk. (HMB guidelines for France, India, and Italy recommend not adding freshly expressed milk to already frozen milk.)[7,8]				
• Storing milk in acceptable food-grade plastic, glass, or stainless steel containers preferably supplied by the HMB.				
• Storing and sealing milk with airtight lids according to the HMB instructions.				
• Labeling or coding all expressed milk with donor's name and date of expression.				
• Unless DHM will be used within the same day, immediately storing milk expressed at the HMB in a freezer.				

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
▸ Expressed milk that is initially placed in the refrigerator is frozen within 24 hours. **Note:** *Guidelines for milk storage can vary according to local resources.*				
▸ Donors should have additional education on:				
• Storing milk in the coldest part of the freezer (usually in the lower part to the rear of the freezer).				
• Regular communication with the local HMB about schedule of fresh milk delivery/pick up to the HMB.				
• **MODIFY** Local resources and guidelines dictate the maximum temperature of domestic freezers used to store freshly expressed milk at home. (HMB guidelines in the United Kingdom recommend maintaining domestic freezers at -18°C or lower.)[6]				
• **MODIFY** Local guidelines dictate the maximum time expressed frozen milk can be stored in a domestic freezer before donation to the HMB. (HMB guidelines for Norway, Switzerland, and the United Kingdom specify three months as the maximum storage time before donation and transportation to HMB.)[4,6] **Note:** *Guidelines for milk transportation can vary according to local resources.*				
• Donors check and document their freezer temperature every day and are provided a thermometer when needed. (Optional)				

Process step 3b. Transportation (home to HMB/health facility)

Key objectives:

- Appropriate refrigeration or freezing temperature is maintained throughout the transportation process.
- Milk should be refrigerated or placed in a freezer as soon as possible after being expressed, and milk kept at room temperature for more than six hours is not accepted for donation.

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
▸ The HMB has a specific procedure for maintaining cold chain as milk is transported from home to the HMB. Procedures maintain the quality of the milk and permit tracking and tracing of samples.				
▸ To ensure DHM remains frozen:				
• Transport milk in secure containers and packaging that is tamper-evident.				
• Transport milk in an insulated and ridged cooler that can be cleaned.				
▸ Tightly package milk in cooler designed to maintain cold chain and minimize free air space.				
▸ Maintain records of collection, journey time to the HMB, and transportation conditions of the milk.				
▸ Develop a documented agreement of the conditions needed for safe transportation if a contracted third party is used for transportation.				
▸ To maintain cold chain, donors have ongoing training on storage and freezing prior to transport.				

Process step 4a. Milk handling: storage

Key objectives:

- HMB has a written SOP detailing quality control procedures for milk storage.

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
▸ Freezer temperature at the HMB is maintained at or lower than -20°C.				
▸ Refrigerator temperature at the HMB is maintained between +2 and +8°C.				
▸ Once received by the HMB, DHM is checked to ensure:				
• It is still frozen.				
• The container has not been damaged during transportation.				
▸ Transfer milk coming to the HMB to the freezer as soon as possible.				
▸ Milk should be stored separately under the following categories: incoming raw milk, screened raw milk, heat-treated milk, and milk released for distribution (after microbiological testing).				
▸ DHM received from a donor who does not meet selection criteria is discarded immediately.				
▸ DHM received from a donor who has not yet met all criteria is isolated from all other milk.				

Process step 4b. Milk handling: transportation

Key objectives:

- HMB has a written SOP detailing the quality control procedures for safe milk transportation.
- HMB maintains records of milk transportation.

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
▸ HMB has a specific procedure for maintaining cold chain as milk is transported throughout the HMB or health facility. Procedures maintain the quality of the milk and permit tracking and tracing of samples.				
▸ When transporting milk, ensure it is in secure containers.				
▸ Maintain detailed records of milk collection, inventory, and distribution to and throughout the HMB.				

Process step 4c. Milk handling: tracking and tracing

Key objectives:

- HMB has a written SOP detailing the procedures for maintaining detailed records to facilitate tracking and tracing.
- All DHM is labeled.
- HMB maintains electronic records on each batch of DHM.

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
▸ DHM is always handled and processed hygienically including:				
• Handwashing with soap and water before handling DHM.				
• Wearing protective garments including hairnets and gloves when handling DHM, especially with open containers.				
▸ All donated milk is handled and processed in hygienic conditions (e.g., cleaned surfaces, adequate air ventilation, free of pests).				

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
▸ DHM is disposed of when it is exposed to excessive temperatures during transportation or handling or improperly handled during transportation or processing.				
▸ Keep detailed records of DHM from donor to recipient or receiving hospital/clinic ward to facilitate tracking and tracing.				
▸ Receiving hospital takes responsibility to complete tracking of the milk to recipient.				
▸ When DHM is expressed at home, the donor is trained on labeling of milk with donor's name, ID, and date of expression.				
▸ Upon arrival at the HMB, all milk is given new label containing:				
• Donor's name and identification number.				
• **MODIFY** Date of expression and an expiration date, which is determined by local guidelines. (HMB guidelines for India and the United Kingdom recommend a maximum of six months after time of expression).[6,7] **Note:** *Guidelines for milk storage can vary according to local resources.*				
• Space for validation of pasteurization, if bottles are not relabeled after pasteurization.				
• Instructions to keep frozen.				
▸ Labels on DHM bottles are checked during all DHM handling and processing.				

SEE TOOL #5

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Guide for Track and Trace Documentation.

Process step 5a. Thawing and pooling

Key objectives:

- HMB has a written SOP detailing the quality control procedures of milk thawing and pooling.

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
▸ Methods of thawing milk include water bath, refrigerator, and room temperature.				
MODIFY ▸ Local resources can dictate the amount of time raw milk can be stored in a hospital-grade freezer before processing. (HMB guidelines for India, Italy, Switzerland, and the United Kingdom set a maximum of three months).[4,6-8]				
MODIFY ▸ Local resources can dictate the temperature and time limits for milk during thawing (HMB guidelines for India and the United Kingdom recommend that milk stays below 8°C for a maximum of 24 hours).[6,7]				
MODIFY ▸ Local resources can dictate the amount of time thawed milk can be stored in a refrigerator before processing. (HMB guidelines for India, Italy, North American, South Africa, and the United Kingdom recommend a maximum of 24 hours).[4-6,8]				
MODIFY ▸ Local resources and disease risk dictate the guidelines for pooling milk among different donors or batches. (HMB guidelines for Brazil, India, Italy, and North American permit pooling milk from different donors).[4,5,7]				
▸ Thawing and pooling process is closely monitored and recorded.				

Process step 5b. Milk screening

Key objectives:

- HMB has a written SOP detailing the quality control procedures for the screening of DHM.

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
▸ A sample of milk from every batch is tested pre-pasteurization for microbial content and possible contamination.				
MODIFY ▸ Pre-pasteurized milk is screened for total viable microbial content, Enterobacteriaceae, Staphylococcus aureus, and other pathogens and contaminants. **Note:** *Guidelines for pre-pasteurization milk screening can vary according to local resources and disease risks.*				
▸ All laboratories performing milk screening communicate test results and comment clearly for appropriate interpretation.				
MODIFY ▸ DHM is discarded when it exceeds the following microbiological content pre-pasteurization: **Note:** *Guidelines for microbiological content pre-pasteurization can vary according to local resources and disease risks.*				
• 10^5 colony-forming units (CFU)/mL for total viable microorganisms.				
• 10^4 CFU/mL for *Enterobacteriaceae.*				
• 10^4 CFU/mL for *Stapphylococcus aureus.*				
MODIFY ▸ Local resources dictate the level of post-pasteurization microbial screening. (Most countries require using microbiological cultures for post-pasteurization testing).[4]				

AN AUDIT TEMPLATE

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
MODIFY ▸ Local resources can dictate the frequency of post-pasteurization microbial testing (batch testing on a schedule or testing each sample). Testing schedule for pasteurized milk is based on the volume and throughput of milk. (HMB guidelines for Brazil, France, and North America require testing microbial content for every batch).[4,5,9]				
▸ Milk is tested for microbial contamination when there is a concern about any part of the procedure or when a new process, equipment, or staff member is introduced.				
MODIFY ▸ DHM with a total viable microbial count of 10 CFU/mL or more post-pasteurization is discarded. **Note:** *Guidelines for microbiological content pre-pasteurization can vary according to local resources and disease risks.*				
▸ To ensure the safety of DHM recipients, the entire batch of pasteurized milk is discarded if contamination is found.				
▸ DHM used during testing is discarded.				
▸ All laboratories performing milk screening communicate test results and comment clearly for appropriate interpretation.				

Process step 5c. Treatment/pasteurization (includes cooling)

Key objectives:

- HMB has a written SOP detailing the quality control procedures of milk pasteurization.
- HMB has a written SOP detailing the quality control procedures for milk cooling and storage post-pasteurization.

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
MODIFY ▸ Method of pasteurization (low-temperature long-time [LTLT] and HTST) varies between HMBs and is selected based on the financial, staffing, and energy resources of the HMB.				
▸ Post-pasteurization:				
MODIFY • Rapidly cool milk to 4°C using either processing equipment manufactured to cool milk or ice baths. Milk should fall from 62.5°C to 25°C within 10 minutes. **Note:** *Guidelines for milk storage can vary according to local resources.*				
• Move the remainder of the batch of milk to the freezer (–18°C or lower).				
MODIFY • Local resources dictate the length of time pasteurized milk can be stored in a freezer. (HMB guidelines for Brazil, India, Italy, Norway, and Sweden recommend discarding milk six months after the date of pasteurization).[4,7,8,10]				
▸ The lid of pasteurized milk is not opened unless it is to test the milk. One bottle of milk is removed each time post-pasteurization testing is conducted.				
▸ All pasteurization is temperature and time controlled.				

Process step 5d. Fortification

Key objectives:

- DHM fortification is based on the needs of the infant and not the responsibility of HMB staff.

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
▸ Need for fortification is determined by attending physician and clinical staff.				

Process step 5e. Disposal of milk

Key objectives:

- HMB has a written SOP detailing the quality control procedures for the disposal of contaminated milk.

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
▸ DHM that is not fit for human consumption is disposed of according to local disposal requirements (down the drain or treated as other clinical waste).				

Process step 6. Allocation and recipient prioritization (issuing of milk)

Key objectives:

- HMB has a written SOP detailing the quality control procedures for DHM allocated to recipients according to prioritization.
- Staff at the administering unit keeps a record of DHM usage.
- Staff at the administering unit has ongoing training on the correct handling and use of DHM.

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
▸ Prioritize using mother's own milk (MOM)—rather than DHM—when available and encourage breastfeeding. Provide mothers lactation support and resources as needed.				
▸ If the demand for DHM is greater than the supply, there is pre-planned and recorded criteria for prioritization.				
▸ Prioritize preterm newborns, low-birth weight newborns, infants with necrotizing enterocolitis, infants with infection, infants taking enteral nutrition, and infants without access to their MOM or when MOM is contraindicated (contraindicated medication, sickness, etc.)				
▸ DHM is only supplied to hospitals or neonatal units that agree to comply with all tracking and tracing procedures for milk, as described by the HMB.				
▸ DHM is used only after consent is provided from the infant's guardian.				
▸ For each bottle of DHM utilized, the administering unit keeps a record of:				
• How the DHM was used.				
• The recipient baby's name, medical record number, date of birth, and date administered.				
• The storage environments of the milk, including condition of sealed container and storage temperature.				
• The batch number of the milk and the date of use recorded in the patient's daily record.				

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
▸ Staff at the administering unit have ongoing training on the correct handling and use of DHM containers including:				
• Labeling of all stored milk.				
• Dispose of milk that is stored too long.				
• Hygienic handling of milk (e.g., handwashing).				
• Storage of milk.				

SEE TOOL #4

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Training Curriculum Template for Hospital and Human Milk Bank Staff, Appendix 2. Donor human milk decision tree.

Process step 7. Staff training

Key objectives:

- All staff has continuous and documented training.

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
▸ All staff (including volunteers as appropriate) have continuous and documented training on:				
• Donor screening.				
• Hygienic handling, storage, and transportation of milk. (Volunteers should be included in training as necessary.				
• Thawing, pooling, and pasteurization procedures for DHM.				

SEE TOOL #4

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Training Curriculum Template for Hospital and Human Milk Bank Staff.

Process step 8. Monitoring and auditing

Key objectives:

- HMB has a written SOP detailing method for monitoring processes, procedures, confidential records, infrastructure, equipment, and staff within the HMB.

Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
▸ SOPs are standardized, accessible to staff, and reviewed annually.				
▸ The HMB has an approved and regular method for monitoring and auditing:				
• Operational processes and procedures.				
• Confidential records.				
• Infrastructure.				
• Equipment.				
• Staff training.				
• Staff performance.				
▸ Internal auditing occurs bi-monthly or quarterly.				
▸ External auditing occurs annually.				
▸ Monitoring and record keeping of HMB activities is continuous.				
▸ Internal audits are performed by a trained HMB professional.				
▸ Certified auditor knowledgeable about HMB processes performs external audits.				
▸ Facility has Hazard Analysis and Critical Control Points (HACCP) certification and adheres to HACCP principles at all processes.				
MODIFY ▸ Local guidelines and resources dictate length of time records and raw data detailing the safety and quality of the DHM are maintained from the date of use, disposal, or expiration. (HMB guidelines for North America and Norway recommend maintaining records and raw data for 10 years.)[4,5]				

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Recommendations	Aligns (Y/N/S)	Deviation (C/NC)	Action Items	Verification
▸ For each batch of DHM, the following records are kept:				
• Information about donor:				
o Medical record number/donor ID.				
o Consent.				
o All relevant medical history.				
o All serological test results.				
• Information about each container before pasteurization:				
o Donor ID.				
o Testing log.				
• Information about each pasteurized container:				
o Samples in batch.				
o Testing log.				
o Details of pasteurization.				
o As appropriate, information about the disposal of DHM, or the hospital or neonatal unit receiving DHM.				
o All records are confidential and secured. Records that are discarded are destroyed securely.				

SEE TOOLS #2a and #2b

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—Establishing Quality Assurance: A Workshop for Developing a Hazard Analysis Critical Control Points Plan (Trainee Workbook) and *(Trainer Guide)*.

SEE TOOL #3

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Guide for Conducting Monitoring and Evaluation.

REFERENCES

[1.] Åsprang AF, Frich JC, Braut GS. Organizational impact of governmental audit of blood transfusion services in Norway: A qualitative study. *Transfusion and Apheresis Science*. 2015;53(2):228-232.

[2.] World Health Organization (WHO). WHO guidelines on good manufacturing practices for blood establishments. Genebra: WHO; 2011. *WHO Technical Report Series*. 961.

[3.] Eidelman AI, Schanler RJ, Johnston M, et al. Breastfeeding and the use of human milk. *Pediatrics*. 2012;129(3):e827-e841.

[4.] *PATH. Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Global Implementation Framework*. Version 2.0. Seattle, Washington, USA, PATH; 2019.

[5.] Human Milk Banking Association of North America (HMBANA). *Guidelines for the establishment and operation of a donor human milk bank*. Fort Worth, TX: HMBANA; 2015.

[6.] National Institute for Health and Clinical Excellence. *Donor Breast Milk Banks: The Operation of Donor Milk Bank Services*. London: National Institute for Health and Clinical Excellence; 2010.

[7.] Ministry of Health and Family Welfare Government of India. *National Guidelines on Lactation Management Centres in Public Health Facilities*. New Delhi, India; 2017.

[8.] Arslanoglu S, Bertino E, Tonetto P, et al. Guidelines for the establishment and operation of a donor human milk bank: Italian Association of Human Milk Banks. *Journal of Maternal-Fetal and Neonatal Medicine*. 2010;23(S2):1-20.

[9.] Legifrance. *Decision of 3 December 2007 defining the rules of good practice provided for in paragraph 3 of Article L. 23231 of the Public Health Code*. 2007.

[10.] Neonatal Care Working Group. *Guidelines for breast milk management in neonatal-care in Sweden*. 2016.

APPENDIX 1.
VERIFICATION PROTOCOL FOR A HOLDER PASTEURIZATION DEVICE

Contents

ABBREVIATIONS

DHM *donor human milk*

HMB *human milk bank*

IEC *International Electrotechnical Commission*

IFTPS *Institute for Thermal Processing Specialists*

ISO *International Standards Organization*

TMS *temperature measuring sensor*

1 INTRODUCTION

1.1 Scope

This document describes the procedure for verifying the performance of a Device suitable for the pasteurization of donor human milk (DHM). This verification protocol is intended specifically for verification of the specifications defined in the related document titled *Performance Specification for a Holder Pasteurization Device*. Both documents are limited to Devices designed to pasteurize DHM by indirectly heating the DHM to 62.5°C in closed containers via a water bath and maintaining the DHM at this temperature for 30 minutes before it is cooled down for later use. This batch pasteurization process is generally referred to as holder pasteurization or low-temperature long-time pasteurization.

Effectiveness of pasteurization is only measured in this verification protocol as acceptable thermal treatment to the holder pasteurization temperature requirements. This assumes that if DHM is effectively treated to the holder pasteurization temperatures, it is safe in terms of viral and bacterial contamination. No verification of actual bacterial load is carried out. If deemed useful by the Oversight Organization, it is recommended that 35 to 45 Treatment Cycles be executed using actual DHM with natural bacterial loads or spiked with selected bacterial loads leading to known viable colony sizes in DHM as a medium. It is also recommended that bacterial testing be carried out for final confirmation of effective treatment.

2 DEFINITIONS

The verbs **should** and **shall** will have distinct and separate meanings within this document. When the verb **shall** is used, it indicates that compliance with a section or part of a section is required. When the verb **should** is used, it indicates that compliance with a section or part of a section is strongly recommended but is not strictly required in order to comply with this performance specification.

Additionally, throughout this document, the following terms and definitions apply, although they may have other or additional meanings outside of this document:

Containers: The physical vessels that are used to hold the donor human milk during pasteurization.

Cooling Period: The time during which the DHM is being cooled by a water bath in order to reach a final temperature at which the DHM will be moved out of the water bath to cold storage or direct use.

Device: The physical components or machine produced or otherwise procured by the Manufacturer for pasteurizing DHM. The Device may include multiple parts and components including—but not limited to—a primary component for heating, a separate component for cooling, removable racks for holding multiple Containers, etc.

Donor Human Milk (DHM): The media that will be pasteurized, exclusively human (breast) milk donated to the organization (generally a Human Milk Bank) that will be using the Device.

Exclusive Containers: Containers intended for Devices designed to use only the specific, Exclusive Containers purchasable from the Manufacturer or their agents.

Heating Period: The time during which the DHM is being heated by a water bath to reach the holding temperature.

Holding Period: The time during which the DHM is being held at an effectively constant holding temperature by a water bath for pasteurization.

Human Milk Bank (HMB): A service or organization established to recruit donors, collect DHM, and then process, screen, store, and distribute the DHM to meet infants' specific needs.

Manufacturer: The legal entity responsible for the production of the Device.

Oversight Organization: The legal entity responsible for reviewing documentation from the Manufacturer and confirming or denying the acceptability of the Device according to this specification, its related verification protocol, and any other related requirements.

Probe: The temperature measurement assembly used to determine the temperature of the DHM by positioning an integrated transducer in a specific location. This assembly as an integral part of the Device and the measurement is used for monitoring and displaying the progress of the Treatment Cycle.

Temperature Measuring Sensor (TMS): A sensor used for measuring temperature during verification testing that is not part of the Device.

Test Lab: The third-party testing organization, unrelated to the Manufacturer, which carries out the verification protocol.

Treatment Cycle: The time during which the DHM is being directly affected by the temperature of a water bath. This includes the Heating Period, the Holding Period, and the Cooling Period.

3 APPLICABLE DOCUMENTS AND REFERENCES

The items below include documents that are and are not specifically referenced in this verification protocol. Some may be useful to certain readers as reference items. Note that some documents are listed as sources of information that may not apply to the Devices discussed in this verification protocol (e.g., medical device specifications standards are listed below that are not directly applicable to holder pasteurization Devices which are not generally considered medical devices by regulatory and standards organizations).

- ISO/IEC 17025:2017 : General requirements for the competence of testing and calibration laboratories. (2017). Available at https://www.iso.org/standard/66912.html.
- Institute for Thermal Processing Specialists (IFTPS). *Guidelines for Conducting Thermal Processing Studies*. Guelph: IFTPS; 2014. Available at http://iftps.org/wp-content/uploads/2017/12/Retort-Processing-Guidelines-02-13-14.pdf.
- ANSI/IEC 60529-2004: Degrees of Protection Provided by Enclosures (IP codes). Available at https://www.nema.org/Standards/ComplimentaryDocuments/ANSI-IEC-60529.pdf.
- ASTM D4991 - 07(2015): Standard Test Method for Leakage Testing of Empty Rigid Containers by Vacuum Method.
- ISO 8601-1. Data elements and interchange formats – Information interchange – Representation of dates and times. Available at https://www.loc.gov/standards/datetime/iso-tc154-wg5_n0039_iso_wd_8601-2_2016-02-16.pdf.
- International Organization for Standardization (ISO). (2015). Quality management systems (ISO/ Standard No. 9001). Retrieved from https://www.iso.org/obp/ui/#iso:std:iso:9001:ed-5:v1:en.
- International Organization for Standardization (ISO). (2016). Medical devices (ISO/ Standard No. 13485). Retrieved from https://www.iso.org/obp/ui/#iso:pub:PUB100422.
- British Standards Institution. (2016). Refrigerating systems and heat pumps. Safety and environmental requirements. Design, construction, testing, marking and documentation (BS EN 378-2:2016).
- British Standards Institution. (2018). Safety of machinery. Electrical equipment of machines. General requirements (BS EN 60204-1:2018).
  Australia New Zealand Dairy Authorities' Committee (ANZDAC). *Guidelines for Food Safety: Validation and Verification of Heat Treatment Equipment and Processes.* ANZDAC; 2007. Available at http://www.agriculture.gov.au/SiteCollectionDocuments/aqis/exporting/dairy/publications/anzdac-validation-heat-treatment.pdf.
- Defense Standardization Program. SD-15 Guide for Performance Specifications. United States Department of Defense; 2009. Available at http://www.navair.navy.mil/nawctsd/Resources/Library/Acqguide/SD_15 2009.pdf.

- Heinz, G, Hautzinger, P. Canning / sterilization of meat products. In Heinz, G, Hautzinger, P. *Meat Processing Technology for Small- to Medium-Scale Producers.* Bangkok, Thailand: Food and Agriculture Organization of the United Nations (FAO); 2007. Available at http://www.fao.org/docrep/010/ai407e/AI407E22.htm.
- National Advisory Committee on Microbiological Criteria for Food (NACMCF). Requisite scientific parameters for establishing the equivalence of alternative methods of pasteurization. *Journal of Food Protection.* 2006;69(5):1190–1216. doi: 10.4315/0362-028X-69.5.1190.
- Picaud, JC, Buffin, R. Human milk—Treatment and quality of banked human milk. *Clinics in Perinatology*. 2017;44(1):95–119. doi: 10.1016/j.clp.2016.11.003.
- United States Food and Drug Administration (FDA). *Grade "A" Pasteurized Milk Ordinance 2015 Revision.* Maryland: FDA; 2015. Available at https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/milk/ucm513508.pdf.
- United States Food and Drug Administration (FDA). Code of Federal Regulations 21CFR113.40 -Thermally processed low-acid foods packaged in hermetically sealed containers (2017). United States of America. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=314.80.
- United States Food and Drug Administration (FDA). Code of Federal Regulations 21CFR1240.61 (2017). United States of America. Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1240.61.
- World Health Organization (WHO). *How to Develop and Publish a PQS Product Performance Specification. 2nd Edition*. Geneva: WHO; 2018. Available at http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/LinkPDF.aspx?UniqueID=5a4cd0be-1468-499b-88e6-b3a226d17e50&TipoDoc=PQS_x0020_Document_x0020_Type&GuidDoc=8d799c26-9e30-467d-8d9c-3e23c2f4bfae.
- USP 661: Plastic packaging systems and their materials of construction. Characterization of a packaging system's materials of construction to evaluate ingredients as probable extractables and potential leachables. Available at https://hmc.usp.org/sites/default/files/documents/HMC/GCs-Pdfs/c661.pdf.

4 TESTING GUIDANCE, APPLICABILITY, AND REQUIREMENTS

The testing and reporting shall be carried out by an independent ISO/IEC 17025 Test Lab or other Test Lab entity approved by the Oversight Organization.

4.1 Responsibilities

4.1.1 Manufacturer

The Manufacturer is responsible for supplying one, complete sample Device for testing. This sample Device shall be produced in exactly the same way as other or subsequent Devices to ensure that the testing and verification is applicable to use as pre-qualification for all subsequent Devices until changes are made by the Manufacturer. The Manufacturer shall package and ship the Device with all documentation and spare parts in the same way that it would be delivered to the user. The Manufacturer shall supply Containers totaling three times plus an additional 25 percent of the maximum, single-load Container capacity of the Device. If the Manufacturer sells Exclusive Containers for the Device, these shall be supplied. If there is more than one type of Exclusive Container intended for use with the Device, the Manufacturer shall provide the same number of each type. If the Manufacturer does not provide Exclusive Containers, they shall select and supply Containers of a type acceptable for use in their Device. In addition, the Manufacturer shall submit the following information to the Test Lab and the Oversight Organization separately before testing can begin:

- Schematic diagram(s) or process flowchart(s) with a descriptive narrative that includes the following:
    - A general description of the heating and cooling processes and locations of key elements in the Device.
    - The position of temperature and any other sensors including, as applicable, indication of which sensors are used as feedback for controls and which for only monitoring purposes.
    - A basic description of the control structure for the Device.
    - Testing data and description of the design and decision process used to select sensor locations (e.g., in a Container with water as proxy, in a Container with other liquid, in process heating medium, etc.) and any calibration, normalization, or offsets applied to sensors.
- Specify the intended nominal fill volume to be used when filling the Containers or a nominal fill volume range (e.g., 50 to 100 mL).
- Specify the Containers to be used, whether they are Exclusive Containers or a non-Exclusive Container type that the Manufacturer deems appropriate for testing.
- Directions for use and explicitly how to run the Treatment Cycle.

4.1.2 Test Lab

The third-party Test Lab shall carry out the testing described in this document, request additional information from the Manufacturer as needed, and produce a full report to be submitted to the Oversight Organization.

4.1.3 Oversight Organization

The Oversight Organization will review the testing report and have the final decision when confirming the recommendations of the testing lab. If partial or conditional acceptance is deemed appropriate, the Oversight Organization may contact both the Manufacturer and Testing Lab to confirm whether the Manufacturer intends to address the issues and submit for re-testing and reassessment of specific items.

4.2 Personnel qualification

All personnel involved in verification testing shall be qualified in accordance with the requirements of the Test Lab's written practice for personnel qualification. Personnel are required to be knowledgeable of the procedures in this document and the information in the related specification document.

For the container closure integrity test, personnel performing the inspection shall have good eyesight (a reasonable qualification may be that they are able to distinguish J1 letters at 12 inches on a Jaeger eye chart). They shall also have no color vision impairment.

4.3 Verification tests

Some sections of the related specification require verification of the effectiveness of the Device according to the requirement. The primary objective of the verification tests is to confirm that under normal operation there is no portion of DHM in a full batch that will receive less than the required heat treatment. The required treatment occurs when the DHM reaches a temperature of at least 62.5°C for the required time of at least 30 minutes. Required verification tests pertain to the minimum requirement specifications to ensure that the Device provides safe DHM.

4.4 Equipment

Test Labs will generally have equipment and processes in place for data acquisition, temperature monitoring, and other general testing procedures. However, since this document may be used as reference or for direction by HMBs, organizations, innovators, or potential manufacturers, some basic information on equipment may be useful.

Data Acquisition System: The data acquisition system should be calibrated prior to use. It should also be equipped with a sufficient number of ports for logging separate TMSs to accurately monitor and record temperature simultaneously for the testing below. Depending on the size of the Device, this may require 15 port capability. It is recommended that a sampling frequency of once per second is used although lower frequency sampling may be acceptable for some studies.

Temperature Measuring Sensors (TMSs): TMSs may be thermocouples, wireless data-loggers, or other similar devices. All TMSs must be of sufficient accuracy, size, and length, and in sufficient quantity, to adequately and accurately monitor the process. As guidance, if an entity is unsure of what to use, thin-wired Type-T thermocouples provide a good balance of minimal thermal interference, accuracy, and ease of use.

Testing fixtures: For most of the thermal testing, some sort of fixture will be necessary for positioning TMSs and holding their lead wires assuming wired TMSs are used. This fixture will most likely need to be custom made for use in different Containers and with different Devices. General design direction and considerations should include:

- Minimizing the heat transfer of the fixture and lead wires.
- Minimizing the potential effect on convection in the Containers due to the fixture (generally making it as small as possible).
- Minimizing the total volume that the testing fixture displaces in a filled Container. As guidance, the volume displaced should not be more than 10 percent of the fill volume and 5 percent or less should be targeted.
- Maximizing the similarity of the sealing in Containers with and without testing fixtures (this may be especially important for Devices that pasteurize containers fully submerged in the water bath).
- Including features that facilitate consistent positioning of TMSs at precise locations.

4.4.1 Equipment variability

The maximum combined variability (accuracy and precision) necessary for all temperature measurements and meeting all temperature requirements is ±0.5°C.

4.4.2 Methods for equipment standardization

Again, Test Labs will generally have processes in place for standardization. However, since this document may be used as reference or for direction by Human Milk Banks (HMBs), organizations, innovators, or potential manufacturers, some basic information on equipment may be useful. The information below on standardization is quoted and paraphrased slightly

from Section 2 of the Institute for Thermal Processing Specialists (IFTPS) Guidelines for Conducting Thermal Processing Studies.

- *"Test equipment used for collecting thermal process data should be suitable for the purpose of the studies being conducted. [Sensors] to collect temperature distribution, heat transfer distribution, and heat penetration data, in general, should be calibrated relative to the expected test conditions and ranges prior to conducting thermal process studies. Ideally, devices should also be calibrated upon completion of thermal process studies."* (IFTPS, 2014)
- *"The reference temperature measurement device must conform to applicable regulations… [T]he temperature indicating devices and reference devices must be tested against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other metrology institute."* (FDA, 2017)
- *"Prior to conducting thermal process studies, standardization or calibration of test equipment should be performed. Thermocouples ideally would be calibrated in the test [Containers]. All thermocouples, extensions, connections and the specific data logger should be assembled as they will be used under the actual test conditions. Consideration for conducting duplicate calibration studies prior to conducting critical thermal processing studies is recommended."* (IFTPS, 2014)
- "An acceptable method of calibration is to bundle all [TMSs] and locate them in close proximity to the known accurate reference [sensor], taking care not to inhibit flow of the heat transfer medium across the reference [sensor]. The [Device] is brought up to the same…temperature…as defined for the test and the [Device] is allowed to equilibrate. The temperature differences between the reference [sensor] and [TMSs] are then calculated and documented. These differences may be applied as correction factors for each [TMS]. A typical range of correction factors for thermocouples is usually not more than 1 to 2°F (0.6 to 1.2°C)."
- *"Process efficacy and success criteria of thermal processing studies may not be met if sensors and measuring devices are inaccurately calibrated."* (IFTPS, 2014)

4.5 Documentation and reporting

Appropriate documentation is required and should follow established standards (e.g., ISO 9001). Results and observations should be documented by the Test Lab and retained for future reference. Images and photos are encouraged to improve descriptions and understanding especially for the Oversight Organization, which may not have the opportunity to physically view or inspect the Device and Containers.

Individual tests below will contain requirements for documentation and inclusion in the report. In addition to explicitly stated reporting requirements, the following should generally be included:

- Descriptions and images of test setups, including physical dimensions; type, characteristic, and locations of sensors; temperature ranges; process controls, etc. that will be useful in understanding and reviewing the report.
- Descriptions and images of variations from one test setup to another.
- Detailed descriptions and images of modifications to the Device or Containers required for testing for example to allow positioning and introduction of TMSs.
- Calibration or standardization results for TMSs and data acquisition systems including the last calibration check dates.
- Descriptions of Device and Container characteristics such as materials, general size and dimensions, orientation for processing, loading configuration (e.g., volume and partial load if permitted), number of containers per layer, etc.
- A description, dimensions, configuration, spacing of the holding mechanism for Containers in the Device.
- Graphs and visualization especially of selected temperature versus time curves to assist in describing outcomes and analysis.

5 TESTING PROCEDURE

All testing shall be carried out in a temperature-controlled environment at a controlled room temperature between 20°C and 25°C. In all tests, data shall be logged and recorded at a recommended frequency of once per second (1 Hz) and at frequency of at least once every ten seconds.

5.1 Type examination

1) Inspect the Device.
   - Report any differences between the Device ordered and that received. Also, report any visible damage or other concerns with Device received.
2) Establish whether the Device conforms or does not conform to each requirement listed in Table 1.
   - Report the results in a table similar to Table 1 with a simple statement of "Yes" or "No" in the column labeled "Conformance." Obtain and include any required documentation or information noted in the far right column as attachments to the testing report.

Table 1. Clauses from the related document titled Performance Specification for a Holder Pasteurization Device (unless otherwise noted). The items require confirmation from the Test Lab but generally no additional testing by the Test Lab. In some cases, testing and certification are required from the Manufacturer or approval is required from the Oversight Organization.

Clause	Requirement description	Conformance	Result, Documentation, Notes
4 (VP)	**Requirements**. The testing and reporting shall be carried out by an independent ISO/IEC 17025 testing laboratory or other testing laboratory approved by the Oversight Organization.		Include documentation of certification or approval from the Oversight Organization.
4.1	**General.** The Device shall conduct an electronically controlled process of DHM pasteurization where the DHM is contained in closed Containers and heat is provided or removed indirectly via a water bath.		
4.1	**General.** The Device shall measure, display, record, and store the temperature data throughout this entire Treatment Cycle.		
4.1	**General**. The maximum combined variability (accuracy and precision) necessary for all temperature measurements and meeting all temperature requirements is ±0.5°C.		Include written documentation from the Manufacturer confirming conformance in addition to documentation deemed sufficient by the Test Lab to verify conformance.
4.2.2	**Heating and cooling method**. Heating of the DHM shall be achieved in a water bath. Cooling of the DHM shall be achieved in a water bath or water and ice bath.		

Clause	Requirement description	Conformance	Result, Documentation, Notes
4.2.4	**Temperature variability.** The limit of error of the Probe shall not exceed ±0.5°C at any point, time, or temperature within the intended operating range of the Device.		Include written documentation from the Manufacturer confirming conformance in addition to documentation deemed sufficient by the Test Lab to verify conformance.
4.2.7	**Display**. The Device shall be equipped with a display in alphanumerical form. The user shall be able to view: ▸ The DHM temperature as measured by the Probe at a resolution of 0.1°C. ▸ The total elapsed time in minutes at a resolution of 0.1 minutes or less. ▸ The temperature display adjustable between °C and °F. ▸ Indication of alarms.		
4.2.8	**Recording and data storage**. The Device shall be equipped with electronic data logging capability and internal memory to store the acquired data in digital format. Alternatively, the Device may be easily connectable to another piece of equipment such as a computer or other data storage machine for direct data transfer.		
4.2.8	**Recording and data storage**. Time and temperature data shall be recorded every 1 to 60 seconds.		
4.2.8	**Recording and data storage**. Records shall be stored and archived for documenting evidence of the Treatment Cycle and expedient retrieval. The Device shall be equipped with a USB port for transferring data. All the data shall be exportable in at least one general format compatible with a broad range of applications such as CSV, ASCII, or similar for external data analysis.		

Clause	Requirement description	Conformance	Result, Documentation, Notes
4.2.9	**Level of automation**. If human intervention is required, the Device shall at a minimum notify and prompt the user for each necessary action.		
4.2.10	**Alarms and notifications.** An audible and visual alarm shall signal if the temperature either falls below 62.5°C±0.5°C for more than one minute during the Holding Period or increases above 64°C±0.5°C for more than one minute at any time.		Include written documentation from the Manufacturer confirming conformance or functionality testing with documentation from the Test Lab verifying conformance.
4.2.10	**Alarms and notifications.** If the Device is not fully automated, it shall additionally emit audible alarms, visual signals, and display instructions or simple indications prompting each necessary action.		Include written documentation from the Manufacturer confirming conformance or functionality testing with documentation from the Test Lab verifying conformance.
4.2.10	**Alarms and notifications.** All alarm and notification conditions shall be accompanied by instructions on the display or other clear, simple indications to the user.		Include written documentation from the Manufacturer confirming conformance or functionality testing with documentation from the Test Lab verifying conformance.
4.3.1	**Water bath.** The materials and design shall prevent the exterior of the Device from getting hot enough to cause accidental burns even after extended use.		Include written documentation from the Manufacturer confirming conformance in addition to documentation deemed sufficient by the testing lab to verify conformance.
4.3.2	**Heating system**. If the heating system consists of submerged heating element(s) or is otherwise exposed, it shall be made of material resistant to chemicals used for cleaning. Heating components should be sheathed or otherwise contained if composed of materials or elements that cannot withstand common detergents or chemicals used for cleaning (e.g., NaOH, bleach).		Include documentation from Manufacturer confirming materials used if necessary.

Clause	Requirement description	Conformance	Result, Documentation, Notes
4.3.4	**Cleaning.** Exposed surfaces and components of the water bath shall be made of material that can withstand exposure to frequent sanitization with NaOH or bleach.		Include documentation from Manufacturer confirming materials used if necessary.
4.3.5	**Electronics**. All electronic parts shall be isolated against any contact with water and moisture.		Include written documentation from the Manufacturer confirming conformance through internal or external testing (e.g., Ingress Protection rating or similar testing recommended).
4.5.2	**Dimensions and weight**. A small-scale Device shall be compact and fit easily on conventional laboratory benches.		
4.5.2	**Dimensions and weight**. Length and width shall be limited to fit through standard door widths in the locations where the Device is intended to be sold.		
4.6.2	**Electrical connection**. If onsite installation is not included with purchase of the Device, the Device shall be supplied with electrical power lead with a sealed-on plug compatible with the electricity socket standard for the intended location of sales and use.		
4.6.2	**Electrical connection**. The Device shall also be equipped with a mechanism specifically designed to turn the power completely on and off (e.g., power switch or button) that is readily accessible to the user but protected from accidental activation.		
4.6.3	**Voltage stabilization and fuses.** If fuses are used in the Device, they shall be easy to access and clearly marked.		
4.7	**Reliability.** The warranty of the Device shall be a minimum of one year from the date of installation.		Include written documentation from the Manufacturer confirming conformance.

Clause	Requirement description	Conformance	Result, Documentation, Notes
4.7	**Reliability.** The temperature drift of the Probe shall not be more than 0.2°C over three months of normal use, as intended.		Include written documentation from the Manufacturer confirming conformance in addition to documentation deemed sufficient by the testing lab to verify conformance.
4.9.2	**Installation and qualification.** The manufacturer shall either provide installation and performance qualification services or include a protocol for both that can be carried out by the end user.		If a protocol is not provided, include confirmation from the Manufacturer in writing that they provide the services.
4.9.3	**Requalification**. The Manufacturer shall provide a protocol for periodically requalifying the performance of the device and a recommended frequency for the requalification.		
4.10.1	**Instructions**. Detailed maintenance instructions shall be provided. If only one language is included, it shall be the language most appropriate to the country of use. Instructions shall cover the following topics: ▸ A description of operations and use. ▸ A detailed guide to all warning lights, other indicators, and displays. ▸ Simple daily, weekly, and monthly maintenance and cleaning tasks. ▸ Periodic preventative maintenance checks. ▸ Diagnostic and repair guidance and procedures for minor damage. ▸ Battery replacement (if applicable). ▸ An itemized list of spare parts including part numbers. ▸ End-of-life resource recovery and recycling procedures.		

Clause	Requirement description	Conformance	Result, Documentation, Notes
4.10.2	**Service**. The Device shall be designed, and components selected, with the aim of achieving at least a five-year life free of repairs or maintenance apart from expected, routine tasks such as cleaning, Probe calibration, and replacement of filters (if any).		Include written documentation from the Manufacturer confirming conformance.
4.10.3	**Spare parts**. The Manufacturer shall supply a list of the spare parts and procedure for procurement.		
4.10.3	**Spare parts**. At a minimum, each Device shall be supplied with five spare fuses of each fuse size and type used in the appliance (if any). The spares fuses are to be attached within or on the appliance.		
4.10.3	**Spare parts**. The manufacturer shall ensure supply of spare parts for a minimum of ten years from the time of purchase of the last Device.		Include written documentation from the Manufacturer confirming conformance.
5.1	**Containers: type and material.** All materials comprising Exclusive Containers shall be resistant to damage or failure when exposed to the operating temperature range identified in section 4.2.1 and when stored at temperatures at least as low as –20°C when filled with DHM that will expand under freezing conditions.		Include written documentation from the Manufacturer confirming conformance in addition to documentation deemed sufficient by the testing lab to verify conformance.
5.1	**Containers: type and material.** Exclusive Containers shall be delivered sealed in sanitary or sterile condition. Alternatively, they may instead remain non-toxic and fully functional when exposed to nominal autoclave temperatures of at least 121°C, in the case that suggested practice is to autoclave the Exclusive Containers before use. They shall also remain non-toxic and fully functional when exposed to multiple freeze-thaw cycles.		Include written documentation from the Manufacturer confirming conformance in addition to documentation deemed sufficient by the testing lab to verify conformance.

Clause	Requirement description	Conformance	Result, Documentation, Notes
5.2	**Containers: safety**. All materials comprising Exclusive Containers shall be non-toxic and intended for food-safe use throughout the operating temperature range identified in section 4.2.1 of the performance specification. Exclusive Containers shall not be sterilized with ethylene oxide by the Manufacturer.		Include written documentation from the Manufacturer confirming conformance in addition to documentation deemed sufficient by the testing lab to verify conformance.
5.3	**Containers: reuse**. If Exclusive Containers are intended for sanitization and reuse, they shall further remain non-toxic and fully functional when exposed to multiple freeze-thaw cycles and nominal autoclave temperatures of at least 121°C.		Include written documentation from the Manufacturer confirming conformance in addition to documentation deemed sufficient by the testing lab to verify conformance.
5.3	**Containers: reuse**. Reusable containers shall be easily cleanable and resistant to standard cleaning and sterilization procedures and chemicals. The number of safe reuses of Exclusive Containers shall be specified and demonstrated by the Manufacturer.		Include written documentation from the Manufacturer confirming conformance in addition to documentation deemed sufficient by the testing lab to verify conformance.
6.1	**Manufacturer certifications**. The Manufacturer should be ISO 9001 or 13485 certified. If the Manufacturer does not hold either of these certifications, they shall provide documentation of similar or equivalent certifications or quality management procedures and protocols to which they adhere.		Include written documentation from the Manufacturer confirming conformance.

5.2 Treatment Cycle

5.2.1 Sub-test 1: Verification of the Cold Point

Objective: Identify the location or locations that heat the slowest in Containers during the Heating Period.

General/purpose: To ensure safe treatment of the DHM, determining the location of the coldest point in a Container is critical to establish the lower extreme of heat treatment delivered in the Treatment Cycle. A cold point location study shall be completed to determine the slowest heating location specific to the Device including the Manufacturer specified containers to be used for testing. Multiple TMSs and a test fixture may influence heating behavior, especially in smaller containers. Care and judgement based on a number of preliminary experiments must be exercised to ensure the cold spot location has been identified.

If there are multiple Manufacturer-specified Container types, the cold point must be defined separately for each type.

Steps:

1. Fill enough Containers with water to fully load the Device. Fill each Container to the nominal, maximum fill volume specified by the Manufacturer.
2. If the Device requires that a Container be filled with a material for measurement or control purposes using the Probe, follow the instructions provided with the Device for filling and preparing this proxy Container.
3. Condition the water-filled Containers at 4°C±0.5°C for at least 24 hours.
4. Position TMSs in the testing fixture as discussed in section 4.4. TMSs shall be located in the following locations (an indicative diagram is included in Appendix 1A).
    a. Four locations vertically separated along the central axis of the Container.
        i. The bottom location shall be between 5 mm and 10 mm above the internal floor or bottom of the Container being sure that the TMS does not contact the container itself.
        ii. The uppermost location shall be between 5 mm and 15 mm from the top surface of the liquid in a filled Container being sure that the measurement location of the TMS remains in the DHM or other liquid.
        iii. The two middle locations shall be spaced approximately equally between the bottom and top locations.

b. Assuming an approximately circularly symmetric Container, use six additional locations to establish axial temperature variations.
    i. Two locations within the same height range as the bottom-center location, one between 5 mm and 10 mm horizontally from the internal container wall, and one between 5 mm and 15 mm horizontally from the central axis of the Container.
    ii. Two locations within the same height range as the top-center location and the same horizontal ranges noted for the bottom-axial locations described directly above in step 4.b.i.
    iii. Two locations approximately vertically centered between the top and bottom locations and within the same horizontal ranges described in step 4.b.i.
c. Depending on the total volume and geometry of the Container, the Test Lab may need to alter these locations slightly. These location descriptions assume a circular Container. If the Container is somewhat rectilinear, the axial locations should be modified by the Test Lab to sample at similarly representative locations near edges, corners, and centered on faces. If the Container is neither circular nor rectilinear, the testing lab shall similarly modify locations in order to sample at enough locations to ensure that variability is comprehensively explored. Any modifications to locations shall be noted in the report and approved by the Oversight Organization.
d. Finally, depending on the setup, the Test Lab may not be able to place ten (or more) TMSs in a single Container due to space limitations in the Container and the potential of affecting the thermal and convective processes in the Container. If this is the case, some locations may be tested in separate test runs. This type of modification shall also be noted in the report and approved by the Oversight Organization.

5. Start data collection.
6. Run the entire Treatment Cycle as specified by the Manufacturer.
7. Repeat steps 1 through 6 two additional times in a different Container in a different position in the Device.
8. If the direction given by the Manufacturer allows different or a range of Container fill volumes, at least three tests with all Containers filled to the upper volume extreme and three tests with all Containers filled to the lower volume extreme shall be carried out.
9. Analyze and compare the temperature data and identify the last point in the Container to reach 63°C (cold point). Identify the cold point at the volume extremes if applicable.
    a. If it is not clear which location is the cold point, it is at the discretion of the Test Lab to either carry out additional testing which may include different locations within the Container and different positions of the Container in the Device. If any additional testing is necessary, the reasoning and conclusions reached by the Test Lab shall be explicitly documented, justified, and reported.
10. Repeat Steps 1 through 8 using each type of alternative Container specified by the Manufacturer if applicable.

NOTE: The method of inserting TMSs into a container and holding them in specific locations should result in a watertight seal that should be verified after testing. Verification may be accomplished through comparison of container weights recorded pre- and post-testing. This is especially important in containers that are fully submerged during the Treatment Cycle. Ingress of hot process water could have a large effect on testing outcomes.

5.2.2 Sub-test 2: Verification of the temperature distribution in the water bath

Objective: Verify the temperature distribution in the water tank in terms of how it affects the temperatures inside the Containers.

General/purpose: The test is intended to define the location in the water bath that leads to the coldest temperatures observed within Containers. It is possible that with very even heat distribution there will not be any locations that are exposed to notably different temperatures. Confirming a coldest location in the water bath (if it exists) is necessary to decide upon the placement of sensors for other verification tests. Verification of the effectiveness of Treatment Cycle must be performed in the coldest zone in the Device's water tank, for the sake of safety. As noted in the scope, effectiveness is only measured in this verification protocol as acceptable thermal treatment to the holder pasteurization temperature requirements. No verification of actual bacterial load is carried out. Water bath temperatures will not be directly measured because the effect on the DHM is the primary focus of the verification testing.

Steps:

1. Fill the same containers used in Sub-test 1 with water. Fill each Container to the nominal, maximum fill volume specified by the Manufacturer.
2. If the Device requires that a Container be filled with a material for measurement or control purposes using the Probe, follow the instructions provided with the Device for filling and preparing this proxy Container.
3. Condition the water-filled Containers at 4°C±0.5°C for at least 24 hours.
4. Place a TMS in each of the Containers identified below at the cold point established in Sub-test 1 above (an indicative diagram is included in Appendix 1).
    a. If the Device treats a single layer of Containers in each batch, place a TMS in:
        i. The Container at the center of the configuration (or a Container near the center if there is not a single Container at the center).
        ii. A Container closest to an outside corner of the Device.
        iii. A Container nearest the center of one wall.
        iv. A Container nearest the center of an adjacent wall.
        v. A Container nearest the center of one of the quadrants defined by splitting the water bath area into even quarters.

   b. If the Device treats two layer of Containers in each batch, place a TMS in a Container in each of the five positions noted above in both the layers.
   c. If the Device treats three or more layers of Containers in each batch, place a TMS in a Container in each of the five positions noted above in the top layer, the bottom layer and the center layer of Containers.
5. Start data collection.
6. Run the entire Treatment Cycle as specified by the Manufacturer.
7. Repeat steps 1 through 6 two additional times.
8. If the direction given by the Manufacturer allows different or a range of Container fill volumes, at least three tests with all Containers filled to the upper volume extreme and three tests with all Containers filled to the lower volume extreme shall be carried out.
9. Analyze and compare the temperature data and identify the last three containers to reach 63°C±0.5°C. Identify the three coldest locations at each of the volume extremes separately if applicable.
   a. If there are not clearly coldest locations over all the tests, calculate the average time it took each measured location to reach 63°C±0.5°C in the three runs. Define the three locations with the highest averages as the coldest locations. It is at the discretion of the test lab whether additional testing should be carried out to establish the three coldest containers. This may include testing different positions in the Device. If any additional testing is necessary, the reasoning and conclusions reached by the Test Lab shall be explicitly documented, justified, and reported. At least three replicate tests shall be carried out if additional testing is used to identify the three coldest Containers.
10. Repeat Steps 1 through 9 using each type of alternative Container specified by the Manufacturer if applicable.

NOTE: The method of inserting TMSs into a container and holding them in specific locations should result in a watertight seal that should be verified after testing. Verification may be accomplished through comparison of container weights recorded pre- and post-testing. This is especially important in containers that are fully submerged during the Treatment Cycle. Ingress of hot process water could have a large effect on testing outcomes.

5.2.3 Verification of the Treatment Cycle

Objective: Verify that in a full batch, all DHM is exposed to a temperature of at least 62.5°C for at least 30 minutes. This test is required to establish whether the Device fulfills the minimum temperature requirements for effective pasteurization of all the DHM in each batch.

Steps:

1. Fill the same Containers used in Sub-tests 1 and 2 with water. Fill each Container to the nominal, maximum fill volume specified by the Manufacturer.
2. If the Device requires that a Container be filled with a material for measurement or control purposes using the Probe, follow the instructions provided with the Device for filling and preparing this proxy Container.
3. Condition the water-filled Containers at 4°C±0.5°C for at least 24 hours.
4. Start data collection.
5. Run the entire Treatment Cycle as specified by the Manufacturer with a TMS at the cold point of a Container in each of the three coldest locations identified above.
6. Repeat steps 1 through 5 two additional times.
7. If the direction given by the Manufacturer allows different or a range of Container fill volumes, at least three tests with all Containers filled to the upper volume extreme and three tests with all Containers filled to the lower volume extreme shall be carried out.
8. Analyze the data from these tests. From the testing above in Sub-test 2, three additional replicate data sets are available. This should make a total of six full data sets from replicates at the coldest points in the coldest three container locations. At a minimum, calculate the following for each Container instrumented with a TMS in each run and include all values in a table:
    a. The amount of time from introduction into the water bath until the first measurement greater than or equal to 58°C±0.5°C.
    b. The amount of time from the first measurement greater than or equal to 58°C±0.5°C until the first measurement greater than or equal to 63°C±0.5°C.
    c. The amount of time from the first measurement greater than or equal to 63°C±0.5°C until the first measurement below 62.5°C±0.5°C after which the temperature remains below 62.5°C±0.5°C for more than one minute (this will be the calculated Holding Period time).
    d. The amount of time after the Holding Period until the first measurement less than or equal to 58°C±0.5°C (measured from the first measurement below 62.5°C±0.5°C after which the temperature remains below 62.5°C±0.5°C for more than one minute).
    e. The amount of time to cool from the first measurement less than or equal to 58°C±0.5°C until the first measurement less than or equal to 25°C±0.5°C.
    f. The amount of time to cool from the first measurement less than or equal to 25°C±0.5°C until the first measurement less than or equal to 4°C±0.5°C.
    g. The sum of the amounts of time calculated in steps 8.a and 8.b (this will be the calculated Heating Period time).
    h. The sum of the amounts of time calculated in steps 8.b, 8.c, and 8.d (this will be the time above 58°C±0.5°C). The time above 58°C±0.5°C, although reported and recommended to be less than 40 minutes, will not be subject to an acceptance or rejection criterion.

i. The sum of the amounts of time calculated in steps 8.d and 8.e (this will be the time to cool to 25°C±0.5°C).

j. The sum of the amounts of time calculated in steps 8.d, 8.e, and 8.f (this will be the calculated Cooling Period time).

9. Repeat Steps 1 through 8 using each type of alternative Container specified by the Manufacturer if applicable.

Acceptance Criteria

All of the following must be true:

- The Heating Period time calculated for all measured locations in all runs was less than or equal to 15 minutes.
- The Holding Period time calculated for all measured locations in all runs was greater than or equal to 30 minutes.
- The time to cool to 25°C±0.5°C calculated for all measured locations in all runs was less than or equal to 15 minutes.
- The Cooling Period time calculated for all measured locations in all runs was less than or equal to 45 minutes.

Rejection Criteria

If any of the following are true:

- Any of the calculated Heating Period times are greater than 15 minutes.
- Any of the calculated Holding Period times are less than 30 minutes.
- Any of the calculated times to cool to 25°C±0.5°C are greater than 15 minutes.
- Any of the calculated Cooling Period times are greater than 45 minutes.
- The temperature at any location in any run is measured as greater than 64°C±0.5°C for more than one minute.
- The temperature at any location in any run is measured as less than 62.5°C±0.5°C for longer than one minute during the Holding Period.

5.3 Proxy verification

Objective: Confirm the suitability of non-DHM material used in the verification tests and potentially for measurement in use.

General/purpose: For some of the verification tests, containers are filled with water as proxy for DHM. However, verification of the suitability of the proxy is required. The goal of the verification test is to ensure that results obtained with the proxy are representative and valid for the pasteurization process with DHM. If possible, DHM should be used in this test, as this is how it will be used in daily operations in HMBs.

Steps:

1. Fill three of the Containers used in Sub-tests 1 and 2 with DHM. If DHM is not available, bovine milk may be used. If bovine milk is used, it should be full fat and non-homogenized to more closely mimic DHM. Fill each Container to the nominal, maximum fill volume specified by the Manufacturer.
2. Fill the rest of the Containers used in Sub-tests 1 and 2 with water to fully load the Device. Fill each Container to the nominal, maximum fill volume specified by the Manufacturer.
3. If the Device requires that a Container be filled with a material for measurement or control purposes using the Probe, follow the instructions provided with the Device for filling and preparing this proxy Container. If the proxy Container is supposed to be filled with the same material that is being treated, it may need to be filled with DHM or bovine milk as well.
4. Condition the filled Containers at 4°C±0.5°C for at least 24 hours.
5. Start data collection.
6. Run the entire Treatment Cycle as specified by the Manufacturer with the three DHM or bovine milk-filled Containers in the coldest container locations identified above and the water-filled containers in the rest of the Container locations.
7. Repeat steps 1 through 6 two additional times. Replace the DHM or proxy between each test (the water-filled containers need not be refilled).
8. If the direction given by the Manufacturer allows different or a range of Container fill volumes, at least three tests with all containers filled to the upper and lower volume extreme shall be carried out.
9. Analyze the data from these tests. At a minimum, calculate the following for each Container instrumented with a TMS in each run and include all values in a table:
    a. The amount of time from introduction into the water bath until the first measurement greater than or equal to 58°C±0.5°C.
    b. The amount of time from the first measurement greater than or equal to 58°C±0.5°C until the first measurement greater than or equal to 63°C±0.5°C.
    c. The amount of time from the first measurement greater than or equal to 63°C±0.5°C until the first measurement below 62.5°C±0.5°C after which the temperature remains below 62.5°C±0.5°C for more than one minute (this will be the calculated Holding Period time).
    d. The amount of time after the Holding Period until the first measurement less than or equal to 58°C±0.5°C (measured from the first measurement below 62.5°C±0.5°C after which the temperature remains below 62.5°C±0.5°C for more than one minute).
    e. The amount of time to cool from the first measurement less than or equal to 58°C±0.5°C until the first measurement less than or equal to 25°C±0.5°C.
    f. The amount of time to cool from the first measurement less than or equal to 25°C±0.5°C until the first measurement less than or equal to 4°C±0.5°C.
    g. The sum of the amounts of time calculated in steps 8.a and 8.b (this will be the calculated Heating Period time).

h. The sum of the amounts of time calculated in steps 8.b, 8.c, and 8.d (this will be the time above 58°C±0.5°C). The time above 58°C±0.5°C, although reported and recommended to be less than 40 minutes, will not be subject to an acceptance or rejection criterion.

i. The sum of the amounts of time calculated in steps 8.d and 8.e (this will be the time to cool to 25°C±0.5°C).

j. The sum of the amounts of time calculated in steps 8.d, 8.e, and 8.f (this will be the calculated Cooling Period time).

10. The values calculated are likely to be different from the tests run with water. However, as long as these DHM verification tests still meet the acceptance criteria, then the test confirms sufficient agreement and treatment between the water proxy and actual DHM.
11. Repeat Steps 1 through 10 using each type of alternative Container specified by the Manufacturer if applicable.

Acceptance Criteria

All of the following must be true:

- The Heating Period time calculated for all measured locations in all runs was less than or equal to 15 minutes.
- The Holding Period time calculated for all measured locations in all runs was greater than or equal to 30 minutes.
- The time to cool to 25°C±0.5°C calculated for all measured locations in all runs was less than or equal to 15 minutes.
- The Cooling Period time calculated for all measured locations in all runs was less than or equal to 45 minutes.

Rejection Criteria

If any of the following are true:

- Any of the calculated Heating Period times are greater than 15 minutes.
- Any of the calculated Holding Period times are less than 30 minutes.
- Any of the calculated times to cool to 25°C±0.5°C are greater than 15 minutes.
- Any of the calculated Cooling Period times are greater than 45 minutes.
- The temperature at any location in any run is measured as greater than 64°C±0.5°C for more than one minute.
- The temperature at any location in any run is measured as less than 62.5°C±0.5°C for longer than one minute during the Holding Period.

5.4 Verification of the temperature-indicating (monitoring) Probe.

Objective: Verify that the Probe used for temperature monitoring in the Device accurately reflects the lowest temperatures to which any portion of DHM is exposed during the Treatment Cycle.

General/purpose: The Probe is the only indication and monitor available to the user for assessing the functionality of the Device. Although there may be other temperature measurements being taken in the Device (e.g., in the water bath or other locations) and used for Device control or diagnostics, these will generally not be displayed to the users. Devices will generally require that the Probe measure temperature in a proxy fluid or in some cases DHM that will be disposed of.

Steps:

1. If the Probe and the Container in which the probe is located are not fixed in the device, locate the instructions for how to prepare and place the Probe and its container.
2. Compare the location of the Probe and its container to the coldest container location(s) established in the previous testing.
3. Compare and measure if necessary the location of the probe in the container and compare this to the cold point established in the previous testing.
4. Inspect and measure if necessary the geometry and materials of the Probe and assess qualitatively whether any properties of the Probe are likely to inhibit its ability to accurately measure temperatures to reflect those temperatures present during the Treatment Cycle in containers without the Probe.
5. Fill the same containers used in Sub-test 1 with water. Fill each Container to the nominal, maximum fill volume specified by the Manufacturer.
6. If the Device requires that a Container be filled with a material for measurement or control purposes using the Probe, follow the instructions provided with the Device for filling and preparing this proxy Container.
7. Condition the water-filled Containers at 4°C±0.5°C for at least 24 hours.
8. Start data collection.
9. Run the entire Treatment Cycle as specified by the Manufacturer.
10. Repeat steps 5 through 9 two additional times.
11. If the direction given by the Manufacturer allows different or a range of Container fill volumes, at least three tests with all containers filled to the upper and lower volume extreme shall be carried out.

12. Analyze the data from these tests. At a minimum, calculate the following from the Probe data in each run and include all values in a table:
    a. The amount of time from introduction into the water bath until the first measurement greater than or equal to 58°C±0.5°C.
    b. The amount of time from the first measurement greater than or equal to 58°C±0.5°C until the first measurement greater than or equal to 63°C±0.5°C.
    c. The amount of time from the first measurement greater than or equal to 63°C±0.5°C until the first measurement below 62.5±0.5°C after which the temperature remains below 62.5°C±0.5°C for more than one minute (this will be the calculated Holding Period time).
    d. The amount of time after the Holding Period until the first measurement less than or equal to 58°C±0.5°C (measured from the first measurement below 62.5°C±0.5°C after which the temperature remains below 62.5°C±0.5°C for more than one minute).
    e. The amount of time to cool from the first measurement less than or equal to 58°C until the first measurement less than or equal to 25°C±0.5°C.
    f. The amount of time to cool from the first measurement less than or equal to 25°C±0.5°C until the first measurement less than or equal to 4°C±0.5°C.
    g. The sum of the amounts of time calculated in steps 8.a and 8.b (this will be the calculated Heating Period time).
    h. The sum of the amounts of time calculated in steps 8.b, 8.c, and 8.d (this will be the time above 58°C±0.5°C). The time above 58°C±0.5°C, although reported and recommended to be less than 40 minutes, will not be subject to an acceptance or rejection criterion.
    i. The sum of the amounts of time calculated in steps 8.d and 8.e (this will be the time to cool to 25°C±0.5°C).
    j. The sum of the amounts of time calculated in steps 8.d, 8.e, and 8.f (this will be the calculated Cooling Period time).
13. Repeat Steps 5 through 12 using each type of alternative Container specified by the Manufacturer if applicable.

Acceptance Criteria:

All of the following must be true:

- Temperature is monitored and recorded throughout the Treatment Cycle by the Probe.
- The Probe is positioned in the coldest location as identified in Sub-Test 2.
- The Probe is positioned at the cold point as identified in Sub-Test 1.
- The Heating Period time calculated in all runs was less than or equal to 15 minutes.
- The Holding Period time calculated in all runs was greater than or equal to 30 minutes.
- The time to cool to 25°C±0.5°C calculated in all runs was less than or equal to 15 minutes.
- The Cooling Period time calculated in all runs was less than or equal to 45 minutes.

Rejection Criteria

If any of the following are true:

- Temperature is not monitored and recorded throughout the Treatment Cycle by the Probe.
- The Probe is not positioned in the coldest location as identified in Sub-Test 2.
- The Probe is not positioned at the cold point as identified in Sub-Test 1.
- Any of the calculated Heating Period times are greater than 15 minutes.
- Any of the calculated Holding Period times are less than 30 minutes.
- Any of the calculated times to cool to 25°C±0.5°C are greater than 15 minutes.
- Any of the calculated Cooling Period times are greater than 45 minutes.
- The temperature at any location in any run is measured as greater than 64°C±0.5°C for more than one minute.
- The temperature at any location in any run is measured as less than 62.5°C±0.5°C for longer than one minute during the Holding Period.

5.5 Container closure integrity test

Objective: Verify that Exclusive Containers prohibit ingress of process water throughout the Treatment Cycle.

General/purpose: This test can be omitted by the Test Lab if the Device is intended for use with non-Exclusive Containers selected by the HMB and not controlled by the Manufacturer. For Exclusive Containers, it is necessary to verify that no process water is allowed into the Containers. Although egress testing is also important generally in determining the effectiveness of a seal, this will not be tested, as it does not as directly affect the safety of the pasteurized DHM. Furthermore, some containers designed to go from cold storage, through heat treatment, and back to cold storage are designed specifically to release expanded air from the headspace during the heat treatment. This then induces a partial vacuum, or at least lower pressure in the Container, forming a reliable seal when the container is cooled.

Steps:

1. Pre-testing: Prior to the primary test, the Test Lab shall carry out pre-testing with the dye (e.g., methylene blue) to be used in this test. The pretesting must confirm that a minimal amount of ingress would be visually distinguishable from no amount of ingress by the specific personnel carrying out the testing and in the lighting and environmental conditions in which the testing will be carried out. The Test Lab can follow these general steps or develop and use another process that similarly confirms the effectiveness of ingress identification.

a. Fill the Device water bath to its nominal fill volume for the Heating Period.
b. Fill three Containers with water.
c. Introduce the amount and type of dye into the water bath that is intended to be used in the primary ingress testing.
d. Mix thoroughly to distribute the dye.
e. Take a dropper or pipette and introduce a single drop of the dyed water bath water into one of the containers.
f. Again, mix thoroughly to distribute the dye.
g. Take a dropper or pipette and from the first Container, remove some dyed water and introduce one drop of it into the second, un-dyed Container.
h. In consistent lighting that will be reasonably unaffected by the time of day or external light sources, confirm that the personnel carrying out the testing can distinguish the two dyed Containers from the third, un-dyed Container.
i. If the cooling bath is different from the heating bath or if a different volume of water is used, repeat this pre-test in with the cooling bath volume.

2. Fill enough previously unused Containers with un-dyed water to fully load the Device. Fill each Container to the nominal, maximum fill volume specified by the Manufacturer.
3. If the Device requires that a Container be filled with a material for measurement or control purposes using the Probe, follow the instructions provided with the Device for filling and preparing this proxy Container.
4. Hand-tighten the closure on each of the Containers. If any more detailed instructions or procedures are given in the Device instruction regarding closure and tightening, follow those instructions.
5. Condition the water-filled Containers at 4°C±0.5°C for at least 24 hours.
6. Add the amount of the Test Lab-selected dye to water bath that was used in the confirmatory pre-testing. If the Device fills the water bath after the Containers are placed, add the dye as soon as the water begins to make contact with any Containers.
7. Run the Treatment Cycle.
8. Add dye separately to the cooling bath if necessary.
9. At the end of the Treatment Cycle, remove and inspect each Container separately and confirm visually whether ingress has occurred.
10. If any ingress is detected, inspect the Container and closure for damage.
11. Repeat steps 2 through 10, replacing all of the used Containers with unused Containers.
12. Repeat Steps 1 through 11 using each type of alternative Container specified by the Manufacturer if applicable.

Acceptance Criteria

None of the Containers show visual signs of ingress.

Rejection Criteria

Any of the Containers show visual signs of ingress. However, the Test Lab may present evidence to the Oversight Agency to recommend acceptance if the Containers or closures that allowed ingress were obviously damaged prior to undergoing the Treatment Cycle. In this case, acceptance should be contingent on the nature of the damage and the likelihood of occurrence and detection if similarly damaged components were received for actual use at an HMB.

5.6 Weight at full capacity

Objective: Verify that the holding mechanism (e.g., rack or basket) is within the weight limit required for easy removal from and placement in the Device.

General/purpose: This test can be omitted by the Test Lab if the Device does not have a removable holding mechanism. For Devices that do include a removable holding mechanism like racks or baskets, each fully loaded holding mechanism shall not exceed 8 kg.

Steps:

1. Fill enough Containers with water to fully load the Device. Fill each Container to the nominal, maximum fill volume specified by the Manufacturer.
2. Place all of the full, sealed Containers in the rack(s) or other holding mechanism(s) of the Device.
3. Measure the mass of each rack or holding mechanism including the full Containers.

Acceptance Criteria

None of the fully loaded racks are measured to be heavier than 8 kg.

Rejection Criteria

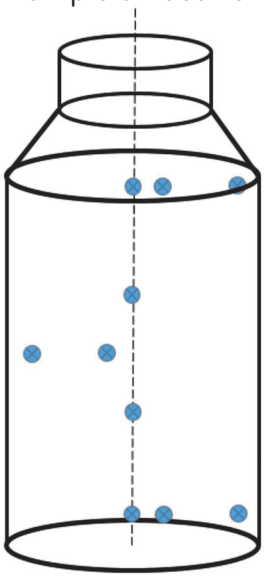
Any of the fully loaded racks are measured to be heavier than 8 kg.

5.7 Post-test inspection

To validate the results of the verification tests, post-test inspection is required. The Test Lab shall assess the condition of the TMSs, Containers, and Device after the completion of all tests to determine if the test results may have been affected by any change in or damage to the physical components as well as any drift in measurement components.

Appendix 1A. Temperature measuring sensor diagrams.

Example of locations to instrument in a bottle.



Example of containers to instrument in a rectangular water bath.

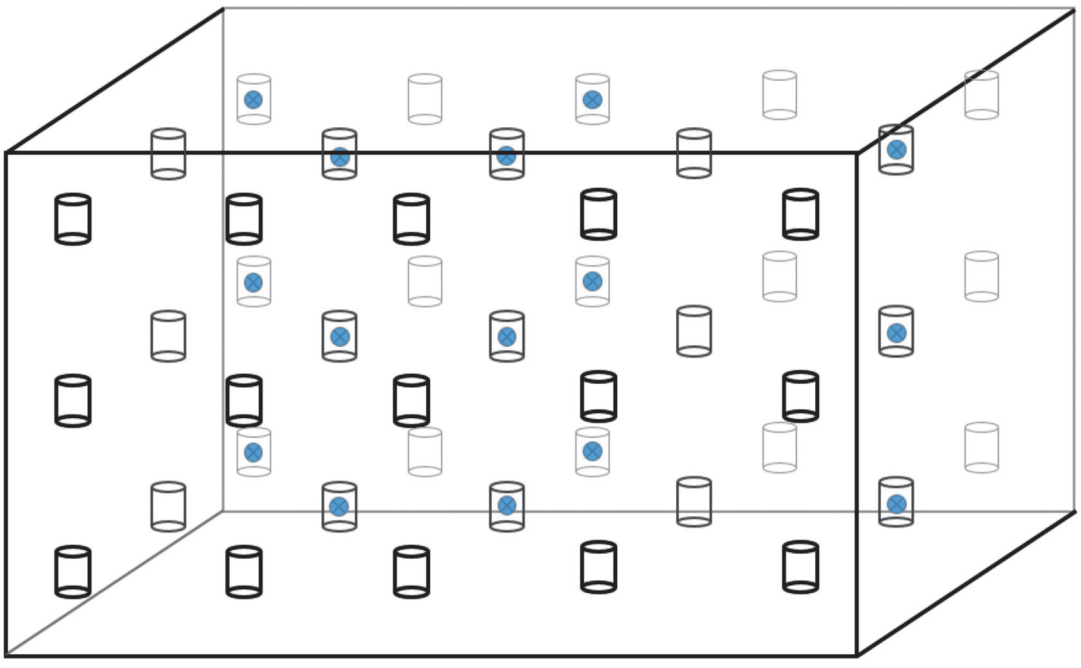


Photo: Cheshire and North Wales Human Milk Bank

APPENDIX 2.
PERFORMANCE SPECIFICATION FOR A HOLDER PASTEURIZATION DEVICE

Contents

ABBREVIATIONS

DHM *donor human milk*

HMB *human milk bank*

ISO *International Organization for Standardization*

LTLT *low-temperature long-time*

1 INTRODUCTION

1.1 Context and Background

Human milk banks (HMBs) are structured in varied ways globally. In most (although not all), the milk is treated in order to minimize risks to the vulnerable population of infants that they serve. Some organizations have instated measures to mitigate some risks associated specifically with the devices used for this treatment while others are questioning how to do this effectively.

With no global body governing HMBs, the objective of this document is to offer a universally applicable, detailed specification to be adopted by regional bodies or country level ministries of health to control the effectiveness, safety, risks, and robustness of devices used to treat human milk. The primary objectives of this process are to:

- Ensure the safety of the treated milk provided to the vulnerable population.
- Preserve the quality of the treated milk.
- Standardize qualification of devices.
- Ensure minimum quality and service of the devices to protect the purchasers and users.
- Ensure safety of the device for users.

The secondary objective is to:

- Provide manufacturers and designers with more explicit technical targets.

In addition to the specification document, an addendum was developed with more detailed explanations and open discussion for each section. Generally, the reasoning and evidence base for many of the sections comes from expert opinions, experience, and the need to establish requirements. It is extremely important to note that strong, statistical evidence is not available to objectively establish many of the recommendations. It should also be noted that with no global body to qualify equipment to these specifications, there is currently no enforcement or regulatory requirement associated with this document.

For some of the primary functional specifications and safety-related sections, a third related document is necessary. This is a verification protocol. The verification protocol establishes testing procedures and acceptance criteria. The specification and verification protocol are modelled off of a portion of the similar process used to prequalify products for use in immunization programs by the Performance, Quality, and Standards group of the World Health Organization.

1.2 Scope

This document defines a set of specifications for Devices suitable for the pasteurization of donor human milk (DHM) in HMB settings. This specification is limited to Devices designed to pasteurize DHM by indirectly heating the DHM to 62.5°C in closed containers via a water bath and maintaining the DHM at this temperature for 30 minutes before it is cooled down for later use. This batch pasteurization process is generally referred to as holder pasteurization or low-temperature long-time (LTLT) pasteurization. The primary purpose is to destroy or inactivate microorganisms and viruses in order to provide safe, pasteurized DHM to vulnerable, low birthweight, preterm, or other infants that do not have access to sufficient milk from their own mothers. The heating, holding, and cooling temperatures are monitored and recorded to allow verification and tracking of the Treatment Cycle and the heat-treated DHM.

Although the primary purpose of these Devices is to destroy or inactivate pathogens in DHM, it is within the scope of this specification to establish some requirements that are additionally intended to preserve beneficial nutritional and bioactive properties inherent in the DHM. Although research on degradation and preservation of these properties is ongoing, limiting heat exposure and peak temperatures is likely to lead to better retention of multiple DHM constituents. A few guiding principles and assumptions lead to the primary requirements set forth in this document. Specifically, this document assumes that:

- Minimizing the time that the DHM is warm—in the ideal temperature range for bacterial growth—is beneficial for guaranteeing safety.
- Minimizing heat exposure, especially above 58°C and even more so above 64°C, leads to higher quality milk through lowered degradation of beneficial components.
- Therefore, approaching as close as possible to thermal step functions in time—i.e., bringing the DHM immediately from refrigeration temperature to pasteurization temperature for the Holding Period and then immediately back down to refrigeration temperature—would be ideal.

This specification does not simply define the minimum requirements for a Device to carry out effective LTLT pasteurization. It is also not intended to be a gold standard or to define an optimal, target device. The intent is to include the minimum performance but build upon that to specify performance and design recommendations and requirements that are balanced to guarantee safety, consider milk quality due to treatment, protect users in terms of safety and investment, and consider cost to Manufacturers in terms of Device and design complexity. Although other heat pasteurization methods exist, this specification is intended to apply to holder pasteurization Devices. Some of the items below will require testing to verify performance. Testing and the related acceptability criteria are detailed in a separate verification protocol.

2 DEFINITIONS

The verbs **should** and **shall** will have distinct and separate meanings within this document. When the verb **shall** is used, it indicates that compliance with a section or part of a section is required. When the verb **should** is used, it indicates that compliance with a section or part of a section is strongly recommended but is not strictly required in order to comply with this performance specification.

Additionally, throughout this document, the following terms and definitions apply, although they may have other or additional meanings outside of this document:

Containers: The physical vessels that are used to hold the DHM during pasteurization.

Cooling Period: The time during which the DHM is being cooled by a water bath in order to reach a final temperature at which the donor human milk will be moved out of the water bath to cold storage or direct use.

Device: The physical components or machine produced or otherwise procured by the Manufacturer for pasteurizing DHM. The Device may include multiple parts and components including—but not limited to—a primary component for heating, a separate component for cooling, removable racks for holding multiple Containers, etc.

Donor Human Milk (DHM): The media that will be pasteurized, exclusively human (breast) milk donated to the organization (generally an HMB) that will be using the Device.

Exclusive Containers: Containers intended for Devices designed to use only the specific, Exclusive Containers purchasable from the Manufacturer or their agents.

Heating Period: The time during which the DHM is being heated by a water bath to reach the holding temperature.

Holding Period: The time during which the DHM is being held at an effectively constant holding temperature by a water bath for pasteurization.

Human Milk Bank (HMB): A service or organization established to recruit donors, collect DHM, and then process, screen, store, and distribute the DHM to meet infants' specific needs.

Manufacturer: The legal entity responsible for the production of the Device.

Oversight Organization: The legal entity responsible for reviewing documentation from the Manufacturer and confirming or denying the acceptability of the Device according to this specification, its related verification protocol, and any other related requirements.

Probe: The temperature measurement assembly used to determine the temperature of the DHM by positioning an integrated transducer in a specific location. This assembly as an integral part of the Device and the measurement is used for monitoring and displaying the progress of the Treatment Cycle.

Treatment Cycle: The time during which the DHM is being directly affected by the temperature of a water bath. This includes the Heating Period, the Holding Period, and the Cooling Period.

3 APPLICABLE DOCUMENTS

The items below include documents that are and are not specifically referenced in this specification. Some may be useful to certain readers as reference items. Note that some documents are listed as sources of information that may not apply to the Devices discussed in this specification (e.g., medical device specifications standards are listed below that are not directly applicable to holder pasteurization Devices which are not generally considered medical devices by regulatory and standards organizations).

- ISO 8601-1. Data elements and interchange formats – Information interchange – Representation of dates and times.
- International Organization for Standardization. (2015). Quality management systems (ISO/ Standard No. 9001). Retrieved from https://www.iso.org/obp/ui/#iso:std:iso:9001:ed-5:v1:en.
- International Organization for Standardization. (2016). Medical devices (ISO/ Standard No. 13485). Retrieved from https://www.iso.org/obp/ui/#iso:pub:PUB100422.
- British Standards Institution. (2016). Refrigerating systems and heat pumps. Safety and environmental requirements. Design, construction, testing, marking and documentation (BS EN 378-2:2016).
- British Standards Institution. (2018). Safety of machinery. Electrical equipment of machines. General requirements (BS EN 60204-1:2018).
- Australia New Zealand Dairy Authorities' Committee (ANZDAC). *Guidelines for Food Safety: Validation and Verification of Heat Treatment Equipment and Processes.* ANZDAC; 2007. Available at http://www.agriculture.gov.au/SiteCollectionDocuments/aqis/exporting/dairy/publications/anzdac-validation-heat-treatment.pdf.

- Defense Standardization Program. SD-15 *Guide for Performance Specifications.* United States Department of Defense; 2009. Available at http://www.navair.navy.mil/nawctsd/Resources/Library/Acqguide/SD_15 2009.pdf.
- Heinz, G, Hautzinger, P. Canning / sterilization of meat products. In Heinz, G, Hautzinger, P. *Meat Processing Technology for Small- to Medium-Scale Producers.* Bangkok, Thailand: Food and Agriculture Organization of the United Nations (FAO); 2007. Available at http://www.fao.org/docrep/010/ai407e/AI407E22.htm.
- National Advisory Committee on Microbiological Criteria for Food (NACMCF). Requisite scientific parameters for establishing the equivalence of alternative methods of pasteurization. *Journal of Food Protection.* 2006;69(5):1190–1216. doi: 10.4315/0362-028X-69.5.1190.
- Picaud, JC, Buffin, R. Human milk—Treatment and quality of banked human milk. *Clinics in Perinatology.* 2017;44(1):95–119. doi: 10.1016/j.clp.2016.11.003.
- United States Food and Drug Administration (FDA). *Grade "A" Pasteurized Milk Ordinance 2015 Revision*. Maryland: FDA; 2015. Available at https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/milk/ucm513508.pdf.
- US Food and Drug Administration. Code of Federal Regulations 21CFR113.40 -Thermally processed low-acid foods packaged in hermetically sealed containers (2017). United States of America. Retrieved from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=314.80.
- US Food and Drug Administration. Code of Federal Regulations 21CFR1240.61 (2017). United States of America. Retrieved from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1240.61.
- World Health Organization (WHO). *How to Develop and Publish a PQS Product Performance Specification*. 2nd Edition. Geneva: WHO; 2018. Available at http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/LinkPDF.aspx?UniqueID=5a4cd0be-1468-499b-88e6-b3a226d17e50&TipoDoc=PQS_x0020_Document_x0020_Type&GuidDoc=8d799c26-9e30-467d-8d9c-3e23c2f4bfae.

4 REQUIREMENTS

4.1 General

The Device shall conduct a controlled process of DHM pasteurization where the DHM is contained in closed Containers and heat is provided or removed indirectly via a water bath. After completion of the Treatment Cycle that includes a Heating Period, a Holding Period, and a Cooling Period, the DHM is cooled and stored. The Device shall measure, display, record, and store temperature data throughout this entire Treatment Cycle.

The maximum combined variability (accuracy and precision) necessary for all temperature measurements and meeting all temperature requirements is ±0.5°C.

4.2 Performance

4.2.1 Pasteurization cycle

The Device shall control the temperature during the Heating Period in such a way that all of the DHM in each batch reaches a target set temperature of 63°C ±0.5°C within a maximum of 15 minutes. Note that because the variability of the Probe is required to not exceed ±0.5°C (section 4.2.4), and in order to ensure that the safe pasteurization temperature of 62.5°C is reached, the Device shall hold the temperature at a measured temperature of 63°C ±0.5°C in case the variability is at the absolute lowest value of –0.5°C. The Device shall then hold the pasteurization temperature at 63°C ±0.5°C continuously for at least 30 minutes.

After completion of the Treatment Cycle, the Device shall control the Cooling Period in such a way that all of the DHM is cooled down to 25°C ±0.5°C within a maximum of 15 minutes and further down to 4°C ±0.5°C within at least 45 minutes of initiation of the Cooling Period.
No part of the DHM should be exposed to temperatures above 58°C ±0.5°C for more than 40 minutes. To preserve the quality of the DHM, the temperature of any part of the DHM should never exceed 64°C ±0.5°C.

4.2.2 Heating and cooling method

Heating of the DHM shall be achieved in a water bath. Cooling of the DHM shall be achieved in a water bath or water and ice bath.

4.2.3 Agitation and mixing

For the purpose of homogeneous temperature distribution, the Device should use agitation or mixing to assure that every particle of the DHM in all containers receives the same treatment, reaching as close to consistent temperatures as possible during the Heating Period, Holding

Period, and Cooling Period. Agitation or other mixing of both or either the DHM and the process water by mechanical means can be effective ways to induce temperatures that are more consistent. However, note that excessive forces on the DHM itself can cause mechanical damage to DHM components at the molecular level, potentially affecting DHM quality.

4.2.4 Temperature variability

The limit of error of the Probe shall not exceed ±0.5°C at any point, time, or temperature within the intended operating range of the Device.
Temperature differences between any two points in the DHM should never be greater than 1°C.

4.2.5 Holding arrangement

The Device should be equipped with a holding mechanism (e.g., rack or basket) that allows consistent arrangement of Containers in the water bath.

Mixing of the DHM in the Containers may be achieved through agitation of the holding mechanism.

4.2.6 Temperature monitoring

The temperature of the DHM during the entire Treatment Cycle shall be monitored and recorded.

To monitor the temperature of the DHM, the Device shall be equipped with a temperature Probe. The Probe should be placed in a container of the same material, dimensions, and fill volume as the DHM Containers undergoing pasteurization.

The location of the Probe shall be such that it monitors the lowest temperature of any portion of the DHM in any of the Containers.

If a proxy fluid (instead of DHM) is used for temperature measurements, it shall be verified to reflect the real temperature of the DHM.

4.2.7 Display

The Device shall be equipped with a display in alphanumerical form. The user shall be able to view:

- The DHM temperature as measured by the Probe at a resolution of 0.1°C.
- The total elapsed time in minutes at a resolution of 0.1 minutes or more exact.
- The temperature display adjustable between °C and °F.
- Indication of alarms.

Additional functionality including the following is recommended but not required:

- The elapsed time of the Holding Period at 63°C ±0.5°C at a resolution of 0.1 minutes or more exact.

- Explanatory alarms or warnings.
- A continually updating graph of time versus temperature.

4.2.8 Recording and data storage

The Device shall be equipped with electronic data logging capability and internal memory to store the acquired data in digital format. Alternatively, the Device may be easily connectable to another piece of equipment such as a computer or other data storage machine for direct data transfer and storage.

The Device shall be equipped with a real time clock and record time and temperature measurements simultaneously. Time and temperature data shall be recorded at a constant rate of every 1 to 60 seconds.

Records shall be stored and archived for documenting evidence of the Treatment Cycle and expedient retrieval. The following should be recorded and stored for each Treatment Cycle:

- The equipment identification number.
- A timestamp according to ISO 8601.
- Unique index number for each Treatment Cycle.
- Duration, start, and end time of the entire Treatment Cycle.
- The DHM temperature as measured by the Probe.
- The duration of the Heating Period to reach 63°C.
- The duration, start, and end time of the Holding Period.
- The minimum and maximum temperature during the Holding Period.
- The duration of the Cooling Period.
- The total elapsed time.
- Alarms.

The Device shall be equipped with a USB port for transferring data. All the data shall be exportable in at least one general format compatible with a broad range of applications such as CSV, ASCII, or similar for external data analysis. Printing capabilities for paper reports and labelling of Containers are recommended for tracking purposes but not required.

4.2.9 Level of automation

Ideally, the Device should manage every step of the Treatment Cycle, including the Heating Period, the Holding Period, and the Cooling Period, automatically. Automation should include pre-set heating, pasteurization, and cooling temperatures and times and should not require manual setting of temperatures or time.

If human intervention is required, the Device shall at a minimum notify and prompt the user for each necessary action.

4.2.10 Alarms and notifications

An audible and visual alarm shall signal if the temperature either falls below 62.5°C±0.5°C for more than one minute during the Holding Period or increases above 64°C±0.5°C for more than one minute at any time. Overheating protection shall be present with both audible and visual alarms to notify the user in the case that the Device itself is heating above safe limits to be designated by the Manufacturer.

If the Device is not fully automated, it shall additionally emit audible alarms, visual signals, and display instructions or simple indications prompting each necessary action. Notifications will likely include instruction at the following points:

- After achieving the set temperature of 63°C±0.5°C.
- After completion of the Holding Period continuously for 30 minutes.
- After achieving the final cooling temperature.

The Device Manufacturer should consider inclusion of automatic self-diagnosis capabilities for mechanical and electrical malfunctions with audible and visual alarms, including automatic monitoring of filling and draining to detect possible malfunctions that could result in under-filling or overflow. Sensors may also control the water level of the water tank to prevent overflow and under-filling.

An automatic Device should emit an audible and visual notification at the beginning and the end of the complete Treatment Cycle.

All alarm and notification conditions shall be accompanied by instructions on the display or other clear, simple indications to the user.

4.3 Materials

4.3.1 Water bath

All parts of the device in contact with water during normal operation should be constructed with no obvious remaining seams and made completely of corrosion-resistant material that is impervious and resistant to heat and temperature changes.

Exterior features should also be corrosion-resistant. They should be smooth and durable, with rounded edges and corners. For temperature consistency and control, the water bath should have a non-removable lid or cover.

The materials and design shall prevent the exterior of the Device from getting hot enough to cause accidental burns even after extended use.

4.3.2 Heating system

If the heating system consists of submerged heating element(s) or is otherwise exposed, it shall be made of material resistant to chemicals used for cleaning. Heating components should be sheathed or otherwise contained if composed of materials or elements that cannot withstand common detergents or chemicals used for cleaning (e.g., NaOH, bleach).

4.3.3 Moving parts

Materials used for moving parts including agitation systems should be resistant to vibration and long-term abrasion and wear.

4.3.4 Cleaning

Exposed surfaces and components of the water bath shall be made of material that can withstand exposure to frequent sanitization with NaOH or bleach.

The exterior of the Device should have smooth, easy-to-clean surfaces and be resistant to the effects of common detergents or chemicals used for cleaning.

4.3.5 Electronics

All electronic parts shall be isolated against any contact with water and moisture.

4.4 Design

4.4.1 General

The Device should be simple, intuitive, and safe to operate. A small-scale Device for pasteurizing smaller batches of DHM should be of bench-top design while a larger-scale Device may be freestanding and mobile.

Switches and other controls should be installed so that they are easily accessible, ergonomic, and recognizable.

4.4.2 Heating and cooling system

The Device may be designed to perform heating, pasteurization, and cooling in a single compartment or location. Separate portions of the Treatment Cycle may alternatively be accomplished in separate Device components. If heating and cooling baths are separate components, transfer of the Containers between the two should be easy, straightforward, fast, and safe.

The heating system should also be capable of maintaining temperature consistently and rapidly counterbalancing any changes in system temperature (e.g., when a large batch of cold Containers of DHM are added).

If the water bath includes inlets and outlets for filling and emptying, each connection should be provided with a shut-off valve. If possible, the system should be designed to ensure that all water entering the water bath is treated and clean. Ideally, the Device design should include the addition of filters for incoming water to prevent microorganisms or other contaminants from entering the water bath. This is especially relevant if the Device may be marketed or used in locations with poor water quality. Because water quality is site-specific, the Manufacturer may alternatively develop guidance and separate engineering solutions independent from the workings of the Device itself in order to adequately address water quality needs.

The water bath should include a non-removable cover with a mechanism to hold it open at an angle greater than 90 degrees and allow easy access for loading and removal of the DHM Containers and cleaning. The lid or cover should ideally also protect hands from hot vapors, allow condensate to drain back into the bath, and not be excessively heavy or difficult to open and close.

4.4.3 Agitation or mixing

If the Device includes mechanical means for agitation or mixing, the mechanism should be isolated to limit vibration and amplification throughout the Device.

4.4.4 Safety

The Device shall be designed for safe operation for the intended use. Contact burns from hot surfaces or hot vapor should be avoided through design, geometry, and materials.

Safety features should include secondary thermostats that automatically disconnect heater power should the bath temperature get too high. Heater power should also automatically shut off if the water bath accidentally runs dry.

The Device should control the liquid level in the water bath to avoid overflow or that the water level is too low or runs dry.

4.5 Physical characteristics

4.5.1 Capacity

The water bath capacity and dimensions should correspond to the intended batch treatment capacity. The ratio of water volume to batch capacity shall allow precise and uniform temperature control.

If the Device is offered as a small-scale Device for lower-volume treatment, it is recommended that batches of approximately 200 to 1500 mL in containers of no more than 100 mL each be accommodated.

Design of Devices (especially larger-scale Devices) shall consider the total weight of a full capacity batch. If full DHM Containers are added and removed in a rack or other mechanism, each rack shall not exceed a total loaded mass of 8 kg.

4.5.2 Dimensions and weight

A small-scale Device shall be compact and fit easily on conventional laboratory benches. The height should be limited as much as possible for easy and ergonomic access and visibility.

A larger-scale Device should be freestanding and mobile on wheels or swivel casters each equipped with a double-locking system. Length and width shall be limited to fit through standard door widths in the locations where the Device is intended to be sold. As guidance, it is recommended that the shorter dimension of an approximately rectangular Device (length or width) not exceed 710 mm. The longer of the two dimensions should not exceed 1700 mm.

The maximum diagonal dimension (i.e., corner-to-corner distance in any plane of a rectangular prism) should not exceed 1850 mm.

4.6 Electrical requirements

4.6.1 Power usage

The Device shall be powered by electrical, mains-supplied power. The Device should be offered with 220–240 V; 50/60 Hz or 100–127 V; 50/60 Hz options dependent on the intended location of sales and use. Performance should be functionally identical between the options, regardless of the nominal mains voltage and frequency.

Additionally, the Device design should consider peak power usage and maximum current draw and minimize them as much as reasonably possible while maintaining effectiveness of the Device to run the Treatment Cycle. As reference, the following may be approaching ideal but may not be possible depending on Device design:

- Maximum 1200 W peak power usage.
- Maximum 15 A current draw.
- 1 phase power system only.

4.6.2 Electrical connection

If onsite installation is not included with purchase of the Device, the Device shall be supplied with electrical power lead with a sealed-on plug compatible with the electricity socket standard for the intended location of sales and use. The Device shall also be equipped with a mechanism specifically designed to turn the power completely on and off (e.g., power switch or button) that is readily accessible to the user but protected from accidental activation.

4.6.3 Voltage stabilization and fuses

Although not required, integrated voltage stabilization should be considered for the Device. Fluctuations in mains power can be sizeable depending on the location of use. If fuses are used in the Device, they shall be easy to access and clearly marked.

4.7 Reliability

The warranty of the Device shall be a minimum of one year from the date of installation. The Device should be designed and built to provide a minimum useful lifetime of five years and 1,500 uses prior to needing repair.

The temperature drift of the Probe shall not be more than 0.2°C over three months of normal use, as intended.

The Device Manufacturer should consider inclusion of self-diagnostic circuity in Device design to provide a constant monitoring of all temperature sensing and be capable of detecting open or short circuits, poor connections and faulty components.

4.8 Environmental requirements

The Heating, Holding, and Cooling Period temperatures should be functionally equivalent in ambient temperatures between 5°C and 35°C.

All temperature sensing and measurements should be unaffected during operation at ambient temperatures between 5°C and 35°C.

No part or material of the Device should be negatively or functionally affected when exposed to temperatures between –5°C and 50°C and relative humidity between 15 percent and 90 percent.

4.9 Installation and training

4.9.1 Shipment

The manufacturer should be aware that products may be exposed to very high temperatures during shipping and dockside storage and should take appropriate actions to mitigate associated risks. The packaging should be of sturdy export quality and of a commercial standard that will provide adequate protection of the Device for carriage by air, sea, and/or road to final destinations worldwide, including locations with adverse climatic and storage conditions and high humidity. To avoid destructive unpacking prior to arrival at the final destination Manufacturers are encouraged to add a resealable observation opening in the packaging to aid inspectors in finding labelling and/or placing additional markings prior to installation. Instructions on the packaging alerting inspectors to use of the opening and what information will be revealed are also advised.

4.9.2 Installation and qualification

The manufacturer shall either provide installation and performance qualification services or include a protocol for both that can be carried out by the end user.

4.9.3 Requalification

Although requalification of Devices in use is not required, the Manufacturer shall provide a protocol for periodically requalifying the performance of the device and a recommended frequency for the requalification. Yearly requalification is recommended.

4.9.4 Training

Training is not required although it is recommended that the Manufacturer have the capability to provide remote or in-person training in the countries where the Device is deployed.

4.10 Maintenance

4.10.1 Instructions

Detailed maintenance instructions shall be provided. If only one language is included, it shall be the language most appropriate to the country of use. Instructions should include easy-to-understand visuals whenever possible to avoid reliance on text. The instructions shall be written for users and repair technicians, need not repeat the information shown on any permanent labels, but shall cover the following topics:

- A description of operations and use.
- A detailed guide to all warning lights, other indicators, and displays.
- Simple daily, weekly, and monthly maintenance and cleaning tasks.
- Periodic preventative maintenance checks.
- Diagnostic and repair guidance and procedures for minor damage.
- Battery replacement (if applicable).
- An itemized list of spare parts including part numbers.
- End-of-life resource recovery and recycling procedures.

4.10.2 Service

Routine cleaning and maintenance will be carried out by the end user. The Device shall be designed, and components selected, with the aim of achieving at least a five-year life free of repairs or maintenance apart from expected, routine tasks such as cleaning, Probe calibration, and replacement of filters (if any).

4.10.3 Spare parts

The Manufacturer shall supply a list of the spare parts and procedure for procurement. At a minimum, each Device shall be supplied with five spare fuses of each fuse size and type used in the appliance (if any). The spares fuses are to be attached within or on the appliance. The manufacturer shall ensure supply of spare parts for a minimum of ten years from the time of purchase of the last Device.

4.11 Documents

Documentation provided with the Device should include:

- Installation plans and safety instructions.
- An operator manual and a quick start guide.
- A troubleshooting manual.
- Maintenance instructions (as required in section 4.10.1).
- A spare parts list (as required in section 4.10.3).
- A warranty statement.
- A Certificate of Conformity.

5 CONTAINERS

5.1 Type and material

All materials comprising Exclusive Containers shall be resistant to damage or failure when exposed to the operating temperature range identified in section 4.2.1 and when stored at temperatures at least as low as –20°C when filled with DHM that will expand under freezing conditions.

Exclusive Containers shall be delivered sealed in sanitary or sterile condition. Alternatively, they may instead remain non-toxic and fully functional when exposed to nominal autoclave temperatures of at least 121°C, in the case that suggested practice is to autoclave the Exclusive Containers before use. They shall also remain non-toxic and fully functional when exposed to multiple freeze-thaw cycles. Manufacturers should be aware that plastics are often not able to withstand these extreme thermal processes due to material deformation and degradation that can lead to sealing issues and subsequent ingress, egress, safety, and storage issues. Additionally, Manufacturers should be aware that some autoclaves will reach higher temperatures in actual use than nominally stated.

5.2 Safety

All materials comprising Exclusive Containers shall be non-toxic and intended for food-safe use throughout the operating temperature range identified in section 4.2.1. Exclusive Containers shall not be sterilized with ethylene oxide by the Manufacturer.

Containers shall not allow ingress of process water or egress of DHM throughout the Treatment Cycle.

Containers should not add to, reduce, or modify the DHM. This includes materials that may release leachables, extractables, or particles or that could potentially inhibit or bind any beneficial component of the DHM. Many polymers will naturally bind DHM components including fats. The manufacturer should be aware of this and attempt to minimize such effects when selecting materials for Exclusive Containers.

5.3 Reuse

If Exclusive Containers are intended for sanitization and reuse, they shall further remain non-toxic and fully functional when exposed to multiple freeze-thaw cycles and nominal autoclave temperatures of at least 121°C. Manufacturers should be aware that plastics are often not able to withstand these thermal processes over multiple cycles due to material deformation and degradation that can lead to sealing issues and subsequent ingress, egress, safety, and storage issues. Additionally, Manufacturers should be aware that some autoclaves reach higher temperatures in actual use.

Reusable containers shall be easily cleanable and resistant to standard cleaning and sterilization procedures and chemicals. The number of safe reuses of Exclusive Containers shall be specified and demonstrated by the Manufacturer.

6 VERIFICATION AND REPORTING

The Manufacturer shall verify minimum compliance of the Device with this specification using the related verification protocol document. Specific testing requirements and steps as well as reporting requirements are included in that document.

6.1 Manufacturer certifications

The Manufacturer should be ISO 9001 or 13485 certified. If the Manufacturer does not hold either of these certifications, they shall provide documentation of similar or equivalent certifications or quality management procedures and protocols to which they adhere.

6.2 Level of quality control and qualification

Although qualification processes are not required for each individual Device that will be produced, the Manufacturer should have internal qualification processes that guarantee that each unit produced will meet the specifications in this document.

6.3 Change notification

The Manufacturer shall inform the Oversight Organization in writing of any changes that may affect the performance of the product after initial acceptance has taken place. Any change that the Oversight Organization considers would alter the test results obtained against the related verification protocol may result in a request for the product to be retested.

The Manufacturer shall further inform the Oversight Organization in writing in the event of safety-related product recalls, component defects and other similar events. If requested to do so by the Oversight Organization, the Manufacturer is to submit a report stating the number of affected systems and the number of component repairs/replacements provided, together with copies of any associated field reports and photographs.

Our vision is that **all children have the best nutrition for a healthy start in life**—through their own mother's breast milk or, when that's not possible, with safe donor human milk.

Of all the known approaches, breastfeeding has the greatest potential impact on child survival.

Scaling up breastfeeding to a near-universal level could prevent an estimated 823,000 deaths in children under the age of five worldwide every year. It's especially lifesaving in resource-limited settings, where a non-breastfed child's risk of death is six times that of a breastfed child. Integrating human milk banks into newborn and nutrition programs ensures that all infants have access to human milk, including vulnerable, preterm, and low-birthweight infants who lack sufficient mother's own milk. This toolkit of templates and resources serves as a systems strengthening guide for integrating human milk banking, making available safe and quality donor human milk for vulnerable infants, with a goal to ensure optimal lactation support and breastfeeding practices.

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