NON-HOSPITAL MEDICAL AND SURGICAL FACILITIES ACCREDITATION PROGRAM

Accreditation Standards

Procedural Pain Management – Ultrasound Modality

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INTRODUCTION

The procedural pain management (PPM) standards are outlined in several documents:

- procedural pain management (core) standards
- imaging modality (e.g. X-ray, ultrasound) standards
- emergency cart standards

Note: The ultrasound probe reprocessing standards in this draft document are for information only. These standards reflect the DRAFT Provincial Infection Control Network of British Columbia's (PICNet) Revised Ultrasound Cleaning and Disinfection Recommendations for All Health Care Settings, dated June 2018. The revised PICNet recommendations have been submitted to the BC Ministry of Health and Ministry approval is pending. The NHMSFAP procedural pain management standards will reflect the final ultrasound reprocessing practice requirements as directed by the Ministry of Health. Currently, community-based physicians using ultrasound probes for needle guidance are required to adhere to PICNet's Recommendations for Cleaning and Disinfection in Medical Ultrasound to Prevent Human Papillomavirus (HPV) Transmission, dated June 2016, which came into effect July 31, 2018.

PROCEDURAL PAIN MANAGEMENT – ULTRASOUND MODALITY

External ultrasound probes used for procedural pain management procedures are considered non-critical devices as they are not intended to contact non-intact skin or mucous membranes. This standard sets out the patient point-of-use and reprocessing practices for external ultrasound probes used for procedural pain management procedures.

PPMUS1.0 STANDARDS PROTOCOLS RESULT IN IMAGES APPROPRIATE FOR THEIR INTENDED USE IN CLINICAL DECISION-MAKING

PPMUS1.1	**There is a comprehensive process in place for protocol adoption and development.**	
PPMUS1.1.1	**M**	Examination procedures are readily available to technical staff operating the equipment during the procedure, as appropriate. *Guidance: If a technologist performs the ultrasound for target visualization, needle guidance and image capture, then procedures and protocol information is readily available.*
PPMUS1.1.2	**M**	Manufacturer's documentation is only used as a supplement to the examination procedure, as appropriate. *Intent: If a technologist performs the ultrasound for target visualization, needle guidance and image capture then there should be documentation for all ultrasound procedures performed at the facility. Equipment or product information supplied by the manufacturer may be used to supplement procedural documentation but cannot be used as a substitute. If the procedural physician is performing the ultrasound, then manufacturer's documentation is sufficient.*
PPMUS1.1.3	**M**	Protocols are reviewed every one to three years by qualified individual(s), as appropriate. *Guidance: If a technologist performs the ultrasound for target visualization, needle guidance and image capture, then procedures and protocol information is readily available.*
PPMUS1.2	**Protocols contain all the information necessary to perform the examination.**	
PPMUS1.2.1	**M**	Protocol information includes clearly specified measurements and imaging views, as appropriate. *Guidance: If a technologist performs the ultrasound for target visualization, needle guidance and image capture, then procedures and protocol information is readily available.*
PPMUS1.2.2	**M**	Protocol information includes the ancillary equipment or supplies needed, as appropriate. *Guidance: If a technologist performs the ultrasound for target visualization, needle guidance and image capture, then procedures and protocol information is readily available.*
PPMUS1.2.3	**M**	Protocol information includes a description of patient positioning, as appropriate. *Intent: Guidance: If a technologist performs the ultrasound for target visualization, needle guidance and image capture, then procedures and protocol information is readily available. At a minimum, a description of patient positioning for interventional and specialized procedures is provided.*
PPMUS1.3	**Examinations are performed following established protocols.**	
PPMUS1.3.1	**M**	Hand hygiene is performed at appropriate points in time. *Guidance: Hand hygiene is performed with plain soap and running water or alcohol-based hand rub. Hand hygiene is performed before and after direct contact with a patient, before putting on gloves for a clean or aseptic procedure, and after gloves are removed.*

PPMUS1.3.2	**M**	Personal protective equipment (PPE) is worn during the ultrasound procedure, as appropriate. *Guidance: In accordance with routine practices (a core principle of infection prevention and control strategies), PPE worn during the ultrasound procedure may include gloves, a mask, protective eye wear and/or face shield, and a waterproof gown.*
PPMUS1.3.3	**M**	The ultrasound probe is delivered clean to point of use. *Guidance: Following low-level disinfection, ultrasound probes are labelled as clean.*
PPMUS1.4	**Image capture and storage is performed when ultrasound is used for guidance or other interventional procedures.**	
PPMUS1.4.1	**M**	There is capture and storage of a minimum of one image per case confirming needle placement.
PPMUS1.5	**Ultrasound probe covers are used for all procedural pain management procedures.**	
PPMUS1.5.1	**M**	Ultrasound probes are covered with a sterile probe cover. *Guidance: Procedural pain management procedures are considered critical/sterile procedures and require the use of a sterile probe cover. All probe covers are considered single use, are applied just prior to use and discarded following the procedure.* ***Use of a sterile probe cover does not remove the requirement that external ultrasound probes are to be pre-cleaned and low-level disinfected between each patient use.***
PPMUS1.6	**Ultrasound gels are appropriately used to minimize the risk of contamination.**	
PPMUS1.6.1	**M**	Sterile gel is used for all procedural pain management procedures. *Guidance: Sterile gel is defined as unopened packets or sachets that are specifically labelled as "sterile." Any unused portion of single-use sterile gel packets is discarded and not reused for another examination.*
PPMUS1.6.2	**M**	Gel is not heated. *Guidance: Heating/warming of gel increases the risk of bacterial contamination and growth within a warm environment.*

PPMUS2.0 EQUIPMENT IS SAFELY OPERATED, MAINTAINED AND MONITORED IN A MANNER THAT ENSURES PERFORMANCE SPECIFICATIONS ARE MET

PPMUS2.1	**The imaging service ensures that equipment is capable of achieving the desired image quality and complies with the requirements of the examination. The following are minimum requirements:**	
PPMUS2.1.1	**M**	The ultrasound system is equipped with real-time, 2D grey-scale imaging.
PPMUS2.1.2	**M**	The ultrasound system is equipped with M-mode imaging.
PPMUS2.1.3	**M**	The ultrasound system is equipped with color and pulsed Doppler.
PPMUS2.1.4	**M**	The ultrasound system is equipped with power Doppler.
PPMUS2.1.5	**M**	The ultrasound system is equipped with harmonic imaging.
PPMUS2.1.6	**M**	The ultrasound system is equipped with a range of transducer frequencies appropriate for the examinations performed.

PPMUS3.0 EQUIPMENT TESTING IS PERFORMED PRIOR TO CLINICAL USE

PPMUS3.1	**Acceptance testing is performed after purchase and prior to clinical use of equipment.**	
PPMUS3.1.1	**M**	Acceptance testing is performed after purchase and prior to clinical use of equipment, and includes a physical and mechanical inspection of the system and probes. *Guidance: Acceptance testing is performed to ensure that the equipment is complete, safe and functioning properly before being used at the facility for the first time for patient care. This is performed by the manufacturer or a qualified biomedical technician when the equipment is received by the facility.*
PPMUS3.1.2	**M**	Acceptance testing is performed after purchase and prior to clinical use of equipment, and includes electrical leakage current (Ohms) testing of probes.

PPMUS4.0 QUALITY ASSURANCE PROGRAMS ARE ESTABLISHED TO ENSURE THE ATTAINMENT OF INTENDED QUALITY

PPMUS4.1	**Daily quality control procedures are established and used to monitor performance of ultrasound systems.**	
PPMUS4.1.1	**M**	Daily quality control testing includes a visual inspection of the system and probes for probe damage and overall system cleanliness.
PPMUS4.2	**Annual quality control procedures are established and used to monitor performance of ultrasound systems.**	
PPMUS4.2.1	**M**	Annual quality control testing includes a physical and mechanical inspection of the system and probes and any other testing as recommended by the manufacturer.
PPMUS4.2.2	**M**	Annual quality control testing includes electrical leakage current testing of all probes. *Guidance: Electrical leakage current testing is also to be performed after probe repair.*

PPMUS5.0 ULTRASOUND PROBES USED FOR PROCEDURAL PAIN MANAGEMENT PROCEDURES ARE REPROCESSED IN ACCORDANCE WITH MINISTRY OF HEALTH REQUIREMENTS

PPMUS5.1	**Following the procedure, ultrasound probes are PRE-CLEANED at point of use.** *Intent: Pre-cleaning of the ultrasound probe always precedes low-level disinfection.*	
PPMUS5.1.1	**M**	The probe cover is removed and discarded. *Guidance: All probe covers are considered single use and are discarded following the procedure prior to cleaning the probe.*
PPMUS5.1.2	**M**	The probe is disconnected from the ultrasound handle/cable prior to pre-cleaning. *Guidance: This step is not required if the probe and ultrasound handle/cable are one continuous piece (i.e. cannot be physically disconnected/disassembled from each other). If the probe can be disconnected from the ultrasound handle/cable, it must be disconnected for reprocessing. Wear and tear is not an acceptable reason for not disconnecting the probe from the ultrasound handle/cable prior to reprocessing.*

PPMUS5.1.3	**M**	The probe is pre-cleaned by wiping it with a moistened lint-free cloth to manually remove the gel residue. *Guidance: Pre-cleaning is performed immediately after completion of the patient procedure to remove gross soil and prevent it from hardening. The probe is pre-cleaned with a moistened (e.g. water, cleaning agent) lint-free cloth. Alcohol wipes are not appropriate for pre-cleaning as the alcohol will adhere the protein soil to the probe, making it hard to remove. If the probe has grooves or crevices, then it should be cleaned with a soft brush prior to any low-level disinfection. Pre-cleaning to remove any gel and soil including blood and body fluids, prior to low level disinfection, is essential.*
PPMUS5.1.4	**M**	Any pre-cleaning cloths, wipes or solutions are discarded and not re-used for the low-level disinfection step. *Guidance: Pre-cleaning cloths, wipes or solutions are never reused for low-level disinfection. Pre-cleaning and low-level disinfection activities are separate steps.*
PPMUS5.1.5	**M**	The ultrasound handle, cable and connector housing is pre-cleaned and then low-level disinfected between each patient use. *Guidance: The ultrasound handle, cable and connector housing is pre-cleaned with a moistened (e.g. water, cleaning agent) lint-free cloth. The ultrasound handle, cable and connector housing is then low-level disinfected using a new low-level disinfectant-moistened lint-free cloth. Low-level disinfectant products include sprays, wipes or solutions. Low-level disinfectants are to be used in accordance with manufacturer's instructions for use. Some low-level disinfectant solutions require pre-mixing/preparation (e.g. dilution).*
PPMUS5.2		**There is a process in place for the manual low-level disinfection of ultrasound probes.** *Intent: Ultrasound probes are pre-cleaned before they undergo manual low-level disinfection.*
PPMUS5.2.1	**M**	Following pre-cleaning, ultrasound probes are low-level disinfected between patients. *Guidance: Pre-cleaning to remove gross soil and gel always precedes low-level disinfection. Pre-cleaning ensures the probe is free of any gel and soil before proceeding with low-level disinfection. This is essential as sometimes these probes may come in contact with non-intact skin, blood and body fluids during procedural pain procedures. Low-level disinfectant products include sprays, wipes or solutions. Low-level disinfectants are to be used in accordance with manufacturer's instructions for use. Some low-level disinfectant solutions require pre-mixing/preparation (e.g. dilution).*
PPMUS5.2.2	**M**	Low-level disinfectants are prepared and used according to the manufacturer's instructions for use (e.g. concentration, dilution, contact time). *Guidance: Low-level disinfectants are to be used in accordance with manufacturer's instructions for use (MIFU). Low-level disinfectant solution is properly diluted in accordance with the MIFU for the volume of water in the sink. Low-level disinfectant moistened wipes are to be moist enough to thoroughly wet the surface of the ultrasound probe for the required contact time as specified by the MIFU.*
PPMUS5.2.3	**M**	The ultrasound probe is completely immersed in the low-level disinfectant solution or completely wetted with low-level disinfectant wipes. *Guidance: If using a soaking solution, immerse the probe in a sink with sufficient low-level disinfectant to fully immerse the procedural end of the probe while protecting the electrical head from water ingress. While immersed, the entire surface of the probe is wiped with a soft lint-free cloth. If using a moistened wipe, thoroughly wet the surface of the probe using the low-level disinfectant-moistened wipe for the required contact time as specified by the MIFU. Some low-level disinfectant wipes may require multiple wipes to sufficiently wet the surface. A new wipe is used if the ultrasound probe cannot be completely wetted with a single wipe.*
PPMUS5.2.4	**M**	Parts of the probe (electrical head and cord) that cannot be immersed are cleaned with a low-level disinfectant wipe.

PPMUS5.2.5	**M**	Contact with low-level disinfectant is maintained for the recommended time. *Guidance: The low-level disinfectant MIFUs are followed with regard to the length of time the probe must be immersed, if soaking, or remain thoroughly wet, if using wipes, to achieve low-level disinfection.*
PPMUS5.2.6	**M**	Ultrasound probes are rinsed if indicated by the low-level disinfectant and probe MIFUs. *Guidance: In accordance with the MIFUs, some products (i.e. solutions) require that the probe be rinsed with water, following low-level disinfection, and then dried with a soft lint-free cloth.*
PPMUS5.2.7	**M**	Ultrasound probes are dried if indicated by the low level disinfectant and probe MIFUs. *Guidance: In accordance with the MIFUs, some products (i.e. solutions) require that the probe be rinsed with water, following low-level disinfection, and then dried with a soft lint-free cloth.*
PPMUS5.2.8	**M**	Low-level disinfectant solutions and wipes are discarded after each use.
PPMUS5.2.9	**M**	Low-level disinfectant solution and wipes are used within their expiry date.
PPMUS5.2.10	**M**	There is a process in place that clearly distinguishes a non-reprocessed ultrasound probe from one that has been reprocessed. *Guidance: Following reprocessing, ultrasound probes are labelled as clean.*
PPMUS5.3	**There is dedicated space for the reprocessing of ultrasound probes (dedicated medical device reprocessing (MDR) area).**	
PPMUS5.3.1	**M**	Reprocessing takes place in a physical space solely dedicated for that purpose. *Guidance: Reprocessing shall not be performed in "sterile areas/rooms." A dedicated area allows for safe use of chemicals, standardized processes, and reduces the possibility of cross contamination.*
PPMUS5.3.2	**M**	There is sufficient counter space to perform reprocessing of ultrasound probes. *Guidance: Adequate space is needed for reprocessing activities to ensure one-way workflow including clear separation between dirty and clean areas.*
PPMUS5.3.3	**M**	There is a sink sufficient in size and depth to perform reprocessing of ultrasound probes, as appropriate. *Guidance: A sink is required if the low-level disinfectant product requires the immersion of the ultrasound probe in a low-level disinfectant solution. If there is no sink in the reprocessing area, then commercially available pre-moistened low-level disinfectant wipes must be used.*
PPMUS5.3.4	**M**	Staff has a means to perform hand hygiene. *Guidance: Dedicated MDR areas should have a double sink for reprocessing activities plus a third sink dedicated for hand hygiene. Hand hygiene should not be performed in a sink used for reprocessing activities, as the sink may be heavily contaminated from the cleaning of dirty medical devices and performing hand hygiene with soap and water may interfere with the efficacy of the cleaning process (e.g. diluting detergent solutions, emollients in hand soap adhering to the medical devices). Where there is only a single sink, the sink must be cleaned between hand hygiene and reprocessing activities. Alcohol-based hand rub may also be used for hand hygiene.*

PPMUS5.3.5	**M**	Working area finishes are appropriate for MDR activities. *Guidance: Counters must be smooth, seamless and composed of a non-porous material so that they can withstand frequent cleaning followed by low-level disinfection. Particulate materials such as wood and laminate products are not suitable as they allow ingress of water or chemical solutions. Floors must be able to withstand frequent mopping with hospital-grade cleaning products. Carpet is not permitted in the reprocessing area.*
PPMUS5.3.6	**M**	One-way workflow from dirty to clean is maintained. *Guidance: One-way workflow must be in place in the reprocessing area. One-way workflow is the practice of ensuring that reprocessing work flows in one direction from the dirtiest to the cleanest to prevent re-contamination. Clean probes are never placed back onto a dirty/soiled surface and are not stored next to used/dirty probes awaiting reprocessing*.
PPMUS5.4	**There is dual-purpose space for the reprocessing of ultrasound probes (reprocessing takes place in a "dual-purpose" space (e.g. exam room)).**	
PPMUS5.4.1	**M**	Patients are never present when ultrasound probes are being reprocessed. *Guidance: As pre-cleaning is performed immediately after completion of the procedure to remove the residual gel and prevent gross soil from hardening, patients may be present when the ultrasound probe is being pre-cleaned. However, patients may not be present during the low-level disinfection of ultrasound probes.*
PPMUS5.4.2	**M**	There is sufficient counter space to perform reprocessing of ultrasound probes. *Guidance: Adequate space is needed for reprocessing activities to ensure one-way workflow including clear separation between dirty and clean areas.*
PPMUS5.4.3	**M**	There is a sink sufficient in size and depth to perform reprocessing of ultrasound probes, as appropriate. *Guidance: A sink is required if the low-level disinfectant product requires the immersion of the ultrasound probe in a low-level disinfectant solution. If there is only one sink in the dual-purpose space, the hand-hygiene sink can be used for the cleaning, rinsing and low-level disinfection of the ultrasound probe provided that the sink is cleaned and low-level disinfected in between cleaning and rinsing activities, before any hand-hygiene activities, and before the next patient enters the room. If there is no sink in the reprocessing area, then commercially available pre-moistened low-level disinfectant wipes must be used.*
PPMUS5.4.4	**M**	Staff have the means to perform hand hygiene. *Guidance: Sinks used for reprocessing become contaminated during the cleaning and disinfection of reusable medical devices. If there is only one sink in the dual-purpose space (e.g. exam room), the sink must be cleaned and low-level disinfected prior to using it for hand hygiene. Alcohol-based hand rub may also be used for hand hygiene.*
PPMUS5.4.5	**M**	Working area finishes are appropriate for MDR activities. *Guidance: Counters must be smooth, seamless and composed of a non-porous material so that they can withstand frequent cleaning followed by low-level disinfection. Particulate materials such as wood and laminate products are not suitable as they allow ingress of water or chemical solutions. Floors must be able to withstand frequent mopping with hospital-grade cleaning products. Carpet is not permitted in the reprocessing area.*

PPMUS5.4.6	**M**	The work area is cleaned and low-level disinfected prior to reprocessing activities being performed. *Guidance: The counters and sink are cleaned with a moistened lint-free cloth or wipe to remove gross soil. Then, using a new lint-free cloth, the counters and sink are low-level disinfected. Low-level disinfectant products include sprays, wipes or solutions.*
PPMUS5.4.7	**M**	One-way workflow from dirty to clean is maintained. *Guidance: One-way workflow must be in place in the reprocessing area. One-way workflow is the practice of ensuring that reprocessing work flows in one direction from the dirtiest to the cleanest to prevent re-contamination. Clean probes are never placed back onto a dirty/soiled surface and clean probes are not stored next to used/dirty probes awaiting reprocessing*.
PPMUS5.4.8	**M**	The sink is cleaned and low-level disinfected between cleaning and rinsing activities. *Guidance: If there is only one sink in the dual-purpose space, the sink is cleaned and low-level disinfected in between ultrasound probe cleaning, disinfection and rinsing activities, before any hand hygiene activities, and before the next patient enters the room.*
PPMUS5.5	**Staff are trained and have readily available the necessary supporting information to perform ultrasound probe reprocessing.**	
PPMUS5.5.1	**M**	Staff performing reprocessing activities have completed training in the safe handling and reprocessing of external ultrasound probes used for procedural pain management procedures. *Guidance: Documentation of training is on file at the facility.*
PPMUS5.5.2	**M**	Written and current manufacturer's instructions for use are available and followed. *Guidance: MIFUs for the ultrasound probe, cleaning agents and low-level disinfectant must be available and followed to ensure compatibility and to prevent potential damage to the ultrasound probe.*
PPMUS5.5.3	**M**	Written procedures for the reprocessing of ultrasound probes are available.
PPMUS5.6	**Occupational Health and Safety standards are followed.**	
PPMUS5.6.1	**M**	Safety data sheets (SDS) are available and current for all cleaning detergents and disinfectants. *Guidance: Workplace Hazardous Materials Information System (WHMIS) provides information on hazardous products as defined and described in the federal* Hazardous Products Act *and Hazardous Products Regulations. The SDS must be readily available to staff. SDSs must have been published, revised or reaffirmed by the supplier within the last three years.*
PPMUS5.6.2	**M**	All cleaning detergents and disinfectants are labeled, stored and handled appropriately. *Guidance: All chemicals used for reprocessing are in their original manufacturer containers, and the containers are in good condition to securely contain the substance. If the original manufacturer label becomes illegible or is accidentally removed from the product or container, it is replaced with a workplace label. The workplace label must include the name of the cleaning detergent or disinfectant as it is named on its SDS, information on the safe handling of the hazardous product, and the availability of a SDS.*
PPMUS5.6.3	**M**	Spill kits are clearly labelled and kept where cleaning detergents and disinfectants are used and stored. *Guidance: Whether a spill kit is needed depends on the chemicals at the facility. The chemical's SDS provides information on what to do and what equipment (i.e. spill kit) is needed in the event of a chemical spill.*

PPMUS5.6.4	**M**	Staff performing reprocessing activities have completed WHMIS training and education for the safe handling of cleaning solutions and low-level disinfectants. *Guidance: Documentation of training is on file at the facility.*
PPMUS5.6.5	**M**	Eating, drinking, storage of food, application of cosmetics, or storage of personal effects does not occur in the reprocessing area. *Guidance: Reprocessing does not take place in the kitchen, staff lounge, food preparation areas, or in washrooms.*
PPMUS5.6.6	**M**	Appropriate personal protective equipment (PPE) is worn when handling/cleaning/reprocessing ultrasound probes. *Guidance: PPE worn during the reprocessing of ultrasound probes may include gloves, a mask, protective eye wear and/or a face shield, and a waterproof gown with full-length sleeves.*
PPMUS5.7	**A clean physical environment is established.**	
PPMUS5.7.1	**M**	Written procedures for the environmental cleaning of the reprocessing area are available and include clearly defined responsibilities.
PPMUS5.7.2	**M**	Written procedures for the environmental cleaning of the ultrasound procedure room are available and include clearly defined responsibilities.
PPMUS5.7.3	**M**	Medical device reprocessing area sinks and faucets are cleaned and low-level disinfected between uses. *Guidance: The sinks and faucets are cleaned and low-level disinfected in between ultrasound probe cleaning, disinfection and rinsing activities. The sinks and faucets are cleaned with a moistened lint-free cloth or wipe to remove gross soil. Then, using a new lint-free cloth, the sinks and faucets are low-level disinfected.*
PPMUS5.7.4	**M**	Medical device reprocessing area sinks and faucets are cleaned and low-level disinfected at the end of each day. *Guidance: Cleaning logs are maintained.*
PPMUS5.7.5	**M**	Medical device reprocessing area horizontal surfaces are cleaned and low-level disinfected when visibly soiled and at the end of the day. *Guidance: Cleaning logs are maintained.*
PPMUS5.7.6	**M**	Medical device reprocessing area floors are cleaned daily. *Guidance: Cleaning logs are maintained.*
PPMUS5.7.7	**M**	The ultrasound procedure room is cleaned and low-level disinfected between each patient. *Guidance: All surfaces and equipment in the ultrasound procedure room that comes into contact with the patient or body fluids is cleaned and low-level disinfected (e.g. exam table, counters).*
PPMUS5.7.8	**M**	The ultrasound machine is cleaned and low-level disinfected between each patient. *Guidance: This includes the monitor, keyboard, cables and probe holder(s).*
PPMUS5.7.9	**M**	The ultrasound procedure room is terminally cleaned at the end of each day. *Guidance: Cleaning logs are maintained.*

Accreditation Standards

Procedural Pain Management – Ultrasound Modality

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