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هيئة الصحة العامة

PUBLIC HEALTH AUTHORITY

Ultrasound Gel Safety Infection Prevention Practice Recommendations

A practical reference to support safe selection, handling, storage, and use of ultrasound gel in healthcare settings

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Background

Ultrasound gel is routinely used in diagnostic, therapeutic, and interventional procedures to support acoustic transmission between the ultrasound transducer and the patient. Although ultrasound gel is commonly used and poses low infection risk in many routine applications, contaminated products or inappropriate handling can result in healthcare-associated infections and outbreaks.

Contamination could occur during manufacture or packaging, or after the product reaches the healthcare facility through storage, warming, handling, nozzle contact, refilling, or repeated use. Healthcare facilities shall therefore establish risk-based processes for product selection, handling, traceability, probe reprocessing, incident reporting, and outbreak response.

Purpose

To provide standardized infection prevention and control (IPC) requirements for the safe selection, procurement, handling, storage, warming, use, traceability, and disposal of ultrasound gel, and for the rapid management of suspected product contamination or associated infection clusters.

Scope

These recommendations apply to all healthcare settings and clinical services in which ultrasound gel is used, including radiology, point-of-care ultrasound, emergency care, intensive and high-dependency care, neonatal care, outpatient clinics, procedural areas, operating rooms, and other diagnostic or interventional services.

Definitions and Concepts

Term	Definition
Sterile single-use ultrasound gel	A sterile product supplied in a unit-dose container intended for one patient and one procedure; any remainder is discarded immediately after use.

Term	Definition
Non-sterile multi-use ultrasound gel	A non-sterile product supplied in a container intended for repeated dispensing; restricted to appropriate non-critical use on intact skin.
High-risk patient	A Critically ill patient; neonatal or pediatric or cardiac intensive care units, adult intensive care unit (ICU)/ high dependency unit (HDU) patient; severely immunocompromised patient; critical ill patient; patient under transmission-based isolation; or another patient assessed by the clinical and IPC teams as having increased risk of invasive infection.
Intrinsic contamination	Contamination introduced during manufacture or packaging before the product reaches the healthcare facility.
Extrinsic contamination	Contamination introduced after manufacture, including through opening, handling, nozzle contact, refilling, warming, storage, or environmental exposure.

Risk-Based Selection of Ultrasound Gel

Gel selection must be based on the procedure, body site, skin or mucosal integrity, likelihood of skin breach, patient risk, and the required transducer reprocessing level. Sterile gel does not replace appropriate probe cleaning, disinfection, sterilization, or use of a suitable probe cover.

Clinical situation	Gel requirement
Intact skin; routine non-invasive examination	Non-sterile multi-use gel could be used if all controls are met
Mucous membrane examination	Sterile single-use gel
Non-intact skin, open wound, or near a fresh surgical site	Sterile single-use gel

Clinical situation	Gel requirement
Percutaneous, invasive, vascular-access, or sterile-field procedure	Sterile single-use gel
High-risk patient	Sterile single-use gel unless an approved risk assessment explicitly supports an alternative for intact-skin, non-invasive use

Core Infection Prevention and Control Requirements

- Perform hand hygiene before and after patient contact and before handling gel or gel containers.
- Use aseptic technique for invasive procedures and whenever a sterile field is required.
- Prevent the dispensing nozzle from touching the patient, transducer, gloves, environmental surfaces, or other equipment.
- Do not use any product that is expired, damaged, leaked, visibly contaminated, improperly stored, recalled, or suspected to be contaminated.
- Remove residual gel from the skin after examination.
- Discard all remaining sterile single-use gel immediately after the procedure; never retain, reuse, or share it between patients.
- Clean and reprocess the transducer, cable, console, handle, holder, and other high-touch components according to approved procedures and manufacturer instructions.

Use of Non-Sterile Multi-Use Gel

Non-sterile multi-use gel must be used only for non-critical examinations involving intact skin and only when the following controls are consistently applied:

- Use the smallest practical container size.

- Keep the container closed when not in use and store it upright in a clean, dry area within the manufacturer-specified temperature range.
- Clearly label the container with the opening date and time and discard it at the end of the manufacturer-validated in-use period or earlier when required by an approved national or facility policy.
- Never transfer or decant gel between containers; never refill, top up, combine, wash, reprocess, or reuse disposable bottles.
- Use a dedicated container for a patient or clinical area when indicated by risk assessment.
- Do not use multi-use containers for patients under transmission-based isolation precautions.
- Discard the container immediately when contamination is suspected, while preserving implicated products required for an investigation as described below.

Use of Sterile Single-Use Gel

Sterile single-use ultrasound gel must be immediately available wherever invasive, semi-critical, or high-risk procedures are performed. It shall be used for procedures involving sterile tissue, the vascular system, mucous membranes, non-intact skin, open wounds, fresh surgical sites, percutaneous access, or a sterile field, and for high-risk patients as defined in this document.

Warming of Ultrasound Gel

Routine warming is not recommended. When a documented clinical need or patient benefit exists, the following controls shall apply:

- Use only a dry warmer specifically designed or approved for ultrasound gel; improvised and water-based warming are prohibited.
- Comply with the gel and warmer manufacturers' instructions, including temperature, duration, container orientation, and compatibility.
- Warm sterile single-use gel only when both product and warmer instructions explicitly permit it and sterility and package integrity will not be compromised.

- Assign responsibility and a documented frequency for cleaning and disinfection; maintain records of cleaning, preventive maintenance, and temperature checks.
- Do not place expired, damaged, leaked, opened single-use, visibly contaminated, or recalled products in a warmer.
- Include the warmer in an epidemiological investigation when it is a plausible source or reservoir.

Storage, Procurement, and Product Traceability

- Procure sterile and non-sterile products from approved sources using specifications that clearly distinguish sterility status, intended use, container type, and validated shelf life or in-use period.
- Store products clean, dry, upright, closed, protected from sunlight, excessive heat, moisture, contaminated items, chemicals, and within the manufacturer-specified temperature range.
- Maintain traceability as a core requirement: manufacturer, product name, sterility status, lot/batch number, expiry date, healthcare facility and unit, and procedure/patient linkage.
- Prioritize patient-level lot traceability for sterile gel and for gel used in invasive, semi-critical, or high-risk procedures so that rapid case finding and recall are possible.
- Routinely inspect stock and storage areas and promptly segregate expired, damaged, improperly stored, or recalled products.

Ultrasound Probe and Equipment Reprocessing

Procedure classification, gel selection, probe-cover use, and transducer reprocessing must be considered together. A probe cover does not eliminate the need for reprocessing, and sterile gel does not compensate for inadequate reprocessing.

- External probes used only on intact skin shall be cleaned and low-level disinfected between patients according to manufacturer instructions.
- Probes contacting mucous membranes or non-intact skin shall be cleaned and high-level disinfected between patients; sterilize when required by intended use, regulation, or manufacturer instructions.
- Critical probes entering sterile tissue or the vascular system shall be reprocessed based on the manufacturer instructions.
- Use only reprocessing chemicals and methods recommended by the manufacturer and compatible with the ultrasound transducer. Follow the specified concentration, contact time, rinsing, and drying requirements.
- Clean and disinfect associated high-touch equipment, including consoles, handles, cables, connectors, holders, gel containers, and warming devices, between patients or at the defined frequency based on manufacturer instructions.

Suspected Contamination and Outbreak Response

Any unusual infection signal, cluster, positive product culture, damaged sterile package, recall notice, or other concern potentially linked to ultrasound gel must trigger immediate assessment. Intrinsic contamination may require product recall and regulatory investigation; extrinsic contamination requires correction of local handling or environmental practices and also require broader escalation.

Step	Required action
1. Stop and secure	Immediately stop use; quarantine all implicated product and related lots. Do not discard suspected product, bottles, packaging, or associated warmer components until the investigation is complete and release is authorized.

Step	Required action
2. Document	Record manufacturer, product, sterility status, lot/batch, expiry, supplier, units supplied, opening details, storage/warming conditions, and exposed procedures or patients.
3. Notify	Notify IPC, clinical leadership, microbiology, quality/patient safety, risk management, supply chain, and facility leadership; notify the Public Health Authority and relevant national regulator, including the Saudi Food and Drug Authority, according to applicable reporting pathways.
4. Find cases	Develop a case definition; identify exposed patients and procedures; review microbiology and clinical data; retain relevant patient isolates.
5. Test strategically	In consultation with Public Health Authority and relevant national regulator, including the Saudi Food and Drug Authority, preserve unopened units because they can help distinguish intrinsic from extrinsic contamination.
6. Compare and control	Use organism identification and assess handling, storage, warming, and probe reprocessing; implement immediate corrective controls.
7. Recall and communicate	Coordinate communication with Public Health Authority and relevant national regulator, including the Saudi Food and Drug Authority, lot retrieval, regulatory action, internal alerts, patient notification when indicated, and documented closure of the investigation.

Routine microbiological culturing of ultrasound gel is not recommended unless required by public health authority.

Governance and Accountability

Function	Primary responsibilities
IPC	Develop requirements; advise on risk classification; educate; audit; lead epidemiological investigation and corrective actions.
Radiology / Ultrasound	Implement safe use and probe-reprocessing workflows; maintain local supplies and competency.
Nursing / Clinical departments	Select gel correctly, apply aseptic technique, document traceability where applicable, and report incidents.
Supply chain / Procurement	Purchase approved products; verify specifications and suppliers; retain distribution records; support quarantine and recall.
Biomedical Engineering	Approve, maintain, and document gel warmers and relevant equipment.
Microbiology / Laboratory	Advise on testing, retain isolates, and characterize organisms.
Quality and Patient Safety	Coordinate incident reporting, risk management, action tracking, and governance reporting.
Facility leadership	Provide resources, clarify accountability, and ensure compliance with national and regulatory requirements.

Education, Monitoring, and Key Performance Indicators

Healthcare facilities shall provide competency-based education to relevant staff and monitor implementation. Suggested indicators include:

Indicator	Suggested calculation
% invasive/semi-critical procedures using sterile single-use gel	Compliant observed procedures ÷ total audited applicable procedures × 100
% high-risk areas with immediate sterile gel availability	Compliant areas ÷ total audited high-risk areas × 100
% multi-use bottles compliant with all controls	Fully compliant bottles ÷ total audited bottles × 100
% gel warmers compliant with cleaning and maintenance	Compliant warmers ÷ total audited warmers × 100
% relevant staff completing competency training	Staff completing training and competency assessment ÷ staff assigned × 100
% investigated signals with documented lot traceability	Signals with complete traceability ÷ total investigated signals × 100
Time to quarantine	Time from recognition of suspected contamination to documented product quarantine

Conclusion

Safe ultrasound gel practice depends on five connected pillars: risk-based gel selection, safe handling and warming, mandatory product traceability, standardized probe reprocessing, and rapid product-associated outbreak response. Facilities shall translate these requirements into internal procedures, education, procurement specifications, monitoring, and corrective action.

References

- Australasian Sonographers Association. Clinical Statement: The Safe Use and Storage of Ultrasound Gel. 2025.
- American Institute of Ultrasound in Medicine. Guidelines for Cleaning and Preparing External- and Internal-Use Ultrasound Transducers and Equipment Between Patients as Well as Safe Handling and Use of Ultrasound Coupling Gel. 2025.
- Society of Diagnostic Medical Sonography. Sonographer Best Practices for Infection Prevention and Control. 2022.
- U.S. Food and Drug Administration. Stop Using All Eco-Med Ultrasound Gels and Lotions Due to Risk of Bacterial Contamination—Letter to Health Care Providers. 2021.
- Centers for Disease Control and Prevention. Guideline for Disinfection and Sterilization in Healthcare Facilities and related ultrasound equipment recommendations.
- Saudi Food and Drug Authority. Applicable medical-device vigilance, safety-alert, defect-reporting, and recall requirements.

Annex A. Decision Algorithm

Decision question	Action
Will the procedure enter sterile tissue, the vascular system, or breach skin?	Use sterile single-use gel; use a sterile cover; apply aseptic technique; perform the required probe reprocessing; document lot/patient traceability.
Will the probe contact a mucous membrane, non-intact skin, an open wound, or a fresh surgical site?	Use sterile single-use gel; use an appropriate cover; clean and high-level disinfect or sterilize the probe as instructed by the manufacturer.
Is the patient high risk?	Use sterile single-use gel unless an approved, documented risk assessment supports another option for intact-skin, non-invasive use.
Is this only an examination on intact skin in a non-high-risk patient?	Non-sterile multi-use gel could be used if all container, storage, in-use period, traceability, and no-refill controls are met.
Was non-sterile gel inadvertently used before a skin-breaching procedure?	Stop; completely remove residual gel; perform appropriate skin antisepsis; replace with sterile single-use gel; report and assess the incident as required.
Is contamination suspected?	Stop use; quarantine and preserve products; document lot/expiry; notify designated teams and authorities; initiate case finding and targeted investigation.

Annex B. Healthcare Facility Implementation Checklist

Requirement	Yes / No / N/A	Evidence / action
Approved products distinguish sterile from non-sterile gel		
Sterile unit-dose gel is available in all applicable areas		
Selection is linked to procedure/body site/patient risk		
Multi-use bottles meet no-refill, labeling, in-use period, and storage controls		
Warmers are approved, assigned, cleaned, and maintained		
Probe covers and reprocessing levels are defined		
Lot/expiry and patient/procedure traceability are implemented		
Quarantine, notification, sampling, recall, and outbreak pathways are documented		
Relevant staff have completed competency assessment		
KPIs are reviewed and corrective actions tracked		