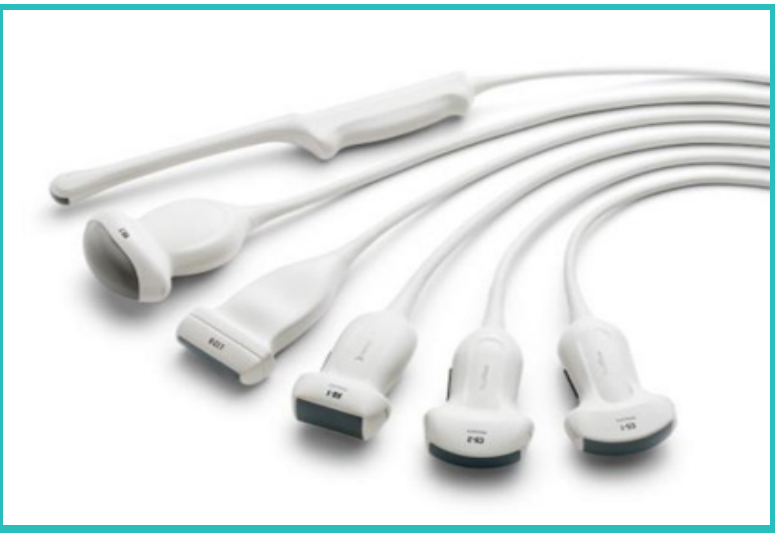
Automated disinfection: best practice for semi-critical ultrasound

Critical Summary

- Automated disinfection of semi-critical medical devices is recommended across Europe and considered best practice by key organisations.
- Automated processes can be validated on site meaning quality assurance and reproducibility for every patient.
- Digitised traceability standardises record keeping, ensuring complete and accurate documentation linking the processing cycle to the patient.
- Automation supports medical device processing compliance and enhances staff and patient safety.



Introduction

Ultrasound probes are reusable medical devices that must be disinfected between each patient to minimise the risk of infection transmission. Automated disinfection methods are standardised and validated, and therefore considered best practice across Europe for semi-critical ultrasound probes. Semi-critical ultrasound probes include ultrasound probes that will contact mucous membranes (e.g. endocavitary ultrasound) or non-intact skin during patient procedures.

European guidelines recommend automated disinfection for semi-critical ultrasound probes

European guidelines have recommended the use of automated processes for the reprocessing of reusable semi-critical devices, including ultrasound probes, since 2012 in Germany.[1] Numerous European health authorities including those of Belgium, Denmark, Netherlands and Ireland have continued this shift, most recently in France.[2-6] These national health authorities recommend automated reprocessing as they are standardised, reproducible processes that remove operator-associated errors and variability commonly associated with manual disinfection such as immersion or wiping.[1-4,6] Automation is also recommended for semi-critical ultrasound probes by several professional societies and other health authorities across Europe (Box 1).[7-9,13,14]

Box 1: AXREM, BMUS & SCoR Ultrasound Transducer Decontamination – Best Practice Summary (United Kingdom).

"Disinfectant-impregnated wipes that contain an effective disinfectant are widely used but the assurance that all surfaces are in contact with liquid disinfectant for the required time is not as easy to achieve as a high-quality assurance standardised and automated process. **Therefore, best practice is the use of an automated system.**"

Automated disinfection is validated

Automated disinfection devices are validated, ensuring reproducible disinfection on all surfaces of the ultrasound probe. On site validation of disinfection ensures the process, when installed and operating within specifications, achieves its expected microbiological performance outcomes consistently without dependence on human factors. This is critical to guarantee reproducible disinfection for every patient, consistently mitigating infection transmission risks.[4] On site validation of disinfection methods must be documented and used to develop standard operating procedures for day to day disinfection.

Validated disinfection is strongly recommended for semi-critical ultrasound probes in parts of Europe and is a mandatory legal requirement in Germany.[1,4,5,10] For example, the Irish health authority prefers validated, automated methods and recognises wipes as the least preferred option for semi-critical ultrasound probe disinfection (Box 2).[4] In Germany, the RKI has confirmed there is currently no method for on site validation of final wipe disinfection (see Spotlight on Validation).[11]

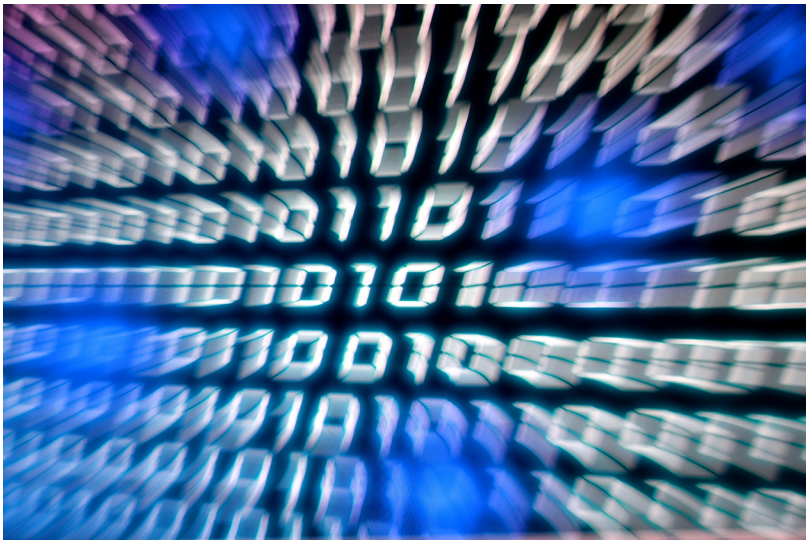
Box 2: - Health Service Executive, Ireland, Guidance for Decontamination of Semi-critical Ultrasound Probes

"HLD using the manual multi-wipe system is the least preferred option for disinfecting (semi-critical ultrasound probes). **Internationally it is recognised that the use of an automated validated process for decontaminating (reusable medical devices) will provide enhanced risk reduction of infection transmission.**"[4]

Digitised traceability supports risk management

Traceability is the capture of processing cycle information and unique medical device identifiers that are linked to the patient record on whom the device is used.[1,2,4,6,12,13] Required for processing semi-critical and critical ultrasound probes, traceability is essential in an outbreak investigation to determine the need for device recalls and the extent of patient notifications in a timely, efficient manner. In a non-outbreak setting, traceability allows a facility to demonstrate they meet their duty of care to patients.

Automated processes offer digitised traceability capabilities that support standardisation and quality care.[2,7] Examples of processing cycle information collected and linked to the patient can include unique probe ID, operator, critical disinfection parameters (e.g. contact time, temperature, concentration of the active ingredient) and chemical indicator or test strip results.[1,3,5,13,14] Digitisation supports risk management by ensuring the information capture and labelling is standardised across the entire ultrasound probe reprocessing workflow (e.g. using RFID technology and printers). Digitised documentation can also help minimise manual administrative burden for staff and the associated risks (e.g. operator error and incomplete record keeping).



Automation enhances staff compliance and safety

Automation supports policy compliance and patient safety by removing human factors from disinfection decision-making. A study from endoscopy found adherence to cleaning and disinfection guidelines increased from only 1.4% to 75.4% with increasing automation of the steps.[15] In ultrasound, manual disinfection methods can also be prone to human error, since staff need to verify and record the critical parameters (e.g. time, temperature, concentration) are met each time on all surfaces of the probe. When critical parameters are not met in an automated process, the operator is notified so that the ultrasound probe is not used on a patient. In contrast, manual disinfection such as wiping and immersion rely solely on staff to confirm critical parameters were achieved.[5]

Automation also supports staff safety. The World Federation for Hospital Sterilisation Sciences recommends automation in preference to manual processes due to the risks associated with chemical exposure from aerosols during handling.[9] The Belgian Hoge Gezondheidsraad/ Conseil Supérieur de la Santé cautions the use of manual disinfection methods due to the risk of respiratory and skin irritation for personnel in contact with the disinfection product.[2] Staff health problems could lead to poor compliance to reprocessing steps, compromising patient safety.[15,16] Automated, enclosed systems enhance safety and mitigate the risk of exposure to harmful chemicals often associated with open, manual disinfection methods.[1,2,5]

SPOTLIGHT ON VALIDATION
Robert Koch Institut clarification, Germany

According to German Federal requirements §8 Clause 1 MPBetreibV & the KRINKO-BfArM Recommendation 2012, on site validation is required as part of the mandatory validation requirements for reprocessing semi-critical devices.[1,17]

Who are the Robert Koch Institut?

The Robert Koch Institute (RKI) is the public health institute for Germany and is regarded as one of the leading infection prevention authorities in Europe.[18]

What have they said?

The RKI released a technical explanation on November 20, 2020 that stated "It is also not yet apparent to us how this could be validated on site as part of the validation of the reprocessing process. Therefore, we currently do not consider the final wipe disinfection of semi-critical medical devices to be validatable."[11]

The RKI was not aware of any guideline or standard that could be an appropriate basis for ensuring sufficient mechanical force and application of disinfectant to all surfaces and geometries of a medical device using wipes.[11] Documentation variability was also identified as a risk factor with final wipe disinfection.[11]

Implications for ultrasound disinfection practices

The Dusseldorf health authority released a statement on the RKI clarification, stating wipe disinfection of semi-critical medical devices are not acceptable.[19] Semi-critical medical devices include endocavitary ultrasound probes and probes that contact non-intact skin according to the KRINKO-BfArM guidelines.[1] Facilities should consider adopting automated disinfection processes for semi-critical ultrasound probes as they are validated, do not rely on human factors and support patient and staff safety.

Conclusion

Disinfection of semi-critical ultrasound probes between each patient minimises the risk of infection transmission. Automated ultrasound disinfection is considered best practice across Europe for its on-site validation and traceability offerings. Implementing an automated ultrasound disinfection process supports facility risk management and patient and staff safety.

Contact your Nanosonics representative today to understand your validation requirements

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Nanosonics Limited 14 Mars Road, Lane Cove, NSW 2066, Australia, T: +61 2 8063 1600 E: info@nanosonics.com.au www.nanosonics.com.au

Nanosonics Europe Limited Unit 2, Linfit Court, Colliers Way, Clayton West, Huddersfield, HD8 9WL, United Kingdom, T: 01484 860581 E: ukinfo@nanosonics.co.uk W: www.nanosonics.co.uk
Nanosonics Europe GmbH (EU Representative) Poppenbütteler Bogen 66, 22399 Hamburg, Germany, T: +49 40 46856885 E: info@nanosonics.eu W: www.nanosonics.eu
Nanosonics France 2, route de la Noue 91190 Gif-sur-Yvette, France, T: 01.64.86.58.59 E: info@nanosonics.eu W: www.nanosonics.fr

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