

AXREM Decontamination & Equipment Cleaning Guidance

AXREM is the trade association representing the suppliers of diagnostic medical imaging, radiotherapy, healthcare IT, and care equipment in the UK. Members supply most of the diagnostic medical imaging and radiotherapy equipment installed in UK hospitals and healthcare premises. Their employees work side by side with Consultants, Radiologists, Radiographers, Practitioners, Oncologists, and a wide range of healthcare professionals delivering healthcare to patients using members equipment and technologies.

AXREM members engineers and maintenance professionals work in hospitals and healthcare premises to ensure vital medical equipment is repaired, serviced, and maintained to the highest standards.

To ensure timely service delivery and provide a safe work environment requires equipment and facilities that have been appropriately cleaned and decontaminated. There have been instances where engineers have arrived on site and the equipment presented has visible blood on it, which is clearly unacceptable.

Since the start of the COVID-19 pandemic there has been an increased focus on decontamination and general cleaning practices, following the manufacturers procedures provided in the product instructions for use (IFU) documentation.

Managing Medical Devices

Guidance for health and social care organisations

January 2021

MHRA Managing Medical Devices

Guidance for health and social care organisations

The MHRA has published guidance about the management of medical devices, covering the acquisition, deployment, maintenance (preventive maintenance and performance assurance), repair and disposal of medical devices. This includes a section about equipment decontamination (section 9), which states:

“Items subject to inspection, maintenance, repair or disposal, either on site or at the manufacturer's or agent's premises, should be decontaminated beforehand. Once decontamination has been completed, the items should be labelled accordingly, and a declaration of contamination status form/label completed (or sent electronically).”

Read in full here: <https://www.gov.uk/government/publications/managing-medical-devices>

The mentioned form of figure 9.2 is missing from the current 2021 document (present in the previous 2015 version). However, many establishments have their own version that can be presented to engineers and others carrying out work on medical equipment. This is a vital procedure to ensure the safety of all personnel.



AXREM Declaration of Decontamination Status Form

To assist those without their own dedicated form to indicate the contamination status of items to be submitted for service, repairs, or transporting offsite, AXREM have produced an Adobe Acrobat PDF form that may be completed electronically or printed out.

This should be completed by the user and handed to the service engineer prior to any work being performed by the engineer on the equipment. This will ensure the engineer is fully aware of the contamination status of the equipment.

This form should also be included with any items being returned after loan (including trial or demonstration equipment) or when items are transported for repairs.

Note: Informing others about the status of the equipment is not only a requirement of the MHRA guidance but also inline with health and safety legislation.

Remember: Cleaning and decontamination of medical devices should only be carried out in accordance with the manufacturer instructions for use (IFR). Using incorrect procedures or chemicals may degrade safety, reliability, performance and/or diagnostic quality of the equipment.

Declaration of Contamination Status			
Owner Details (Consigner)			
Reference Number:		Company Name:	
Name:		Street:	
City:		Postcode:	
Contact Name:		Contact telephone:	
Recipient Details (Consignee)			
Company Name:		Street:	
City:		Postcode:	
Contact Name:		Contact Telephone:	
Equipment			
Type of equipment:		Manufacturer:	
Model No.:		Serial No.:	
Description:			
Other ID marks:			
Fault:			
Contamination Status			
Is the item Contaminated?	Yes* <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>
*State type of contamination: blood, body fluids, respired gases, pathological samples, chemicals (including cytotoxic drugs), radioactive material or any other hazard below:			
Has item been decontaminated?	Yes† <input type="checkbox"/>	No‡ <input type="checkbox"/>	Don't know <input type="checkbox"/>
† What method of decontamination has been used? Please provide details below:			
Cleaning:			
Disinfection:			
Sterilisation:			
‡ Please explain why the item has not been decontaminated?			
Contaminated items should not be returned without prior agreement of the recipient			
The item has been prepared to ensure safe handling and transportation			
Name:		Position:	
Signature:			
Date:		Telephone:	
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