



MALMET (AUSTRALIA) PTY LTD

Standards Malmart Compliance Washer Disinfections

Malmart is a leading Australian Manufacturer of Specialised Hospital equipment and Infection Control Solutions for Aged Care, CSSD, Theatre and Ward Utility Rooms.

All equipment is compliant with current relevant electrical safety & Watermark Standards and carries Australian Register of Therapeutic Goods (ARTG) Certification to industry highest Class 11b level.

All Malmart products are manufactured in the facility at Leeton NSW, which is ISO 9001:2015 and ISO 13485:2016 Certified

Malmart Bedpan, Urinal Bottle & Utensil/Bowl Washers comply with **AS 5369:2023**, Reprocessing of reusable medical devices and other devices in Health and non- health related facilities, and the relevant parts of **ISO 15883** for Washer Disinfectors. The equipment has been microbiologically tested as per recommendations outlined in **ISO 15883** by an independent NATA Certified Laboratory to ensure the wash efficacy is satisfactory for the intended load.

In 2014 a new set of Australian Infection Control Standards **AS/NZ 4187:2014 Reprocessing of reusable medical devices in health service organisations** was released which recognised **ISO 15883** as the manufacturing standards for Bedpan Washer Disinfectors and the previously recognised standard **AS 2437 Flusher/sanitizers for bed pans and urine bottles** was withdrawn.

In 2023 **AS 5369:2023 Reprocessing of reusable medical devices and other devices in Health and non- health related facilities** was released which has replaced **AS/NZS 4187:2014** this change in standards has no material change to the requirement of washer disinfectors.

To comply with these standards, Malmart only manufactures machines with detergent functionality for the reprocessing of 'non-critical Reusable Medical Devices' (RMD's). A non-critical RMD as defined by the standards, states: 'A medical device that comes in contact with intact skin but not mucous membranes.'

Malmart Washer Disinfectors have undergone design upgrades since the previously recognised Australian Standard – **AS 2437 Flusher/sanitizers for bed pans and urine bottles**, to which the products were designed and manufactured, was withdrawn in 2017. All Malmart Washer Disinfectors are now designed and manufactured to satisfy the requirements of the international standard **ISO 15883** which is recognised as the only standard for Washer Disinfectors in Australia.

The upgraded Bedpan and Urinal Washer Disinfectors has had the following components and functions added to the design:



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Detergent flow sensor

To ensure that the correct dosage of detergent (cleaning agent) is injected for every cycle. If detergent injection is not satisfied the machine will fault and lock the user from the load until a successful cycle is completed.

Independent temperature sensor

A temperature sensor independent from the cycle controller has been added to validate that the cycle parameters are met. If the verified temperature does not satisfy the temperature requirements, or if the temperature difference between the two sensors is too great, the machine will fault and lock the user from the load until a successful cycle is completed.

Blockage Sensor

The blockage sensor will detect if the drain is blocked and the water level in the chamber is above the door. If this is detected the door will be locked to prevent spillage.

Standards References:

AS/NZ 5369:2023

3.2 'Cleaning Agents' – a cleaning agent shall be used to remove residual soil and organic matter from a used RMD / other device. Cleaning agents shall be included in the ARTG when supplied in Australia.

4.3.3 Equipment used for reprocessing of RMDs shall comply with the applicable standards, the applicable standard noted by AS 5369 for Washer-disinfectors being ISO 15883.

5.1.2 'Classification for reprocessing' – refer 'non-critical reusable medical devices (RMD's)'

5.1.2 (iii) States the RMD must go through a validated cleaning process

Table 5.1 'General Criteria for Reprocessing & Storage of RMDs / other devices in facilities.

6.2.3 (f) Validation of mechanical cleaning process should reference ISO: 15883 relevant parts.

ISO 15883 -1, -2, -3

This Standard is specific to the manufacturing process and equipment parameters as applicable to manufacturers of Washer Disinfectors employing thermal disinfection for human waste containers, bowls, utensils etc.

ISO 15883 specifies the performance requirements for washer disinfectors.



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Malmart's wash efficacy and disinfection lethality processes are validated by testing as per the requirements of the applicable parts of ISO15883. Our validated cleaning process includes a dosed volume of detergent to achieve a detergent solution for the cleaning/washing stage to satisfy this requirement of AS 5369 and ISO 15883 standards.

NSQHS (National Safety & Quality Health Service Standards) second edition 2021.

Standard 3, 'Reprocessing of reusable equipment and devices', **Action 3.17** states:

'When reusable equipment and devices are used, the health service organisation has:

'Processes for reprocessing that are consistent with relevant National and International standards, in conjunction with manufacturers' guidelines'

Ao Concept – Comparative Lethality of moist heat processes * ISO 15883

'For a moist heat disinfection process, a particular time at a particular temperature can be expected to have a predictable lethal effect against a standardized population of organisms.'

'A level of Ao60 is recognised as being the usually acceptable minimum for products which are intended to come in contact with intact skin and are unlikely to contain high numbers of heat resistant pathogenic organisms.

An Ao value of 600 is the minimum required for reprocessing of utensils, bowls etc.

Malmart Washer Disinfectors are designed to reach a minimum of Ao600 for disinfection stages on all Washer Disinfectors. To ensure this value is reached in real life conditions the parameter to begin the disinfection stage is set at >90 Degrees Celsius with a holding time of 60 seconds. This ensures that the entire load, carriers and chamber are disinfected to a satisfactory level every cycle. Extensive testing on Malmart Washer Disinfectors has been carried out and has shown the lowest level of disinfection achieved in the wash chamber is greater than Ao1200. The reason for this is, although a temperature of 90 degrees requires 60 seconds to achieve an Ao value of 600, the lethal temperature for the organisms begins at 65 degrees.

See the table below as an example for the holding time at varying temperatures to achieve the recognised Ao values.



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Process temp.	Exposure time for A ₀ =3000 (critical MDs)		Exposure time for A ₀ =600 (semi-critical MDs)		Exposure time for A ₀ =60 (non-critical MDs)	
	Sec	Min	Sec	Min	Sec	Min
70	30000	500	6000	100	600	10
75	9487	159	1897	32	190	3.2
80	3000	50	600	10	60	1
90	300	5	60	1	6	0.1

Your Infection Control Manager would be best placed to advise you on how these standards are implemented within your organisation, and to provide any further information in regards to compliance and timelines.

Should you need any further information, or supporting documentation, please contact your local Malmet representative direct on 02 69537677.