

# **General Specification for**

**REQUIREMENTS and TESTS for WASHER  
DISINFECTORS employing THERMAL  
DISINFECTION for HUMAN WASTE CONTAINERS.**

date September 2009

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### INTRODUCTION

#### Scope

This Specification is designed to be used for the purchase of Human Waste Containers – Washer Disinfectors.

It is intended to be read in conjunction with EN ISO 15883-2006:

Part 1-General requirements, terms and definitions

Part 3- Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers

EN ISO/TS 15883-5: Test soils and methods for demonstrating cleaning efficacy

**AMENDMENTS: to the above documents and other relevant guidance shall be highlighted and specified in the following sections and clauses.**

Washer Disinfectors are intended to be used for emptying, flushing, cleaning and thermal disinfection of containers used to hold human waste for disposal by one operating cycle.

#### Assembly of Specification

When issued to invited Tenderers, this Section shall contain **ONLY** the following:-

- I. Part C Index.
- II. Part C Element 01: References.
- III. Part C Element 02: General.
- IV. Part C Element 03: Technical.
- V. Part C Element 04: Test Methods
- VI. Part D Completed by the Purchaser as required. To be completed by the Tenderer as requested.
- VII. Drawings and supporting information.

#### Section D

The following Clauses of Section D are to be completed by the Designer prior to distribution:-

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All instances of choice in the above Clauses are cross-referenced in the relevant Clause in Section C. It is the responsibility of the Designer to check that all Clauses of Section D requiring input from Section C are completed. Advice from a Registered Authorising Engineer (Decontamination) will ensure correct completion of Section D.

The following Clauses of Section D are to be completed by the Tenderer:-

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### **Guidelines for assessing sizes and numbers of WD's**

Precise information on the sizes and numbers of WDs required for particular applications is difficult to give since there are considerable variations in patterns of use. The number of WDs required will depend on the cycle time and the loading capacity of the machine and in some circumstances on the flexibility of operation that may be required, eg whether items to be processed can wait until there is a full load for the WD or need to be processed immediately.

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### Throughput time

Throughput time is affected by three key factors:

- cycle time;
- machine capacity;
- machine availability.

### *Cycle time*

The processing time varies depending upon:

- the number and the duration of the flushing and washing stages;
- the disinfection time;
- the drying time.

With modern microprocessor-based control systems, several cycle options may be programmed into the same machine.

The cycle time may be determined from the WD manufacturer's specification either for the particular items to be processed or for the "worst case" load for which the cycle time will equal or exceed that required for the products to be processed: **please note in any of the cases above the Washer Disinfector cycles/programmes shall be preset to the INTENSIVE cycle/programme, resulting in selection of any load/cycle from the machine menu shall be the INTENSIVE/cycle.**

### *Machine capacity*

The machine capacity, specified by the manufacturer, will normally be stated in terms of the number of load items that can be accommodated in one load.

### *Workload estimate*

The workload should be estimated from historical records of operational activity or based on proposed work loads.

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### WASHER-DISINFECTORS HUMAN WASTE CONTAINERS

#### Part C INDEX

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## **ELEMENT 01**

### **STANDARD REFERENCES**

**01**

The materials, components and completed installations shall conform as applicable with the relevant Standards and Guidance's, detailed in EN ISO 15883-1-2006, Bibliography. Importantly these shall include all amendments and revisions, current at the time of tendering.

**End of Element**

## **GENERAL**

**02**

### **1.0 Scope**

## **ELEMENT 02**

This Specification covers the supply and/or installation and/or commissioning of washer-disinfector equipment as defined generally below and in the following element(s). Details specific to the scheme or site are included in Section D which must be completed by the Tenderer and returned to the Purchaser as part of the completed Form of Tender.

If the Contractor's tender does not strictly comply with any or all of the details of this specification then the contractor shall declare in the tender any such deviations together with full details of the alternative(s) offered.

### **2.0 Changes to Specification**

The client shall be notified by the manufacturer in writing not less than 14 working days before commencement of manufacture, of any intent to make changes from the offer on which the contract was awarded in respect of the specification and design of specified components, including any alterations resulting from changes in relevant standards. No such change shall be made without the written consent of the client.

#### **Pre-Tender visits**

Tenderers are advised to visit site before submitting a tender, and this can be arranged by contacting the officer detailed in section D.

### **3.0 Warranty Period**

The Manufacturer shall accept liability for defects for the washer-disinfector, which occur within a 12 calendar months or 5,000 operational hours (whichever is the greater) period after acceptance of the washer-disinfector. Satisfactory completion of the required/specified performance tests will be a prerequisite of acceptance.

This warranty period shall also include such of the following items as have been supplied including, but not limited to:

- software provide as part of the washer-disinfector control system
- Loading accessories (tabling, conveyors, load carriages, baskets, adapters etc)
- Any water treatment plant supplied by the manufacturer

All service connections supplied by the Manufacturer (including but not limited to pipework, control equipment and ductwork).

The guarantee shall cover all parts and labour. This shall include those parts identified as



## **ELEMENT 02**

replacement items in the maintenance schedule.

The length of warranty period offered shall be specified in the return tender documentation.

The Washer-disinfector shall be designed to withstand use for not less than 12 months or 5,000 operational hours (whichever is the greater) without suffering failure other than those components identified on the maintenance schedule as requiring periodic replacement.

The repair and/or replacement of components (other than those specified within the maintenance schedule for periodic replacement) within the warranty period shall be at the manufacturers expense (parts and labour). This includes for making good free of charge any part thereof found to be defective or showing signs of any weakness or undue wear in consequence of faulty workmanship or materials.

Manufacturers shall state within the section D clause 35 the mean time between failures (MTBF) figure and gauranteed uptime for the washer-disinfector.

The manufacturer shall inform the client of any recommended or required updates or upgrades to the software system with an option for purchase for a period of 5 years from acceptance of the washer-disinfector. Distinction shall be made between those updates/upgrades that provide “bug fixes” or are maintenance releases and those that are providing added or new features.

### **4.0 Manufacturers Quality System**

Conform to the requirements of EN ISO 15883-1-2006.

In either case the manufacturer shall ensure that each supplier of accessories, fittings and other materials also operates an appropriate quality system and where appropriate the supplier shall comply with the relevant Essential Requirements of Medical Devices Regulations.

Manufacturing records and quality system documentation shall be available for audit/inspection if requested by the client.

### **5.0 Regulatory Requirements**

The washer-disinfector shall comply with the relevant Essential Requirements of Medical Devices Regulations and shall be CE marked.

The supplier shall provide information on any relevant Standards or guidance documents used to demonstrate compliance with the Regulations.

### **6.0 The Process**

Shall:-

Conform to the performance required in EN ISO 15883-1- 2006(4.0 to 4.6 & 5.6) and part 3.

## **ELEMENT 02**

remove soiling of the various load types e.g., "bedpans", "commode bowls", "vomit bowls", "urine bottles", "suction bottles" and "kidney dishes" etc.

remove any chemical additives employed during processing through the washer disinfectant.

not distort, damage or otherwise impair the utility of items processed through the machine where the manufacturer of the items to be processed has indicated that they are suitable for processing in an automated WD.

disinfect the items processed so that they may subsequently be handled without risk of infection from viruses, vegetative bacteria or fungi.

where required, dry the cleaned items so that they are free from visible water

achieve this performance specification by an automatic operating cycle which has a number of pre-set variables and specified stages including those for:-

- a) cleaning
- b) disinfecting
- c) rinsing
- d) drying (where required)

### **7.0 Acceptable Processes EN ISO 15883-3:2006, 4.0 to 4.7 & 5.2)**

Shall:-

for cleaning be deemed to have been achieved if, when tested in accordance with the methods described in element 04, the specified test soil can be shown to have been removed completely leaving no proteinaceous residues and the temperature of the in-flowing water in a pre-wash stage

## ELEMENT 02

does not exceed 35°C.

for thermal disinfection, be deemed to have been achieved if, when tested in accordance with element 04, the specified minimum temperature is achieved on all surfaces of the load and specified surfaces of the WD chamber and load carriers for the specified minimum (hold) time.

### Thermal Disinfection Temperature Bands

Disinfection temperature (°C) <sup>a</sup>	Minimum exposure time (minutes)	Maximum allowable temperature (°C)
65	10	70
73	3	78
80	1	85
90	0.2 <sup>b</sup>	95

Note.

a. The disinfection temperature is measured at the surface to be disinfected.

b. The exposure time of 1 second (as specified in BS 2745 Part1) is too short for reliable measurement and a minimum time of 12 seconds (0.2 min) should be used.

Include a rinsing stage which reduces the concentration of process chemicals on the products to a level not exceeding that specified by the manufacturer, or supplier, of the process chemical(s) as safe in the context of the intended use of the products.

where drying is required, have air of a quality which will not impair the standard of cleanliness or disinfection achieved by the process prior to drying.

where drying is required, produce a visibly dry load at the end of the process.

**End of Element**

## TECHNICAL

**03**

### 01 Chamber Operational life

Shall:-

be designed to withstand 25,000/T operating cycles where T is the minimum operating cycle time in hours, specified by the manufacturer.

## **ELEMENT 03**

### **02 Washer Disinfector Construction**

Shall:-

be in accordance with EN ISO 15883-2006 (5.0 - 5.1) and IEC 61010-2-045

have all components and surfaces free from sharp edges, burrs etc.

### **03 Frame and Panels**

Shall:

be provided with means to compensate for irregular surfaces.

be finished smooth, to make surfaces easy to clean.

give due regard to the means of access for component maintenance and general cleaning.

be designed so that maintenance access panels can be easily removed and re-installed but not without the use of a tool or key and properly secured.

### **04 Door(s)**

Shall:-

meet the requirements in EN ISO 15338-1-2006 (5.4)

have a single door, hinged at the bottom and incorporate a mechanism to control the opening/closing movement

have a mechanism such that the force to be applied by an operator in order to either lock or unlock the door does not exceed 250N at the intended point of grip.

### **05 Pipework and fittings**

Shall:-

conform to EN ISO 15338-1-2006 (5.5)

be in accordance with EN ISO 15883-2006 and be designed to allow the removal and maintenance of individual components and sections of pipework without distortion of any associated equipment.

be of a type that has been demonstrated not to support the growth of *Legionella pneumophila* when non-metallic materials are used for conveying water or aqueous solutions.

### **06 Water Tanks**

Shall:-

conform to EN ISO 15338-1-2006 (5.3)

be fitted with an overflow and have wherever necessary, a removable and cleanable coarse

## **ELEMENT 03**

filter to filter re-circulated water.

### **07 Heating Sources**

Shall:-

conform to EN ISO 15338-1-2006 (5.3,5.8)

employ heating mediums as specified by clause D11.

be fitted with a temperature controlling device.

be removable for replacement or maintenance purposes.

incorporate one or more over-temperature cut-out, capable of being manually reset, to protect the load from exposure to excessive temperature.

### **08 Instrumentation – general**

Shall:-

conform to EN ISO 15883:2006 (Pt1 5.12,5.15 & 5.22 and Pt3 5.1, 5.2)

be such that the location of all sensors, whether connected to the controller or other process device, is appropriate and provides data which can be correlated to conditions throughout the chamber and load.

### **09 Temperature Indicators**

Shall:-

conform to EN ISO 15883:2006 (Pt1 5.13, 5.9 and Pt3 5.1, 5.2)

### **10 Measurement Systems (Including control and down loading process devices)**

Shall:-

conform to EN ISO 15883:2006 (Pt1 5.17, 5.9 & 5.15 and Pt3 5.1, 5.2)

### **11 Cycle data archiving - General**

Shall:-

conform to EN ISO 15883:2006 (Pt1 5.17, 5.9 & 5.15 and Pt3 5.1, 5.2)

be fitted with the necessary components to facilitate down loading process information i.e. the key variables of the operating cycle as listed

### **ELEMENT 03**

- the temperature of water in the chamber at each stage in the operating cycle
- the time at each stage in the operating cycle
- the holding time at disinfection temperature
- disinfection temperature
- the volume of each chemical additive admitted, and the time at which it was admitted, at each stage in the operating cycle
- Ao – Comparative lethality

Allow process data to be down loaded to local computer, storage device or central net work server system.

Have specific software to facilitate cycle interrogation and archiving the variables listed below:

- the temperature of water and air in the chamber at each stage in the operating cycle
- the time at each stage in the operating cycle
- the holding time at disinfection temperature
- the volume of each chemical additive admitted, and the time at which it was admitted, at each stage in the operating cycle

### **12 Verification of Calibration of WD Test Instruments and Automatic control test**

Shall:-

conform to HTM 2030 part 3 & EN ISO 15883-1-2006 (5.11, 6.13)

### **13 Control systems**

Shall:-

comply with EN ISO 15883:2006 (Pt1 5.18, 5.19, 5.15, 5.20 & 5.22 and Pt3 5.1, 5.2)

be supplied complete with all necessary power supplies, software, sensors and down load devices.

be supplied complete with evidence that any software used to control the machine has been produced in accordance with a formal documented quality system and then subjected to a formal validation programme.

### **14 Microprocessor Systems**

Shall:-

comply with EN ISO 15883-1-2006 (5.20 & 5.22)

sited where they will be affected by heat or moisture. The instrumentation and controls to be located clear of the area above the washer-disinfector door or chamber.

### **ELEMENT 03**

at all times maintain safe conditions within the chamber and be arranged such that in the event of a failure it will not cause a safety hazard.

#### **15 Cycle Counter**

Shall: -

comply with EN ISO 15883-1-2006 (5.16)

be a tamper-proof or sealed 5 digit counter to indicate the cumulative total of cycles started and be visible to the operator.

#### **16 Dosing Systems**

Shall: -

comply with EN ISO 15883:2006 (Pt1 5.7 and Pt3 4.2)

have mechanisms for delivery and operation of chemical additives in accordance with Control of Substances Hazardous to Health Regulations 1999 (COSHH) and keep additives free from contamination and prevent mis-use.

have mechanisms for replacement of chemical additives that minimises manual handling in accordance with the Manual Handling Operations Regulations 1992.

#### **17 Load carriers**

Shall:-

comply with EN ISO 15883:2006 (Pt1 5.27 and Pt 3 6.5)

#### **18 Maintenance Access**

Shall:-

be such that all parts requiring servicing are easily accessible and where the washer-disinfector is enclosed in a cabinet, be so designed that all panels are easily removable for maintenance purposes.

be constructed as to enable changing components without dismantling other, unconnected parts of the machine.

#### **19 Electrical Supply, Wiring and Switchgear**

Shall:-

be via one electrical connection to the machine complete with all internal electrical wiring.

shall include earth leakage detection and be fitted with a low impedance earth of less than  $0.1\Omega$  over the measurable loop..

### **ELEMENT 03**

have earth connections on removable panels, complete with sufficient flex to enable the panel to be removed via an identifiable conductor (not reliant on a hinge or the panel screw).

be designed to operate with an electrical supply provided with means to isolate all poles simultaneously from the mains supply. Each pole shall be fused separately.

include an accessible means of emergency isolation provided on the front fascia of the washer-disinfector for single door machines and on both loading and unloading sides for double door machines.

such that all individual switches on the outside surfaces of the Washer-disinfector have an IP rating of 44 when tested in accordance with EN 60529 : 1991

have the control/indicator panel designed to be resistant to the ingress of water, steam and/or condensate during normal operation of the machine

have switches provided for start ie cycle commence and for cycle selection.

be marked with an appropriate symbol and labelled with a description of the function which is legible at a distance of 1 m from the machine.

Note:

These switches may be combined with the indicators shown in IEC 73.

The symbols to be used shall conform to the requirements of IEC 417 and/or ISO 7000. When new symbols are defined these shall be designed in accordance with the requirements of IEC 416.

if specified in clause D19 incorporate a waterproof (IP44 rated) RCD protected 230V 13A double socket outlet mounted on the fascia of the washer-disinfector for connection of test instrumentation.

## **20 Ventilation Systems**

Shall **comply** with EN ISO 15883-1-2006 (5.24)

## **21 Water supply**

Shall comply with EN ISO 15883-2006 Pt1 (5.23) & Pt3 (5.4)



### ELEMENT 03

if specified in clause D20, include in the tender, separately priced, the cost of providing water softening plant to satisfy the requirements of clause D20. This shall include installation and commissioning costs.

The quality of water that should be used in washer-disinfectors for Human Waste Containers shall be **125 [mg/l] CaCO<sub>3</sub>, Total hardness.**

## 22 Noise Emission & Sound Power

### Note:

The perceived level of noise in the immediate vicinity of the WD during operation is of concern. In the HSE Noise at Work Regulations (1989) there is a Legal requirement as an employer to prevent damage to the hearing of workers. Action needs to be taken if noise causes risks other than hearing damage, or creates risks to other workers, for example, if the background noise reduces the audibility of a warning sound. The perceived noise level depends not only upon the sound power level of the equipment but also on three major noise control principles:

- a) Absorption
- b) Insulation
- c) Isolation.

These must be determined with the WD installed and working normally.

There are three action levels defined in the Noise at Work Regulations (1989).

- a) The First Action Level a daily personal noise exposure (LEP,d) of 85 dB(A)
- b) The Second Action Level - a daily personal noise exposure (LEP,d) of 90 dB(A)
- c) The Peak Action Level - a peak sound pressure of 200 pascals (140 dB re 20 mPa)

Information about noise reducing measures may be found in HTM 2030 'Design considerations. When any person is likely to be exposed to the First Action Level or above or to the Peak action level or above, it is essential that a Trained Competent Person makes the noise assessment, which is adequate for the purpose.

All daily personal exposure levels are based on an 8-hour working day. Where the normal daily working hours exceed this figure, advice should be taken as to the exposure levels for the number of hours worked.

Shall:-

using the procedure described in clause 8.1 of BS 4196 Part 6, whilst the washer-disinfectors are operating, determine the following;

### **ELEMENT 03**

- a) the daily personal noise exposure (LEP'd)
- b) the peak sound pressure level.

the test should be considered satisfactory, if the following requirements are met :-

- a) the daily personal noise exposure
  - i) 55dBA for a WD installed in an operating suite, ward, treatment room or other noise sensitive area;
  - ii) 70 dBA for a WD installed in a sterile services department.
- b) in both the loading and unloading area, the peak A-weighted sound pressure does not exceed the daily personal noise exposure.

be the manufacturers responsibility to carry out any modifications to the Washer-disinfector(s) resulting from the failure of the above assessment.

comply with HTM 2030 Validation and Verification, section 9.

### **23 Thermal Emission, Surface Temperatures and Insulation**

Shall:-

ensure that no surface exceeding 55°C is exposed to the room when the machine is closed and working under its normal operating conditions.

where practicable, have all pipework lagged with sectional lagging. Sectional glass silk is excluded for these purposes.

consist of materials which are non-flammable and heat resistant which, when applied, allow for any access to all components for maintenance purposes. Asbestos is excluded for these purposes.

### **24 Manufacturers Installation**

#### **Note**

It is strongly recommended that the successful bidder meets with the purchaser to discuss their particular installation requirements. Minutes of such meetings should be kept and made available in the event of dispute.

## **ELEMENT 03**

Shall:-

comply with EN ISO 15883-1-2006 (8.0 to 8.3)

### **25 Operating Instructions**

Shall:-

comply with EN ISO 15883-1-2006 (8.0 to 8.3)

be provided and fixed to the fascia panel and comprise a permanently marked notice giving clear and simple operating instructions and stating the classes of articles which can be processed in each individual cycle of the machine eg “bedpans”, “commode bowls”, “vomit bowls”, “urine bottles”, “suction bottles” and “kidney dishes” etc as appropriate.

### **26 Delivery and Packing**

Shall:-

comply with EN ISO 15883-1-2006 (8.3 to 9.2)

include for delivering the washer-disinfector to site and off-loading from the delivery vehicle and moving it to its final location, as defined in Clause D01a, packing to be as defined in Clause D07.

### **27 Technical Documents, Manuals, and Other Documentation**

Shall:-

comply with EN ISO 15883-1-2006 (8.0)

be supplied upon delivery of the washer-disinfector(s) and comprise three complete sets or a number specified in Clause D06 of technical literature on the operation, maintenance and overhauling of **ALL** items of equipment incorporated on the washer-disinfector, together with two copies of record drawings showing the pipework and installation diagrams, pneumatic, pipework and electrical circuitry of the machine.

The literature to include a complete planned preventive maintenance programme showing the tasks to be carried out at regular intervals compatible with the standard planned preventive maintenance intervals in use in NHS Hospitals, which are:-

- (a) weekly
- (b) monthly
- (c) quarterly
- (d) half yearly
- (e) yearly
- (f) two yearly

include for the supply of an operational chart showing the detailed sequence of events and

### **ELEMENT 03**

operating parameters during a normal cycle and indicate what will happen at each stage or sub-stage of the cycle if the parameter controlling that stage or sub-stage, eg level of water pressure, temperature etc is not satisfied. For microprocessor-controlled machines the following programming features and menus to be provided:-

- (a) Door operation and cycle, start procedures.
- (b) Door operation at the end of a cycle.
- (c) Aborting a cycle.
- (d) User's menu.
- (e) Maintenance engineer's menu with optional mimic diagram.
- (f) Operating security levels.
- (g) Address lists, and values of process variables.
- (h) Calibration of instruments.
- (i) Interrogation of registers holding process variables.
- (j) Input and output status at all stages.
- (k) Diagrams to show the status of all inputs and outputs for each stage of the process.

list typical causes of failure during a faulty cycle and their remedy.

validation documentation including 3 bound copies of all installation and validation test results.

copies of all relevant certification and type approvals including calibration certificates for all instruments fitted to the washer-disinfector.

### **28 Training**

Shall:-

be provided by the contractor as defined in clause D23.

during the defects liability period , be provided as detailed in the clauses above in respect of any upgrade or modification carried out by the manufacturer that requires a change in either maintenance or operational policy.

### **29 Commissioning and performance testing**

Shall:-

comply with EN ISO 15883 Pt1, Table A.1 and Pt3 Annex A)

be witnessed by a representative of the Purchaser (e.g. Authorising Engineer (Decontamination)) as specified in Clause D24. Where a client representative has been nominated all validation documentation shall be available for audit prior to acceptance of the machine(s) by such persons.

### **ELEMENT 03**

be arranged by the manufacturer with at least 14 days clear notice to be given of the planned date of test. Any expenditure involved as a consequence of the manufacturer cancelling the arranged date for witnessing the tests will be met by the manufacturer.

be undertaken using test loads supplied by the Purchaser if specified in clause D21.

be undertaken using only test equipment calibrated as recommended in EN ISO 15883-1&3:2006, HTM 2030 and to UKAS calibration.

### **30 Servicing and Maintenance**

The manufacturer shall:-

specify the service time required to carry out all routine maintenance tasks and for the replacement of all major components.

undertake service visits in accordance with the recommended planned maintenance schedule. The number of visits included during the warranty period shall be documented in the return tender in clause D28.

submit a comprehensive, written, service report in respect of each service visit, giving full details

### **ELEMENT 03**

of the work carried out.

not change during servicing operational values of any of the variables established during performance testing as critical to successful processing without the prior written consent of the purchaser.

on completion of the appropriate service, carry out the quarterly testing specified in EN ISO 15883-1&3-2006 & HTM 2030 to verify that the performance criteria established during commissioning remain valid.

in the event of a breakdown and at the request of the purchaser, provide a service engineer on site within the response time requested by the client as specified in section D25.

hold a stock of all replaceable components, either at their premises or at the purchasers premises, for use in the event of breakdown, for a period of not less than 7 years from the date of installation. These shall be charged for only as and when they have been supplied and fitted.

provide a list of recommended service spares and consumable items for one year's use to be included and priced. The spare parts list shall be comprehensive with clear identification of those items held in stock (i.e. available on site within 4 hours by courier delivery if required see above). The lead times required for delivery of non-stock items shall be specified. Details of the quantity and frequency with which each consumable item is required shall be included.

**End of Element**

## ELEMENT 04

### TEST METHODS

04

**Note:**

The tests described within this element are only those deemed adequate to establish the particular requirements of element 02 clause 7.0. The range of tests required for assuring conformity can be found in EN ISO 15883:2006 Pts 1 & 3 (Installation, Operational and Performance Qualifications). For new washer-disinfectors the following Validation tests shall be undertaken after satisfactory completion of IQ tests.

#### 01 General

Testing shall be carried out in accordance with HTM 2030 Pt 3 and EN ISO 15883:2006 Pts 1 & 3 using specified test loads (commonly used within the Hospital wards and departments, please note these load types shall be specified in section D of this specification) except as modified within this specification.

From the time when testing commences on site all test runs, whether successful or not, shall be recorded and documented.

The cycle data from the machine controller and process down load device shall be retained as part of the record of each cycle.

The test report shall include a summary sheet identifying all test cycles run.

The results of all cleaning tests shall be demonstrated within the report. This may require adequate photography (time and date stamped) of items prior and post cleaning.

The instruments used to test the WD and those used to calibrate the test instruments shall be calibrated to UKAS accreditation standards and relevant guidance found in HTM 2030 and EN ISO 15883 Pts 1 & 3.

#### 02 Load Cleanliness EN ISO 15883:2006 (Pt1 6.10.3 and Pt3 4.4)

The cleaning efficacy of the washer-disinfector shall be tested by determining its ability to remove a standard test soil from either a standard test load or a typical load of the type to be processed in the unit. The test soil to be used will conform to the specification given in HTM 2030 and EN ISO/TS 15883-5.

Satisfactory soil removal will be determined by visual inspection and, at the discretion of the purchaser, by determination of the absence of residual protein using a qualitative method as defined in **HTM 2030 Validation and Verification**.

Cleaning shall be regarded as satisfactory when not less than three challenge loads for each type of goods to be processed have been satisfactorily cleaned.

## **ELEMENT 04**

### **03 Chamber and Carrier Cleanliness** EN ISO 15883:2006 (Pt1 6.10.2 and Pt3 4.4)

The efficacy of cleaning of the chamber and load carrier surfaces shall be tested using the same test soils used for bedpans and acceptance criteria as were used for testing the load cleanliness.

### **04 Thermal Disinfection (Thermometric tests)** EN ISO 15883:2006 (Pt1 6.8 and Pt3 4.5)

The attainment of thermal disinfection shall be determined by the measurement of the temperature attained on the surfaces to be disinfected for a defined time as specified in Element 02:07.

The attainment of disinfection conditions shall be demonstrated for the following:-

04.1 Automatic control test and Verification of calibration of WD instruments EN ISO 15883-1-2006 (6.13 & 5.15).

04.2 Chamber wall and Load carrier temperature tests EN ISO 15883-1-2006 (6.8.3 & 6.8.2), [1x cold start and 3x hot starts] for each type of load /carrier used.

04.3 Load temperature tests EN ISO 15883-1-2006 (6.8.2), [1x cold start and 3x hot starts]

### **05 Over-temperature tests.**

EN ISO 15883-1-2006 (6.8.5)

### **06 Load dryness.**

EN ISO 15883:2006 (Pt16.12 and Pt3 4.7), however acceptance to this general requirement will depend on Hospital specific demands e.g. nature of load and maximum cycle time.

### **07 Additional functional tests**



#### **ELEMENT 04**

In addition to the above all of the following functional operational tests shall be demonstrated with documentary evidence in support of such tests included in the validation report:

- a. EN ISO 15883-1-2006 [6.3] tests on doors, interlocks and fault indicators
- b. EN ISO 15883-1-2006 [5.7] dosing systems
- c. EN ISO 15883-1-2006 [6.5] tests on pipework
  - free draining of chamber and load carriers 6.5.2
  - chamber leak tightness 6.5.3
  - free draining of tanks 6.5.4.
- d. EN ISO 15883-3-2006 [6.3] Flushing of non absorbent materials
- e. EN ISO 15883-3-2006 [6.4] Flushing of absorbent materials
- f. EN ISO 15883-3-2006 [6.5.1 & 6.5.2] Safety of loading and emptying of containers

**End of Element**

## **D Particular**

### **WASHER-DISINFECTORS**

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**End Index D**

## **D Particular**

**Scope** (Ref C02.01, C03.30)

01

This section shall:-

be read in conjunction with Part C.

be completed, where required, by the Purchaser and, where indicated, by the Tenderer.

be returned by the Tenderer duly completed, signed and witnessed to the Purchaser as part of the Tender Documents.

Please complete sub clause D01a for detailing specific machine requirements.

## D Particular

### Specific Machine Requirements

01a

The washer-disinfectors covered by this Section are (washer-disinfectors for Human Waste Containers to be included within the tender):-

No.	TYPE OF HUMAN WASTE CONTAINERS WD REQUIRED	CYCLES REQUIRED	DRYING Yes/No	LOCATION
1	Free standing, single door.	1 intensive cycle suitable for decontamination of all types of bedpans and urine bottles.	Yes	Southern Health and Social Care Trust – exact location to be confirmed.
2				
3				
4				
5				
6				
7				
8				

## **D Particular**

### **Personnel Nominations**

02

Nominations: -Sandra McLoughlin

Contact Number: 028 38 612453

Purchaser: - Southern Health and Social Care Trust

Architect: - N / A

Engineer: - N / A

Authorising Engineer (Decontamination):-  
John Singh, HEIG, DHSSPSNI

Contact Number: - 028 90 523802

Test Person (Sterilizers): - TBC

Designated User: - Sandra McLoughlin

Contact Number: 028 38 612453

Authorising Person (Decontamination):- Paul Marshall

Contact Number 028 38 612332

### **Selection of Terms and Conditions**

03

Please state the terms and conditions documentation set to be used with this specification:  
**(Health and Social Care Trust to complete)**

### **Site Access**

04

Expected date when site will be ready for delivery:

N/A

Access Details :

### **Schedule of Drawings Included with Specification**

05

<b>Drawing Number</b>	<b>Title</b>
	N/A

## D Particular

--	--

### Documentation and Record Drawings Required at Installation (Ref C03.27)

06

Number Required	Description
	N/A

### Packing Method (Ref C03.26)

07

- \* ~~unpacked with normal covering~~
- \* ~~in dustproof packing~~
- \* in weatherproof packing
- \* ~~in dustproof packing and timber casing~~

Other Details .....

\* DELETE AS NECESSARY

Details:

### Quantities of Process Chemical Supplies Required

08

Details:

Sufficient chemicals to carry out all commissioning tests plus 3 months supply based on 10 cycles per day. These chemicals must be accompanied by a COSHH data sheet detailing the active chemicals and recommendations for storage, spillages or splashes.

## **D Particular**

### **Material for Fascia Panelling and Access Door(s) (Ref C03.03)**

09

Details:

N/A

### **Door Requirements (Ref 03.04)**

10

Particular door requirements (e.g. hinged bottom):

Hinged bottom with automated opening.

Details:

### **Required Heating Medium (Ref 03.07)**

11

For water:..... Electric

For drying Air..... Electric



## D Particular

### Control Process Monitoring (Ref 03.11)

12

Monitor variables listed as default in clause 03.13

\*YES / ~~NO~~

If No please give details of requirements:

temperature of water in the chamber at each stage in the operating cycle

\*YES / ~~NO~~

temperature of air during drying stage in the operating cycle

\*YES / ~~NO~~

volume of each chemical additive admitted, at each stage in the operating cycle

\*YES / ~~NO~~

holding time at disinfection temperature

\*YES / ~~NO~~

Other process variable:

.....

Other process variable:

.....

Other process variable:

.....

\* DELETE AS NECESSARY

### Machine electronic down load device (Ref 03.11)

13

Archive data storage device required (for controller data)?  
N.B. Must be easily accessible for Estates personnel

\*YES / ~~NO~~

Location of archive data storage device:

Within bedpan washer. Must be capable of being easily connected to a Trust laptop.

Location of system computer for down load data:  
Trust supplied portable laptop.

## D Particular

### **Cycle Control System Required** (Ref 03.14) 14

\* Microprocessor control \*YES / ~~NO~~

\* ~~Electro-mechanical control~~

\* DELETE AS NECESSARY

### **Details of Microprocessor Controller(s)** (Ref C03.13 & C03.14) 15

"Failed Cycle" format: \*YES / ~~NO~~

Coded entry for process control required? \*YES / ~~NO~~

\* DELETE AS NECESSARY

### **Chemical Dosing Systems** (Ref C03.16) 16

Number of chemical dosing systems required (if more than two):

Details: Maximum of 2

### **Number and type of load carriers required** (Ref 03.17) 17

Details (to include sizes, types of, special fitments etc):

Load carriers supplied shall be suitable for the following load types:-

Must be compatible with the SHSCT inventory of bedpans, commode bowls, urine bottles, slipper bedpans.

N.B. The tenderer is advised to contact the SHSCT to obtain an up to date inventory.

## D Particular

### Socket Outlets (Ref 03.19) 18

Fascia mounted 230V 13A Double switched socket outlet required :

\*YES / ~~NO~~

\* DELETE AS NECESSARY

### Ventilation Systems (Ref 03.20) 19

General room ventilation in which the washer disinfectors (s) are installed shall be adequate however where special ventilation requirements are required they shall be listed by the Tenderer

### Water Treatment Plant (Ref C03.21) 20

Water Softener required?  
(To comply with water hardness criteria)

YES / ~~NO~~

N.B. It is the responsibility of the tenderer to undertake water quality testing to ensure compliance with EN 15883 2006 Part 1 and Part 3.

Details and deviations from C03.33 if required:

### Equipment & Materials to be Provided within the Tender for Testing on Site 21 (ref C03.29, C03.24)

Number	Details
Sufficient quantity to carry out all commissioning tests.	Test soils specifically manufactured for bedpans and urine bottles.

## D Particular

--	--

### **Installation Services to be Included within the Tender** (Ref C03.24) 22

Details:

Tenderer to be responsible for installation of services / connections to within 1 metre of washer disinfectors.

### **Staff Training Required** (Ref C03.28) 23

Number of Estates Staff to be trained: 5

Number of User Staff to be trained: 15

Details of room and training aids. to be made available by Purchaser:

Items to be included (delete where inapplicable):-

**Introduction** - An explanation of the purpose of the Washer-disinfectors for Human Waste Containers and the cycles.

**User Instructions** - An introduction to the Washer-disinfectors (including load limiting factors such as load orientation), starting a cycle, unloading, routine tasks eg cleaning seals, replacing record charts.

**Maintenance Instruction** - An introduction to the Washer-disinfectors from the maintenance perspective, identification of major components.

**The Maintenance and Instruction Manual** - Each course member shall be given a copy of the appropriate maintenance or user manual, the contents, its layout and the information in each section is to be described.

**PPM** - Using the manual, every ppm task shall be demonstrated on the Washer-disinfectors.  
(Note: the tasks are to be demonstrated without reference to frequency.)

**Cycle Control** - A cycle shall be completed and the Washer-disinfectors stalled in every stage or sub-stage. By using the manual each valve, relay etc contributing to that stage to be identified and demonstrated to be operating satisfactorily.

**Repair of Components** - The dismantling, repair or maintenance of Washer-disinfectors components shall be demonstrated upon similar components to those fitted to the Washer-disinfectors or by using sectioned components. The tasks shall be cross-referenced to the manual. Components on the Washer-disinfectors are not to be used.

**Fault Finding** - By cross-reference to the manual, common faults shall be introduced and attendees given the opportunity to fault find.

## D Particular

For microprocessor-controlled Washer-disinfectors more time may be required to enable each attendee to gain "hands on" experience of using the facilities available to the maintenance person.

\*Advanced Training options and costing required

**YES/NO**

\* DELETE AS NECESSARY

### Testing (ref C03.41 and 04:01 to 07)

24

1. Washer-disinfectors ~~will~~/will not be examined/checked by the Purchaser (or Agent) during manufacture.
2. All testing to be witnessed by - Authorising Person (Decontamination) and Authorising Engineer (Decontamination)
3. Installation testing (as per HTM 2030) to be performed by... - tenderer
4. Operational testing (as per EN ISO 15883 Pt1, Table A.1 and Pt3 Annex A) to be performed by... - tenderer

\*Details of **deviations** from HTM 2030 Validation and Verification for Installation testing:

5. Performance Qualification tests (as per EN ISO 15883 Pt1, Table A.1 and Pt3 Annex A) to be performed by:... - tenderer for the load types detailed below:

Details of PQ Tests Required:

bedpans, commode bowls, urine bottles, slipper bedpans

### Service Response (Ref C03.30)

25

Required service response time (for engineer to arrive at site):

Tenderer to specify their service response time.

## **D Particular**

### **INFORMATIONN TO BE COMPLETED BY TENDERER**

#### **Details of Microprocessor Control System (Ref C03.13 & C03.14)**

26

**The following information shall be provided by the Tenderer.**

Details of independent body where complete programme and software are lodged:

Details of interface and file protocol requirements for transfer of data in the storage device to an external computer:

Details of diagnostic checks incorporated in the system:

Details (including cost) of the data storage device:

Maximum ambient temperature within the protective case .....°C

with an ambient temperature of .....°C

#### **Warranty Details**

27

Length of standard/free warranty period offered:

Number of included service visits during warranty period:

Conditions of warranty:

## D Particular

Projected mean time between failures:

Guaranteed up-time:

Please state definition of up-time

.....  
.....  
.....  
.....

Please state remedy available to trust if guaranteed up-time is not achieved

.....  
.....  
.....  
.....

Extended warranty options for service and maintenance:

Please complete the following schedule with regard to a planned preventative maintenance and emergency call out contract to cover all items shown in the individual site schedule and to commence 12 / 24 / 36 \* months after acceptance if required by the purchaser:

Number of service visits ..... per annum

Duration of service visits .....hours

Normal working hours are **0830-1730**, unless otherwise stated:

All emergency call-outs included yes / no \*

Price for emergency call-out during normal working hours,  
(including travel and subsistence) if not included £..... per hour

All out of hours working included yes / no \*

Price for Saturday working £.....per hour

Price for Sunday working £.....per hour

Price for evening working £.....per hour

Price for bank holiday working £.....per hour

Response time to emergency call-outs (engineer on site) ..... hours

## D Particular

Latest time on a working day to guarantee engineer on site same day .....

Base of engineer to service this trust .....

How many other trusts does he/she service .....

Number of engineers available to service this trust .....

All spare parts included yes / no \*

Please list any parts that are not included that appear on the following lists :

Ten most used commodities by volume

Description	Part No	Delivery lead time	Price (exc VAT)
1.....			
2.....			
3.....			
4.....			
5.....			
6.....			
7.....			
8.....			
9.....			
10.....			

Ten most used commodities by value:

Description	Part No	Delivery lead time	Price (exc VAT)
1.....			
2.....			
3.....			
4.....			
5.....			
6.....			
7.....			
8.....			
9.....			
10.....			

Location of spare parts .....

Delivery lead time for spare parts .....



## D Particular

Software Upgrades (during warranty or maintenance contract period):

Safety / Defect Upgrades	Free of charge / At cost *
--------------------------	----------------------------

New Applications                      Free of charge / At cost \*

Annual maintenance contract costs including validation to **EN ISO 15883 Pt1, Table A.1 and Pt3 Annex A)** including PQ tests as defined in section D Particular:

Contract price for one year                      £..... exc VAT

Five year maintenance contract (fixed to retail price index) £..... exc VAT

Annual maintenance contract costs excluding validation:

Contract price for one year                      £..... exc VAT

Five year maintenance contract (fixed to retail price index) £..... exc VAT

Contract price for five years paid annually (including warranty)

Discount if payments for process chemicals or consumables are included with maintenance payments .....%

\* Delete as appropriate

## D Particular

### Service Requirements

28

**The following information shall be provided by the Tenderer.**

SERVICE	REQUIREMENTS
machine number	.....
water flow rate	.....
water supply pressure	.....
water consumption per cycle	.....
drain flow rate	.....
drain size	.....
drain type	.....
drain vent size and type	.....
electricity voltage	.....
electricity current	.....
electricity maximum power kW	.....
sound power per washer-disinfector	.....
total sound power all specified washer-disinfector(s)	.....
process chemical cost per cycle:	.....
washer-disinfector water treatment plant (if required) operating cost per cycle	.....
total energy cost per ..... cycle (please specify cycle type)	.....

## D Particular

Total cost of processing typical reference load,  
2x bedpans and 2x urinal bottles.  
(including energy and process chemical costs): .....

energy cost basis:

Mains cold water	£	/m <sup>3</sup>
Hot water	£	/m <sup>3</sup>
Electricity		p/kWh
Other.....		.....

**Overall Cycle(s) Time(s)**

29

**The following information shall be provided by the Tenderer.**

Load (reference load)	Maximum Cycle Time

## D Particular

### Overall Washer-disinfector Dimensions

30

The following information shall be provided by the Tenderer.

m/c no	max floor area l w	height h	max floor loading force kN/m <sup>2</sup>	max fascia opening (if applic.) w h

### Porterage Details

31

The following information shall be provided by the Tenderer.

Details (including weight and dimensions):

### Heat Emission

32

The following information shall be provided by the Tenderer.

Heat emission during normal operation at ambient temperature of 25°C:-

Single Door:  
to installed room - with door closed ..... W

## **D Particular**

### **Contract Completion**

33

**The following information shall be provided by the Tenderer.**

time required from receipt of order in works ..... weeks

time required for installation and ..... weeks  
pre-commissioning on site

time required for carrying out work ..... weeks  
as specified in clause 32, on site

notice required for carrying out work .....weeks  
as specified in clause 32, on site

## D Particular

### Detailed Cost Breakdown:

34

The following information shall be provided by the Tenderer.

Item Type	Model Name/No	No. of	List Price per Unit	Discount %	Actual price per Unit	Total Price
Washer-Disinfector						
Chemicals						
Controls						
Wall Storage Racks for equipment specified i.e. bedpans and urine bottles.						
Additional Options						

## D Particular

### Summary of Tender

35

The following information shall be provided by the Tenderer.

	£
supply .....Human Waste Containers washer-disinfectors(s) ex works.....	.....
supply process monitoring, data down load device and archive storage.....	.....
delivery, offloading & positioning ..... washer-disinfectors(s)	.....
enabling works and installation of ..... washer-disinfectors (s)	.....
site commissioning, ie installation checks and tests	.....
testing to EN ISO 15883 Pt1, Table A.1 and Pt3 Annex A)	.....
warranty period service including minimum 4 off quarterly visits and quarterly revalidation	.....
supply, installation and validation of water treatment plant (if applicable)	.....
staff training, consisting of ..... days	.....
supply dosing system for one chemical	.....
supply of detergent process chemicals	.....
supply load carriers	.....
supply ..... set(s) of recommended service spares	.....
contingency - to be set by Purchaser (if applicable)	.....
SUB-TOTAL	.....
..... VAT@..... %	.....

**D Particular**

**TOTAL**

Signature: .....

Witness: .....

Position: .....

Address: .....

Company: .....

.....

Date: .....

Date: .....

**End of Section D Particular**

**End of Specification**