

OWNER'S MANUAL

Operation and Installation

Prestige PM-D3 Washer Disinfector (PRFL0202)



PRESTIGE MEDICAL

P.O. Box 154,
Clarendon Road
Blackburn,
Lancashire,
BB1 9UG.
England.

Tel: (+)44 (0) 1254 682622
Fax: (+)44 (0) 1254 682606
E-mail: sales@prestigemedical.co.uk
Web: www.prestigemedical.co.uk

Section 1

OPERATING INSTRUCTIONS

Prestige PM-D3 Washer Disinfector

Memorandum of Registration

Note to Person Installing this Product

This Memorandum of Registration MUST be completed by the person undertaking installation and witnessed by the owner of the product.

Note to Owner of this Product

Be sure that this Memorandum of Registration is completed by the person undertaking to install the product. In the event of a Warranty Claim the information contained within this Registration is your evidence that the product has been correctly installed. **Failure to provide this evidence in the event of a warranty claim may result in the claim being rejected** (this does not affect your statutory rights as a customer).

Owner's Name:

Installation Address:

Installation Date:

--	--	--	--	--	--	--	--

Serial Number:

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Software Version:

P	R	F	L	0	2	0	2
---	---	---	---	---	---	---	---

Installed by:

Witnessed by:

Service and Maintenance Requirements:

The Prestige PM-D3 Washer Disinfectant should be serviced on a regular basis to ensure that the product continues to perform within the guidelines recommended in the Health Technical Memorandum 2030 (HTM2030). See page 27 for further information.

Important Information



IMPORTANT:

The loading door cannot be opened unless the product is connected to a mains power supply. For manual release, see page 10.

Product Identity

The model and serial number are located on the silver label to the rear of the unit.

The software version is displayed for a brief period when first applying mains power to the unit.



Electrical

The power cord and connector supplied with this machine are wired according to the following colour code:

<i>Brown</i>	<i>Live</i>
<i>Blue</i>	<i>Neutral</i>
<i>Green/Yellow</i>	<i>Earth</i>

If the supplied connector is removed, be sure to observe the colour code when reconnecting to an appropriate plug or fused spur.

	WARNING
	<p>HAZARDOUS VOLTAGE. Contact may cause electric shock or burn. Turn off and isolate power before servicing.</p>

Dangerously high voltages are present inside the unit. Do not open the cabinet. Refer servicing and repair to qualified personnel only.

To prevent fire or shock hazard, do not expose the unit to rain or moisture.

Installation and Maintenance

Observe the Installation Instructions (page 23), the Maintenance Instructions (page 11), and the Servicing requirements outlined on page 27 of this manual.



Decontamination

This product **MUST** be decontaminated in accordance with local regulations before transporting. In the event that the product must be returned to the supplier, it is vital that the Decontamination Certificate on page 28 of this manual is completed and returned with the product.



Heat

The temperature within the unit can exceed 85°C. during and after operation. Take care when removing items on completion of a cycle and allow good time for the items to cool to a safe temperature before handling.



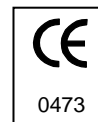
Chemicals

Read the chemical Safety Information on pages 18-21 of this manual before use.

Using non-approved chemicals may cause damage to the machine and could void both your warranty and your guarantee of performance.

Declaration of CE Conformity:

The Prestige PM-D3 Washer Disinfector is designed and manufactured in the UK and complies with the essential requirements of the Medical Devices Directive 93/42/EEC (where appropriate).



	<p>IMPORTANT:</p> <p>This product MUST complete at least one disinfection cycle every day!</p>
--	--

Contents

Section 1 Operation

Memorandum of Registration	page 2
Important Information	page 3
Contents	page 4
Introduction & Changing Language	page 5
Identifying Controls	page 6
Operating Instructions	page 7
Changing Programmes	page 9
Emergency Door Release	page 10
Routine Checks	page 11
AWT Fluid Replenishment	page 12
Warranty and Extended Warranty	page 13

Section 2 Installation

Unpacking	page 15
Technical Specification	page 16
Chemical Data	page 18
Dimensions	page 22
Installation	page 23
Setting Time and Date	page 24
Operating Process	page 25
Troubleshooting	page 26
Service Record	page 27
Decontamination Certificate	page 28

Introduction

Intended Purpose and Performance

The intended purpose of the Prestige PM-D3 Washer Disinfector is to clean, or clean and disinfect surgical instruments and associated products. This is achieved through the use of separate wash and disinfection stages which are controlled and monitored using sophisticated electronics to ensure optimum decontamination.

Washing is achieved using a unique, specially formulated and clinically validated decontamination liquid which is introduced into the cycle during the programme.

Raising the temperature of the water within the wash chamber to a predetermined level, and then maintaining this temperature for a specified period of time, effectively achieves thermal disinfection.

If a wash/disinfect cycle fails to achieve any one of the predetermined parameters then the system reports a failed cycle. The unit registers such a failure and brings it to the attention of the operator, who is then unable to remove the load without being aware that the cycle has been aborted.

To improve cleaning performance, and to help reduce scaling during thermal disinfection, a dedicated water treatment additive (AWT Fluid) is automatically introduced into the cycle. This helps ensure that the unit maintains optimum performance throughout its' operational life.

The Prestige PM-D3 Washer Disinfector has been designed to perform within the guidelines recommended in the Health Technical Memorandum 2030 (HTM2030). A stringent quality control programme ensures that every unit is manufactured and tested under controlled conditions to ensure that all units perform identically.

Changing Language

The LCD display on the front panel of the Prestige PM-D3 can be programmed to display text in one of four different languages:

French
German
Spanish
English

Once selected, a language becomes the default setting until the procedure is repeated and an alternative selection is made.

1. Disconnect product from power supply, wait a few seconds, and then reconnect.
2. Observe the messages shown on the LCD display and follow this procedure:

PRESTIGE Washer
Model PRFL0202



Press and hold **START** button until 'select language' prompt is displayed

Select Language
French



Press and hold **START** button until required language is displayed



Press **DOOR RELEASE** button once

3. The selected language is now stored.

Identifying Controls



IMPORTANT

The door cannot be released unless the product is connected to a mains power supply.

To manually open door, please refer to page 10.

DOOR RELEASE

Press to open door

Also used to select alternative programmes

STATUS INDICATORS

READY

Unit will begin cycle when START button is pressed

PRE-WASH

Cold water pre-wash stage of cycle is in progress

WASH

Main wash stage is in progress.

RINSE

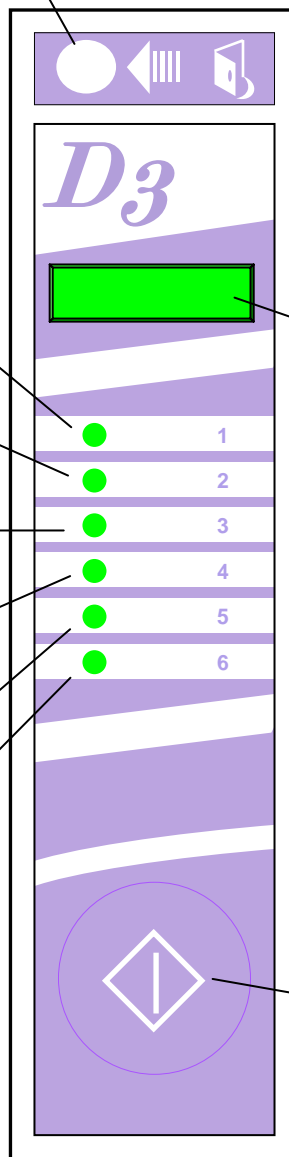
Load is being rinsed prior to disinfection stage

DISINFECT

Disinfection stage is in progress.

COMPLETE

Cycle is complete and load may be removed once cooled



LCD DISPLAY

Indicates status of washer and displays any error messages

START BUTTON

Press once to start or pause the wash cycle, hold to abort

Also used to change default settings.

Operating Instructions

Operating the PM-D3 Washer Disinfector



1. Apply power to the machine and press the **DOOR RELEASE** button to open the door.
2. Load the instruments to be cleaned into the Large Basket, Small Instrument Basket, Plate Rack, and Instrument Trays as required. Slide Large Basket into chamber.



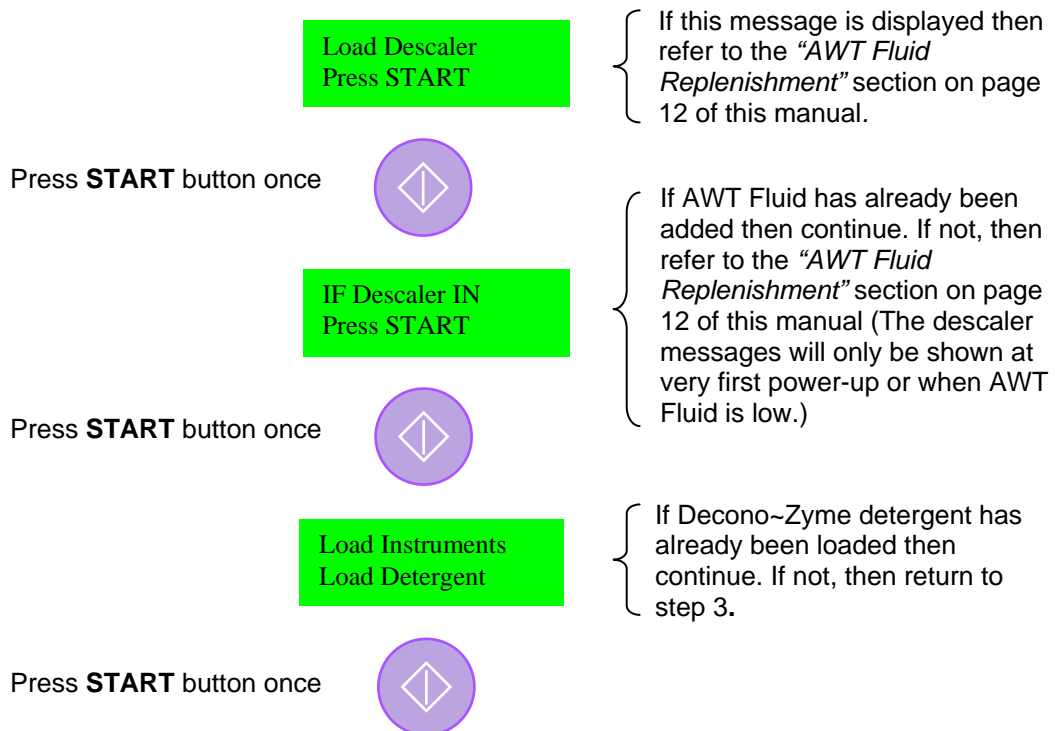
Do not overload the Large Basket so that water spray is obstructed.

Water is sprayed up from the bottom of the chamber so large items, such as trays and bowls, should NOT be placed flat on the bottom of the Large Basket as this will obstruct the water spray.

Note:

Whenever hollow instruments are included in the load it is important that any spare luer connectors are blanked off with the caps supplied with the connectors. This will ensure that an effective irrigation flow is achieved through each hollow device and not by-passed through the spare luer connectors.

3. Take a sachet of Decono~Zyme Gel, tear or cut off one corner of the pack and empty the entire contents into the door cavity marked '**DETERGENT**' and close door.
4. Observe the messages shown on the **LCD DISPLAY** and follow this procedure:



Operating Instructions (cont.)

IF All Loaded
Press **START**

If Decono~Zyme has already been loaded then continue. If not, then return to step 3.

Press **START** button once



The Wash and Disinfection cycle will now commence and proceed automatically as detailed in “*Operating Process*” on page 25 of this manual. When the cycle is complete the door will automatically unlock and the following message will be displayed:

Cycle complete
Press **START**

The following message sequence will now be displayed and repeated:

WARNING
Chamber Hot

Open Door
Carefully

Unload
Press **START**



WARNING

Beware when removing instruments at this time as the temperature within the chamber can be in excess of 85° C.

Pausing or Aborting a Wash Cycle

To **pause** operation at any time during the wash and disinfect cycle, press the **START** button once.

To **resume** operation after pausing, press the **START** button once.

To **abort** a wash and disinfect cycle, press the **START** button once and then the **DOOR RELEASE** button. The program will automatically go to drain, the cycle will be aborted, and the following message will be displayed.

PROGRAM ABORTED

Changing Programmes

Wash & Disinfect Function

Three separate programmes allow the Prestige PM-D3 to function as a washer disinfecter, or as a washer only. The two wash/disinfect programmes enable a choice of disinfection times, whilst the wash only mode provides a 55°C final rinse stage to enable instruments to dry faster before being transferred to a separate disinfecter or sterilizer.

The following tables indicate the target wash/disinfect parameters for each of the three selectable programmes which must be met to ensure compliance with HTM2030 guidelines. The accuracy of these parameters may be monitored by observing a print-out from the Thermal Printer (optional extra, see page 15) or by viewing the Front Panel LCD as a cycle progresses. This should be done every month as part of the routine checks (see page 11).

Programme 1 (wash & disinfect)

Pre-Wash <i>duration</i>	3 mins
Main Wash <i>duration</i>	5 mins
Main Wash <i>temperature</i>	43-45°C
Rinse 1 & 2 <i>duration</i>	2 mins
Disinfection <i>duration</i>	2 mins
Disinfection <i>temperature</i>	85°C

Programme 2 (wash & disinfect)

Pre-Wash <i>duration</i>	3 mins
Main Wash <i>duration</i>	5 mins
Main Wash <i>temperature</i>	43-45°C
Rinse 1 & 2 <i>duration</i>	2 mins
Disinfection <i>duration</i>	10 mins
Disinfection <i>temperature</i>	85°C

Programme 3 (wash only)

Pre-Wash <i>duration</i>	3 mins
Main Wash <i>duration</i>	5 mins
Main Wash <i>temperature</i>	43-45°C
Rinse 1 & 2 <i>duration</i>	2 mins
Final rinse <i>duration</i>	2 mins
Final rinse <i>temperature</i>	55°C

Note: If programme 3 is set as the default then at least one disinfect programme (programme 1 or 2) MUST be run each day.

Changing Programmes

Once selected, a programme becomes the default operating programme until the procedure is repeated and an alternative selection is made.

To change programmes follow this procedure:

1. Open loading door.
2. Press and hold DOOR RELEASE BUTTON.



3. Use START button to scroll through time and date settings until the following programme prompt is displayed.

Set Clock & Prog
PROG 1

4. Holding the START button will cause display to scroll through programmes 1 to 6. Release when the required programme is displayed.
5. Press DOOR RELEASE BUTTON once to save changes and exit menu.

Emergency Door Release

If your Prestige PM-D3 Washer Disinfector should fail to operate due to a fault with the supply to the product, the loading door will remain locked until power is restored.

However, in the unlikely event that an internal fault causes a failure, the loading door must be released manually to gain access to the screws securing the outer cover.

The following procedure will enable the loading door to be released manually using the Door Release Probe supplied with the product.



This procedure should ONLY be used after it has been confirmed that the fault is internal to the product.



1. Remove mains connector from supply socket.
2. Locate and unscrew small plastic access plug towards the top, right-hand side of the outer cover (*fig 1*)
3. Insert Door Release Probe into exposed hole and push firmly (*fig 2*)
4. The loading door will now be released.
5. Replace small plastic plug.



Consult a suitably qualified Maintenance Person before restoring power to the product. Advice on fault diagnosis and repair may be found in the Service and Maintenance Manual.



Fig 1. Location of access plug covering door release hole

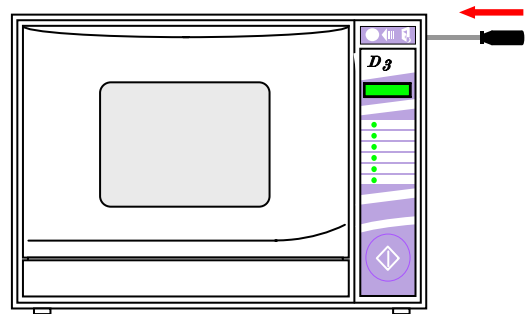


Fig 2. Insert Door Release Probe and push firmly in direction of arrow

Routine Checks

To ensure that your Prestige PM-D3 Washer Disinfector continues to operate within the design parameters it is recommended that the following checks are performed on a regular basis. Consulting the Trouble-Shooting guide on page 26 of this manual may prove useful when conducting the checks. **Please note that completion of these checks is not a substitute for regular servicing and maintenance by a suitably qualified engineer.**

Daily Checks

The following checks should be performed before use each day:

- **Check cleanliness of all external surfaces.**

The outside of the unit may be cleaned with a weak mixture of detergent and water.

- **Check that the inside of the unit is clean and free from any deposits.**

Remove any deposits by cleaning with a weak mixture of detergent and water.

- **Check that perforated sump cover at bottom of wash chamber is not clogged.**

Remove any debris by cleaning with AWT Fluid and then flush through with fresh water.

- **Check holes in rotating spray bar are not blocked.**

The rotating spray arm may be removed by unscrewing clockwise, cleaned with AWT Fluid, and then flushed through with fresh water.

- **Check that rotating spray bar is free to rotate without restriction.**

- **Check that manifold hoses and Distal Connectors are in good condition.**

Ensure that manifold hoses are not perished or blocked and washers in Distal Connectors are not split. Replace as necessary.

Weekly Checks

The following checks should be performed every week:

- **Check cleaning efficiency of unit.**

Place a TOSI (or equivalent) test strip in the centre of the Large Basket and run a wash cycle. Check that the test strip is completely cleaned with no red or clear residue remaining.

- **Verify accuracy of electronic control systems.**

Select a printout (if the optional printer has been specified) and compare the parameters with the target figures shown in the chart on page 9 of this manual.

Monthly Checks

The following checks should be performed every month:

- Check that all hoses are secure with no evidence of leaking.
- Check that mains power cord is undamaged.
- Check that door is free to open and close without restriction.
- Check that rubber seal around door opening is undamaged.
- Check that basket docking port at rear of wash chamber is free from blockages and damage.

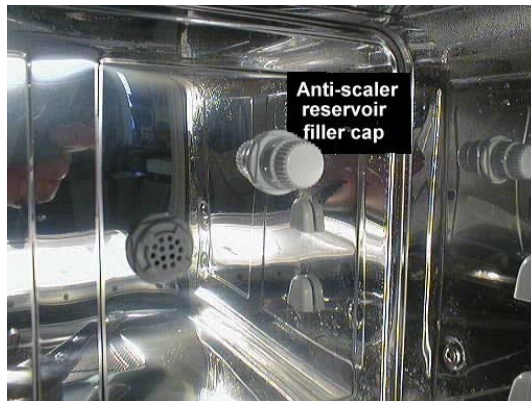
AWT Fluid Replenishment

When full, the AWT Fluid reservoir contains sufficient anti-scaling fluid for around 40 wash and disinfect cycles. On completion of 25 cycles, the **LCD DISPLAY** will indicate that more fluid is required and the unit will not proceed with a new wash and disinfect cycle until you confirm that it has been added.

To add AWT Fluid, the following procedure applies:



1. Apply Power to the Machine. Press **DOOR RELEASE** to open door.
2. Unscrew the reservoir cap which is located on the inside rear of the wash chamber.



3. Using the **AWT** dispenser bottle, slowly top up the reservoir until it begins to overflow.
4. Refit the cap on the reservoir.

Warranty

PRODUCT WARRANTY

To ensure continued efficiency and long operational life, your new Washer Disinfector is covered by a one year or 500 cycles (whichever occurs first) warranty which is arranged and administered by Prestige Medical. Details of the warranty are explained in this section.

Subject to the following terms and conditions, Prestige Medical warrants that any item of THE BASIC WARRANTY ITEMS of the unit (hereinafter called "*new Washer Disinfector*") shall be free from any defects in material and workmanship under normal use.

Any item of THE BASIC WARRANTY ITEMS covered by the limited warranty will be repaired or replaced free of charge by Prestige Medical or any distributor authorised by Prestige Medical to act as their agent (hereinafter called "*authorised Prestige Medical dealer or distributor*").

THE BASIC WARRANTY ITEMS

THE BASIC WARRANTY ITEMS are any items (except THE SPECIFIC EXCLUDED ITEMS) of this *new Washer Disinfector* which are warranted by an *authorised Prestige Medical dealer or distributor* within 12 months or 500 cycles (whichever occurs first) of the WARRANTY START DATE when this *new Washer Disinfector* is first installed by or for you (the original purchaser) as set forth on the Memorandum of Registration.

THE BASIC WARRANTY ITEMS listed below are warranted within 12 months or 500 cycles (whichever occurs first) from the WARRANTY START DATE against defects in manufacture.

- solenoid valves
- electric motor and pump
- switches
- electronic control circuits
- water heating element

THE SPECIFIC EXCLUDED ITEMS

THE SPECIFIC EXCLUDED ITEMS are any items of this *new Washer Disinfector* which are not included in THE BASIC WARRANTY ITEMS and are therefore not subject to the terms and conditions of the PRODUCT WARRANTY.

Expendable items which will deteriorate and require replacement with normal use of the Washer/Disinfector (for example: rubber door seal strip (lower), rubber door seal (surround), water inlet filter element, various types of gaskets and hoses, lamp bulb (if fitted), and other expendable parts not specifically listed)

Fair wear and tear of any part, normal maintenance service items, and the parts and any material used in connection with the *new Washer Disinfector*.

Normal deterioration or damage to plated parts, paint coat, and rubber parts caused by daily wear and exposure to atmosphere and environment.

Minor irregularities not affecting quality, performance or function of the *new Washer Disinfector* parts thereof (e.g. slight noise or vibration) or which appear only under particular abnormal conditions.

Damage caused by insufficient or improper maintenance (e.g. negligence of the daily, weekly, and monthly periodic inspections and any servicing requirements as described and specified within this manual).

Damage caused by using a part or lubricants not approved by an *authorised Prestige Medical dealer or distributor* or being repaired or replaced by a person who is not an *authorised Prestige Medical dealer or distributor*.

Damage caused by accident, abuse, or negligence of the proper handling as set out in this Owner's Handbook, misuse of the *new Washer Disinfector*, use of the *new Washer Disinfector* under unusual conditions, and modifications of or to the *new Washer Disinfector* or any component/parts thereof not recommended or approved by an *authorised Prestige Medical dealer or distributor*.

Damage caused by external influences such as chemical spillage, accident, fire, and disasters due to human fault or negligence or Act of God.

Damage to the external casing, wash chamber, load carriers, or any part of the *new Washer Disinfector* which may come into contact with the load carrier during the process of loading/unloading the *new Washer Disinfector*.

All charges incidental to breakdowns, such as loss of use of the *new Washer Disinfector*, loss of time, inconvenience, telephone, transportation, loss or damage to personal property or loss of revenues, or other matter not specifically included.

Damage caused by incorrect installation of the *new Washer Disinfector* which could cause operational failure or impairment either immediately after such installation or at any time within the period of this PRODUCT WARRANTY.

Prestige Medical reserves the right of final decision on all manufacturers' warranty claims.

Nothing herein affects the statutory rights of a consumer.

EXTENDED WARRANTY

Prestige Medical offer a choice of Service Contract and Extended Warranty packages which also provide continued breakdown cover and periodic validations. All are performed by an authorised Prestige Medical engineer.

For further details please contact your supplier or Prestige Medical at the address shown on page 3 of this manual

Section 2

INSTALLATION

Prestige PM-D3 Washer Disinfector (UK)

Unpacking

Unpacking

Read this manual and familiarise yourself with all components and controls before attempting to install or operate the unit.

Carefully unpack your Prestige PM-D3 Washer Disinfector and retain the carton and all packaging materials. If the unit needs to be returned to the supplier for any reason then the original carton and packaging materials should be re-used.



IMPORTANT

The PM-D3 Washer Disinfector MUST be connected to a suitable mains power supply to enable the loading door to be released.

The unit is despatched with a range of accessories to enable easy installation and efficient operation. Their use is detailed throughout this manual. Open door and remove basket and accessory pack (see note above). Ensure that all these items are present before attempting to install or operate the unit. Complete the Enclosures Check List and notify supplier of any shortages or damaged components as soon as possible.

The Prestige PM-D3 Washer Disinfector is not supplied with a printer. This may be purchased separately. Use the following code when ordering a printer from your supplier.

Thermal Printer

Pt # MED1014

Printer Power Supply

Pt # MED1015

Roll of Paper

Pt # MED1014.1

Enclosures Check List

- 1 Grey drain hose
- 1 Blue cold water hose
- 1 Carrier system with divider
- 1 Large Tray c/w Manifold
- 2 Instrument Tray
- 1 Dish Rack
- 6 Hose & Luer Assemblies
- 6 Distal Connectors
- 1 Small Instrument Basket
- 1 Bottle AWT Fluid**
- 1 Pack (10) Decono~Zyme sachets**
- 1 RS232 data (printer) lead
- 1 Door Release Probe
- 1 Owner's Manual

Replacement Parts and Consumables

A range of replacement parts and consumable items approved for use with the PM-D3 Washer Disinfector may be purchased from your supplier. The use of these compatible, approved products will ensure continued and reliable operation of you washer/disinfector.

AWT Fluid*

(4 X 0.5 Litre bottle)

Pt # MED1000.09

Decono~Zyme Gel packs**

(100 x 30ml sachets)

Pt # MED1000.10



Using non-approved chemicals, accessories, and replacement parts may cause damage to the machine and could void your warranty.

Technical Specification

General:

Model:	PM-D3 Washer Disinfectant
Description:	Washer Disinfectant, Class IIa
Type:	Cabinet (single chamber) machine (type 1)
Purpose:	To clean or clean/disinfect surgical instruments, hollow instruments, and associated products
Operating Process:	Moist heat thermal disinfection
Applied Standards:	BS2745: part 1: 1993 BS2745: part 3: 1993 EN60601-1-2: 1993 EN61010-2-045 (2001) EN61326: 1997 & A1: 1998

Wash Cycle Parameters:

Wash temperature:	42°C. to 45°C.
Disinfection Conditions:	Moist heat @ 80°C. to 85° C.
Disinfection Period Band:	80 - 85° C. for a minimum period of 1 minute
Holding Time (prog 1)	2 minutes @ Disinfection Conditions
Holding Time (prog 2)	10 minutes @ Disinfection Conditions
Equilibration Time:	approximately 3 minutes
Plateau Period:	approximately 5 minutes
Min. Temp. During Cycle:	determined by temperature of water supply
Max. Temp. During Cycle:	85°C.
Accuracy of Temp. Measurement:	< 2% @ 85°C.
Vol. of Dispensed Chemicals:	AWT Fluid: 2ml (approx) Decono~Zyme: 30ml maximum

Required Services:

Electricity Supply:	
Supply Voltage (230v):	single phase 230v (nominal) AC
Supply Voltage (110v):	single phase 110v (nominal) AC
Supply Frequency:	50/60 Hz
Lead Length:	1.83M (6 feet)
Water Supply:	
Supply Connection:	¾" BSP Male Union
Acceptable Pressure Range:	1 – 3 BAR (15 – 45psi)
Effect of Lower Pressure:	increased filling time leading to extended total cycle time
Acceptable Flow Range:	not less than 2 litres/min
Effect of Reduced Flow:	increased filling time leading to extended total cycle time
Volume Used per Cycle:	9 litres maximum
Acceptable Temp. Range:	15 - 25°C.
Hardness:	not more than 5mg/L (5ppm) CaCo ₃

Technical Specification (cont.)

Required Services (cont):

Drain:

Discharge Orifice Type:	18mm outside dia. unthreaded hose tail
Max. Flow to Drain:	4 litres/min
Max. Temp. of Effluent:	85°C

Ventilation:

Max. Heat Output of Load:	85°C
---------------------------	------

Chemicals:

Size and Nature of Containers:

AWT Fluid:	0.5litre plastic bottle with spout
Decono~Zyme:	30ml sachet

Storage Instructions:

AWT Fluid:	Refer to pages 18 & 19 of this manual
Decono~Zyme:	Refer to page 20 & 21 of this manual

Safe Handling Instructions:

AWT Fluid:	Refer to page 18 & 19 of this manual
Decono~Zyme:	Refer to page 20 & 21 of this manual

Quantity Used per Cycle:

AWT Fluid:	2ml (approximately)
Decono~Zyme:	30ml

Weight:

Dry weight:	27kgs (empty)
Operational Weight:	31kgs (with fluids)
Shipping Weight:	31kgs

Dimensions:

Wash Chamber Volume: 53,760cm³

Outer Cabinet Dimensions: 570mm (w)
500mm (d)
440mm (h)

Carton Dimensions: 640mm (w)
540mm (d)
480mm (h)

Installed Clearances: See page 22

Chemical Data

This document conforms with Regulation 6 of the Chemicals (Hazardous Information and Packaging for supply) Regulations 1994 (CHIP 2) - Second Edition

Revision No: M105/01
Date of Publication: 21/01/02
Product: AWT Liquid

1. IDENTIFICATION OF THE PRODUCT AND COMPANY

1.1	<u>Trade Name:</u>	AWT LIQUID
1.2	<u>Type of product:</u>	Scale Preventor and Water Conditioner
1.3	<u>Manufacturer/Supplier:</u>	Medisafe UK Limited
1.4	<u>Marketing Address:</u>	The Snap Factory Twyford Road Bishop's Stortford Hertfordshire CM23 3LJ United Kingdom
1.5	<u>Manufacturing Address:</u>	as above

2. COMPOSITION/INFORMATION ON INGREDIENTS

2.1	<u>Chemical type:</u>	Mildly Acidic Solution.
2.2	<u>Major ingredients:</u>	
	Sequestriants	<5%
	Citric Acid	<15%
	Wetting Agent	<5%
	Demineralised water	Balance

3. HAZARDS IDENTIFICATION

No specific hazards

4. FIRST-AID MEASURES (Must be taken immediately)

4.1	<u>Inhalation:</u>	Non-toxic: avoid long term inhalation of neat liquid. Remove to fresh air.
4.2	<u>Eye contact:</u>	Rinse eyes copiously with water for 10 minutes. Seek medical advice as necessary.
4.3	<u>Skin contact:</u>	Wash affected area with soap and water. Avoid prolonged contact.
4.4	<u>Ingestion:</u>	Do not induce vomiting. Give milk or water to drink. Seek medical advice where necessary.

5. FIRE-FIGHTING MEASURES (Not flammable solution)

5.1	<u>Extinguishing media:</u>	Any available means.
5.2	<u>Explosive quality:</u>	Nil.
5.3	<u>Specific hazard:</u>	No specific hazard
5.4	<u>Specific protective measures:</u>	Not required.

6. ACCIDENTAL RELEASE MEASURES

6.1	<u>Environmental precautions:</u>	Product is biodegradable under OECD conditions operational 6/1995.
6.2	<u>Clean up method:</u>	Flush to drain with copious water or soak up onto inert material and dispose of with clinical waste.
6.3	<u>Clothing for disposal:</u>	Wear gloves and apron, avoid prolonged skin contact.

7. HANDLING AND STORAGE

7.1	<u>Handling guidelines:</u>	Safe handling by trained professional staff in accordance with label instructions only. Not to be mixed with other chemicals. Keep from children.
7.2	<u>Storage guidelines:</u>	Store in dry place not below 0 deg.C. or above 30deg.C. and out of direct sunlight. Keep lidded. Keep from foodstuffs and drinks.

Chemical Data (cont.)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- | | | |
|-----|--------------------------------|--|
| 8.1 | <u>Personal protection:</u> | Use with care, avoid eye contact and prolonged skin contact. Gloves and safety glasses recommended if available. External use only. Not for ingestion. |
| 8.2 | <u>Skin contact:</u> | Low risk: may degrease skin leading to dryness if excessive contact. |
| 8.3 | <u>Eye contact:</u> | Low risk: may cause temporary discomfort. |
| 8.4 | <u>Inhalation:</u> | Low risk: no known hazard. |
| 8.5 | <u>Inhalation (long term):</u> | Low risk: no known hazard. |
| 8.6 | <u>Ingestion:</u> | Low risk: substantial ingestion will cause discomfort to mouth and digestive tissues. |

9. PHYSICAL AND CHEMICAL PROPERTIES

- | | | |
|-----|---|--------------------------------|
| 9.1 | <u>Physical State:</u> | Viscous Liquid |
| 9.2 | <u>Appearance and Odour:</u> | Green with a neutral fragrance |
| 9.3 | <u>Evaporation Rate:</u> | As water. |
| 9.4 | <u>Boiling Point:</u> | 110 deg.C. |
| 9.5 | <u>Freezing Point:</u> | -20 deg.C. |
| 9.6 | <u>% Volatile (by weight):</u> | >95% |
| 9.7 | <u>Solubility in Water (20 deg. C):</u> | Soluble. |
| 9.8 | <u>pH:</u> | 3.0 approximately |
| 9.9 | <u>Specific Gravity:</u> | 1.02 @ 20 deg.C. |

10. STABILITY AND REACTIVITY

- | | |
|------|--|
| 10.1 | No decomposition if stored and used as directed. |
| 10.2 | Hazardous decomposition products: none under normal use. |

11. TOXICOLOGICAL INFORMATION

- | | |
|------|---------------------------|
| 11.1 | No specific data on file. |
|------|---------------------------|

12. ECOLOGICAL INFORMATION

- | | |
|------|---|
| 12.1 | No known adverse effects from normal use. |
|------|---|

13. DISPOSAL CONSIDERATIONS

- | | | |
|------|--------------------------------|---|
| 13.1 | <u>Packaging:</u> | Can be disposed of as normal waste in accordance with local authority regulations. |
| 13.2 | <u>Contaminated Packaging:</u> | May be disposed of safely under normal conditions in accordance with local authority regulations. |
| 13.3 | <u>Product:</u> | Solution to be disposed of in accordance with spillage instructions as detailed in Section 6. |

14. TRANSPORT INFORMATION

- | | |
|------|---|
| 14.1 | No special conditions apply. Not dangerous. |
|------|---|

15. REGULATORY INFORMATION

Not a licensed medicine.

16. OTHER INFORMATION

SAFETY PHRASES

- | | |
|---------|--------------------------------------|
| (24/25) | Keep out of reach of children |
| (50) | Avoid contact with the skin and eyes |
| (50) | Do not mix with other chemicals |

Chemical Data (cont.)

This document conforms with Regulation 6 of the Chemicals (Hazardous Information and Packaging for supply) Regulations 1994 (CHIP 2) - Second Edition

Revision No: M104/01
Date of Publication: 21/01/02
Product: Decono~Zyme Gel

1. IDENTIFICATION OF THE PRODUCT AND COMPANY

- | | | |
|-----|-------------------------------|---|
| 1.1 | <u>Trade Name:</u> | DECONO~ZYME GEL |
| 1.2 | <u>Type of product:</u> | Machine Cleaning Gel |
| 1.3 | <u>Manufacturer/Supplier:</u> | Medisafe UK Limited |
| 1.4 | <u>Marketing Address:</u> | The Snap Factory
Twyford Road
Bishop's Stortford
Hertfordshire
CM23 3LJ
United Kingdom |
| 1.5 | <u>Manufacturing Address:</u> | as above |

2. COMPOSITION/INFORMATION ON INGREDIENTS

- | | | |
|-----|-----------------------------------|-----------|
| 2.1 | <u>Chemical type:</u> | Solution. |
| 2.2 | <u>Major ingredients:</u> | |
| | Mixed Enzyme Solution | <5% |
| | Isopropanol | <15% |
| | Monopropylene Glycol | <15% |
| | Low Foam Surfactants | <5% |
| | Demineralised water, solubilisers | Balance |

3. HAZARDS IDENTIFICATION

No specific hazards

4. FIRST-AID MEASURES (Must be taken immediately)

- | | | |
|-----|----------------------|---|
| 4.1 | <u>Inhalation:</u> | Non-toxic: avoid long term inhalation of neat liquid. Remove to fresh air. |
| 4.2 | <u>Eye contact:</u> | Rinse eyes copiously with water for 10 minutes. Seek medical advice as necessary. |
| 4.3 | <u>Skin contact:</u> | Wash affected area with soap and water. Avoid prolonged contact. |
| 4.4 | <u>Ingestion:</u> | Do not induce vomiting. Give milk or water to drink. Seek medical advice where necessary. |

5. FIRE-FIGHTING MEASURES (Not flammable solution)

- | | | |
|-----|--------------------------------------|----------------------|
| 5.1 | <u>Extinguishing media:</u> | Any available means. |
| 5.2 | <u>Explosive quality:</u> | Nil. |
| 5.3 | <u>Specific hazard:</u> | No specific hazard |
| 5.4 | <u>Specific protective measures:</u> | Not required. |

6. ACCIDENTAL RELEASE MEASURES

- | | | |
|-----|-----------------------------------|--|
| 6.1 | <u>Environmental precautions:</u> | Product is biodegradable under OECD conditions operational 6/1995. |
| 6.2 | <u>Clean up method:</u> | Flush to drain with copious water or soak up onto inert material and dispose of with clinical waste. |
| 6.3 | <u>Clothing for disposal:</u> | Wear gloves and apron, avoid prolonged skin contact. |

7. HANDLING AND STORAGE

- | | | |
|-----|-----------------------------|---|
| 7.1 | <u>Handling guidelines:</u> | Safe handling by trained professional staff in accordance with label instructions only. Not to be mixed with other chemicals. Keep from children. |
| 7.2 | <u>Storage guidelines:</u> | Store in dry place not below 0 deg.C. or above 30deg.C. and out of direct sunlight. Keep lidded. Keep from foodstuffs and drinks. |

Chemical Data (cont.)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- | | | |
|-----|--------------------------------|--|
| 8.1 | <u>Personal protection:</u> | Use with care, avoid eye contact and prolonged skin contact. Gloves and safety glasses recommended if available. External use only. Not for ingestion. |
| 8.2 | <u>Skin contact:</u> | Low risk: may degrease skin leading to dryness if excessive contact. |
| 8.3 | <u>Eye contact:</u> | Low risk: may cause temporary discomfort. |
| 8.4 | <u>Inhalation:</u> | Low risk: no known hazard. |
| 8.5 | <u>Inhalation (long term):</u> | Low risk: no known hazard. |
| 8.6 | <u>Ingestion:</u> | Low risk: substantial ingestion will cause discomfort to mouth and digestive tissues. |

9. PHYSICAL AND CHEMICAL PROPERTIES

- | | | |
|-----|---|--------------------------------|
| 9.1 | <u>Physical State:</u> | Soft Gel |
| 9.2 | <u>Appearance and Odour:</u> | Mauve with a neutral fragrance |
| 9.3 | <u>Evaporation Rate:</u> | As water. |
| 9.4 | <u>Boiling Point:</u> | 110 deg.C. |
| 9.5 | <u>Freezing Point:</u> | -20 deg.C. |
| 9.6 | <u>% Volatile (by weight):</u> | >95% |
| 9.7 | <u>Solubility in Water (20 deg. C):</u> | Soluble. |
| 9.8 | <u>pH:</u> | 8.0 approximately |
| 9.9 | <u>Specific Gravity:</u> | 1.02 @ 20 deg.C. |

10. STABILITY AND REACTIVITY

- 10.1 No decomposition if stored and used as directed.
 10.2 Hazardous decomposition products: none under normal use.

11. TOXICOLOGICAL INFORMATION

- 11.1 No specific data on file.

12. ECOLOGICAL INFORMATION

- 12.1 No known adverse effects from normal use.

13. DISPOSAL CONSIDERATIONS

- | | | |
|------|--------------------------------|---|
| 13.1 | <u>Packaging:</u> | Can be disposed of as normal waste in accordance with local authority regulations. |
| 13.2 | <u>Contaminated Packaging:</u> | May be disposed of safely under normal conditions in accordance with local authority regulations. |
| 13.3 | <u>Product:</u> | Solution to be disposed of in accordance with spillage instructions as detailed in Section 6. |

14. TRANSPORT INFORMATION

- 14.1 No special conditions apply. Not dangerous.

15. REGULATORY INFORMATION

Not a licensed medicine.

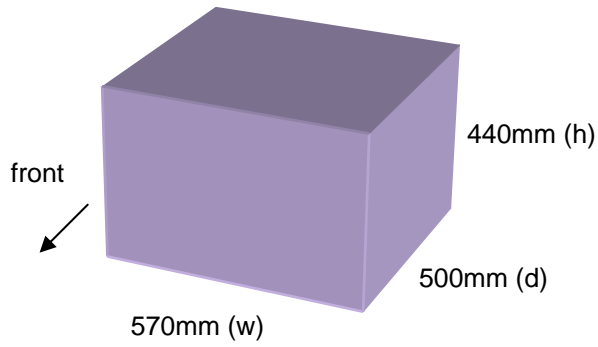
16. OTHER INFORMATION

SAFETY PHRASES

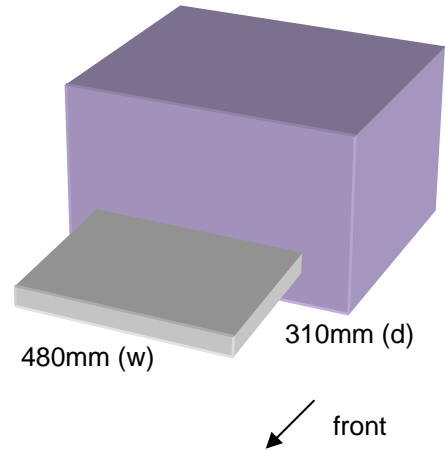
- Keep out of reach of children
 (24/25) Avoid contact with the skin and eyes
 (50) Do not mix with other chemicals

Dimensions

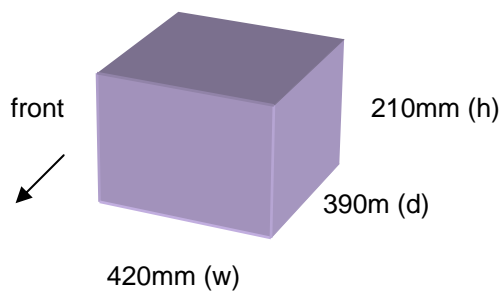
Overall dimensions of outer cabinet:



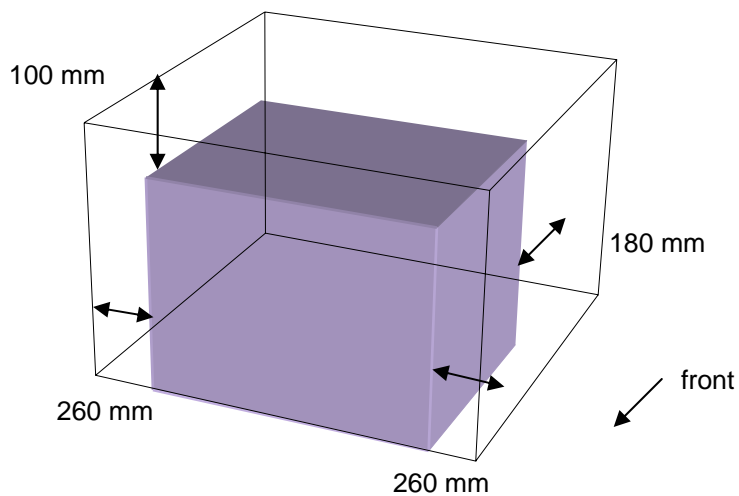
Dimensions of loading door:



Internal dimensions of chamber:






Installation clearances required:




Installation

Connecting the Prestige PM-D3 Washer Disinfector:

1. Unpack the machine and place it on a sturdy, level surface. The unit should be positioned within 1.83m of a mains supply (two supplies if the optional printer has been specified), a suitable drain, and a suitable cold mains water supply.
-  2. Plug the mains plug into a suitable switched outlet and switch on.
3. Open door and remove any protective packaging and loose items from inside the wash chamber.
-  4. Close door, switch mains off at power outlet, and remove mains plug
5. Identify the grey plastic, convoluted drain hose supplied with the unit. The elbow end of the hose should be connected to the drain outlet at the lower rear of the unit. The non-elbow end should be connected to a suitable drain. **The non-elbow end should be connected to a suitable drain which is below the level of the drain outlet on the unit.**
6. Identify the blue cold water hose supplied with the unit. The straight threaded connector should be screwed onto the cold water inlet at the lower rear of the unit. **Ensure the black plastic washer fitted to the hose end is in place before tightening.** Connect the elbow end of the hose to a suitable cold water supply.
7. Turn on the water supply and check for leaks.
-  8. Plug the mains plug into a suitable switched outlet and switch on.
9. Load the AWT Fluid as detailed in the “*AWT Fluid Replenishment*” section on page 12 of this manual.

Your Prestige PM-D3 Washer Disinfector is now ready for use.

Installing the Thermal Printer (optional):

1. Identify the RS232 Data Lead supplied with the unit. Connect the 9 way ‘D’ Type connector to the data port on the lower rear panel of the unit.
2. Connect the other end of the RS232 Data Lead to the connector on the rear of the thermal printer.
-  3. Identify the plug-top power supply packed with the printer. Connect between the printer and a suitable mains supply outlet.
4. Switch on printer.

Your Thermal Printer is now ready for use.

Setting Date and Time

1. Open loading door.
2. Press and hold **DOOR RELEASE BUTTON**.
3. After a few seconds the following screen will be displayed with a prompt flashing before the HOUR segment of display. Press and hold **START** button until correct HOUR is displayed.

Set Clock & Prog
TIME _00:00:40
4. Momentarily press **START** button
5. The following screen will now be displayed with prompt flashing between the HOUR and MINUTES segments of display. Press and hold **START** button until correct MINUTES are displayed.

Set Clock & Prog
TIME 14_00:40
6. Momentarily press **START** button
7. The following screen will now be displayed with prompt flashing after SECONDS segments of display. Press and hold **START** button until correct SECONDS are displayed.

Set Clock & Prog
TIME 14:30:40_
8. Momentarily press **START** button
9. The following screen will now be displayed with prompt flashing before the DAY segment of display. Press and hold **START** button until correct DAY is displayed.

Set Clock & Prog
DATE _01:01:00
10. Momentarily press **START** button
11. The following screen will now be displayed with prompt flashing between the DAY and MONTH segments of display. Press and hold **START** button until correct MONTH is displayed.

Set Clock & Prog
DATE 01_08:00
12. Momentarily press **START** button
13. The following screen will now be displayed with prompt flashing between the MONTH and YEAR segments of display. Press and hold **START** button until correct YEAR is displayed.

Set Clock & Prog
DATE 01:08_00
14. Momentarily press **START** button
15. The following screen will now be displayed. Holding the **START** button will cause display to scroll through programmes 1 to 6. See page 9 for more details on setting the correct programme.

Set Clock & Prog
PROG 1
16. Press **DOOR RELEASE BUTTON** once to save changes and exit menu.

Operating Process

Overview

The Prestige PM-D3 Washer Disinfecter uses a microprocessor controlled operating sequence to alternately spray accurately measured amounts of temperature-controlled water from a rotating spray bar onto items loaded into purposely designed baskets and containers, and to flow water through the centre of hollow instruments connected to a manifold via Distal Connectors. A specially formulated detergent gel is added to the water to clean away fat, protein, starch, body fluid residue, etc. A small quantity of scale inhibitor prevents the formation of deposits on both the items being cleaned and the component parts of the washer itself.

Cold water continues to enter the wash chamber from the mains water supply via an electronically controlled valve until a level sensor interrupts and cuts off the incoming water. If a failure should occur in the level sensor then a second, independent sensor will react to cut off the water supply and prevent overflowing.

Once the wash chamber is filled the pre-wash stage begins to remove larger deposits from the load. A pump circulates water from a sump, cycling it between a rotating spray bar in the base of the wash chamber and through a docking port which connects, via a manifold, to the basket containing hollow instruments. The pressure of the water passing through this spray bar causes it to rotate, thereby assisting even distribution and a constant flow of water over and around the items to be cleaned and disinfected. The pressure of water passing through the hollow instruments assists in removing deposits and residue.

The sump, situated in the base of the wash chamber, contains an element which is used to heat the water to 43°C (depending on detergent programme selected) before a further wash commences. Once complete, the water is then drained and replaced with fresh water to perform the first of two rinse stages. Immediately prior to the second rinse, a

small quantity of scale-inhibitor (AWT Fluid) is automatically injected into the rinse water.

If one of the disinfection programmes (programmes 1 & 2) have been selected then the unit next heats the water to the correct temperature. In order to aid thermal efficiency and to reduce the overall cycle time, the water is intermittently circulated within the tank and through the hollow instruments during the heating period.

Once the correct temperature is reached the disinfection cycle begins. The microprocessor then accurately controls the temperature of the water via two independent temperature sensors located adjacent to the sump. This ensures that the correct washing and disinfection temperatures are maintained during the 2 or 10 minute disinfection stages.

If the wash only programme (programme 3) has been selected then the water is heated to 55°C. and a final rinse stage is completed.

Finally, the circulation pump is driven in reverse to drain the wash chamber for the final time. Once the wash chamber is emptied the LCD Display indicates that the cycle has been successfully completed. If for any reason an error was recorded during the cycle then the washer will advise this by displaying the message "**cycle failed**" at this time. In order to prevent unclean/non-disinfected items from being removed prematurely, the loading door will remain locked until the failed cycle is acknowledged. Such an interruption to the cycle will be notified with a "**PROGRAM ABORTED**" message.

Each cycle has a unique, sequential number and contains information regarding date, time, temperature, and duration of each stage of the cycle to afford total trace-ability. Although this information is retained within the microprocessor, an RS232 Data Port at the rear of the washer allows the connection of an external Thermal Printer to display the data in printed form. For details of a suitable printer see page 15.

Troubleshooting Guide

The following table will enable a non-technical user to diagnose basic problems and affect a cure that will enable the unit to resume operation as soon as possible.

If the problem persists after performing these checks it will be necessary to contact your supplier.

Symptom	Check the following
Loading door will not open	<ul style="list-style-type: none"> • Check power cord is properly connected • Check mains supply is switched on
No read-out on LCD Display and no LED illumination on front panel	<ul style="list-style-type: none"> • Check power cord is properly connected • Check mains supply is switched on
Unit fails to take in cold water but LCD Display indicates "Filling ... "	<ul style="list-style-type: none"> • Check that cold water supply is connected • Check that cold water supply is switched on
Unit fills too slowly with cold water	<ul style="list-style-type: none"> • Check that filter in cold water inlet valve is not blocked
LCD Display on unit indicates "PROGRAM ABORTED" during cycle	<ul style="list-style-type: none"> • Check that door has not been opened during cycle
LCD Display on unit indicates "Power failure cycle aborted ... "	<ul style="list-style-type: none"> • Mains supply to unit has not been temporarily disconnected and then reinstated within a timescale which has compromised the cycle
Weekly TOSI test shows clear residue	<ul style="list-style-type: none"> • Check that expiry date of Decono~Zyme gel has not passed
Weekly TOSI test shows red residue	<ul style="list-style-type: none"> • Check rotating spray bar is not clogged. If clogged, then clean with AWT Fluid and flush out with fresh water • Check rotating spray bar is free to rotate without obstruction or restriction
Printer (if applicable) fails to operate	<ul style="list-style-type: none"> • Check that printer is connected to mains supply • Check that mains supply is switched on • Check that data lead is securely plugged into sockets on Washer Disinfector and printer • Check that printer has not run out of paper
Inside of wash chamber is coated with white scale	<ul style="list-style-type: none"> • AWT Fluid needs replenishing (see "<i>AWT Fluid Replenishment</i>" section on page 12 of this manual)
Perforated sump cover in bottom of wash chamber is blocked	<ul style="list-style-type: none"> • Remove cover, clean by immersing in AWT Fluid, and then flush out
Holes in rotating spray bar are blocked	<ul style="list-style-type: none"> • Remove bar by unscrewing the knurled nut in a clockwise direction and clean by immersing in AWT Fluid and then flushing out

Service Record

Medisafe recommend that your PM-D3 Washer Disinfector is serviced in accordance with the schedule contained within the PM-D3 Service Manual at intervals of 12 months (or 3 months if full HTM2030 compliance is required). This record must be completed by the Engineer conducting the Service and should be made available in the event of a warranty claim or breakdown repair.

No user serviceable parts inside. Service and repair should be referred to qualified persons only.

3 months			6 months			9 months		
Serviced by / date			Serviced by / date			Serviced by / date		
Cycles since last service			Cycles since last service			Cycles since last service		
Next service due	cycles	date	Next service due	cycles	date	Next service due	cycles	date

12 months			15 months			18 months		
Serviced by / date			Serviced by / date			Serviced by / date		
Cycles since last service			Cycles since last service			Cycles since last service		
Next service due	cycles	date	Next service due	cycles	date	Next service due	cycles	date

21 months			24 months			27 months		
Serviced by / date			Serviced by / date			Serviced by / date		
Cycles since last service			Cycles since last service			Cycles since last service		
Next service due	cycles	date	Next service due	cycles	date	Next service due	cycles	date

30 months			33 months			36 months		
Serviced by / date			Serviced by / date			Serviced by / date		
Cycles since last service			Cycles since last service			Cycles since last service		
Next service due	cycles	date	Next service due	cycles	date	Next service due	cycles	date

DECONTAMINATION CERTIFICATE

**ENSURE THAT ITEMS RETURNED TO YOUR SUPPLIER ARE
DISINFECTED IN ACCORDANCE WITH THE APPROPRIATE
HOSPITAL PROCEDURE FOR EQUIPMENT OF THIS TYPE**

This form **MUST** be completed and attached to the outside of the carton when returning the product to your supplier. Without this form being visible the courier and/or your supplier are at liberty to refuse handling of the product.

I hereby certify that the machine referred to in this document by model number and serial number has been disinfected in accordance with Hospital Procedure

Model No: Prestige PM-D3 Washer Disinfector

Serial No:

Hospital:

Name:

Signature: Date:

