



## *KHAMSIN User manual*

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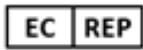
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**This manual must be read  
before using the Khamsin Automated Cleaning System for flexible  
endoscopes.**

This ensures that it is used under the safest and most efficient conditions.



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For any questions concerning the equipment, its maintenance, breakdowns, or end-of-life, please contact your after-sales representative.

The description of the automated cleaning system is accurate on the date this manual is printed.

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## 1 INTRODUCTION

### 1.1 Presentation of the KHAMSIN

#### 1.1.1 Intended use

**The KHAMSIN is an Automated Cleaning System used for endoscope reprocessing post an endoscopy procedure prior to high-level disinfection in your chosen Endoscope Washer Disinfector.**

#### 1.1.2 Certified endoscopes

Contact your PFE Medical representative for information on certified endoscopes. **If a new Endoscope is procured please speak to your PFE Medical representative to ensure that it is compatible and that the correct connectors are available prior to cleaning the Endoscope in the Khamsin.**

- Double-channeled will need to be cleaned in the Khamsin one at a time so that all the channels are connected e.g. Double Gastroscopes
- Endoscopes over 1.4m with large channels will need to be cleaned in the Khamsin one at a time to ensure that the Endoscope is fully submerged e.g. Enteroscopes

#### 1.1.3 Users and environment

The KHAMSIN is intended for use in hospitals and decontamination hubs.

It is designed to be used by healthcare professionals.

#### 1.1.4 Training

It is the responsibility of the department manager where the device is installed to ensure that:

- All users are trained with regard to the instructions and warnings contained in this manual.
- All users are aware of the risks and the preventive measures described in this manual.

### 1.2 Recommended use

- The KHAMSIN is an automated cleaning system, replacing the manual cleaning process prior to the Endoscope being high-level disinfected as part of the endoscope reprocessing cycle.
- This device must be used in compliance with the operating procedure described in the Section 4 "Use".

### 1.3 Accessories

- Leak test connectors
- Endoscope connectors- amount may vary depending on endoscope make and model
- Button cleaning adaptors

### 1.4 Technology

The KHAMSIN is an automated system using a combination of ultrasonics and nano-technology to clean both external and internal surfaces of flexible endoscopes

## 1.5 Certification

The KHAMSIN model is the **KH01**: it is compliant with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices and the Medical Devices Directive 93/42/EEC (UK Medical Device Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)).

The KHAMSIN is a class I device under these regulations.

This model carries the marking:



In accordance with the requirements of the above regulations, the KHAMSIN is compliant with the following standards:

Standard	Application
EN 61326-1:2012	Electromagnetic compatibility
IEC 61010-1:2010 IEC 61010-2-40:2015	Electrical safety including specific requirements for sterilizers and disinfecting washers. Europe/US/CAN deviations
EN ISO 14971:2012	Risk management
EN 62366-1:2015	Application of usability engineering
IEC 62304:2015	Medical-device software
EN 10993-1:2009 AC2010	Biological evaluation of medical devices - Part 1: Evaluation and testing

## 1.6 Technical characteristics

Dimensions	H78.5 cm x W75 cm x D77.5 cm
Weight	TBD
Power supply	240v 3 pin plug
Power consumption	TBD
Disinfection efficacy	Cleaning only
Cleaning-cycle duration	20 minutes
External operating temperature	+10°C to +40°C
Relative humidity	Less than 90% without condensation
Maximum operating altitude	2000m
Acoustic power	32 db

## 2 REGULATORY INFORMATION, SAFETY RULES, AND OPERATING PRECAUTIONS

### 2.1 Safety rules

The following rules must be distributed by the department manager to all potential users of the KHAMSIN.

**Please note: Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the Competent Authority.**

#### 2.1.1 Handling



*The User must never touch the ultrasonic pods at the bottom of the bowl enclosed within the body of the Khamsin when connected to power, to prevent risk of electrocution.*

- Do not use the KHAMSIN if there is any suspicion of damage.
- Never force open the lid, especially not during an operating cycle.
- Do not attempt to disassemble or repair the device. The KHAMSIN must be repaired exclusively by the manufacturer. Opening the equipment's panels will result in voiding the warranty.
- Do not bypass the equipment's safety systems and interlocks.
- Ensure the Endoscope is loaded into the cleaning chamber and connected correctly

#### 2.1.2 Environmental conditions

- Do not store the KHAMSIN or its accessories at temperatures below -10°C or above 50°C.

#### 2.1.3 Use

- The KHAMSIN is intended to be used exclusively for the use described previously, in the environment described previously, and by the personnel described previously. Do not use this equipment in any other way.
- The KHAMSIN is not intended for the reprocessing of single-use devices.
- The KHAMSIN is not a storage cabinet.

#### 2.1.4 Electricity

- The equipment must be connected to a grounded power outlet. Ensure that the power cable used is effectively that provided with the equipment.
- Connect the equipment only to a power supply having the appropriate voltage and frequency, as specified in Section 3.3 "Installation". The use of an incorrect voltage may damage the equipment.
- Any attempt to disassemble one of the components of the equipment may cause electrocution.
- When shutdown is controlled by the switch on the control panel, certain parts of the cabling remain powered. The KHAMSIN must therefore be disconnected from the power supply before any technical intervention.
- The user must take all precautions to avoid the ingress of liquid into the equipment other than for that intended for maintenance (see Section 5 "Maintenance"), which could create an electrical hazard.

### 2.1.5 Electromagnetism

- Warning: It is recommended to avoid using this equipment adjacent to other equipment or stacked on top of other equipment as this may result in incorrect operation. If this type of use is necessary, the operation of this equipment and any other equipment must be observed to verify normal operation.
- Warning: Portable RF communication devices should not be used (including peripherals such as antenna cables and external antennas) at less than 30 cm (12 inches) from any part of the KHAMSIN, including the cables specified by the manufacturer. If not, the performance of such equipment may be adversely affected.
- Warning: The use of accessories other than those specified or provided by the equipment manufacturer may result in an increase in electromagnetic emissions or a reduction of the equipment's immunity and cause inappropriate operation.

### 2.1.6 Upkeep and maintenance

Scheduled maintenance must be performed every year. This should include the replacement of all dosing pump tubing.











*Non-compliance with this period and the recommended operations may result in dangerous situations as the equipment may be damaged, the user and third parties may be seriously injure and adjacent equipment and the environment may be at risk.*

Only a technician approved by PFE Medical is authorized to perform maintenance operations on the KHAMSIN.

Scheduled maintenance includes:

- A general system check
- A cleaning of external and internal parts if necessary
- The replacement of wear parts, if necessary
- ACT test
- Verifications of Calibrations
- Operational Checks
- Faults Verification
- Reproducibility of chemical additive
- Daily & weekly safety checks
- External faults
- Fault indications
- Chemical additive low level alarms
- Doors & interlocks

## 2.2 Marking

<p>Model – KH01                  Input – 230v AC                  AMPS - 8 max                  Frequency – 50 – 60                  Serial number KH-XXX                  Manufacturer: Partners for Endoscopy</p>	<p><b>Rating plate:</b>  <b>Manufacturer’s identification</b>  <b>Description of the equipment</b>  <b>Model</b>  <b>Serial number</b>  <b>Electrical characteristics</b>  <b>Country of manufacture</b>  <b>Markings</b>  <b>UDI</b></p>
	<p><b>Electric shock risk</b>                  Only authorized personnel may open the access drawer to the maintenance zone.</p>
	<p><b>Do not dispose of with municipal waste</b>                  This symbol indicates that waste originating from electrical and electronic equipment (WEEE) must be handled with care and must not be disposed of with unsorted municipal waste. WEEE can pollute the environment and must be handled in a waste stream that is appropriate for WEEE. Contact the manufacturer or a company specialized in waste disposal to handle the disposal of this equipment.</p>
	<p><b>Manufacturer</b>                  This symbol adjacent to PFE Group indicates that PFE Group is the manufacturer of this equipment.</p>
	<p><b>Information in the manual</b>                  This symbol indicates that the user must read the manual before using the device.</p>
	<p><b>Medical Device</b></p>
	<p><b>EU Authorised Representative</b></p>
	<p><b>UKCA</b></p>
	<p><b>CE Mark</b></p>

### 3 INSTALLATION, ADJUSTMENTS, AND COMMISSIONING

#### 3.1 Packaging contents

The packaging contains the following components:

<u>ITEMS</u>	<u>QUANTITY</u>
KHAMSIN	1
MESH TRAY	1
KEY (FRONT LATCH)	1
SUCTION BIOPSY CONNECTOR (RED)	2
AIR/WATER CONNECTOR (BLUE)	2
AUXILIARY CONNECTOR (BLACK)	2
SINGLE LEAK TEST CONNECTOR (YELLOW)	1
DOUBLE LEAK TEST CONNECTOR (YELLOW)	1
BLOCKER	2
BUTTON CLAMP	2
EZYMATIC	1
CLEVER STUFF	1
BORING STUFF	1
MANUAL	1
IFUS (LAMINATED)	2
LID MAGNET (IF APPLICABLE)	1
MACHINE GLEAM	1
ADDITIONAL PIPEWORK (IF APPLICABLE)	1
DELIVERY NOTE	2
TEMPERATURE GAUGE	1
COSHH SHEETS 1 PER CHEMICAL	1
BOSTAMATIC PUMP	1

## 3.2 Presentation of the interfaces

### Connection to the AC power supply

The AC power connector is positioned on the KHAMSIN rear panel. Connection to AC power is via the IEC-standard cable provided with the equipment.

### User interface

#### Touch Screen

The Khamsin has a touch screen which is for the user to start the KHAMSIN and to pause the cycle if needed when indicated. This also acts as a diagnostic display screen so that if the KHAMSIN does fail the screen will indicate the reason.

## 3.3 Installation

### 3.3.1 Verification



*Any damage during transport or storage may be a source of danger.  
Therefore, the user must check the integrity of the device before installation.*

### 3.3.2 Placement

The Khamsin needs a mixed water supply of potable water at 32° with ¾" BSP as well as a drain pipe with the diameter of 2".

These need to be 600mm from ground level. The KHAMSIN also needs a 240V 3 pin socket outlet.

**Please be aware- if the flow to the Khamsin is below our specification it will increase the cycle time.**

### 3.3.3 Connection to electrical power



#### **Warning**

*The Khamsin must be connected to an electrical installation that is compliant with the current regulations. This connection must be performed by a qualified person.*

*The Khamsin is connected to a AC power supply that must have a voltage of 240v. Check that the power source is in accordance with that indicated on the label. This product is of electrical class 2. Only power cables provided with the equipment may be used to connect it.*

*The power cable is used as a circuit-breaking system (cut-off of electrical power if necessary) and must therefore be accessible.*

### 3.3.4 Connection of accessories



*Never connect peripherals other than those indicated below to the connectors.*

## 4 USE

### 4.1 Switching on



*As for any electrical equipment, malfunctions may arise over the lifetime of the product. Therefore, before switching on, ensure that the installation steps described above have been properly completed and that the maintenance has been performed in accordance with the indications set out in Section 6 “Scheduled maintenance”. In the event that these operations are not performed, the equipment’s interlocks could be undermined, the equipment may be damaged, the user and third parties may be seriously injured, and the environment may be at risk.*

The device will be switched on using an ON/OFF switch located on the front of the device.

1. To switch on the unit, turn the switch to on
2. The devices’ Siemens display panel will turn on
3. The KHAMSIN is now powered on, meaning the device is ready for a cleaning cycle

### 4.2 Switching off



*The system should never be switched off directly using the AC power switch at the risk of irretrievably damaging it and losing the saved traceability data.*

1. To switch off the unit, use the ON/OFF user switch on the front panel
2. Then turn off at the socket
3. The KHAMSIN is now powered off and has no power going to it

### 4.3 Prerequisites to endoscope cleaning

Follow HTM guidance for the preparation of an endoscope prior to cleaning. At the time of this manual going to print the endoscope channels need to be flushed with detergent as soon as possible after the procedure prior to leaving the procedure room including a wipe of the external parts of the Endoscope with a bedside kit. (Cleanup)

## 4.4 Cleaning an Endoscope Using the Khamsin



*Install only one endoscope at a time.*

*Ensure that the endoscope does not come into contact with the equipment.*

1. The endoscope must be initially cleaned (Bedside clean-by drawing detergent through the working channel)
2. To prevent protein drying on the endoscope, no more than 3 hours between the procedure and the cleaning process.
3. Using identification card scan in the user on the RFID reader
4. Using the RFID tag/s scan in the Endoscope/s
5. Place the endoscope onto the tray and the distal tip into the mini chamber
6. Connect all of the channels (see details separate list)
7. Then load the second Endoscope if applicable with the distal tip in the mini chamber
8. Place the suction valve/s into the clamps and place into the chamber with the other Endoscope/s accessories
9. Close the lid of the Khamsin
10. Press the start button.
11. The Khamsin will carry out the automated leak test
12. Visually confirm the whole endoscope/s is immersed
13. Audibly confirm ultrasonic are active.
14. At the end of the cycle, lift lid and confirm all connections are still intact.
15. Remove endoscope and continue in the decontamination process.
16. In the event of an error, the cycle is stopped automatically. In this case, refer to Section 7 "Troubleshooting".

\*In the case of extreme soiling, clean the Endoscope in a sink using the manual procedure as per your WPI's prior to loading into the Khamsin.

**IF THE ENDOSCOPE IS SUSPECTED TO HAVE BEEN INCONTACT WITH vCJD PROCESS THE ENDOSCOPE ON ITS OWN IN THE KHAMSIN AND THEN RUN AN EMPTY CYCLE AFTER THE ENDOSCOPE HAS BEEN REMOVED FROM THE KHAMISN.**

## 5 UPKEEP

### 5.1 External cleaning

For cleaning the outside of the equipment, use a cloth or paper cloth, dampened with water or a surface cleaner/disinfectant. Machine Gleam is available for the external part of the Khamsin.



*Do not spread liquid inside and over the Khamsin.*

### 5.2 Cleaning of the chamber

For cleaning of the chamber use a surface disinfectant wipe. This should be done at the end of the day and more frequently if required.

## 6 SCHEDULED

## MAINTENANCE

Scheduled maintenance must be performed every year.



*Non-compliance with this period and the recommended operations may result in dangerous situations as the equipment's interlocks could be undermined, the equipment may be damaged, the user and third parties may be seriously injure and adjacent equipment and the environment may be at risk.*

Only a technician approved by PFE Group is authorized to perform maintenance operations on the KHAMSIN.

Scheduled maintenance includes:

- A general system check
- A cleaning of external and internal parts if necessary
- The replacement of wear parts, if necessary

## 7 TROUBLESHOOTING

The KHAMSIN is equipped with multiple sensors for proper operation.

If the KHAMSIN detects a malfunction during the cycle, even if only temporary, the cycle is stopped and the system goes into error mode. This function always guarantees the validity of the cleaning cycle.

PLEASE CALL YOUR PFE MEDICAL REPRESENTATIVE

## 8 TRANSPORT AND STORAGE

Comply with the equipment's storage and transport requirements

## 9 DISPOSAL

When the KHAMSIN reaches the end of its life, PFE Group will dispose of the equipment in accordance with the current applicable regulations.

## 10 WARRANTY

The KHAMSIN has a 1-year warranty as of the unit's date of delivery. This warranty covers defective parts and repair labor.

The KHAMSIN must be repaired exclusively by the manufacturer or a repair center authorized by the manufacturer. Contact your after-sales representative to organize this repair before returning the equipment.

## 11 CONTACT

For any further information, contact your after-sales representative or the PFE Group customer

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