Keeler Cryomatic

Cryosurgical console

Instructions for use

Keeler

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1. Copyright and trademarks

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As part of our policy for continued product development we reserve the right to make changes to specifications and other information contained in this document without prior notice.

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2. Introduction

Thank you for purchasing your Keeler Cryomatic.

We have taken the greatest care in the design, development and manufacture of this product to ensure that you get many years of trouble free service. However, it is important that you read the descriptions, installation and operating instructions carefully prior to installing or using your new Cryomatic.

About this Manual

This handbook forms the Instructions for Use for the Keeler Cryomatic, a clinical instrument for cryogenic ophthalmic surgery.

It contains complete, step-by-step instructions for the Cryomatic and is intended for use by trained medical personnel. This manual does not contain clinical instructions or any recommendations for medical applications. The use of the Cryomatic in any surgical procedure must always be at the discretion of a licensed medical practitioner.

Intended use

The Keeler Cryomatic System and probes are for use in ophthalmic surgery such as cryopexy for retinal detachment, cyclo destructive procedures in refractory glaucoma, extraction of fragments within the vitreous cavity, cataract extraction, cryo destruction of lash follicles for trichiasis and treatment of retinopathy of prematurity (ROP).

Once the Cryo probe has been correctly positioned the freeze control is activated and an ice ball is formed around the tip of the Cryo probe and the adjacent area.

Please read and follow these instructions carefully.

2. Introduction

Product Description

The system comprises a control console and interchangeable Cryo probes which are connected to the console for use. The Cryo probe is re-usable and can be sterilized by autoclaving or other approved methods. The system requires mains electricity and Nitrous Oxide or Carbon Dioxide gas to function, this is the responsibility of the user.

Console

The Cryomatic console is a self contained system. The console provides the connection points for the Cryo probe, footswitch, mains electricity, gas supply and scavenging system. Freeze cycles are controlled by the user operating the footswitch. When the footswitch is depressed the Cryo probe freezes and when the footswitch is released the Cryo probe defrosts. Routine functions, like purging the Cryo probe are performed automatically when the Cryo probe is connected to the system.

Cryo Probes

The Cryo probe is connected to the Cryomatic console via a simple quick release coupling. The system will not operate until this connection is correctly made. Each Cryo probe is a complete assembly and no attempt should be made to dismantle or separate the coupling from the probe.

When the footswitch is pressed, high pressure cryogen gas is circulated through the Cryo probe, rapid gas expansion in the probe tip causes freezing according to the Joule-Thompson principle. The freezing zone of the Cryo probe is limited so that the iceball propagates only at the tip. When the footswitch is released, an active de-frost is caused by the equalisation of pressure on either side of the Joule-Thompson nozzle. The gas condenses releasing its latent heat causing a rapid de-frost.

The Cryo probe assembly is re-usable and as such is fully autoclaveable according to the procedures outlined in this manual.

Please read and follow these instructions carefully.

3. Symbols

Read user instructions for warnings, cautions and additional information

CE 0088

The CE mark on this product indicates it has been tested to and conforms with the provisions noted within the 93/42/EEC Medical Device Directive

Consult instructions for use

Manufacturer's name and address

This Symbol on the product or on its packaging and instructions indicates that it was put on the market place after August 2005 and that this product shall not be treated as Household Waste

Type BF protections against shock

Mandatory action sign

High voltage

Trip hazard

Pressurized cylinder

Freeze hazard

Non-ionizing radiation

This way up

Keep dry

Fragile

Material suitable for recycling

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4. Safety

Device classification

CE Regulation 93/42 EEC: IIb
FDA: II

Carefully read this Instruction Section before using your Keeler product. For your own safety and that of your customers observe all cautionary information provided in this section. The following information is intended to highlight potential safety hazards that can be associated with misuse, or damage.

Warnings and cautions

Warning

- WARNING: To avoid the risk of electric shock this equipment must only be connected to a supply mains with a protective earth. Extension lead should not be used
- Check your Cryomatic for signs of transport / storage damage prior to use
- Do not use if the product is visibly damaged, and periodically inspect for signs of damage
- Do not use in the presence of flammable gases / liquids, or in an oxygen rich environment
- This product should not be immersed in fluids

Do not fit mains power adapter into a damaged mains outlet socket

Route power cords and footswitch cable safely to eliminate risk of tripping or damage to equipment

- US Federal law restricts this device to sale by or order of a physician or practitioner

High pressure gases are present inside the unit. Maximum operating pressure 45 Bar / 650 PSI, maximum cylinder pressure 83 Bar / 1200 PSI

Observe the usual safety precautions associated with the use of medical gases, at all times. Copies of these guidelines will be available from the gas supplier.

Ensure the correct disposition of gas exhausted from the system so as to minimise the exposure to Nitrous Oxide or Carbon Dioxide. This is the responsibility
of the user.

4. Safety

Caution

- Use only genuine Keeler approved parts and accessories or device safety and performance may be compromised
- The product has been designed to function safely when at an ambient temperature between +10°C and +35°C
- Keep out of the reach of children
- To prevent condensation from forming, allow instrument to come to room temperature before use
- For indoor use only (protect from moisture)
- Keep the console away from sources of liquids and do not spray with water
- This product is suitable for use with only Nitrous Oxide or Carbon Dioxide medical gases
- Care should be taken not to trap fingers in pinch points during gas bottle change
- Follow guidance on cleaning / routine maintenance to prevent personal injury / damage to equipment

Switch off the electrical supply and disconnect from the mains electrical supply before cleaning and inspection

- Do not use hypercarbonate or phenolic based cleaning solutions or disinfectants containing cationic surfactants (e.g. Dettox) to clean the console
- Failure to carry out recommended routine maintenance as per these Instructions for Use may reduce the operational lifetime of the product
- There are no user serviceable parts inside. Contact authorised service representative for further information
- At product end of life dispose of in accordance with local environmental guidelines (WEEE)
- In the unlikely event that the probe fails to defrost, immediately switch off the console and apply saline solution to the probe
- Do not obstruct the vent holes on the disposable probe (located on the tube) and reusable probe, located as indicated below

4. Safety

Safety considerations

Before you connect system to the mains socket, carefully read and understand all the installation instructions in Section 6.

The system has been designed to comply with the following regulatory standards for Safety and Electromagnetic Compatibility:

- IEC60601-1, UL60601-1 & CAN/CSA-C22.2 No 601.1
- IEC60601-1-2

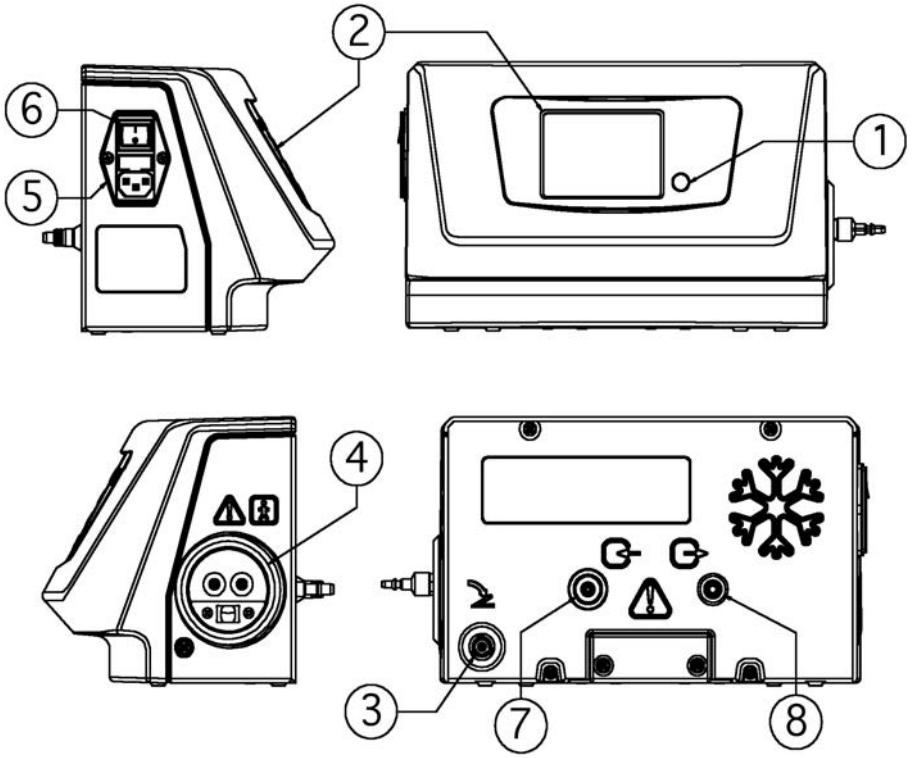
Although compliant with applicable EMC standards, this equipment may still be susceptible to excessive emissions and/or may interfere with other more sensitive material. This system should be installed and used following the EMC environment guidelines contained in section 13 of this manual.

This system should only be used in conjunction with the relevant accessories and mains leads as supplied by the manufacturer or distributor. Failure to do this may affect the EMC performance of the system i.e. increased emissions or reduced immunity. Relevant accessories are listed in the Spare Parts and Accessories section.

For your own safety and the safety of the equipment, always take the following precautions:

- Ensure that the system is inspected by properly trained personnel once per annum for performance and safety checks
- Inspect the Cryo tip for damage before every use. If there is any sign of damage return to the manufacturer for servicing prior to use
- Do not try to straighten a bent Cryo tip
- Do not try to re-shape a Cryo tip
- Ensure that the system is clean and dry prior to storage
- Keep this operator manual safe for future reference

5. Controls, indicators and connections



1	**Mute Key**	Allows the audible sounder to be disabled by the operator.
2	**Cryomatic Display Screen**	Graphical LCD used to provide system information to the user; such as probe information, gas cylinder status and freeze timer.
3	**Footswitch Connection**	Connection point for footswitch plug.
4	**Cryo Probe Interface**	Pneumatic and electrical connections for probe.
5	**Electrical Input**	IEC connection for mains input lead.
6	**On/Off Switch**	On/off mains rocker switch.
7	**Gas Inlet**	Connection point for cylinder hose.
8	**Exhaust**	For connection of vent hose (see Section 6).

6. Installation and commissioning

Preparing the Cryomatic system for use

The Cryomatic system consists of the following:

- Cryomatic console.
- Cryo probe(s).
- Footswitch.
- Mains cord.
- High-pressure gas hose.
- Exhaust hose.
- Adjustable wrench.
- Instructions for use.
- 2 spare mains fuses.

If any of these parts are missing, contact your distributor immediately.

Installing Exhaust Hose

Connect the exhaust hose provided from the gas exhaust connection of the console to a scavenging system or suitably ventilated area (see page 10).

It is the responsibility of the user to ensure the safe disposition of exhaust gases.

Connecting the Footswitch

Connect the footswitch to the appropriate connection point on the rear of the console noting the alignment of the orientation key (see page 10).

The footswitch can be disconnected for storage and to facilitate cleaning. Disconnection is achieved by pulling the collar of the footswitch connector.

Installing the High Pressure Gas Hose

Connect high-pressure hose to the inlet connector at the rear of the Cryomatic system using the spanner that has been provided. Ensure that the coupling is tightened adequately (see page 10).

Connecting/Changing Gas Cylinders

Gas cylinders must be stored upright, and for a minimum of eight hours at ambient room temperature prior to use.
Ensure that the gas cylinder is secured properly before use.
Use the following procedure for
connecting or changing gas cylinders:

Keeler

6. Installation and commissioning

Connection of Cylinder

1. Secure cryogen cylinder correctly in the upright position.
2. Connect the high pressure hose to the cylinder using the relevant adaptor.
3. Open cylinder valve (using the spanner provided).
4. Any noise of escaping gas indicates that the cylinder has not been connected correctly – turn off the gas valve and check connections.
5. Ensure the maximum cylinder pressure does not exceed 1200 PSI/83 Bar.

Keeler recommends fitting a regulator, set below 83bar, between the cylinder and the Cryomatic MKII console to prevent overpressure due to temperature variations in the cylinder.

Removal/Disconnection of Cylinders

1. Ensure that cylinder valve is closed.
2. Disconnect the adaptor from the cylinder.
3. Replace cylinder with a fresh one.

The cylinders must be medical grade vapour withdrawal types to ensure that liquid cryogen is not delivered to the system.

Cryogen gas cylinders used must meet national regulations and be in accordance with ISO/R 32 and ANSI/NFPA 99 (USA).

Ensure there is enough gas in the Cylinder prior to starting the procedure. The console Cylinder Symbol indicates empty when the gas supply pressure drops below 350 PSI/24 Bar (2415 kPa) and the gas cylinder should be replaced at or before this point. After this the system will continue to function in the usual way, however freeze performance will be reduced.

Information regarding the correct storage and handling of gas cylinders should be obtained from the gas supplier.

Electrical Supply

The Cryomatic system requires connection to a mains electrical supply for operation.

1. Connect the system to a suitable mains supply using the mains cord that has been supplied.
2. Switch on power via the rocker switch at the side of the system.

3. The cylinder symbol is activated while the Cryomatic system prepares itself.
4. The equipment is now ready for use.

7. Operation

These instructions cover day-to-day operation of the system. Other operations, such as maintenance and repair, should only be carried out by fully trained personnel who are employed by, or authorized by, the supplier.

Initialisation

Before using the Cryomatic system, make sure it has been correctly installed in accordance with Section 6. At this stage the probe must NOT be connected.

1 Ensure that the equipment is switched on using the mains inlet rocker switch.

2 An activity bar within the Cylinder Symbol indicates that the gas supply is being checked.

If an overpressure warning is displayed contact distributor or manufacturer for assistance.

3 When the initialisation checks are complete verify that there is adequate cryogen gas supply - this is indicated by the Cylinder Symbol on the front panel display.

4 The equipment is now at REST. The Cryo Probe can now be connected.

Cryo Probe Connection

Observe sterilization protocol before using a Cryo probe.

Allow Cryo probe to cool to room temperature after a sterilization.

Before connecting the Cryo probe inspect it for signs of obvious damage.

1 Connect the Cryo probe to the console by aligning the coupling on the spigots and pushing to a positive click. (It is impossible to connect the coupling the wrong way round – correct orientation is with the release button uppermost). When the probe is properly connected the relevant Probe Symbol is displayed together with the probe serial number.

2 The system automatically initiates a purging cycle of 90 seconds. During the purge cycle an animated Wait Symbol is displayed alongside the Probe Symbol.

3 Three short beeps signal that the purge cycle is complete. The equipment is now ready for use as indicated by the timer and the Ready Symbol.

While the probe is purging all footswitch operations are disallowed to ensure that the Cryo probe has completed the minimum purge.

7. Operation

WARNING: Probe tip reaches extremely low temperature in use

Freeze/Defrost Cycles

Freezing of the Cryo probe is controlled manually by the operator using the footswitch.

1 Ensure that the Cryo probe is correctly positioned.

2 Press the footswitch down. Freezing starts immediately and the digital timer will increment.

3 An audible warning sounds every second during the freeze cycle and the Freezing Symbol is displayed.

4 In addition there is a graphical indication of probe performance

5 De-frosting is achieved by releasing the footswitch. The timer will stop counting and the Defrosting Symbol is displayed.

6 Subsequent freeze cycles can be carried out by simply repeating steps 1-4 as soon as the Ready Symbol is displayed.

The freezing function is often accompanied by a characteristic ‘pulsing’ sound which indicates that the Cryomatic is regulating the gas to the optimum pressure for the probe. The ‘pulsing’ may vary or cease completely depending on the pressure of gas in the cylinder.

If the probe performance drops below 100% permanently check the cylinder gas pressure or suspect a blocked probe.

Cryo Probe Disconnection

1 When the procedure is complete the Cryo probe can be disconnected by pressing the probe release button on the probe coupling body.

2 When the probe has been disconnected the system will automatically check the gas supply in readiness for the next use. This will be indicated by an activity bar with the Cylinder Symbol.

3 When this short check is complete the system will be ready for the connection of another Cryo probe.

The system shuts off the gas supply immediately the Cryo probe is disconnected providing a safe condition in the event of inadvertent operation of the release button.

It is not recommended that the Cryo probe is disconnected during use as this could result in a pressure lock within the probe assembly which may make reconnection more difficult.

7. Operation

Mute Function

The audible indicator is normally active during freeze and purge cycles as indicated on the LCD screen.

It can be disabled by simply pressing the key adjacent to the symbol. The symbol is changed accordingly.
The indicator can be reactivated by simply pressing the key again (see Section 5 [1]).

Fault Conditions

The Cryomatic system has the ability to detect a range of system faults. In the unlikely event of a fault condition arising, the fault symbol icon will flash and a short error message will be displayed.

Contact distributor or manufacturer for assistance.

Caution

In the event of power interruption during use the device valves fail safely closed.

End of Use

Ensure that the following procedures are carried out at the end of the current usage:

1. Close the cylinder valve.
2. Switch off the electrical supply.
3. Ensure that the mains cord, footswitch and the Cryo probes are stored properly to avoid accidental damage.

8. Cryo probes

The following ranges of ophthalmic Cryo Probes may be used with the Cryomatic.

Standard Range

	Part No.	Description
	**2509-P-8000**	2.5mm Standard Retinal Probe
	**2509-P-8001**	2.5mm Extended Retinal Probe

Special Range

	**2509-P-8002**	2.5mm Mid Reach Retinal Probe
	**2509-P-8005**	3mm Glaucoma
	**2509-P-8003**	0.89mm Intra Vitreal Retinal Probe
	**2509-P-8004**	1.5mm Curved Cataract Probe
	**2509-P-8006**	4 x 10mm Collins Trichiasis Probe

9. Cleaning and sterilization

Cryo Probe - Care, Cleaning & Sterilization (In accordance with ISO 17664)

Devices	
All reusable Cryo Probes supplied by Keeler Ltd. as part of the Keeler Cryomatic ophthalmic cryosurgery system.	
Warnings and Precautions	
General	Cryo probes are precision instruments and should be handled with care at all times. **It is important that the flexible hose does not become kinked during normal use, storage, transportation or reprocessing.** If this does occur the probe must be returned to the manufacturer for repair.
Limitations On Reprocessing	Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use rather than reprocessing. Cryo Probes are tolerant of alkaline cleaning agents when followed by acidic neutralization and/or thorough rinsing. Gamma irradiation or dry air sterilization methods involving temperatures in excess of 139°C should not be used since they may damage the Cryo probe.
Instructions	
Before use, the complete Cryo Probe must be sterilized. Sterilization by steam autoclave has been validated.	
Point Of Use	No particular requirements although excess soiling can be removed with disposable cloth/paper wipe.
Containment & Transportation	Care should be taken to ensure that the flexible hose of the Cryo probe is not coiled too tightly or kinked during reprocessing. Used instruments **must be** transported to the central supply in closed or covered containers to prevent unnecessary contamination risk. It is recommended that instruments are reprocessed as soon as is reasonably practical following use.
Preparation For Cleaning	No particular requirements. Disassembly not required.
Cleaning and Disinfection: Automated	Use equipment meeting relevant standards[1] and which uses the following typical automated sequence: • Pre-Rinse/Wash • Detergent wash; hot water using (detergent specified by the washer/disinfector manufacturer) • Thermal Rinse: hot purified water 80-85°C (176-185°F) for 10 minutes OR 90-93°C (194-199°F) for 1 minute • Hot Air Dry [1] *HTM2030 and BS EN ISO 15883 or equivalent*
Cleaning: Manual	Not recommended – use an automated system if possible. If manual cleaning is carried out care should be taken not to use abrasive materials on the Cryo probe stem.

9. Cleaning and sterilization

Instructions continued	
Drying	Hot Air Dry
Maintenance	Check for obvious signs of damage – return to manufacturer if any damage is noted.
Inspection & Function Testing	Visually inspect for damage and wear. Check probe tips for signs of bending, distortion or other damage. Connect Cryo Probe to 'Cryomatic' console to check correct and smooth function of probe quick release coupling.
Packaging	Pouch or Tray - Refer to the product-specific instruction manual for compatibility with steam sterilization.
Sterilisation	Cryo Probe must be cleaned prior to sterilization. Thorough cleaning removes both micro-organisms and organic material. Failure to remove organic material decreases effectiveness of the sterilization procedure. After cleaning, make sure that the instrument is carefully dried Place the instruments in appropriate instrument trays or pouches. Wrap or seal them adequately. Do not seal the instruments in close contact with each other as this might impair the sterilization effect. Never rinse the instruments with cold water for cooling. Be careful when unloading the autoclave, the contents may be hot. Make sure that the sterile package of the instruments is not damaged. If the package has been perforated, if the sealing has been opened, if the packaging is wet or if the packaging is damaged in any other way, repackage and then re-sterilize the instruments. Disinfection is only acceptable as a precursor to full sterilization for reusable surgical instruments. See Table 1 for recommended sterilization parameters using equipment meeting relevant standards. Sterilizer manufacturer recommendations should **always** be followed. When sterilizing multiple probes in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded.

Table 1

Sterilizer type	Temperature	Pressure	Exposure time	Drying time
Pre-vacuum (porous load)	134 – 137 °C (273-279 °F)	-	3 minutes	20 minutes
Gravity	121-124°C (250-255°F)	-	30 minutes	

It is the responsibility of the user to validate any sterilisation process that deviates from these recommendations.

9. Cleaning and sterilization

Instructions continued	
Storage	As the product's transport packaging is not designed for storage, do not store the product in the transport packaging. Use instrument tray systems for storage. Cryo probes should be coiled loosely during storage. Store the sterile, Cryo probes in a clean and dry condition at room temperature • Do not expose the equipment to direct sun light. • Do not expose the equipment to sources of X-ray radiation. • Do not store the equipment in a location where liquids may splash. • Do not store the equipment under environmental conditions such as: - high atmospheric pressure - high or low temperatures - high or low humidity - direct ventilation - direct sunlight - dust - salty or sulfurous air • Do not store the equipment where there is a risk of flammable gases. The storage life of sterilized instruments depends on the type of packaging and the storage conditions. Refer to national and local laws and guidelines.

Cleaning the Console

The Cryomatic console can be cleaned using a disposable cloth soaked in mild detergent and warm water. Do not use abrasive compounds or pads. The user should avoid getting electrical parts wet during the cleaning process.

Warning:

Switch off the electrical supply to the console and disconnect the power cord from the mains supply before cleaning and inspection.

10. Servicing and preventative maintenance

Scheduled Maintenance

The Cryomatic system should be inspected annually by Keeler trained personnel. This service will include performance checks, cleaning or replacement of inlet filters and safety checks on pneumatic couplings.

User Maintenance

There are no user serviceable parts in the Cryomatic system and operator maintenance is restricted to the following:

a Cleaning the Cryo probe tip. Non-abrasive metal polish should be used.

b Cleaning the console surface.

c Inspecting the Cryo probes for signs of damage before every use.

d Inspecting the footswitch and cord for signs of damage before every use.

e Inspecting the mains cord for signs of damage before every use.

f Inspecting the high pressure hose and exhaust hose for signs of damage before every use.

All repairs should be carried out only by Keeler trained personnel or their representatives.

Potentially dangerous voltages are present inside the equipment – under no circumstances should the covers be removed.

11. Troubleshooting guide

The following table provides a troubleshooting guide for the Cryomatic system in the event of minor problems. If the problem is not cleared then the supplier must be contacted for further assistance.

In the unlikely event that the probe fails to defrost, immediately switch off the console and apply saline solution to the probe.

Problem	Possible Cause	Corrective Action
Front panel blank – equipment appears dead.	Mains fuse(s) blown.	Disconnect equipment from mains supply and replace with fuses of the correct rating.
Probe coupling will not connect correctly.	Probe is still too hot after a sterilisation procedure (this may cause possible expansion of some coupling components).	Allow probe to cool to room temperature before trying to connect it.
Probe is connected but automatic purging does not start.	Possible damage to electrical contacts of console or probe. Dirty or oxidised probe contacts.	Inspect contacts and clean carefully if necessary. If fault does not clear then contact supplier for repair.
Probe does not freeze at all.	Insufficient gas supply or gas cylinder valves not opened properly – cylinder symbols on front panel will be shown as empty.	Replace empty* gas cylinders with full ones. Ensure that all gas valves are opened correctly (see Section 3).
	Footswitch may have become disconnected.	Reconnect footswitch to console. If fault does not clear, contact supplier for repair.
Probe freezes but performance is poor.	Possible partial blockage in the probe (possibly caused by excess moisture after sterilisation procedure). Probe may appear to begin to freeze but then block or perform poorly.	Ensure correct sterilisation procedures are followed, including a drying cycle (in sterilizer or drying oven). Disconnect and reconnect probe to force another purging cycle. If this fails, then probe should be left to dry completely before use.
	Exhaust hose is blocked or occluded.	Check the exhaust hose for blockages or occlusions and replace if necessary.
Probe freezes correctly initially but then performance is reduced or probe does not freeze.	Blocked probe.	Release footswitch. Allow console to back-flush the probe before attempting another freeze.
	Gas supply has run out.	Replace empty* gas cylinder. Ensure that the gas valve is opened correctly. If fault does not clear, contact supplier for repair.
Probe freezes correctly but Cryomatic delivery system is not pulsing.	Cylinder pressure has dropped due to usage, but performance is still above the acceptable level.	Gas cylinder pressure has reduced (indicated on front panel display).
Auto Defrost takes longer than usual.	Possible leaking internal hose connectors.	Return the console and probe for repair.
	Possible fault in console.	

*gas cylinders are deemed to be empty when the internal pressure is less than 350 PSI/25 Bar (2415 kPa)

12. Specifications and electrical ratings

Cryogenic System	
Gas Specification	Medical Grade Nitrous Oxide (N2O) or Medical Grade Carbon Dioxide (CO2) in non-syphon cylinders.
Operating Pressure Range	3100–5860 kPa (450–850 PSI/31-58 Bar)
Maximum Cylinder Pressure	8275 kPa (1200 PSI/83 Bar)

Electrical Ratings	
Input Voltage Range	100-240Vac (50/60Hz)
Power Rating	100VA
Fuses	2 x T2AH 250V

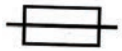
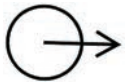
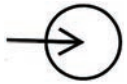
Dimensions	
Width	305mm (12”)
Depth	200mm (8”)
Height	190mm (7.5”)
Weight	4.5kg (10lbs)

Classification and Safety Standards	
Equipment Classification	Class 1, Type BF (Applied Part)
Mode of operation	Continuous
Protection against ingress	Console IPx0 Footswitch IP68

Transport, storage and operating conditions			
	Transport	**Storage**	**Operation**
Temperature range	-20°C to +50°C	+10°C to +40°C	+10°C to +35°C
Relative humidity	10% to 80%	30% to 70%	30% to 70%
Atmospheric pressure	500hPa to 1060hPa	700hPa to 1060hPa	700hPa to 1060hPa

12. Specifications and electrical ratings

Screen Icons Used On The Equipment	
	Gas cylinder status. *This symbol contains an activity bar whenever the gas supply is being checked. It is solid when reporting cylinder pressure.*
	Ready Symbol. *Displayed whenever the freeze function can be activated via the footswitch.*
	Wait Symbol. *Animated icon that is displayed for the duration of the purge cycle.*
	Freezing symbol. *Displayed with the probe symbol while in freezing mode.*
	Probe performance meter. *Displayed with the probe symbol while in freezing mode.*
	Defrosting symbol. *Displayed with the probe symbol while in defrosting mode.*
	Audible sounder enabled during freezing mode.
	Audible sounder disabled during freezing mode.
	Fault Condition

Symbols used on the equipment			
All symbols used are in accordance with BS EN60417-2:1999 (Graphical Symbols for use on Equipment).			
	BF (Applied Part)		Fuse rating
	Attention, consult accompanying documents		Footswitch connection
	Dangerous voltages present inside the equipment		Exhaust connection
	AC voltage input		Gas inlet connection

13. Annex I – EMC statement and guidelines

The Keeler Cryomatic is a medical electrical instrument. The instrument requires special care concerning electromagnetic compatibility (EMC). This section describes the suitability in terms of electromagnetic compatibility of this instrument. When installing or using this instrument, please read carefully and observe what is described here.

Portable or mobile-type radio frequency communication units may have an adverse effect on this instrument, resulting in malfunctioning.

13. Annex I – EMC statement and guidelines

Guidance and manufacturer's declaration – electromagnetic immunity			
The Keeler Cryomatic is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD). IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst. IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge. IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% U_T (> 95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (> 95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Keeler Cryomatic requires continued operation during power mains interruptions, it is recommended that the instrument be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field. IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at a level characteristic of a typical location in a typical commercial or hospital environment.

Note U_T is the a.c. mains voltage prior to application of the test level.

13. Annex I – EMC statement and guidelines

Guidance and manufacturer's declaration – electromagnetic emissions		
The Keeler Cryomatic is intended for use in the electromagnetic environment specified below. The customer or user should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	**Group 1**	The Keeler Cryomatic uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	**Class B**	The Keeler Cryomatic is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	**Class A**	
Voltage fluctuations / flicker emissions IEC 61000-3-3	**Complies**	

13. Annex I – EMC statement and guidelines

Guidance and manufacturer's declaration – electromagnetic immunity			
The Keeler Cryomatic is intended for use in the electromagnetic environment specified below. The customer or user should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Keeler Cryomatic, including cables, than the recommended separation distances calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	**Recommended separation distance** $d = 1.2 \sqrt{p}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m	$d = 1.2 \sqrt{p}$ 80MHz to 800 MHz $d = 2.3 \sqrt{p}$ 800MHz to 2.5GHz Where p is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1], should be less than the compliance level in each frequency range.[2] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1 At 80MHz and 800MHz, the higher frequency range applies.

Note 2 These guide lines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[1] Field strengths from fixed transmitters, such as base stations (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Keeler Cryomatic is used exceeds the applicable RF compliance level above, the Keeler Cryomatic should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the Keeler Cryomatic.

[2] Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3 V/m.

13. Annex I – EMC statement and guidelines

Recommended separation distances between portable and mobile RF communications equipment and the Keeler Cryomatic

The Keeler Cryomatic is intended for the use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Keeler Cryomatic can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Keeler Cryomatic as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80MHz $d = 1.2\sqrt{p}$	80MHz to 800MHz $d = 1.2\sqrt{p}$	800MHz to 2.5GHz $d = 2.3\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

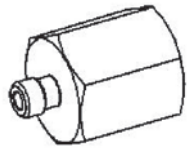
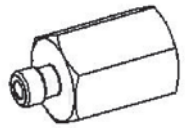
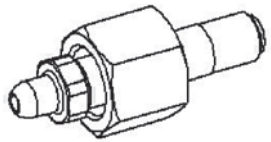
Note 1 At 80MHz and 800MHz, the higher frequency range applies.
Note 2 These guide lines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

14. Spare parts and accessories

The following accessories are supplied with the device:

Part Number	Description
MIS094	Spare mains fuse (x2)
MIS100	Mains cord
MIS103	Adjustable wrench
2509-P-8010	Exhaust hose
2509-P-8012	Instructions for use
2509-P-8013	Footswitch assembly
2509-P-8014	High-pressure gas hose (2m)

The following additional accessories are available from the distributor:

Part Number	Description
2508-P-7016	Cylinder Adaptor CO_2 Size VF 
2508-P-7018	Cylinder Adaptor N_2O Size VF 
2509-P-8009	Cylinder Adaptor N_2O (US - CGA326) 
2509-P-8011	High Pressure Hose (1m)
2509-P-8015	Probe Sterilising Box

15. Warranty

The Cryomatic and its components are covered by warranty that they meet their performance standards and are free from any defects in materials or workmanship. Within 12 months from delivery by Keeler, the manufacturer shall at no charge to the customer, upon written notice from the customer, repair or replace any components which are defective in material or workmanship.

The customer agrees that it shall have no remedy in the event of any breach of the foregoing warranty other than as provided above. This warranty is exclusive and in lieu of all other warranties, expressed or implied, and all implied warranties of merchantability or fitness for a particular purpose are expressly disclaimed.

The obligations of the manufacturer as set forth in this warranty are expressly conditional upon the following:-

(i) No alterations or repairs of any malfunction of the system shall be made to the system except by the manufacturer or his authorized representative, without the prior written approval of the manufacturer or his authorized representative (and in no case will the manufacturer assume responsibility for repairs or alterations made by those other than the manufacturer or his authorized representative).

And

(ii) The customer shall give notice to the manufacturer or their authorized representative of any malfunction of the system and shall not use the system in any surgical operation after they are aware of any malfunction.

(iii) The customer complies with manufacturer's recommended Preventative Maintenance (see Section 10) and can provide proof of such action.

16. Contact and disposal information

Keeler Limited
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Windsor
Berkshire SL4 4AA
England

Freephone: 0800 521 251
Tel: +44 (0)1753 857177
Fax: +44 (0)1753 827145

Keeler Instruments Inc
3222 Phoenixville Pike
Building #50
Malvern, PA 19355
USA

Toll Free: 1 800 523 5620
Tel: 1 610 353 4350
Fax: 1 610 353 7814

Disposal of old Electrical and Electronic Equipment

(Applicable in the European Union and other European Countries with separate Collection Systems).

This symbol on the product or on its packaging and instructions indicates that it was put on the market place after August 2005 and that this product shall not be treated as Household Waste.

To reduce the environmental impact of WEEE (Waste Electrical Electronic Equipment) and minimise the volume of WEEE entering landfills we encourage at product end of life that this equipment is recycled and reused.

If you need more information on the collection reuse and recycling then please contact B2B Compliance on 01691 676124 (+44 1691 676124).

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