Keeler Cryomatic

Instructions for use

Keeler

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Keeler

1. Safety Considerations

Before you connect system to the mains socket, carefully read and understand all the installation instructions in Section 3.

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
- IEC60601-1-2:2001

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 Annex I 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 & Accessories section.

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

- Keep the console away from sources of liquids and do not spray with water.
- 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.
- Ensure that the system is clean and dry prior to storage.
- 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.
- Ensure that the system is inspected by properly trained personnel once per annum for performance and safety checks.
- Keep this operator manual safe for future reference.
- 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.

SAFETY WARNINGS

Electrical equipment may be hazardous if misused. The equipment covers should only be removed by authorised technical personnel.

Do not use the system in the presence of flammable gases such as anaesthetic agents.

2. Introduction

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.

About Cryomatic

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

Product Description

The system comprises a control console and interchangeable Cryo-Tip probes which are connected to the console for use. The Cryo-Tip 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-Tip 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-Tip probe freezes and when the footswitch is released the Cryo-Tip probe defrosts. Routine functions, like purging the Cryo-Tip probe are performed automatically when the Cryo-Tip probe is connected to the system.

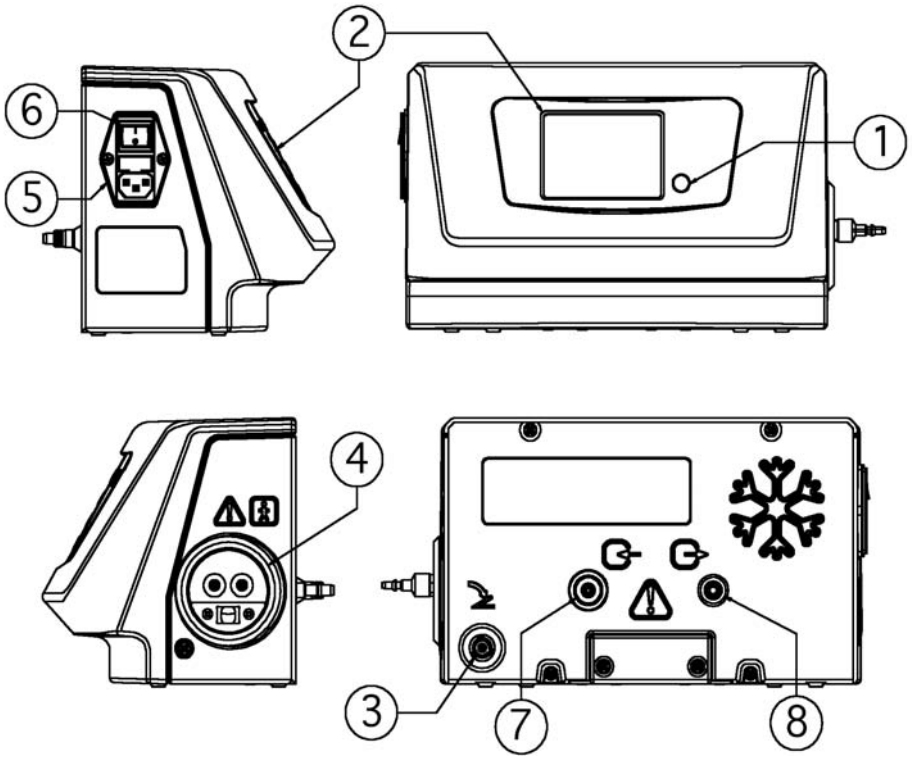
Cryo-Tip Probes

The Cryo-Tip 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-Tip 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-Tip probe, rapid gas expansion in the probe tip causes freezing according to the Joule-Thompson principle. The freezing zone of the Cryo-Tip probe is limited so that the ice-ball 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-Tip probe assembly is re-usable and as such is fully autoclaveable according to the procedures outlined in this manual.

3. Controls, Indicators & 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-Tip 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 4).

4. Installation & Commissioning

Preparing the Cryomatic system for use

The Cryomatic system consists of the following:

- Cryomatic console.
- Cryo-Tip 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 5).

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 5).

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 5).

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:

4. Installation & 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.

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.

5. 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 4.

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.

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-Tip Probe can now be connected.

Cryo-Tip Probe Connection

Observe sterilization protocol before using a Cryo-Tip probe.
Allow Cryo-Tip probe to cool to room temperature after a sterilization procedure.

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

1 Connect the Cryo-Tip 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-Tip probe has completed the minimum purge cycle.

5. Operation

Freeze/Defrost Cycles

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

1 Ensure that the Cryo-Tip 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-Tip Probe Disconnection

1 When the procedure is complete the Cryo-Tip 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-Tip probe.

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

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

5. 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 3 [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.

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-Tip probes are stored properly to avoid accidental damage.

6. Cryo-Tip Probes

The following ranges of ophthalmic Cryo-Tip 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

7. Cleaning & Sterilization

Cryo-Tip probes are reusable and should be sterilized before each use. The following reprocessing guidelines are in accordance with ISO 17664.

Warnings & Precautions	
General	Cryo-Tip 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-Tip 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-Tip probe.
Instructions	
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-Tip 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: Automated	Use equipment meeting relevant standards1 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 (80-93°C/176-200°F); 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-Tip probe stem.

7. Cleaning & Sterilisation

<table>
<tr><th colspan="2">Instructions continued</th></tr>
<tr><td>Drying</td><td>No particular requirements.</td></tr>
<tr><td>Maintenance</td><td>Check for obvious signs of damage – return for manufacturer if any damage is noted.</td></tr>
<tr><td>Inspection & Function Testing</td><td>Visually inspect for damage and wear. Check probe tips for signs of bending, distortion or other damage.
Connect Cryo-Tip Probe to ‘Cryomatic’ console to check correct and smooth function of probe quick release coupling.</td></tr>
<tr><td>Packaging</td><td>No particular requirements.</td></tr>
<tr><td>Sterilisation</td><td>Disinfection is only acceptable as a precursor to full sterilisation for reusable surgical instruments. See Table 1 for recommended sterilization parameters using equipment meeting relevant standards. Sterilizer manufacturer recommendations should always be followed. When sterilising 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
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.</td></tr>
<tr><td>Storage</td><td>Sterile, packaged Cryo-Tip probes should be stored in a designated, area that is well ventilated and provides protection from dust, moisture and temperature/humidity extremes. Cryo-Tip probes should be coiled loosely during storage.</td></tr>
</table>

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.

8. 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:

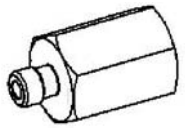
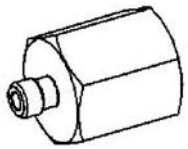
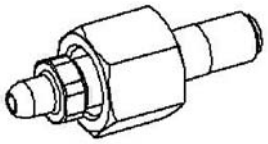
a) Cleaning the Cryo-Tip probe tip. Non-abrasive metal polish should be used.
b) Cleaning the console surface.
c) Inspecting the Cryo-Tip probes for signs of damage before every use.
d) Inspecting the footswitch and cord for signs of damage before every use.
e) Inspecting the mains cord for signs of 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.

9. Spare Parts & Accessories

The following parts are available from the distributor:

Part Number	Description
2508-P-7018	Cylinder Adaptor N_2O Size VF 
2508-P-7016	Cylinder Adaptor CO_2 Size VF 
2509-P-8009	Cylinder Adaptor N_2O (US - CGA326) 
2509-P-8012	Instructions For Use
2509-P-8011	High Pressure Hose (1m)
2509-P-8014	High Pressure Hose (2m)
2509-P-8013	Footswitch Assembly
2509-P-8010	Exhaust hose
2509-P-8015	Probe Sterilising Box

10. 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.

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)

Keeler

11. 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 8) and can provide proof of such action.

12. Disposal

Ensure that this equipment is disposed of in accordance with local regulations.
Please contact the supplier if in doubt.

13. Technical Data

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 Pressure	8275 kPa (1200 PSI/83 Bar)

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

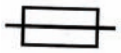
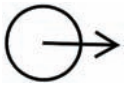
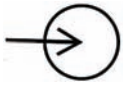
Dimensions	
Width	305mm (12”)
Depth	200mm (8”)
Height	190mm (7.5”)
Weight	2.5kg (6lbs)

Classification & Safety Standards	
Complies with	EN60601-1, UL60601-1 & CAN/CSA-C22.2 No 601.1
Equipment Classification	Class 1, Type BF (Applied Part)
Mode of operation	Continuous
Protection against ingress	Console IPx0 Footswitch IP68

Environmental Conditions		
	Storage	Operating
Temperature Range	-20°C to +50°C	+10°C to +40°C
Relative Humidity	10% to 80%	30% to 70%
Atmospheric Pressure	500hPa to 1060hPa	700hPa to 1060hPa

13. Technical Data

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

Annex I - EMC Statement and Guidelines

Guidance and manufacturer's declaration – electromagnetic emissions		
The Cryomatic is intended for use in the electromagnetic environment specified below. The customer or user of the Cryomatic should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Cryomatic System 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 Cryomatic System 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	

Annex I - EMC Statement and Guidelines

Guidance and manufacturer's declaration – electromagnetic immunity			
The Cryomatic is intended for use in the electromagnetic environment specified below. The customer or user of the Cryomatic should assure that it is used in such an environment.			
Immunity Test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+6kV contact +8kV 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	+2kV for power supply lines +1kV for input/output lines		Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+1kV differential mode +2kV common mode		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% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec		Mains power quality should be that of a typical commercial or hospital environment. If the user of the Cryomatic requires continued operation during power mains interruptions, it is recommended that the Cryomatic be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Annex I - EMC Statement and Guidelines

Guidance and manufacturer's declaration – electromagnetic immunity			
The Cryomatic is intended for use in the electromagnetic environment specified below. The customer or user of the Cryomatic should assure that it is used in such an environment.			
Immunity Test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150kHz - 80MHz 3 V/m 80MHz - 2.5GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Cryomatic, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz - 800MHz $d = 2.3\sqrt{P}$ 800MHz – 2.5GHz where P is the maximum power output 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 surveya, should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with this symbol: 
NOTE 1: At 80MHz and 800MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects and people.			
a: Field strengths from fixed transmitters, such as base stations for radio (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 Cryomatic is used exceeds the applicable RF compliance level above, the Cryomatic should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Cryomatic. b: Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V/m.			

Annex I - EMC Statement and Guidelines

Recommended separation distances between portable and mobile RF equipment and the Cryomatic			
The Cryomatic is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Cryomatic can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Cryomatic as recommended below, according to the maximum power output of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz 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	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated 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 guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects and people.			
The Cryomatic should not be used adjacent to or stacked with any other equipment. If this configuration is required then normal operation of the Cryomatic should be verified in this setting.			

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As part of our policy of continued product improvement we reserve the right to alter specifications at any time without prior notice.

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