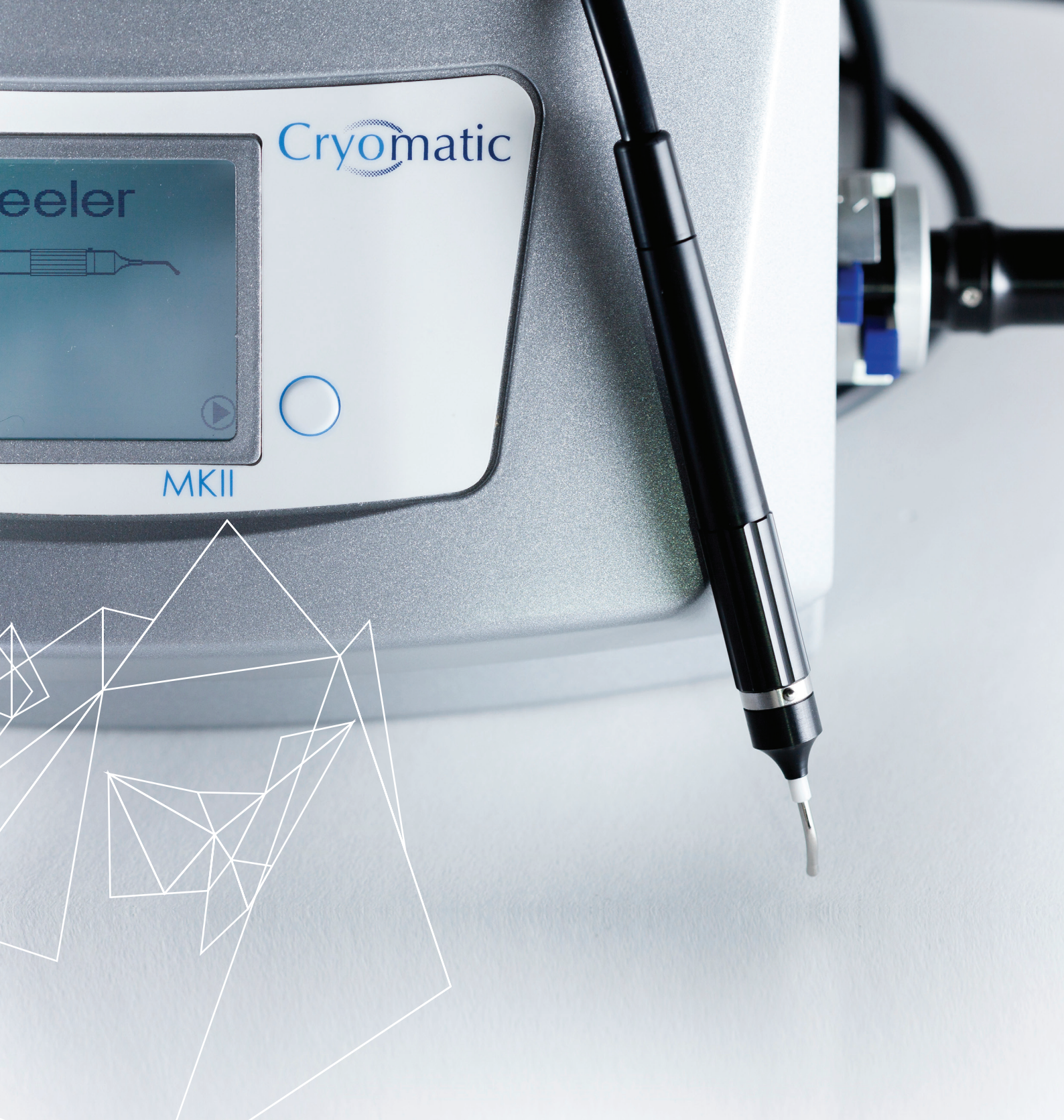


Cryomatic MK II

Keeler

– A world without vision loss –

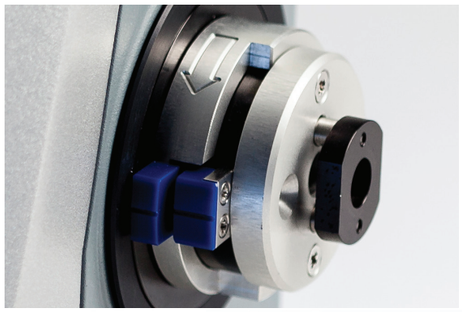
The Cryomatic MK II

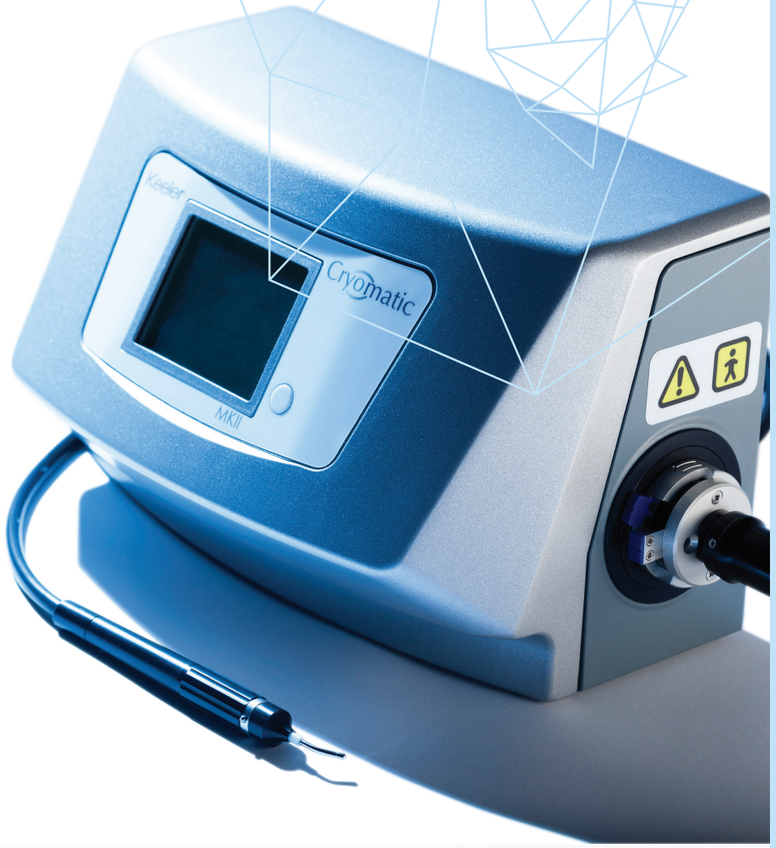
Perfection evolved

The Keeler Cryomatic MKII System and probes are intended 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).

Building on the exceptional reliability of its' predecessor, the Cryomatic MK II delivers quality and versatility when using either disposable or reusable probes.

The Cryomatic MK II's new coupling system allows you to connect either a single use disposable or reusable probe without the need for an adaptor. The new integral software automatically detects the type of probe in use and adjusts the unit accordingly, meaning the unit is ready for use in a matter of minutes.



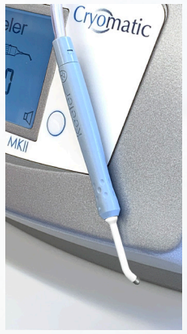


Cryomatic MK II Probes

No Purge Cycle for Single Use Probes!

When using single use probes, the Cryomatic MK II will instantly allow the user to couple the probe to the console and it's ready to go - no more waiting for a purge cycle!

The Cryomatic MK II has all new reusable probes; designed for ease of connection and, with a classic tip form, are perfect for your needs. The integral software will automatically detect and optimise its' parameters for perfect performance, whichever type of probe you are using, and ensure a short purge cycle time after time.



❶ **2509-P-8020** – Standard retinal Probe
❷ **2509-P-8021** – Extended Retinal Probe
❸ **2509-P-8022** – Mid-Reach Retinal Probe
❹ **2509-P-8025** – Glaucoma Probe
❺ **2509-P-8024** – Curved Cataract Probe
❻ **2509-P-8023** – Intra-Vitreal Probe
❼ **2509-P-8026** – Collins Trichiasis Probe

Cylinder adapters

Your Cryomatic can be used with either Carbon Dioxide (CO_2) or Nitrous Oxide (N_2O) gas from non-syphonic bottles via one of the Pin Index Yoke (PIY) or screw thread adapters or cylinder adapters below.

2508-P-7017
Pin Index Yoke for E Size Nitrous Oxide Gas Cylinder

2508-P-7015
Pin Index Yoke for E Size Carbon Dioxide Gas Cylinder

2508-P-7016
Adapter for F Size Carbon Dioxide Gas Cylinder

2508-P-7018
Adapter for F Size Nitrous Oxide Gas Cylinder

Size E Cylinder
Dimensions (cm) 50x15
Gr. Weight (kg) 7

Size F Cylinder
Dimensions (cm) 86x14
Gr. Weight (kg) 18

Part numbers

2509-P-1010 Cryomatic Console with footswitch

Cryomatic Standard Probe Range

2509-P-8020 2.5mm Standard Retinal Probe
2509-P-8021 2.5mm Extended Retinal Probe

Single Use Cryosurgical Probes

2509-P-8033 Keeler Single Use Retinal Probes, Box of 10

NEW!

Cryomatic Special Order Probe Range

2509-P-8022 2.5mm Mid-Reach Retinal Probe
2509-P-8023 0.89 mm Intra-Vitreal Probe
2509-P-8024 1.5mm Curved Cataract Probe
2509-P-8025 3mm Glaucoma Probe
2509-P-8026 4 x 10mm Collins Trichiasis Probe
2509-P-8030 Classic Retinal Probe

Accessories

2508-P-7016 Adapter for F Size Carbon Dioxide Gas Cylinder
2508-P-7015 Pin Index Yoke for E Size Carbon Dioxide Gas Cylinder
2508-P-7018 Adapter for F Size Nitrous Oxide Gas Cylinder
2508-P-7017 Pin Index Yoke for E Size Nitrous Oxide Gas Cylinder
2509-P-8015 Probe Sterilisation Boxes (for Cryomatic Probes Only)
2508-P-7005 Cryo Trolley

Cryomatic

Cryomatic Key Features

- Integral software automatically detects the type of probe in use and adjusts the unit accordingly, meaning the unit is ready for use in a matter of minutes. This ensures a short purge cycle time after time.
- Back-flush facility – During purging and 20 seconds after footswitch is released, the gas reverses its flow at a lower pressure (removes debris and moisture – eliminates risk of problems during surgery).
- Wide range of reusable probes (see more about these on the back).
- No purge cycle for single-use, disposable probes.
- Delivers quality and versatility when using either disposable or reusable probes.
- Rapid freeze and quick defrost.
- Ease of use with graphic display.

Unit Specifications

Cryo System	2509-P-1010
GAS SPECIFICATION	Medical grade nitrous oxide (N_2O) or medical grade carbon dioxide (CO_2) in non-syphonic cylinders.
OPERATING RANGE	3100–4480kPa (450–650PSI/31–45Bar).
MAXIMUM CYLINDER PRESSURE	8275kPa (1200PSI/83Bar).
DISPLAY	LCD Display [95mm x 70mm]

Electrical Ratings

INPUT VOLTAGE RANGE	100–240Vac (50/60Hz).
POWER RATING	15–30VA.
FUSES	2 x T2AH 250V.

Dimensions

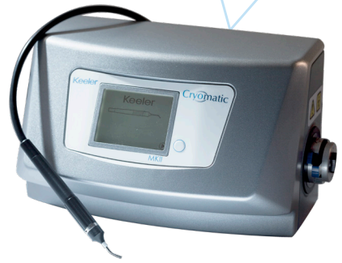
WIDTH	350mm (14”).
DEPTH	200mm (8”).
HEIGHT	190mm (7.5”).
WEIGHT	4.5kg (10lbs).

Classification and Safety Standards

COMPLIES WITH	EN60601-1, UL60601-1, and 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 IPX7.

Unit Overview

The Cryomatic MKII console is a self-contained system. The console provides the connection point 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.



What’s in the box?

- Cryomatic MK II console.
- Footswitch.
- Mains cord.
- High-pressure gas hose.
- Exhaust hose.
- Adjustable wrench.
- Instructions for use.
- 2x spare mains fuses.

Manufacturing address:

Keeler Ltd.
Clewer Hill Road
Berkshire
SL4 4AA

CE

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CRYOMBROEN.DD.200513v01

Keeler
Ophthalmic Instruments

EC Declaration of Conformity to:
Medical Device Directive 93/42/EEC

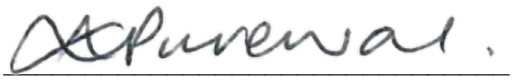
Legal Manufacturer:	Keeler Ltd Clewer Hill Road, Windsor, Berkshire SL4 4AA United Kingdom
Manufacturing Site(s):	Cryo MK II Console: Keeler Ltd Clewer Hill Road, Windsor, Berkshire SL4 4AA United Kingdom Cryo MK II Probes: Nu Perspectives Ltd, 9a, Stonefield Park, Martins Lane, Chilbolton SO20 6BL United Kingdom
EU Authorised Representative:	Visiometrics, S.L., Vinyals, 131 08221 Terrassa, Spain
Device Description/Family:	Cryomatic MK II Cryosurgical System, Pencils and Accessories (See below Product Schedule)
EC Product Classification:	Class IIb, Annex IX, Rule 9
GMDN:	46052 – Ophthalmic Cryosurgical System, electronic An assembly of mains electricity (AC-powered) devices designed to apply cold from a gaseous or liquid refrigerant (cryogen) [e.g., liquid nitrogen (LN2), nitrous oxide (N2O), carbon dioxide (CO2)] to a target tissue for its destruction and removal during an ophthalmic surgical procedure. The system typically includes an electronic control unit which controls the flow of cryogen contained in a connected cylinder, dedicated cryogen-cooled hand-held applicators (probes) to apply the cold to the tissue, a foot-switch, and interconnections. It is commonly used for cryopexy for retinal detachment, cataract extraction, and to treat glaucoma, trichiasis, and retinopathy of prematurity (ROP).

We herewith declare, as the sole manufacturer, that the product(s) listed above and detailed in the attached Product Schedule meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 as amended, concerning medical devices.

Applied Directives:	• Medical Device Directive (MDD) - 93/42/EEC • Restriction of Hazardous Substance (RoHS) – 2011/65/EU • Waste Electrical and Electronic Equipment (WEEE) Directive – 2012/19/EU • MEDDEV 2.7/1 Rev. 4
Applied Standards:	• BS EN 1041:2008 +A1:2013 • EN ISO 13485:2016 • EN ISO 15223-1:2016 • EN ISO 14971:2012 • EN ISO 10993-1:2009 • EN ISO 14155:2011 • EN ISO 15004-1:2009

	• EN 62366-1:2015 • EN 50419:2006 • IEC 60601-1:2006+A12:2014 • IEC 60601-1-2:2014 • EN 60601-1-6:2010+A1:2015 • EN 62304:2006 +A1:2015 • EN ISO 17664:2004 • EN ISO 11737-1:2006 • EN ISO 11737-2:2009 • ISO 10993-7:2008 • ISO 14644-1:2015
Notified Body:	***SGS Belgium NV*** SGS House, Noorderlaan – 87, Antwerp, 2030 Belgium +32 3 545 44 00 https://www.sgs.be/en/ **Notified Body Number: 1639**
CE Certificate Number:	Annex II exc. Section 4 (EC Certificate No. GB20/965236, valid until 30 September 2022)
Date of Issuance of Original CE Certificate:	10 September 1995

DofC Reference to Tech File: DofC 10 **Rev: 14**

Signed: 

Arminder Purewal

Date: 05 May 2021

Head of Regulatory Affairs & Quality Assurance,
Keeler Ltd

Keeler
Ophthalmic Instruments

Product Schedule:
Cryomatic MK II Cryosurgical System, Pencils and Accessories

Part Number	Description	Product Classification	UDI-DI
2509-P-1010	CRYOMATIC MKII SYSTEM	IIb	05055272711753
2509-P-8020	2.5MM STANDARD RETINAL PROBE CRYO II	IIb	05055272711760
2509-P-8021	2.5MM EXTENDED RETINAL PROBE CRYO II	IIb	05055272711814
2509-P-8022	2.5MM MID REACH RETINAL PROBE CRYO II	IIb	05055272711821
2509-P-8023	0.89MM INTRA VITREAL PROBE CRYO II	IIb	05055272711838
2509-P-8024	1.5MM CURVED CATARACT PROBE CRYO II	IIb	05055272711845
2509-P-8025	3MM GLAUCOMA PROBE CRYO II	IIb	05055272711852
2509-P-8026	4x10MM COLLINS TRICHIASIS PROBE CRYO II	IIb	05055272711869
2509-P-8030	CLASSIC RETINAL PROBE CRYO II	IIb	05055272718981

Accessories		
Part Number	**Description**	**UDI-DI**
2508-P-7005	CRYOMASTER TROLLEY	05055272707466
2508-P-7015	PIN INDEX YOKE FOR E SIZE CO2 CYLINDER	05055272707497
2508-P-7016	ADAPTOR FOR F SIZE CO2 CYLINDER	05055272707503
2508-P-7017	PIN INDEX YOKE FOR E SIZE N2O CYLINDER	05055272707510
2508-P-7018	ADAPTOR FOR F SIZE N2O CYLINDER	05055272707527
2509-P-8007	CRYO HOSE ASSEMBLY REPAIR KIT	05055272715119
2509-P-8008	CRYO GAS COUPLING KIT	05055272715126
2509-P-8015	CRYOMATIC STERILISATION BOX	05055272707732
2508-P-8026	DISPOSABLE PROBE ADAPTOR	05055272717304
2509-P-8027	CRYOMATIC STEM NUT ASSEMBLY TOOL	05055272715096
2509-P-8028	CRYO II HOSE ASSY REPAIR KIT	05055272716208

EC Certificate Full Quality Assurance System: Certificate GB20/965236

The management system of

Keeler Ltd

Clewer Hill Road, Windsor, Berkshire, SL4 4AA, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Keeler Cryomatic MKII Console & Pencils for use in ophthalmic surgery
Laser Indirect Ophthalmoscope (LIO)
for use in ophthalmic surgical procedures

Tonometers to aid diagnosis and measurement of intraocular pressures:
Pulsair Intellipuff – Non-Contact Tonometer
TonoCare – Non-Contact Tonometer
Pulsair Desk Top Tonometer
Keeler Digital Applanation Tonometer (D-KAT)
Keeler Digital Applanation Tonometer (D-KAT), Z Type

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 28 February 2020 until 30 September 2022
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 10 September 1995
and first certified by SGS Belgium NV since 28 February 2020

Certification is based on reports numbered GB/PC 240569

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 **f** +32 (0)3 545-48-49 www.sgs.com