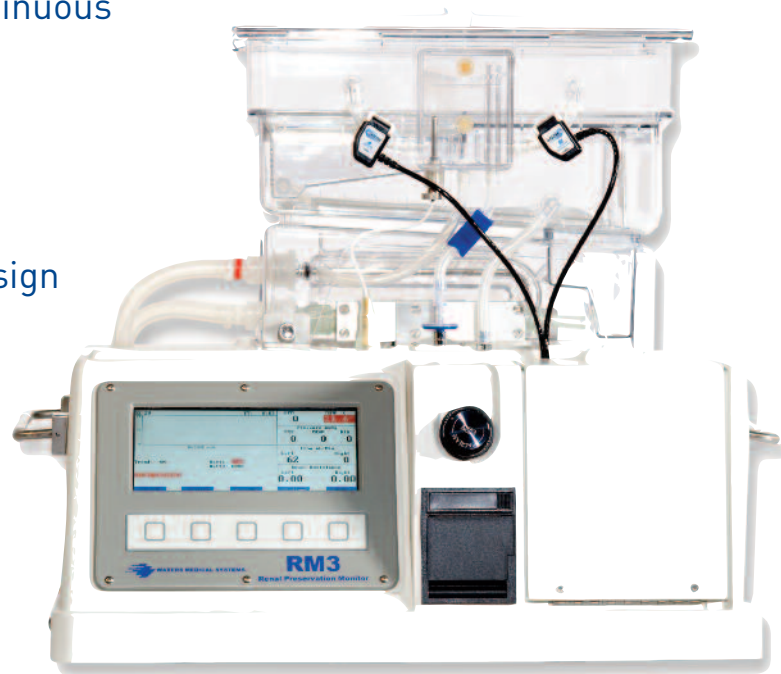


The IGL logo consists of the letters 'IGL' in a white, serif font, centered within a dark blue square. The square has rounded corners and a thin white border. The background of the top of the slide features a close-up of water droplets on a metallic surface, with a teal-to-white gradient.

RM3[®]

Organ preservation by pulsatile perfusion

- Development of the continuous hypothermic perfusion technique
- Increase in donor pool
- Dual kidney cassette design allows for cost-effective perfusion



Optimizing Organ Preservation

THE RM3

The RM3 control unit regulates the pulsatile perfusion of the perfusate. The RM3 will perfuse and monitor real-time pressure, flow and temperature of the perfusate. It will display all parameters that it monitors for visual confirmation of perfusion activity and trend that data for objective evaluation of the kidney prior to transplantation. The user can select the data and waveforms to print.

Customer Service

Waters Medical Systems provides toll free telephone support to assist you with product information and placing orders for instruments, parts and disposable components. The same toll free number can be used for technical and non-technical support by requesting the Technical Support Centre.

Customer Service:

800-288-7777 - 8:00 A.M. to 5:00 P.M. CST

507-252-3784 International

+1-507-252-3700 Facsimile

Statement of intended use

The RM3 Renal Preservation System was developed by Waters to maintain kidneys for transplant. The device provides a simple and efficient method for hypothermic pulsatile preservation for one or two kidneys by maintaining pressure, flow and temperature. It is not to be used for direct contact to any patient.

The components, options and supplies of the RM3 are intended to be used for the hypothermic pulsatile perfusion of kidneys. These products are to be used in accordance with the instruction manual, associated documents and accepted medical standards.

Ethylene Oxide (EO) Gas Sterilization

Low temperature (+65°C) ethylene oxide may be used to sterilize Transonic flowprobes.

Follow the standard sterilization cycle time for your EO system.

Package the instruments in gas-permeable packaging material specifically warranted to the manufacturer for use in EO sterilization. Ethylene oxide gas is toxic and flammable. Caution must be used when sterilizing with EO. Follow guidelines established in the Association for the Advancement of Medical Instrumentation (AAMI) Standards and Recommended Practices, Volume I: Sterilization, p 409-443, 1992.

Warning

Explosion Risk. Do not use automotive chargers. They will overcharge the gel-cell battery used in the RM3. Overcharging the batteries will cause permanent damage and will vent hydrogen and oxygen gas, which are explosive.

Battery Shelf Life & Storage

(Excerpt from Power Sonic)

Low internal resistance and special alloys in the electrodes assure a low self discharge rate and, consequently, a long shelf life.

GENERAL FEATURES

- Molded plastic cabinet and coolant tank
- Solid state pressure sensing
- Two ultrasonic flow transducers
- Uses DCM100 cassette and DCM50 cassette
- Battery compartment front accessible, uses one or two 12 volt, 12 amp/hour batteries. Battery voltage level indication on the display. Two fully charged batteries are included. Battery clamp for one or both batteries.
- Has RS232 serial port for data transfer; DCE communication device. Using 9 pin "AT" D-sub male connector
- Built-in thermal printer; General Scanning AR42
- 24 Hour time and date
- Temperature measuring for perfusate
- Graphical display; TFT LCD NEC NL6448BC26-01

SIZE

(Excluding cassette)

- Width: 21.25 in (54.0 cm)
- Depth: 15.75 in (40.0 cm)
- Height: 10.83 in (27.5 cm)
- Cassette height: 10.5 in (26.7 cm)
- Total height (app.): 21.00 in (53.3 cm)

WEIGHT

(Excluding batteries and cassette)

- Dry: 34.4 lb (15.64 kg)
- Battery (ea.): 10.4 lb (4.73 kg)
- Cassette: 4.85 lb (2.2 kg)
- Coolant: 7.5 lb (3.41 kg)
- Wet weight (est.): 67.6 lb (30.73 kg), (excluding kidneys & perfusate)

POWER

- AC 90 to 253 volts, 47 to 447 Hz
- DC 12 volt battery (internal)
- Auxiliary input for 12 volt DC

Note: Battery to back up system upon AC power failure.

COOLANT CAPACITY

- 3.75 liters, ice and water
- March Mfg. 12 volt DC submersible
- 3.5 L/M flow through cassette

GRAPHIC DISPLAY

- 2.75 in x 6.73 in (69.34 mm x 170.94 mm)

RECORDER

- 25 mm/sec real-time pressure waveform
- Trends plotted
- Report will print UNOS ID if entered - *Note: In the event of an alarm condition, a dated and timed report will be printed automatically*

ULTRASONIC FLOWMETER

- Transonic, two channel built into RM3
- Transducer placed at each kidney inlet tube
- Manual flow operation with built-in timer
- Accuracy: $\pm 7\%$

TEMPERATURE SENSOR

- Thermistor, 2000 Ω at 25°C
- Accuracy: $\pm 0.5\%$

PRESSURE TRANSDUCER

- Honeywell 26PC Series
- 0 - 2 psi range, 20 psi maximum over pressure
- Accuracy: $\pm 5\%$

PERFUSATE PUMP

- Water MOX pulsatile
- 12 volt DC, 0 - 76 PPM

REMOTE ALARM RELAY

- 0.5 Amp, 100 volts DC or peak AC
- 10 VA maximum, 0.15 Ω contact resistance
- Contacts normally open, closed upon alarm.

MARKETING AUTHORISATION HOLDER

Manufactured by:



Waters Medical Systems

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Rochester, MN 55901
USA



Tel. +1 507 288 7777

Fax +1 507 252 3700

www.groupe-igl.com

welcome@groupe-igl.com

FDA Class II Medical Device



Read attentively the instruction for use.

Optimizing Organ Preservation...

Coming from the research

IGL develops specific programs that have led to the development of products designed specifically to improve organ recovery, preservation, transport and evaluation systems before transplant.

Flushing Transport Perfusion

IGL develops, manufactures and markets three lines of products with only one goal: improve the quality of the transplanted grafts, offering to the transplantation teams a line of efficient and adapted preservation products, as well as a scientific & technological support.

IGL: a reference in organ preservation and transplantation.



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Federal and international law restricts the sale of this device to or on the order of a physician or licensed practitioner.
Please contact us for a complete list of references and authorizations.