'MOX' DCM-100
WARRANTY

Waters Medical Systems warrants that during the *useful life of the cassette, each new cassette sold or manufactured by Waters is free from defects in material and workmanship under normal installation, use and service. Waters Medical Systems agrees that any such defect shall be repaired or replaced at its discretion, provided the part is delivered intact to the factory for examination with shipping costs prepaid by the owner.

This warranty does not extend to any cassette which has been subjected to negligence, accident, abuse, misuse, or other improper operation, or has been tampered with or altered.

The purchaser assumes all liability for claims, losses or damages incurred by the use or misuse of the instruments, when placing and accepting delivery of an instrument or supporting parts and disposables. AT NO TIME SHALL WATERS MEDICAL SYSTEMS, THEIR EMPLOYEES, REPRESENTATIVES, OR THEIR DEALERS BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM OR CAUSED BY ANY DEFECT, FAILURE OR MALFUNCTION OF ANT PRODUCT, OR CLAIMS, LOSSES, DAMAGES OF ANY THIRD PARTY OR FOR LOST PROFITS OR INDIRECT OR CONSEQUENTIAL DAMAGES OF ANY KIND EVEN IF WATERS HAS BEEN INFORMED OF THE POSSIBILITY OF SUCH DAMAGES.

THIS WARRANTY IS GIVEN EXPRESSLY AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. PURCHASER AGREES THAT THERE IS NO WARRANTY OF MERCHANTABILITY AND THAT THERE ARE NO OTHER REMEDIES OF WARRANTIES, EXPRESSED OR IMPLIED, WHICH EXTEND BEYOND THE DESCRIPTION OF THE FACE OF THIS AGREEMENT.

SOME STATES DO NOT ALLOW LIMITATIONS ON THE DURATION OF IMPLIED WARRANTIES, OR EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES FOR CERTAIN PURCHASES, SO THE ABOVE EXCLUSIONS OR LIMITATIONS MAY NOT APPLY TO YOU.

THIS LIMITED WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU ALSO HAVE OTHER RIGHTS WHICH VARY FROM STATE TO STATE.

Waters Medical Systems warrants that the 'MOX' DCM-100 is sterile, provided that the cassette is used prior to the Use Before Date and the sealed plastic bag has not been punctured, torn, or damaged.

*Useful life refers to the sterility period of the cassette. Do not use the cassette if the Use Before Date has expired.

0002699.000 Rev 3

'MOX' DCM-100
DISPOSABLE CASSETTE

Re-order number 0008190.000

CE

READ ALL INSTRUCTIONS, WARNINGS AND PRECAUTIONS CAREFULLY PRIOR TO USE

STERILE EO — STERILE AND NON-PYROGENIC only if sterile wrap is not damaged.

DO NOT REUSE.

STORAGE 5°C to 50°C.

Caution: Federal Law restricts this device to sale by or on the order of a physician.

WATERS MEDICAL SYSTEMS
P.O. Box 6117, Rochester, MN 55901-6117 U.S.A.
Telephone: (507) 252-3784 or (800) 426-9877
FAX: (507) 252-3700

EC REP
CEpartner4U
3951DB; 13. NL.
+31 (0) 6-516.536.26

INTENDED USE / DESCRIPTIONS

The Waters MOX DCM-100 Disposable Organ Preservation Cassette is intended for use with the Waters RM3 Renal Preservation System. The RM3 Renal Preservation System is intended to be used to maintain kidneys for transplant. The Waters DCM-100 is made of polycarbonate plastic. The pre-sterilized cassette contains a complete circulatory system (refer to diagram), designed for use on the Waters RM3, 'MOX' 100 Transport and Console units.

INSPECTION

Upon receiving individual cassette and container, inspect outside box for any damage. Remove cassette and sterile wrap from container. Inspect wrap for any punctures or tears. If sterile wrap shows any signs of being damaged, DO NOT USE. Call Waters Medical Systems to make arrangements for returning cassette. Call Customer Service at 1-800-426-9877.

When the cassette is removed from the sterile wrap, inspect the cassette for damage prior to mounting in unit. If the fittings, support leg and main body are not damaged, mount the cassette and proceed.

CAUTION

Contents guaranteed sterile unless polyethylene bag is damaged or open. Cassette is ETO gas sterilized. This is a single-use device. Waters Medical Systems does not recommend reuse of this device.

INSTRUCTIONS

INSTALLATION

Place the cassette on the RM3, Transport or Console. Insert the pulsatile pumphead into the unit's pumphead bracket. Position the pumphead so that the pressure plate compresses the pumphead and not the one-way valves. Secure the cassette to the unit with the mounting screws.

Insert the temperature probe into the bubble trap and connect it to the unit's temperature jack.

Connect the coolant lines to the cassette's heat exchanger. It is recommended that the tube which delivers coolant to the heat exchanger be connected to the "IN" connector, and the return tube be connected to the lower "OUT" connector.

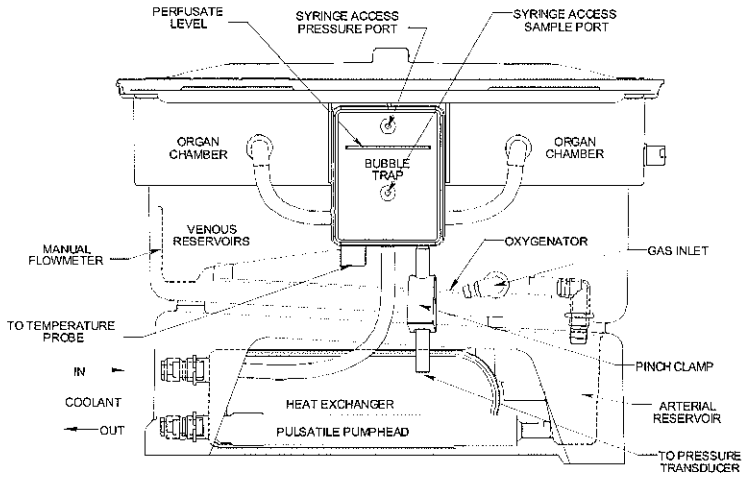
BUBBLE TRAP

With the perfusate flowing through the cassette, the fluid level can be adjusted as follows:

A. Initially allow the perfusate to rise up to the perfusate level mark on the bubble trap. This can be done by venting the pressure gauge tube to the room. When the perfusate rises to the top of the temperature probe, connect the tube to the unit.
B. To increase or decrease perfusate level, insert a suitable size syringe with w 22 gauge needle into the top Pressure port.
C. To remove a sample of perfusate, insert a syringe into the bottom Sample port.
D. The perfusate level should be kept at the perfusate level line on the bubble trap.

CAUTION

Due to the design characteristics of the molded cassette, it is recommended that timing interval for flow measurements be between the 20 and 80 cc marks. The 20 ml per division scale is roughly ± .5 ml.



REORDERING INFORMATION

Waters model DCM-100 Sterile Disposable Cassette may be ordered directly from Waters Medical Systems Call 1-800-426-9877.