BRACCO

LIFE FROM INSIDE

CardioGen-82®
INFUSION SYSTEM USER'S GUIDE

CE 0086

Manufactured By:

RbM Services, LLC

For
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CardioGen-82 Infusion System
Limited Warranty

ACIST Medical Systems, Inc. ("ACIST") warrants the CardioGen-82 Infusion System (the "Infusion System") against any defects in materials and workmanship for a period of one year from the date of installation. ACIST's warranty covers all parts, repair labor and its associated expenses for failures of the Infusion System to perform to its specifications during the warranty period, subject to the following exceptions: (i) misuse, (ii) abuse, or (iii) alteration (without ACIST's express written consent).

Any part or component of the Infusion System that is judged to be defective by ACIST in material or workmanship during the warranty period will be repaired or replaced by ACIST at its sole option and its expense. Remedies available under this warranty are limited to repair or replacement of malfunctioning parts, system replacement, or refund of the purchase price with the specific remedy subject to election by ACIST in its sole judgment.

Application for a warranty remedy must be made to ACIST within (30) days of the apparent malfunction.

EXCEPT AS EXPRESSLY PROVIDED HEREIN, ACIST MAKES NO ADDITIONAL WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO THE INFUSION SYSTEM, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE OR PURPOSE.

ACIST SHALL UNDER NO CIRCUMSTANCES BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL OR EXEMPLARY DAMAGES OF ANY NATURE, WHATSOEVER, INCLUDING BUT NOT LIMITED TO, COMMERCIAL LOSS FROM ANY CAUSE, BUSINESS INTERRUPTION OF ANY NATURE, LOSS OF PROFITS OR REVENUE, REAL OR PERCEIVED LOSS OF USE, LOSS ARISING FROM A DEFECT IN DESIGN, MATERIAL AND/OR MANUFACTURE OR WORKMANSHIP, OR ARISING OUT OF THE PURCHASER'S FAILURE TO COMPLY WITH ALL OR ANY OF THE PROVISIONS OF THE INFUSION SYSTEM MANUAL AND/OR THE FAILURE OF THE INFUSION SYSTEM TO PERFORM AS SPECIFIED, EVEN IF ACIST SHALL HAVE BEEN ADVISED TO THE POSSIBILITY OF SUCH DAMAGES.

The Infusion System should only be serviced by personnel authorized by ACIST. Any service other than ACIST-authorized personnel will void this warranty.
For product complaints or questions regarding the operation and service of the system, please contact your assigned Bracco Representative.

SAFETY SUMMARY

The "!" mark inside of a triangle as labeled on the CardioGen-82 Infusion System, as well as the label showing "a person looking at a book" is meant to reference the user to this User's Manual in order that the individual will understand the complete operation of the system and understand all safety precautions.

Radiation Safety

The CardioGen-82 Generator supplied by Bracco Diagnostics, Inc for use with the CardioGen-82 Infusion System emits radiation. All applicable radiation safety regulations should be followed by the user.

DANGER: EXPLOSION HAZARD. DO NOT USE IN THE PRESENCE OF FLAMMABLE ANAESTHETICS.

CAUTION!

To reduce the risk of electrical shock, do not remove. Refer servicing to qualified service personnel. Refer to ACIST Medical Systems, Inc. User Manual for servicing.

Power Source

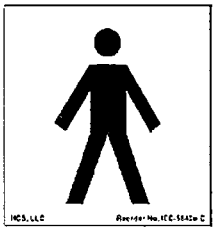
This system can be set for 100/120/220/240V~ operation via the power entry module. For 230V~ operation use the 240V~ setting. To change this setting, ensure that the system is unplugged from its power source, and use a small flat screwdriver to remove the fuse drawer of the power entry module. Remove the small voltage selector card and rotate the card until the desired voltage is shown. Then replace the card and fuse drawer. Only use the fuse type and rating as indicated on the system label located near the power entry module. System power is 2.5A. The protective ground connection via the grounding conductor in the power cord is essential for safe operation.

Grounding the System

This system is equipped with a three-conductor ac power cord marked "Hospital Grade." The power cord must be plugged into an approved three-contact electrical outlet marked "Hospital Only" or "Hospital Grade" to assure a reliable ground. Use only a power cord that is in good condition.

The "Hospital Grade" detachable 10 foot power cord, supplied with this system, P/N 4040010-00, is recommended. The use of a cable other than the cable specified may result in increased emissions and decreased immunity of the CardioGen-82 Infusion System.

Do not operate this system in an explosive atmosphere, such as, flammable gases or fumes.



The type B symbol refers to the fact that all applied parts of this system are categorized as Type B with regard to electrical shock per IEC 60601 Safety Standards for Medical Electrical Equipment.

Do Not Remove Covers or Panels

To avoid personal injury, do not remove or operate this system without all appropriate covers and panels in place. Refer all service to authorized personnel.

Fusing

To avoid fire hazard, use a fuse of the correct type, voltage rating and current rating as specified.

The following fuses and values are used in the system:

Power entry module: Use only the fuse type and rating as indicated on the system label located near the power entry module. **Internal fuses should only be replaced by qualified personnel.**

F1, Power chassis assembly (rear panel), ¼ x 1 ¼ T2, 5AL250V~ (2.5A, 250V~ time delay
F2, Power chassis assembly, ¼ x 1 ¼ T1, 5AL250V~ (1.5A, 250V~ time delay

EMC Compliance

The CardioGen-82 Infusion System is compliant with EN/IEC 60601-1-2 Medical electrical equipment- Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility- Requirements and tests. Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. CardioGen-82 Infusion System should be observed for normal operation when used with other electronic equipment. The Use of cables other than those specified may result in increased emissions and decreased immunity of this system. Portable and mobile communications equipment can and may affect Medical Electrical Equipment.

Guidance and manufacturer's declaration –electromagnetic emissions		
The CardioGen-82 Infusion System is intended for use in the electromagnetic environment specified below. The customer or the user of the CardioGen-82 Infusion System should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The CardioGen-82 Infusion 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 A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	The CardioGen-82 Infusion System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies used for domestic purposes.

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