MicroSim COS

Cardiac Output Simulator

"The one and only that simulates a true waveform"

Operating Manual



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Warranty

Netech warrants the **MicroSim COS** against defects in materials and workmanship for one year from the date of original purchase. The standard warranty is extended for a second year if the instrument is returned to Netech for its recommended yearly recalibration.

During the warranty period, we will repair or, at our option, replace at no charge a product that proves to be defective, provided you return the product shipping prepaid to Netech Corporation.

This warranty does not apply if the product has been damaged by accident or misuse or as the result of service or modification by other than Netech Corporation, or if its serial number is defaced or removed.

Netech reserves the right to discontinue the MICROSIM COS at any time, and change its specifications, price, or design without notice and without incurring any obligation. Netech guarantees violability of service parts for 5 years after the manufacture of the unit is discontinued.

The warranty is void if you elect to have the unit serviced and / or calibrated by someone other than Netech.

The warranty covering your product becomes void when the tamper-resistant Quality Seal is removed or broken without proper factory authorization.

We strongly recommend, therefore, that you send your instrument to Netech Corporation for factory service and calibration, especially during the original warranty period.

The purchaser assumes all liability for any damages or bodily injury, which may result from the use or misuse of the unit by the purchaser, his employees, agents, or customers.

In no event shall Netech Corporation be liable for consequential damages

General Information

Trademarks

MicroSim is the trademark of Netech Corporation. Any other trademark names used in this manual are only for editorial purposes and the benefit of the respective trademark owner with no intention of improperly using that trademark.

Copyright

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Quality Assurance

Netech is ISO 9001-2000 Certified. This instrument was thoroughly tested and inspected according to Netech's ISO 9001-2000 quality standards and test procedures and found to meet those specifications when it was shipped from the factory.

Refunds and Credits

Please note that only serialized products and their accessory items (i.e., products and items bearing a distinct serial number tag) are eligible for partial refund and/or credit. Non-serialized parts and accessory items (e.g., cables, carrying cases, auxiliary modules, etc.) are not eligible for return or refund. Only products returned within 90 days from the date of original purchase are eligible for refund/credit.

In order to receive a partial refund/credit of a product purchase price on a serialized product, the product must not have been damaged by the customer or by the carrier chosen by the customer to return the goods, and the product must be returned complete (meaning with all manuals, cables, accessories, etc.) and in "as new" and resalable condition.

Products not returned within 90 days of purchase, or products, which are not in "as new", and resalable condition, are not eligible for credit return and will be returned to the customer. The Return Procedure (see below) must be followed to assure prompt refund / credit.

Restocking Charges

Products returned within 30 days of original purchase are subject to a minimum restocking fee of 15 %, in excess of 30 days, 20 %. Additional charges for damage and / or missing parts and accessories will be applied to all returns.

Return Procedure

All items being returned (including all warranty-claim shipments) must be sent freight-prepaid to our factory location. When you return an instrument to Netech Corporation, we recommend using United Parcel Service, Federal Express, or Air Parcel Post. We also recommend that you insure your shipment for its actual replacement cost. Netech Corporation will not be responsible for lost shipments or instruments that are received in damaged condition due to improper packaging or handling. Use the original carton and packaging material for shipment.

Returns for Refund / Credit

A Return Material Authorization (RMA) number must be obtained from our service or customer service dept, before a product is returned for refund or credit. The RMA number should be clearly marked on the package along with the a statement indicating the reason for return..

Repair and Calibration

Products returned for repair or recalibration must obtain the service form which can be down loaded from our website <u>www.Netech.org/service</u> or contact:

Netech Corporation

Service Dept. 110 Toledo Street, New York, 11735, Tel: 1-800-547-6547 Email: Service@Netech.org

WARNING

Unauthorized user modifications or application beyond the published specifications may result in electrical shock hazards or improper operation. Netech Corporation will not be responsible for any injuries sustained due to unauthorized equipment modifications.

<u>Changes or modifications to this unit not expressly</u> <u>approved by the manufacturer could void the user's</u> <u>authority to operate the equipment.</u>

Electromagnetic Interference

FCC CLASS A (USA)

MicroSim[™] COS (Simulator Series) has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment

CE This Product bears **CE** mark based on the following standards listed below

EC Directive 04/108/EEC Electromagnetic Compatibility

Emissions - CLASS A

The system has been type tested and found to meet the requirements of EN 61326-1:1998 for Radiated Emissions and Line Conducted Emissions. Verification of compliance was conducted to the limits and methods of the following:

CISPR 16-1:1993 and CISPR 16-2:1996

Immunity

The system has been type tested and found to meet the latest harmonized European emissions and immunity standard requirements of EN 61326 for commercial measurement equipment. Verification of compliance was conducted to the limits and methods of the following:

EN 61326-1 IAW EN 61000-4-2 Electrostatic Discharge

EN 61326-1 IAW EN 61000-4-3 Annex D Radiated & Conducted EM

EN 61326-1 IAW EN 61000-4-4 Electrical Fast Transient/Burst

EN 61326-1 IAW EN 61000-4-5 Surge Immunity

EN 61326-1 IAW EN 61000-4-6 Conducted Disturbances

EN 61326-1 IAW EN 61000-4-11 Voltage Interrupts

EC Directive 73/23/EEC Low Voltage

The system has been type tested and found to meet the requirements of EC Directive 73/23/EEC for Low Voltage. Verification of compliance was conducted to the limits and methods of the following: **EN 61010-1**

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1.1 Introduction

The **MICROSIM COS** is a compact cardiac out put simulator, designed to test and verify the functionality of most cardiac output monitors. It simulates an ideal cardiac output waveform for various preset values for selected Blood temperature and injectate temperatures.

The **MICROSIM COS** utilizes a proprietary complex software algorithm to generate a realistic cardiac output waveform. It is recommended and used by many Medical equipment manufacturers to verify the performance of their cardiac out put monitors.

It is compact, lightweight, and rugged. The **MICROSIM COS** is operated via easy to use menus displayed on its LCD display. It is battery operated.

1.2 Specifications

Catheter Size: 7F Injectate Volume: 10cc Computational Constant: 0.542

Cardiac output Selections: 3, 5, 6, 7 LpM (letter/minute) Accuracy 2% +/- .1 LpM

Blood Temperature: 37°C and 38°C Accuracy 2% +/- 0.1°C

Injectate Temperature: 5°C and 20°C Accuracy 2% +/- 0.1°C

Electrical:

Power: 9 Volt Alkaline Battery Battery life: 100 hours Continues operation

Mechanical:

Size: 4.75x2.75x1.25" Unit Weight: .5Lbs with Battery Shipping Weight: 3 Lbs.

1.3 Accessories (Standard)

PN: 11101	Baxter Edwards Compatible Interface Cable
PN: 11104	Carrying case

Various Interface cables are available. Contact Netech.

2.1. Getting Started

Before unpacking the MICROSIM COS inspect the shipping box for any visual damage. If damage is found, do not unpack the unit and immediately notify the shipping carrier.

If no damage is found to the shipping box, open the box and perform a visual inspection of the MICROSIM COS. If any damage to the unit is observed please contact Netech Customer Service.

The Netech warranty statement is listed in the warranty section of this manual. When shipping an instrument to Netech for repair or calibration make sure that the instrument is properly packed. A completed the Service Return Form must be included with the returned instrument to ensure the timely repair and return of your instrument. The Service Return Form may be obtained at our web site <u>http://www.defibrillatoranalyzer.com/</u> or from the Netech Customer Service Department.

2.2 Instrument Familiarity



MicroSim Cardiac Output Simulator Shown with Baxter Edwards compatible Interface Cable

2.3 Controls and Menu Structure

Controls

The control consists of four function keys **F1** – **F4**, a left arrow (<), a right arrow (>), **Esc** key and power On/Off.

Each function key is active based on the context of each menu. Function keys are assigned to selections appearing along the bottom line of the display. When there are more selections than can fit on one screen, left and right arrows will be displayed, and the arrow keys become active to permit scrolling of selections. For most menus, the **Esc** key returns you to the Main Screen without making any selections. The display consists of a 16x2 character LCD display. The menu structure is as follows.

Initialization Menu

On power-up, the initialization screen will appear:

Internal tests are performed during power on initialization, If all initialization tests pass, the unit will move on to the Simulator Main menu as below.

Simulator Main Screen

BT:37°C	ΙΤ:	5 ° C
C O : 5 L p m	Sel	Str
	F3	F4

Menu Abbreviations:

BT: Blood Temperature IT: Injectate Temperature CO: Cardiac Output Sel: Selection menu Str: Start waveform

Active selection keys in the Main Screen are F3 and F4: (F3): Selects other CO values. The default value is set at 5 LpM. (F4): Starts the CO waveform.

Press (F4) to start simulation. A progress bar will appear at the

lower right as simulation starts. It provides a visual indication of the percentage of the elapsed waveform. During a simulation, the COS will not respond to any keys pressed. To show the simulation has completed, the progress bar will become a series of dashes as shown:



Pressing F3, F4, or Esc will reset the simulator and return to the Main Screen.

Selection Menu

Press $({\rm F3})$ 'Sel' from the Main Screen to enter the Selection Menu:

	Selec	tion	
со	ΙТ	ВТ	Cfg
F1	F2	F3	F4

Active keys in the Selection Menu:

- CO (F1): Enters the CO rate selection menu.
- IT (F2): Enters the Injectate Temperature selection menu.
- BT (F3): Enters the Blood Temperature selection menu.
- Cfg (F4): Enters the Configurations menu.
- Esc: Returns to the Main Screen.

CO Output Selection Menu

со	rate:	5 L p m	
< 3	5	6	7 >
F1	F2	F3	F4
со	rate:	5 L p m	
< 5 0	al		>
F1			

In the CO Rate menu, four CO rate wave types are available in Liters per minute: 3, 5, 6, and 7. 5Cal is a 5Lpm square wave calibration output. The current setting is displayed. Selecting a new value returns you to the Main Screen. Press **Esc** to leave the current setting unchanged.

Injectate Temperature Select Menu

Injectate Temperature selections simulate the resistance of a Coset Probe thermistor. The two selections available are 5°C and 20°C. The current setting is displayed. Selecting a new value returns you to the Main Screen. Press **Esc** to leave the current setting unchanged.

Blood Temperature Select Menu

в	I	ο	ο	d		t	е	mp	:	3	7	0	С
3	7			3	8								
	F1				F2								

Blood temperature selections simulate the resistance of an ideal Catheter thermistor. The two selections available are 37°C (98.6°F) and 38°C (100.4°F). The current setting is displayed. Selecting a new value returns you to the Main Screen. Press **Esc** to leave the current setting unchanged.

Configuration Menu

Con	fig	Menu	
< S a v	Ver	Mdl	PN >
F1	F2	F3	F4
Con	fig	Menu	
< R O M	ЕΡ		>
F1	F2		

Active keys in the Config Menu:

•Sav (**F1**): Allows you to save the current combination of CO Rate, BT, and IT as the power-up defaults.

Service related selections:

- Ver (F2): Displays firmware version identification.
- •Mdl (F3): Displays machine model identification.
- •PN (F4): Displays machine Part No. identification.

Diagnostic selections:

- •ROM (F1): Performs a ROM checksum to verify the integrity of the processor's memory. A pass/fail message will display. This function is also performed on power-up.
- •EP (**F2**): Performs a non-volatile memory (EEPROM) checksum to verify the integrity of the machine calibration constants. A pass/fail message will display. This function is also performed on power-up.

Notes on proper operation

- •When a change in temperature selection is made (either Blood Temp. or Inj. Temp.), the simulated resistance outputs experience a small amount of fluctuation. For best results, allow 10 seconds for the baseline to stabilize before starting a simulation.
- •The battery voltage is continually monitored during normal operation. If a low battery condition is detected, a "LOW BATTERY" message will appear and all functions will be disabled.

2.5 Operating COS

- 1. Connect the MICROSIM COS to the monitor under test, using the correct interface cable.
- 2. Set the Computation Constant to 0.542 on the patient monitor.
- 3. Turn the MICROSIM COS On.
- 4. Select the desired blood temperature, injectate temperature, and CO rate settings as outlined in section 2.3.
- 5. Allow 10 seconds for the baseline to stabilize.
- 6. Press the Start button on the monitor under test.
- 7. Press Str (F4) on the MICROSIM COS to begin a waveform simulation.
- 8. When the test is complete, verify the reading on the patient monitor.
- 9. Repeat steps 4 through 8 for other values of blood temp., injectate temp., and CO rates.

3.1 Error Codes

• Error 1: Low Battery.

Display reads, "Low Battery", "Turn unit off." The battery voltage has fallen below the safe operating limit and all functions have been disabled. Turn off the unit and replace the battery.

• Error 2: ROM Checksum error.

A fault has been found in the processor's permanent memory. This is a fatal error, the unit should be returned to the factory for service.

• Error 3: EEPROM Checksum error.

A fault has been found in the Non-Volatile Memory storage. This is a fatal error, the unit should be returned to the factory for service.

• Error 4: Cal jumper short.

This is a calibration procedure error. It is meant as a reminder to disable calibration before leaving a calibration lab. If this error should appear during normal operation, an internal fault condition may exist and the unit should be returned for service.

• Error 5: Coeffs invalid.

The calibration coefficients may have become corrupted. If this error appears, enter the Configuration Menu described in section 2.3 and select EP (**F2**). This will test the readability of the EEPROM contents. Cycle power. If this error persists, the unit will have to be considered out of calibration and should be returned for service.

• Error 6: DCP out of tolerance.

This error can only be set during a calibration. It is meant as a troubleshooting aid during service and can not be set during normal operation.

