COVIDIEN™

REF 186-0137
P/N 185-1006

BIS™

Simulator Sensor

en **Instructions For Use**

Instructions For Use
Insert 2CH/4CH BIS™ sensor simulator service tool into patient interface cable. Impedance test will be initiated by BIS™ monitoring system when it detects that simulator has been inserted.

Note: This product is NOT intended for use with the DSC-2.

Description of tool: The 2CH/4CH BIS™ sensor simulator is a service tool that allows for the verification of proper impedance values being detected by the BIS™ monitoring system during the "Sensor check". This test is part of the initial test that each monitor performs. The simulator also allows for safety testing of BIS™ monitors in the field by allowing connection of the test equipment to the monitor via the patient interface cable (PIC).

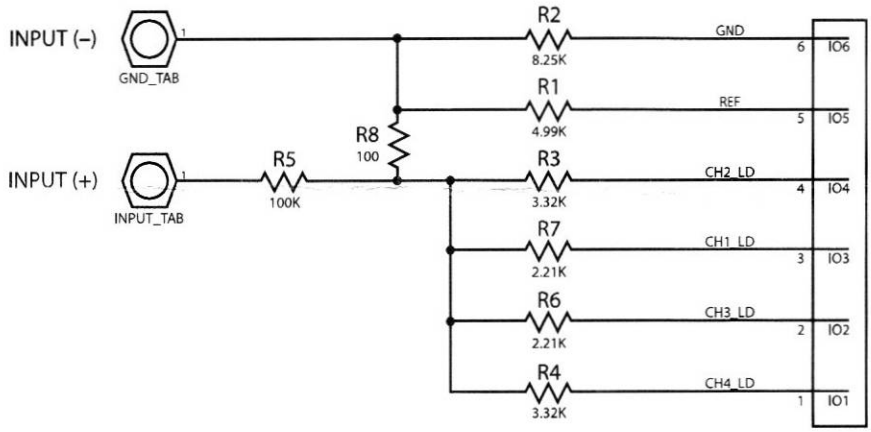


Figure 1: Schematic of the 2CH/4CH BIS™ sensor simulator circuitry. IO3 – IO6 connect to 4 input signal pins on a 2 channel patient interface cable. IO1 – IO6 connect to 6 input signal pins on a 4 channel patient interface cable. The Inputs (+ and -) are where one connects the test signals to test the BIS™ monitor.

Test types allowed
Sensor check: This checks and verifies that the monitor is reporting the proper impedances that it sees from the BIS™ sensor simulator. This procedure verifies the proper functionality of the BIS™ monitoring system.

1. Connect the BIS™ sensor simulator to the BIS™ monitor at the patient interface cable.
2. The monitor should proceed to recognize that a sensor was connected and report the proper impedance values as shown below in table 1:

Electrode # DSC/BISx	1	2	4	3
Acceptance Range in Kohms	4 - 6	8 - 17	3 - 5	2 - 4
Electrode BISx4	C	G	LE/RE	LT/RT

Table 1: BIS™ sensor simulator individual electrode impedance range

A-2000 monitor only: The monitor then proceeds to display the BIS™ screen. The BIS™ value is blanked and after a few seconds, SQI=100.

PIC Cable Diagnostics (Applicable to BIS™ VISTA monitor with 3.00 or higher S/W, and select OEM monitoring systems)
This test checks that the PIC cable is functioning properly and does not contain any open or short circuits by verifying the monitor is reporting the proper impedances that it sees from the BIS™ sensor simulator. After simulator connection to the PIC cable, the monitor should initiate a sensor check and display a screen or message similar to the ones below:

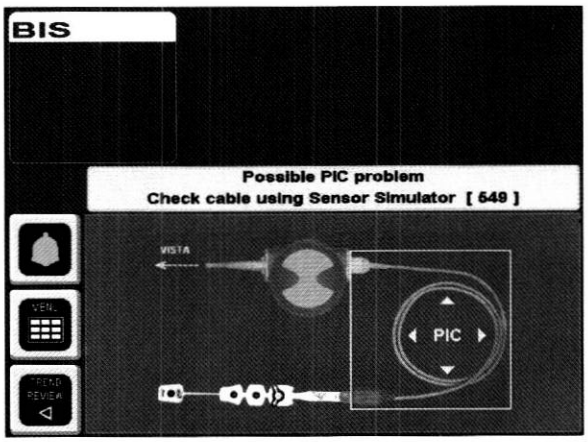


Figure 2

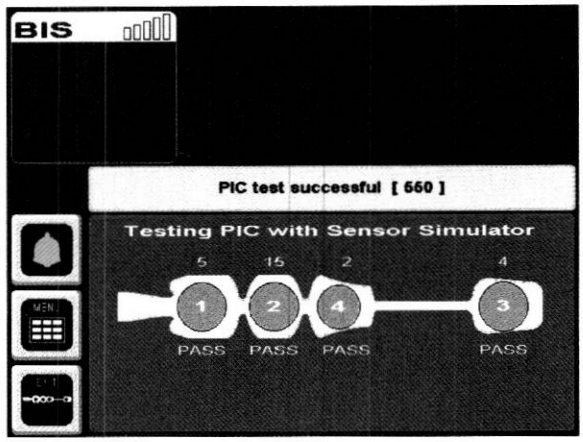


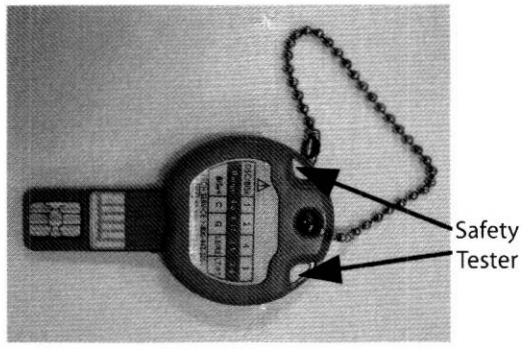
Figure 3

Figure 2 shows the situation where the sensor check electrode impedances reported are out of expected BIS™ sensor simulator electrode impedance range as shown in table 1. This indicates a potentially defective PIC cable. The PIC cable should be replaced and the test repeated to determine if the PIC cable or the BIS™ sensor simulator is faulty and needs to be replaced.

Figure 3 shows the situation where the sensor check electrode impedances reported are in the expected BIS™ sensor simulator range.

Safety Testing: Leakage Current
Leakage current testing should be performed by a qualified Engineering Technician or authorized personnel only.

1. Connect the BIS™ sensor simulator to the patient interface cable of the BIS™ monitor as if it was a sensor connection.
2. Short the two circular terminals at the end of the simulator using conventional methods such as jumpers or alligator clips.
3. Connect the test signal to the shorted terminals. Make sure that you are not touching the BIS™ sensor simulator beyond this point.
4. Proceed to test instrument for Leakage current as per established facility protocols and procedure for safety testing of medical devices.



Simulator Cleaning

1. Wipe simulator surfaces with a wet cloth soaked in lukewarm tap water containing beach solution of 10% by volume.
2. Wipe simulator surfaces with a wet cloth of lukewarm tap water.
3. Dry with a clean cloth and allow to dry.

	Not made with natural rubber latex
	Not made with DEHP
	Consult Instructions for Use
	Caution: Consult Accompanying Documents
	Authorized for sale in European countries
	Authorized Representative in the European Community
	REF Catalogue number
	Manufacturer
	Lot number

Not made with natural rubber latex

Consult instructions for use

Part No. PT00084149 Rev B 2018-10

Covidien llc, 15 Hampshire Street, Mansfield, MA 02048 USA.
EC REP Covidien Ireland Limited, IDA Business & Technology Park, Tullamore, Ireland.

www.covidien.com