



INSTRUCTION FOR USE

SENTRON

PRESSURE MEASUREMENT SYSTEM

V0237.0

Pressure Interface, cat. no. SPI-110, USA- version

SENTRON Pressure Measurement System

Instruction for use
September 2002

This instrument was packed and shipped in a box especially designed to protect it. The interface however should be inspected as soon as received. If damaged occurred, a claim should be made with the carrier.

Please send a copy to your CD LEYCOM agent. CD LEYCOM will take arrangements for repair or replacement.

Please check if your mains power plug is in accordance with the local main power outlets.

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1. General Information

1.1 Introduction

This SENTRON Pressure Measurement System is a system for continuous measurement of intra arterial and intracardiac pressure in situ, as for example in heart catheterization.

The SENTRON Pressure Measurement System measures blood pressure (with respect to atmospheric pressure) accurately providing an analog high-level output for recording purposes and an analog low-level output for connection to pressure monitoring systems. The system consists of a stand-alone Pressure Interface cat. no. SPI-220 (230 Volt AC \pm 10%) or cat. no. SPI-110 (115 Volt AC \pm 10%), to be used with all Pressure and Pressure / Volume catheters with or without lumen cat. CA##-##-#-PN or PL / CS##-##-# PL. See instructions in the Catheter Manual supplied with each CD LEYCOM catheter.

1.2 Features of the SENTRON Pressure Measurement System are:

- accurate pressure measurement in situ
- simple set up of entire system
- high level analog output for recording purposes
- low level analog output for connection to standard pressure monitoring systems
- automatic sensor calibration
- automatic zero-procedure
- tactile response membrane switches for output calibration
- mode and failure indicators- microprocessor controlled functions
- automatic self-diagnosis of electronics

1.3 Classification

This SENTRON Pressure Interface is constructed to comply with IEC 601-1 and is classified as being:



Class I – type CF equipment, defibrillator proof

TYPE CF



Drip proof enclosure

1.4 Cleaning

Do not sterilize the SENTRON Pressure Interface because temperatures exceeding 70°C (158°F) or ionizing radiation will damage the instrument. Cleaning should be done with a damp cloth moistened with water and a detergent or alcohol.

Do not use acetone, ethyl ether or chlorinated solvents.

Do not immerse in any agent.

Do not use ultrasonic cleaning.

2. Description

2.1 Principle of pressure measurement

The pressure transducer consists of a silicon membrane that shows elastic deformation when subjected to pressure. The deformation is measured by means of piezo-resistive elements. Four piezo-resistors are implanted in the membrane near the edge, sensing radial and tangential stresses.

The layout of the resistors is such that by the induced stresses two of them increase and two decrease in value. These resistors are combined in a full bridge.

2.2 The Pressure Interface

The interface is controlled by a microprocessor as shown in the block diagram (fig. 1). The sensor is excited by a constant current source. The resulting bridge voltages are measured. These values are available to the microprocessor through an analog to digital converter. The microprocessor calculates the temperature correction for the pressure sensor signal. This correction is performed by means of a digital to analog converter, which provides for an offset correction. Automatic adjustment of gain is performed by the microprocessor on the bias of sensor characteristics. These characteristics are stored in a memory (PROM), which is mounted in the catheter connector.

Memories are available to the microprocessor containing the program (EPROM), temporary results (RAM) and catheter data (PROM). Communication with the user takes place interactively by means of two electric output functions, two push buttons and three LEDs.

The software contains a diagnostic program to evaluate sensor and interface performance. Memory, power supply, temperature and pressure signals are checked by the microprocessor.

Great care has been taken to provide the best possible electrical insulation (= security) for the patient. The patient-connected part is separated from the mains connected part.

The analog outputs of the interface may be connected to other mains powered equipment. Adequate electrical insulation between the patient part of the interface and this connected equipment is provided by opto-couplers.

The insulation of the interface meets or exceeds the IEC-601-1 standards for medical equipment.

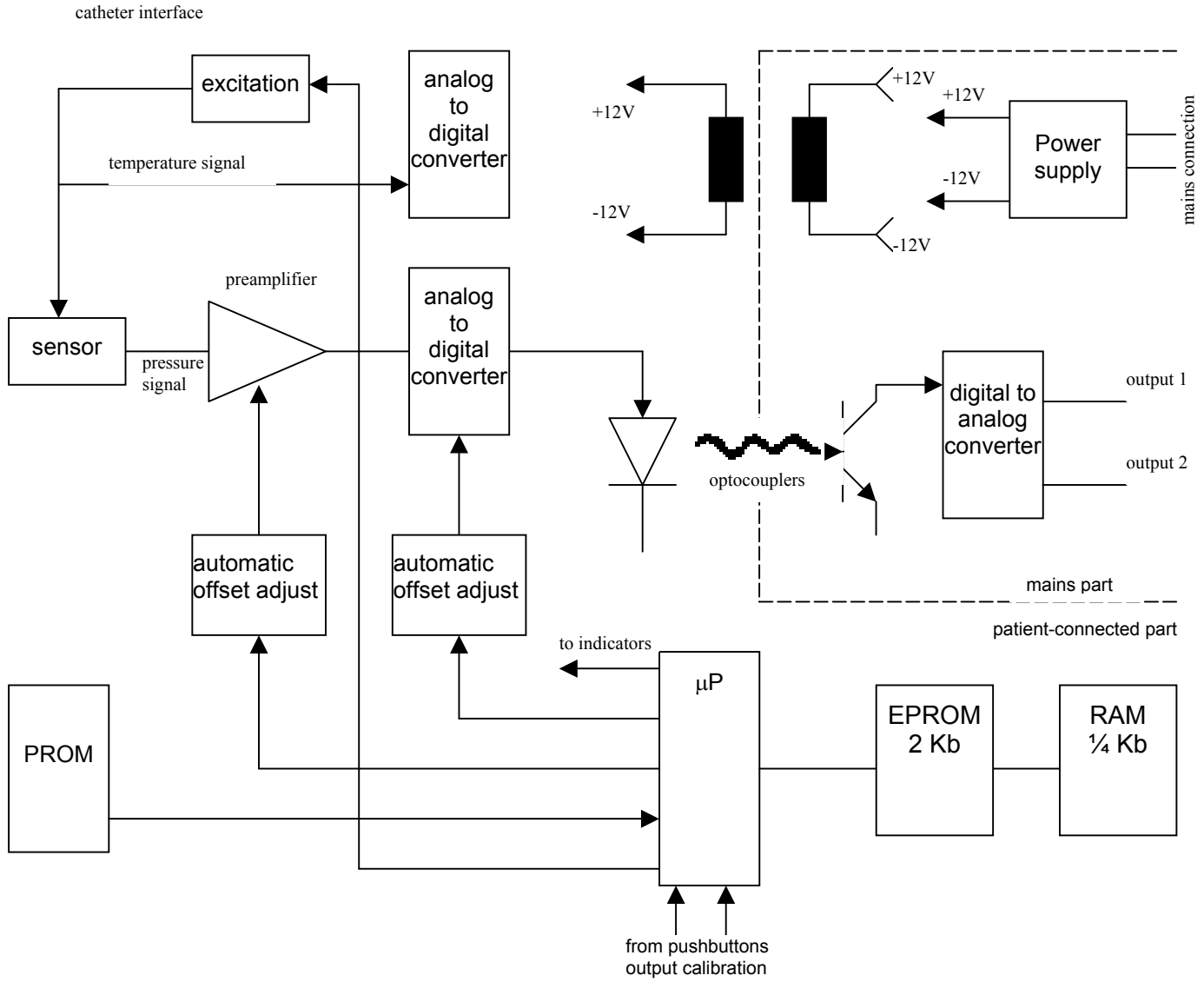


Figure 1: Pressure Interface block diagram

3. Using the pressure measurement system

3.1 Start-up procedure

Connect the power cord to an earthed mains supply outlet. Switch the Pressure Interface on by means of the “power-on” switch (“I” = ON, “0” = OFF), located on the rear panel (fig. 3). The “power-on” indicator (green LED) will light. The “instrument inoperative” (red LED) lights for approximately 5 seconds while the instruments perform a self-diagnosis by checking the electronics. Upon completion this indicator is (automatically) turned off. The “sensor inoperative” indicator (red LED) lights for approximately 5 seconds then commence to flash if a catheter is not connected.

3.2 Connecting a catheter

Flush the catheter first with a sterile saline solution. Then wet the sensor by immersing the distal portion of catheter for approximately 10 seconds in a saline solution. Remove catheter from saline, lay catheter on sterile table and cover sensor with sterile gauze.

Connect the catheter’s pressure connector to the socket (fig 2.: No 5) on the Pressure Interface.

The catheter should not be moved until the “sensor inoperative” indicator (fig 2: No 2) turns off (after approximately 1 minute). During this period several calibration values of the catheter are determined (initialization procedure).

Please turn to chapter 4 (trouble shooting) whenever the “Sensor inoperative” indicator does not turn off but will go in flashing mode.

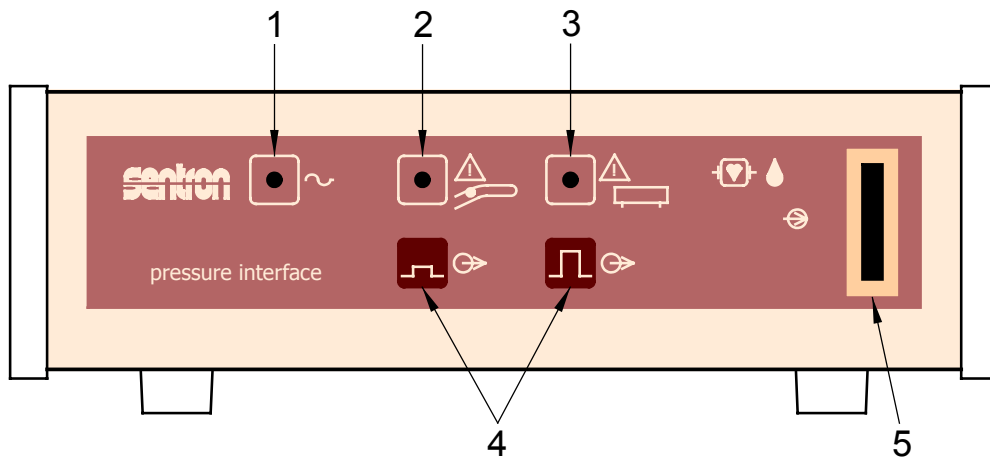


Figure 2: front panel Pressure Interface

1. “Power On” indicator (green LED)
2. “Sensor inoperative” indicator (red LED)
3. “Instrument inoperative indicator (red LED)
4. Output calibration push buttons
5. Receptacle for connection of SENTRON Pressure Measuring Catheter

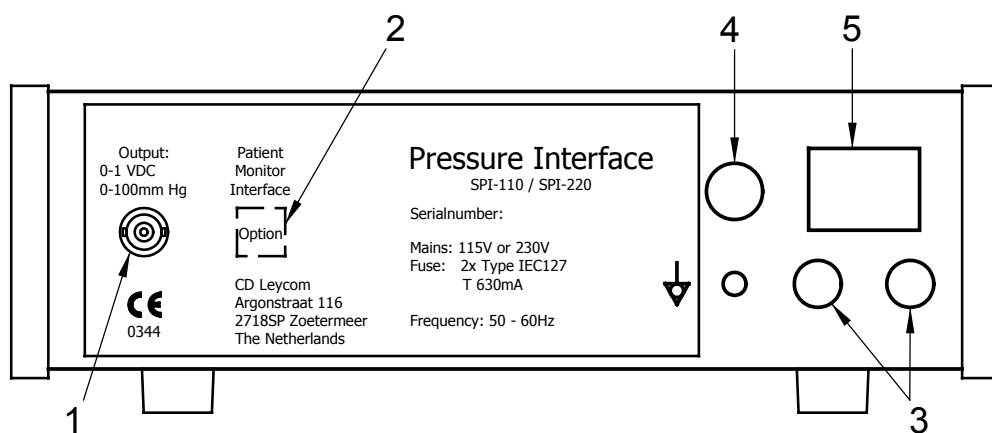


Figure 3: rear panel Pressure Interface

1. Output signal, high level; BNC-connector
2. Output signal, low level; Berg-connector
3. Fuse holders
4. Power cord
5. Power ON/OFF switch

3.3 Introducing the catheter

The catheter may now be introduced as described in the instruction for use accompanying each CD LEYCOM Pressure Measuring Catheter.

After the initial connection of a CD LEYCOM Pressure Measuring Catheter, this catheter is recognized to the interface. The catheter may be disconnected and reconnected without having to repeat the initialization procedure if the interface has not been turned off at the mains.

(A disconnection will activate the “sensor inoperative”-indicator.) After re-connecting the same catheter, the catheter will be “recognized” by the instrument. The system will return to the measuring mode as it was before it was interrupted. (The “sensor inoperative”-indicator will be turned off.)

Note

“Recognition” is only possible, when no other catheter has been connected to the interface in between.

Warning

Do not switch off the power supply during this period. If the power supply switched off the interface will lose its information on the catheter. No back-up system is built-in, so a new initialization procedure will be necessary.

3.4 Analog output signals


Two output connectors are located on the rear of the interface (see fig. 3).


One high-level output (fig. 3: No 1), a standard BNC-connector for connection to a recorder, oscilloscope or data-acquisition system (like the Leycom CFL-512 or Sigma-5DF) and one optional low-level output (fig. 3: No 2), a 7-pin Berg-connector for custom made connection to a specific pressure amplifier module or patient-monitor.

From the moment the “instrument inoperative” indicator (fig. 3: No 3) stops flashing, the two analog output signals are available.

3.5 Output calibration

For calibrating to the connected equipment two push buttons are essential (fig 2: No 4).

When the left push-button () is activated both outputs will supply an electrical zero (which not necessary equals zero pressure) for 10 seconds; followed by 20 seconds of a signal equivalent to 1,4 kPa (10 mmHg). See fig. 4a.

When activating the right push-button () the output will supply 10 seconds of electrical zero followed by 20 seconds of a signal equivalent to 13,3 kPa (100 mmHg). See figure 4b. Calibration may be repeated at any time, without interfering in the actual pressure measuring process.

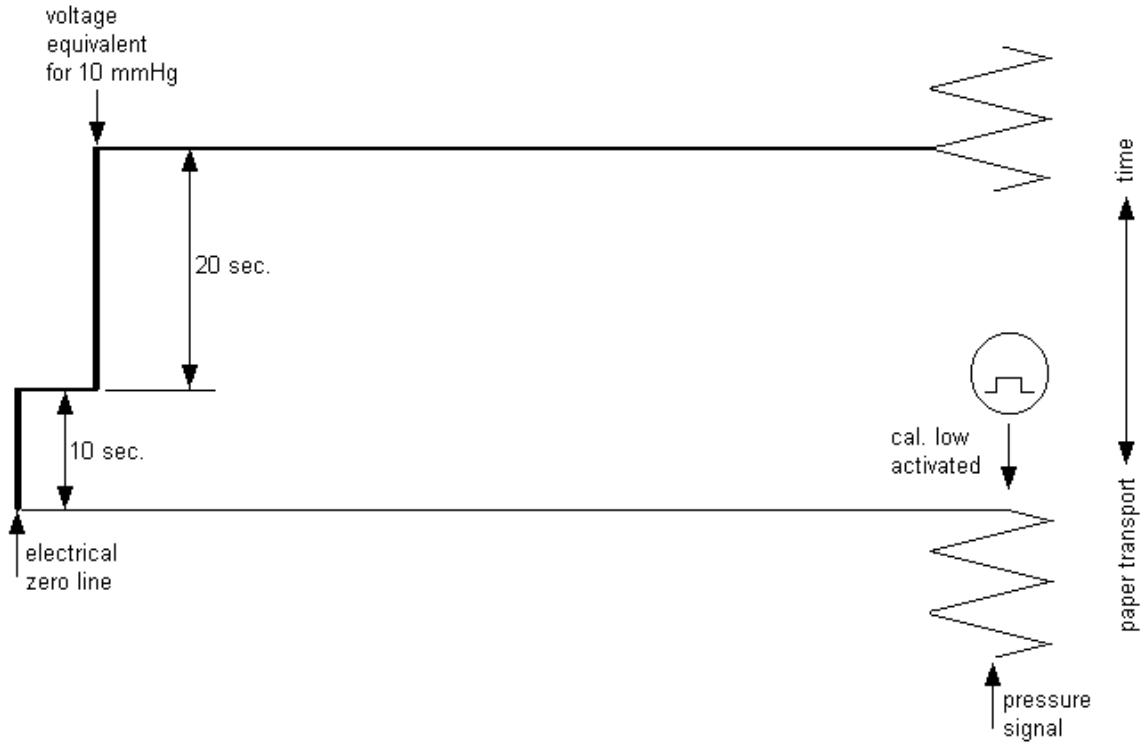


Figure 4a: cal. low (10 mmHg)

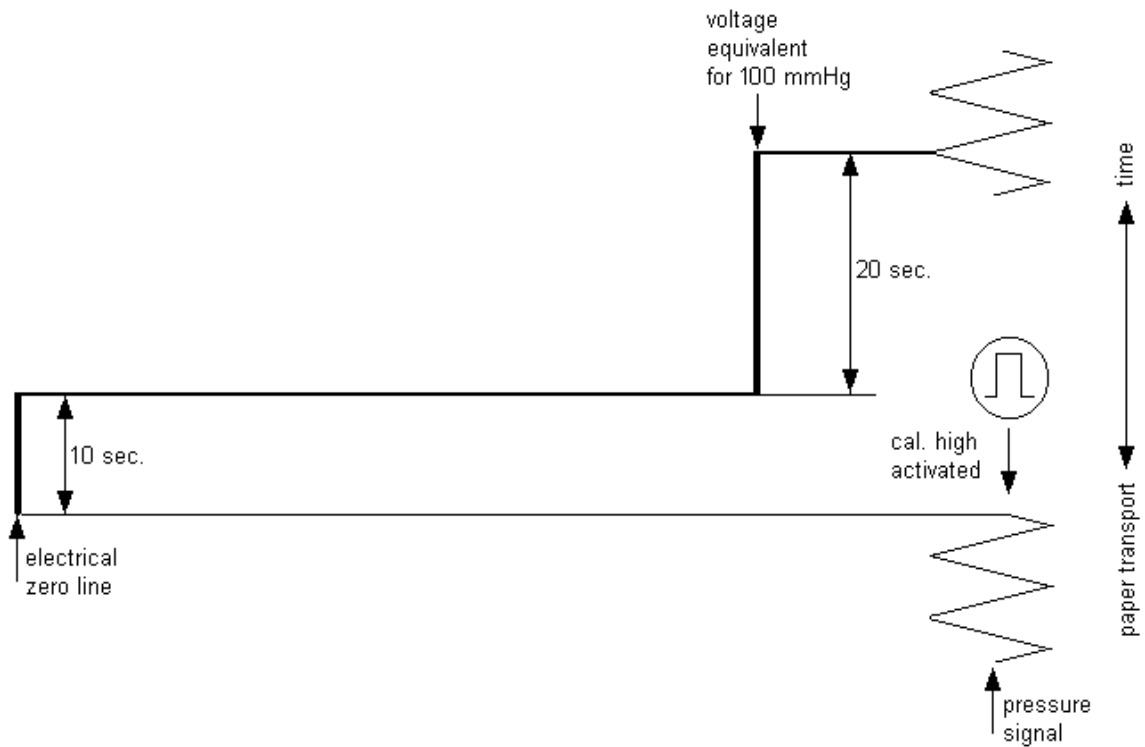


Figure 4b: cal. high (100 mmHg)

3.6 Cautions

Defibrillation protection: this Pressure Interface is protected against defibrillation shocks. Nevertheless the Pressure Measuring Catheter may not be defibrillation proof. This strongly depends on the location of the catheter tip with respect to the paddles of the defibrillator.

Pacemaker influence: The effect of pacemaker pulses on the pressure signal is negligible. Neither catheter nor interface will be damaged.

Electro surgery/Interference: Electro surgery will be detected as high frequency interference and temporarily the pressure signal will cease. When the interference exceeds certain limits the “sensor inoperative” LED will flash. Disconnect and reconnect the catheter when the indicator commences flashing.

The catheter could be damaged by electro surgery, due to the high voltages involved. The interface is protected against high voltages; however, if the active electrode of the electro surgery system is brought into the immediate vicinity of the catheter tip, both the catheter and the interface may be damaged.

If the catheter tip is not in close proximity to the body area used for electro surgery, damage is unlikely.

5. Specification

Pressure Measurement System

Operating range	: -6,65 to 40 kPa (-50 to 300 mmHg)
Total inaccuracy over full pressure range at 37°C	: 2% FS
Base-line drift	: 0,13 kPa (1 mmHg) per hour
Max allowable pressure on sensor	: 133 kPa (1000 mmHg)

Pressure Interface

Power supply	: 230V ($\pm 10\%$) 50/60 Hz (cat. no. SPI-220)
Fuses (slow)	: 115V ($\pm 10\%$) 50/60 Hz (cat. no. SPI-110)
Low-level output signal (optional)	: standard transducer output signal according to customer specification (7-pin Berg connector)
High-level output signal	: -0,50 to 3,00 V DC corresponding to pressure in the range -6,65 to 40 kPa (-50 to 300 mmHg) (BNC-connector)
Push buttons	: tactile feedback membrane switches
Dimensions	: 270 mm wide 90 mm high 300 mm deep
Weight	: 5 kg
Environmental conditions	: Operating : Temperature : 10 to 30°C Relative humidity : 30 to 75% Storage : Temperature : -15 to 55°C Relative humidity : 10 to 80%

Note

Due to our continuous efforts and research to improve our products specifications may change without notice.

6. Service and Liability

The SENTRON Pressure Interface is designed to perform reliably, and it meets or exceeds the manufacturer's specifications at the time of sale. In spite of the care exercised in design and manufacture, it is impossible to eliminate malfunction due to ordinary wear and tear and random component failure. Accordingly CD LEYCOM agrees that when the product is used and maintained in accordance with the accompanying instructions it will, at its option, replace or repair the unit on a non-charge basis for 1 year following the date of purchases.

In view of the varied conditions under which the unit will be utilized, it is sold "as is". CD LEYCOM's responsibility does not go beyond the terms set forth above.

If the unit fails to operate as described in these instructions, call your local Sales Representative or call CD LEYCOM:

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If the problem cannot be corrected easily, CD LEYCOM will authorize the return of the unit. Use the packaging materials, which the unit was shipped, or request that new packaging materials are sent to you.