

Manufacturer

**Spiegelberg
(GmbH & Co.) KG
Tempowerkring 4
21079 Hamburg
Germany**

**Phone: +49-40-790-178-0
Fax: +49-40-790-178-10
Email: info@spiegelberg.de
<http://www.spiegelberg.de>**



CE-marking according to directive
93/42/EEC

Technical alterations reserved.

Spiegelberg:

IAP-Monitor
IAP 32.1

Operating-Instructions

Innovative
Measurement
Technology for
Medicine

Pinout of DB 9 Socket

1: Uref Input	6: Uref Output (2,5 V)
2: RxD	7: Digital Gnd
3: TxD	8:
4:	9: Analog Gnd.
5: Analog Output	

For use as a voltage output pins 1 and 6 are connected by a jumper.

For use as a monitor output the excitation voltage is fed into the reference input and the analog output is scaled down by a resistive divider.

Data Transmission across the RS 232 C Interface

The IAP-Monitor responds to single ASCII bytes:

To the monitor	Response
'A'	Mean pressure in ASCII string format, terminated by 'Carriage Return'.
'B'	Mean pressure in binary format, 1/10 mm Hg resolution, two's complement, two bytes, high byte first.
'C'	Instantaneous pressure in binary format, 1/10 mm Hg resolution, two's complement, two bytes, high byte first. Response only after new value is read in (every 10 ms).

Contents

Safety instructions	2
Indication and Method	3
Monitor Operation	4
Cleaning	5
Connections	6
Faults	7
Technical Specifications	8
Accessories	10

Safety Instructions

The IAP-Monitor and the accompanying catheters are designed for the measurement of intraabdominal pressure. The manufacturer accepts responsibility for the safety, reliability and performance of the monitor only if:

- the installation, extensions, readjustments, modifications and repairs are performed by authorized personnel,
- the electric installation of the room is in accordance with the national regulations concerning rooms used for medical purposes,
- the monitor is used in accordance with the operating instructions, and
- the monitor is used with the approved accessories.



Warning

The device is not intended for use in areas where there is a danger of explosion.



Warning

The device may be repaired only by persons or companies that are authorized to do so.



Warning

The device is not intended for use during Electro-Surgery/Diathermy.



Warning

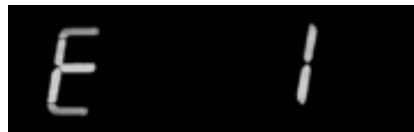
Grounding reliability can only be achieved if the device is connected to an equivalent power cord marked „hospital grade“ or „hospital only“.

Faults

The air-tightness of the air-pouch system is checked regularly. If a leak is detected, the red warning indicator shows alarm. When the leak is removed the red warning indicator disappears and the measurement is continued. If the leak has not been removed after one minute, in addition to the alarm display a chirp sound is emitted. To reset the alarm the monitor must be switched off and on again. The chirp sound stops after one minute, unless the monitor has been switched off before, and the digital display disappears. The warning indicator continues to flash.



If a pressure limit is exceeded during probe filling the filling process is interrupted, the digital display shows 'E1' and the chirp sound is emitted. This can happen if the air-pouch resists unfolding or if the tube is clamped. Switching off and on the monitor resets the system.



If the digital display shows 'E2' or 'E3' during operation an internal fault has been detected. Contact the service in this case.



Warning

The unit cannot be repaired by the user.

Monitor operation



After placement of probe the tube connector is inserted into the monitor socket and fastened by a slight clockwise turn. The soft material of the connector guarantees airtightness.



Pressure measurements are started by switching on the monitor. No manual zero adjustment or calibration is required.



On the digital display the mean pressure is shown in mmHg.

During the first ten minutes after switching on the pulse amplitude (i.e. systolic pressure minus diastolic pressure) is additionally displayed marked by an 'A'.

During this time the mean pressure is displayed for three seconds, then the amplitude is displayed for one second.



Cleaning

After removal of the power cord the unit can be wiped off with a damp rag using a common disinfectant. No liquid whatsoever must be introduced into the catheter or into the connector of the monitor.



Warning

Unplug the power cord prior to cleaning.



Warning

No fluid should be allowed to enter the probe connector.



Warning

In case of unintentional wetting of the device, the power cord is to be disconnected immediately.

Connections

Connection of a Patient Monitor

To connect a patient monitor the connecting cable is inserted into the socket of the IAP-Monitor and connected to the pressure transducer input of the patient monitor. Connect probe to the IAP-Monitor. Switch on the Brain-Pressure Monitor. Wait for the digital display of the mean ICP. The pulsatile signal is displayed now on the monitor screen.

Zero Adjustment of the Patient Monitor

Disconnect the catheter from the IAP-Monitor. Leave the IAP-Monitor and the patient monitor switched on. Zero patient monitor using the zero button. Reconnect the probe. Switch off the IAP-Monitor. Switch it on again. Observe the display of the mean ICP on the IAP-Monitor and the pulsatile signal on the patient monitor.



Connection of a Strip-Chart Recorder

To connect a strip-chart recorder with voltage input the appropriate cable is connected with the socket at the rear panel of the monitor and the input socket of the recorder.

Connection of a Computer

The RS 232 C interface permits communication with any computer.

Connection of a CPP-Monitor

Connect the IAP-Monitor to the RS 232 IAP socket of the CPP-Monitor.

Indication and Method

The IAP-Monitor and the catheters are intended for the monitoring of intraabdominal pressure in the stomach.

The air-pouch system consists of a hollow body connected to a pressure transducer by tubing. The pressure transducer, the electronic hardware, and the device for filling the air-pouch are integrated in the IAP-Monitor.

For intraabdominal pressure measurements the air-pouch is placed in the stomach of the patient. The intraabdominal pressure is transmitted across the thin pouch wall to the air volume in the pouch and transformed into an electric signal by the pressure transducer.

On the digital display the mean pressure is shown. At the monitor output both the mean pressure and the pulsatile signal are available.

Once every hour the IAP-Monitor opens the pressure transducer to atmospheric pressure for zero adjustment. The air-pouch is then filled with the exact air volume required for accurate pressure transmission.

Technical specifications

REF	IAP 32.1
Measurement range	-50 to +100 mmHg
Operating voltage	230 V~, 50/60 Hz or 115 V~, 50/60 Hz
Current requirement	0,1 A at 230 V~ 0,2 A at 115 V~
Fuses	125 mA T at 230 V~ 250 mA T at 115 V~
Voltage output	1V/50 mmHg at 1 k Ω
Pressure monitor output	5 μ V/mmHg/V
RS 232 C interface	9600 Bd (other baud rates upon request)
Accuracy class	2
Safety class	I / BF
Weight	3 kg
In accordance with standards	IEC 60601-1 IEC 60601-1-2

1.9.2003 AS/az

EG-Konformitätserklärung
Declaration of Conformity

Das Produkt

IAP-Monitor HDM IAP 32.1

entspricht den grundlegenden Anforderungen gemäß Anhang I der Richtlinie 93/42/EWG. Es ist als Klasse IIa klassifiziert.

Das Qualitätsmanagementsystem entspricht den Forderungen der Norm ISO 13485:2001 gemäß Zertifikat Nr. 18737 der DQS, benannte Stelle Nr. 0297.

The Product

IAP-Monitor IAP 32.1

is in accordance with the requirements of Annex I of the Manual Devices Directive 93/42/EEC. It is classified as class IIa.

The Quality Management System is in accordance with the requirements of the standard ISO 13485:2001 according to certificate no. 18737 of DQS, Notified Body No. 0297.

Spiegelberg (GmbH & Co.) KG

Dr. A. Spiegelberg

Accessories

Description	Order number
CPP-Monitor	CPP 21.x
IAP-Catheter	IAP 32.1.11
Interconnect Cable for Spiegelberg CPP-Monitor 21.x	KBL 21.005.00
Monitor Cables	
Bruker VM800/900	KBL 13.014.00
Corometrix	KBL 13.020.00
Datex-Cardiacap	KBL 13.007.00
Dräger VM 300	KBL 13.001.00
Hellige 4. Generation up	KBL 13.003.00
Hellige 3. Generation	KBL 13.019.00
Hewlett-Packard	KBL 13.004.00
Horizon	KBL 13.015.00
Kontron	KBL 13.018.00
Marquette	KBL 13.005.00
Marquette 7010	KBL 13.005.01
Nihon-Kohden	KBL 13.008.00
Nihon-Kohden BMS 8300	KBL 13.008.01
Philips CM130	KBL 13.011.00
Propaque/Mennen	KBL 13.009.00
Schiller CM-8	KBL 13.010.00
Siemens-Sirecust	KBL 13.002.00
Space-Labs	KBL 13.006.00
S&W, Danica	KBL 13.013.00
Recorder Cables for Recorders with Voltage Input	
BNC-Plug	KBL 13.030.00
Banana Plug 4 mm	KBL 13.031.00
Computer Cable RS 232 9-pin	KBL 13.033.00