SBMEDIC

MANUAL

for

ALGOMETER TYPE II

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SBMEDIC Electronics

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CHAPTER 1. INTRODUCTION

1.1 GENERAL DESCRIPTION.

Algometer type II is a battery operated, hand-held device, which resembles a pistol. It is used to determine the sensitivity to pain and function of non myelinized C-fibers. It is also a good tool to diagnose such as fibromyalgia in humans. The end of the "gun barrel" is a small round surface, called the "probe". By holding the Algometer in your hand, and with the probe apply pressure to a predetermined area of a patient, such as an axis, and by increasing the pressure at a predetermined rate, called the "slope", you can determine the patient's pain threshold to pressure.

The "probe" area can be changed. By default, there are three different "probes". The most common is 1 cm², but also 0.5 cm² and 2 cm² can be used.

Even the "slope" can be changed. The five different settings, which can be used are 10, 20, 30, 40 and 50 kPa / s. To use the "slope" practical, in the unit's display there is a kind of thermometer scale. In order to exercise the right "slope", the investigator should strive to hold a plus-sign (+) as close to the middle of the thermometer scale as possible.

The settings of the selected "probe" and "slope" are done in a submenu, using the push buttons that are located to the left of the display. The settings can be read from the display.

The measurement of a patient requires cooperation from the patient to determine the pain threshold. The patient notifies the investigator when the pain threshold has been reached, and the investigator as soon as possible thereafter relieves the pressure, and the highest value will be locked in the display. This value can then be stored in an internal memory, that after the investigation can be recalled.

1.2 FEATURES:

• Simultaneous display of: Actual pressure.

Maximum registered pressure.

Slope (desired rate of change of pressure on a bar graph).

Adjusted slope.

Adjusted probe area.

- Automatic registration of maximum pressure.
- Manual storing of a total of 100 registrations of maximum registered pressure values, with adjusted probe and slope in the memory, numbered in consecutive order from 1 100.
- Control of memory content via pushbuttons on the Algometer.
- Erase of memory content via pushbuttons on the Algometer.
- Battery independent data memory.
- Possibility to use probes with 3 different areas.
- Manual adjustment of probe area between 0.5 cm²-2.0 cm² in 3 steps.
- Automatic adjustment of pressure value depending on probe area.
- Manual adjustment of slope between 10 kPa/s 50 kPa/s in 5 steps.
- Automatic adjustment of slope depending on probe area.
- Automatic indication of weak batteries.
- Buzzer indication at power on and off, and when using the patient operated switch.
- Warning signal and warning text on the display when risk for overload.
- Automatic power shut off when display is in normal mode, approximately 2 minutes after the last measurements have been taken and the Algometer is not in use.
- Manual power shut off of the Algometer.

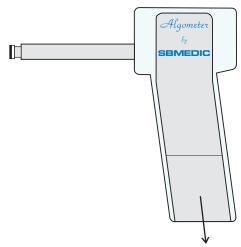
CHAPTER 2. INSTALLATION

2.1 UNPACKING.

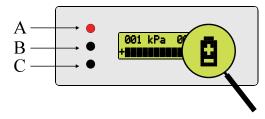
- a/ First inspect the package for external signs of transport damage. If any sign of damage is noted, please notify us as soon as possible.
- **b**/ Be careful when unpacking. The Algometer is a very delicate instrument.
- c/ Save all packaging material!. It has been specially designed for this instrument, and it will be needed if the instrument is to be shipped in the future.
- **d**/ When unpacked, check the Algometer for any external signs of transport damage. If damage is noticed, notify us as soon as possible.

2.2 INSTALLATION OF BATTERY PACK

a/Put the Algometer on a table with the battery compartment visible



- **b**/ Push the battery compartment cover downwards.
- c/ Connect the cable from the battery pack to the connector in the compartment. It can only be connected one way. Use no force. **Be sure that the cable from the battery pack is not getting jammed when the battery compartment is closed.** Next check the display. If the instrument is operational, the display will first show a value of approximately 300 kPa and after 10 seconds will return to normal conditions. If nothing happens push the **A** button. If the values have not appeared, please contact us
- **d**/ When the batteries are getting bad a battery symbol will be shown to the right on the bottom line of the display.



Then it is time to change batteries.

If the algometer after replacement of battery shows peculiar signs in the display, it could be necessary to uncharge the electronic by removing the battery. Push thereafter all pushbuttons simultaneously repeated times. Wait approx. 2 min. Connect the battery. The display will thereafter work as normal.

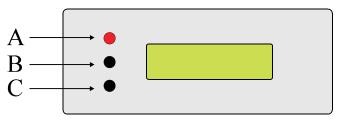
2.3 DESCRIPTION OF BUTTONS.

On top of the Algometer is a display, and three pushbuttons. One is red (A), and the other two are black. (B,C).

The red one is only used for: 1

- 1. Switching the Algometer on.
- 2. Resetting the display.
- 3. Storing adjustments.

The black pushbuttons are used one at a time or in combination.

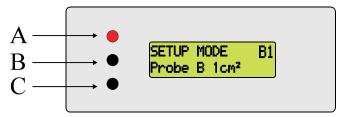


To switch the Algometer on:

push A.

A/ Adjustment of probe size:

push **B**+**C** simultaneously.



The display will show the text "SETUP MODE" on the upper line, and on the lower line "PROBE B 1 cm 2 . With **C** button the size can be chosen between 0.5 cm 2 and 2 cm 2 .

When the desired size has been chosen push A.

The adjusted value is indicated on the upper line second to the right according to the following:

 0.5 cm^2 :

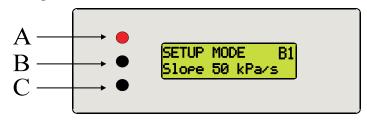
1.0 cm²:

 2.0 cm^2 :

B/ Adjustment of slope:

Push **B**+**C** simultaneously.

The text "SETUP NODE" will be shown on the upper line, and on the lower line "PROBE B 1 cm 2 . Thereafter push **B.**



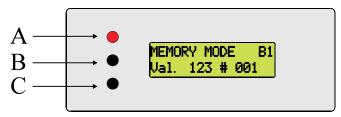
On the lower line the text "SLOPE 10 KPR/5 will be shown. Using **C** the desired slope between 10 kPa/s and 50 kPa/s can be chosen in 5 intervals. When the desired value is achieved press **A**. The adjusted value is indicated on the upper line to the right according to the following:

10 kPa/s: 1 20 kPa/s: 2 30 kPa/s: 3 40 kPa/s: 4 50 kPa/s: 5

To be able to perform measurements with the adjusted "slope" there is a bar graph on the lower line. The bar graph will be further described in chapter 3.2

C/ To display stored values:

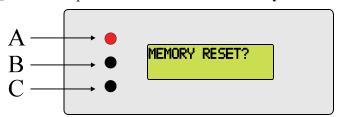
push **B**+**C** simultaneously twice.



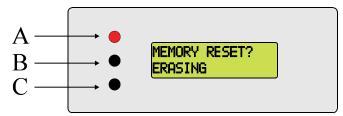
The text "NENORY NODE" is shown on the upper line. At the same time the text "Val. XXX #001 will be shown on the lower line, which means Value XXX in memory position 001. By pushing **C** the memory positions will be stepped forward to the last stored position. By pushing **B** the memory positions will be stepped backwards. If it is impossible to step forward from position no. 1 there is nothing stored in the memory.

D/ Erasing the memory:

push both B+C simultaneously 3 times.



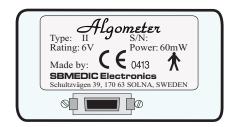
The text "MEMORY RESET?" is shown on the upper line. To erase, push C twice.



The text "ERASING" is shown on the lower line. If no erasing is desired just simply push \mathbf{A} . E/ Power off: push \mathbf{B} at normal display mode.

2.4 OPTION: CONNECTING PATIENT OPERATED SWITCH

a/Locate the rectangular connector at the bottom of the Algometer.

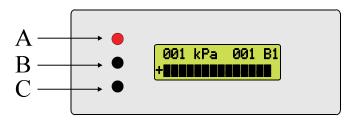


b/ Connect the switch connector. PLEASE NOTE!! The connector can only be used one way. Don't use force while it may damage the connector.

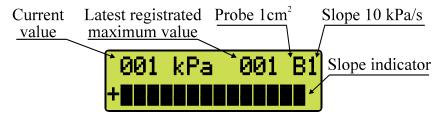
CHAPTER 3. OPERATION.

3.1 FUNCTION CONTROL.

- a/ Switch the Algometer on by pushing A.
- **b**/ Let the instrument stay on for approx. 1 min.
- c/ Thereafter push A again. The display now will show 1-3 units current value, and 1-3 units maximum value.
- **d**/ Adjust the desired probe area and "slope" and whenever applicable change the probe.
- e/ The instrument is now ready to use. If necessarily connect the patient operated switch.
- **f**/ The display thereafter will look like below.

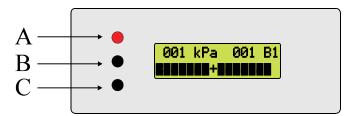


g/Below is a description of the display.



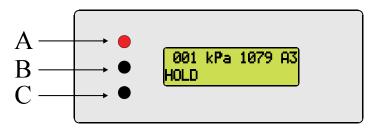
3.2 SLOPE INDICATOR

- a/Before every separate measurements the Algometer must be reset by pushing A.
- **b**/ Establish a threshold by pressing the probe against the tissue. To achieve the adjusted slope, strive for to increase the pressure in such a way that the "+" sign in the bar graph is kept in the middle of the scale like the picture below.



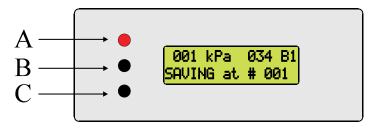
3.3 MEMORY OPERATIONS

a/ If the patient operated switch is used, the patient is instructed to press the button when feeling pain.



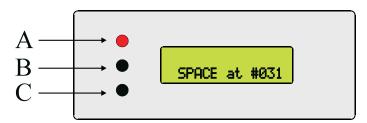
The text "HOLD" will then be shown on the lower line.

The achieved maximum pressure is shown to the right on the upper line. If the value is regarded relevant it can be stored by pushing C.



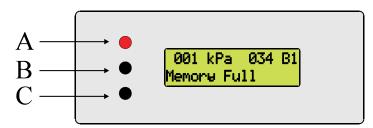
The display will show: "SAL/ING AT # XXX", where CO1 is the memory position where the value is stored (between 1 and 100). If the value is not to be stored just push **A**. The registered maximum value is then erased from the display.

- **b**/ If the patient operated button is not used, the patient is instructed to tell the investigator when he/she is feeling pain. If the investigator at that time reduces the pressure from the achieved value, the maximum value will be locked to the right on the upper line. This value then can be stored as described according to a/ above.
- c/ There is a possibility to separate patients in the memory. By pressing C continuously for about 2 sec. a "space" will be stored on a location in the memory, and new measurements can be made.

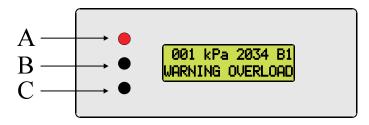


The display then will show: "SPACE AT #XXX"

d/ When the memory is full the text "MEMORY FULL" will be shown on the lower line. This means 100 values has been used.



e/ When overloading the Algometer (more than 2000 kPa with probe 1 cm²) a buzzer will sound and the text "UARNING OVERLOAD" will be shown on the display. The warning text is erased by pushing **A**.



 $\mbox{f}/$ After the investigation has been finished the stored values can be recalled according to chapter 2.3 C/

CHAPTER 4. MAINTENANCE

4.1 DAILY MAINTENANCE

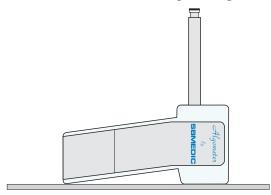
The Algometer normally needs no maintenance. If the instrument needs cleaning it can be done with a mild soap solution. Just wipe the device with a wet cloth. Do not submerge the device in the solution, it will damage the circuitry. Wipe the end of the probe with a cloth of alcohol after each patient Be careful not to drop the Algometer on the floor, this might damage the built-in pressure transducer and make the instrument unusable.

To examine and test:

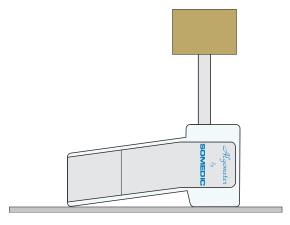
- a/ Open the battery compartment cover.
- **b**/ Remove the battery pack
- c/ Don't try to open the instrument.
- **d**/ If excess humidity is suspected, place the instrument in a warm place, but not over 50° C, for at least 2 days.
- e/ Replace the battery pack according to chapter 2.2
- f/ Perform a function control according to chapter 3.1.
- g/ If the instrument in spite of this doesn't operate, please contact us.

4.2 CALIBRATION

- a/ Adjust the probe area to 1 cm² according to chapter 2.3 A/
- **b**/ Place the Algometer on a flat surface according to the picture below.



- c/ Push A and observe the display. It should show approx. 0-2 kPa. If not push A again.
- **d**/ Place the enclosed brass weight carefully at the probe according to the picture below.



e/ Read the value to the left in the display. It should read 100 kPa \pm 2% . If this is not the case, repeat the calibration from the beginning. If it still doesn't read 100 kPa \pm 2% please contact us.

4.3 CALIBRATION PROTOCOL FOR ALGOMETER TYPE II S/N.....

Calibration according to 4.2 should be done at least every 10th day the instrument has been in use. The table below is for your own purpose.

Date	Reference (kPA)	Display (kPA)	Notes	Sign.

CHAPTER 5. TECHNICAL DATA.

5.1 DATA SHEET

PHYSICAL.

Length :161 mm Width :170 mm Depth :30 mm

Weight :460 g. including batteries

FUNCTIONAL

Range probe 0.5 cm^2 :0-1000 kPa probe 1 cm² :0-2000 kPa probe 2 cm² :0-4000 kPa

Accuracy :±2% of reading +2 Maximum pressure :see range above Slope :10-50 kPa (±10%)

Environmental temperature :+15°C - +30°C (non condensing)

ELECTRICAL

Voltage :6V =
Current consumption power on :<10 mA
power off :<100 uA

Continuously operating time :approx. 100 hours
Normal operating time (approx. 1h/day) :approx. 5 months

Battery pack, 1 pcs. :SBMEDIC part.no. 560010

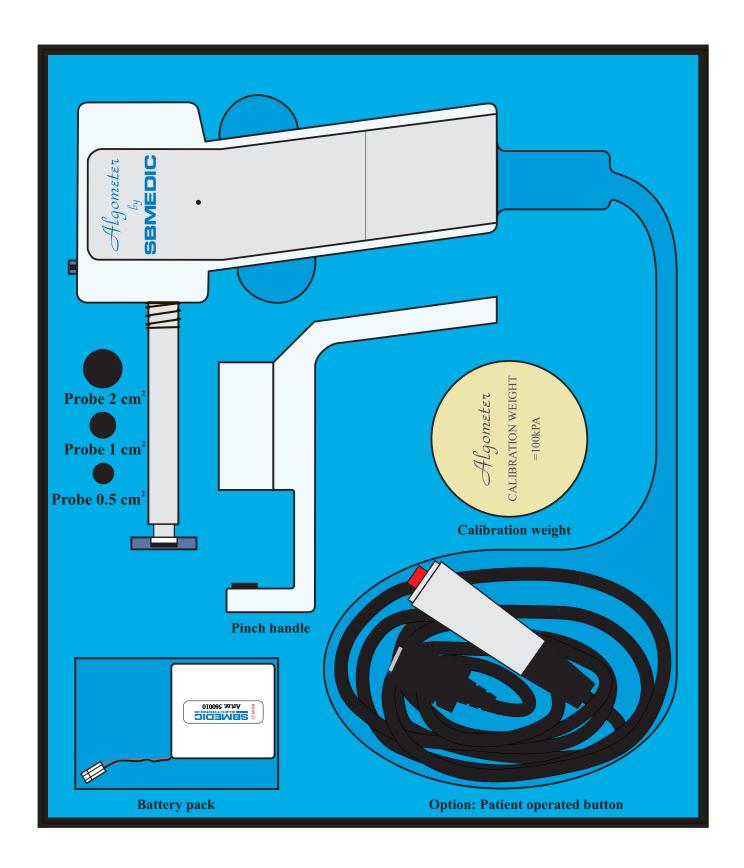
INCLUDED ACCESSORIES

Case :1 pcs. 0.5 cm^2 Probe :1 pcs. 1 cm^2 :1 pcs. " 2 cm^2 :1 pcs. Battery pack :1 pcs. Pinch handle :1 pcs. Calibration weight 100kPa :1 pcs.

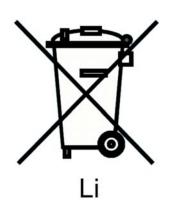
OPTIONAL ACCESSORIES

Patient operated button, not for sale in the EEC-market. Probe 4 cm²

5.2 VIEW OF DEVICE AND PARTS IN CASE



CHAPTER 6. INFORMATION ON RECYCLING OF ELECTRICAL EQUIPMENT



NOTE! DO NOT DISCARD THIS PRODUCT IN THE TRASH!

Used electrical and electronic equipment must be treated in accordance with applicable environmental laws and recycling regulations.

6.1 EU-countries

Under current EU rules, all have the opportunity to submit electrical equipment for recycling. This equipment contains batteries that must first be removed and handled in accordance with local environmental regulations.

By handling the product in accordance with these regulations, it will be disposed of and recycled in the appropriate manner, thus preventing potential adverse health and environmental effects.

If the product should be discarded:

Contact SBMEDIC Electronics or its distributors for information on how to go about returning the product. It may be a charge for transportation and recycling. Small products (in the case of a few) may be returned to local recycling facilities.

6.2 Countries outside the EU

Please contact your local authorities and ask for the correct method of disposal.