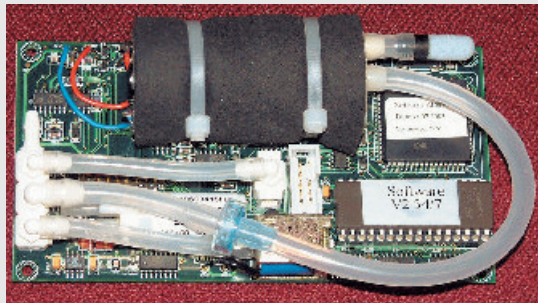


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Non Invasive Blood Pressure OEM board

NIBP2000



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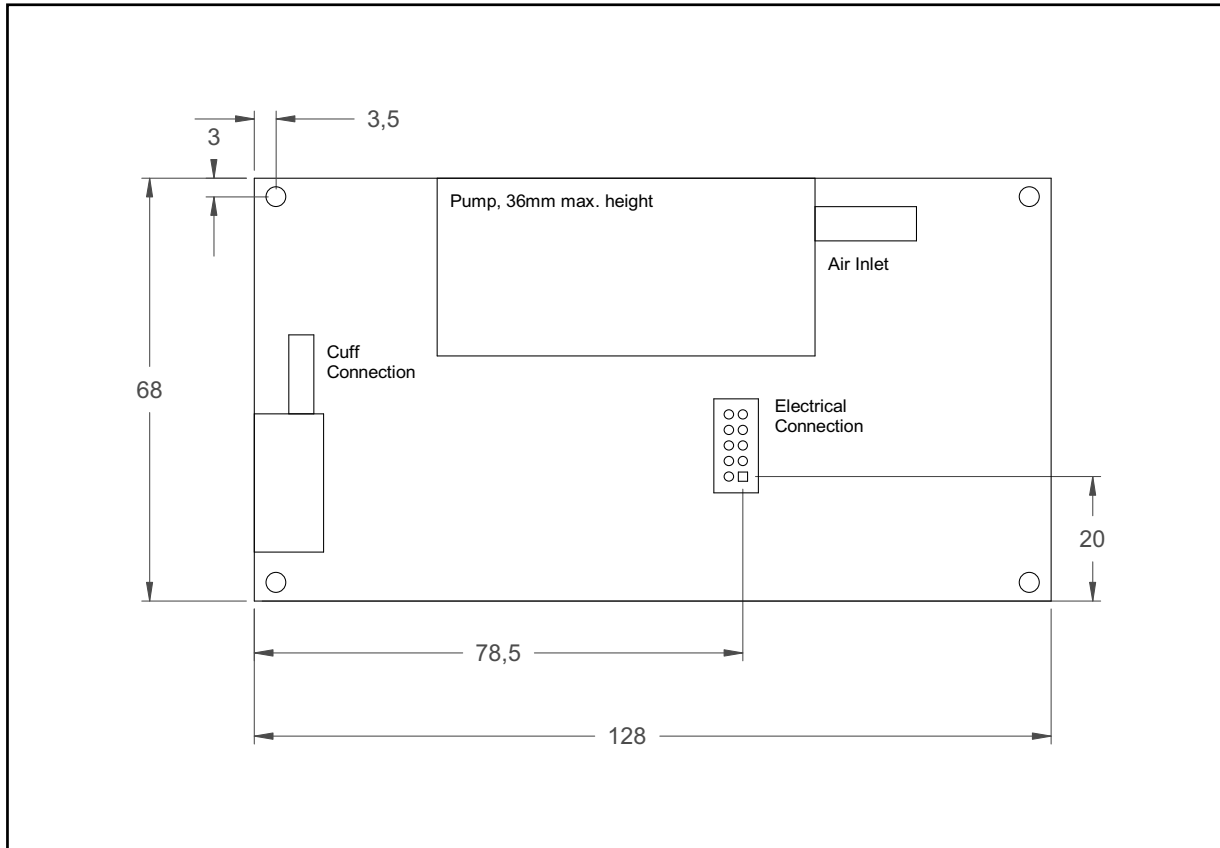
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Mechanical dimensions of the module



Mechanical drawing of top view of the PCB

Overview:

The scope of this document is the description and specification of Medlab's noninvasive blood pressure board NIBP2000. It should help anybody who is familiar with programming and basic electronics both to select the proper hardware and software version for his application as well as to help him integrate the board into his own electro-medical system.

The NIBP2000 uses the oscillometric method for measuring a person's systolic, mean and diastolic pressure. Also the pulse rate is calculated. There is a plausibility check to recognize and suppress artifacts during measurement. If there is too much motion during measurement, error messages are generated instead of pressure values after the measurement ends. The user is then free to determine if he wants to start another cycle. During inflation and deflation of the cuff, the current cuff pressure is transmitted 5 times per second.

The module has a selectable internal "cycling" mode, that automatically starts a measurement after a given time. The period of these cycles are adjustable by commands sent by the user. It is of course also possible to start the measurements directly ("manually") by transmitting another command.

Technical Data (Specifications):

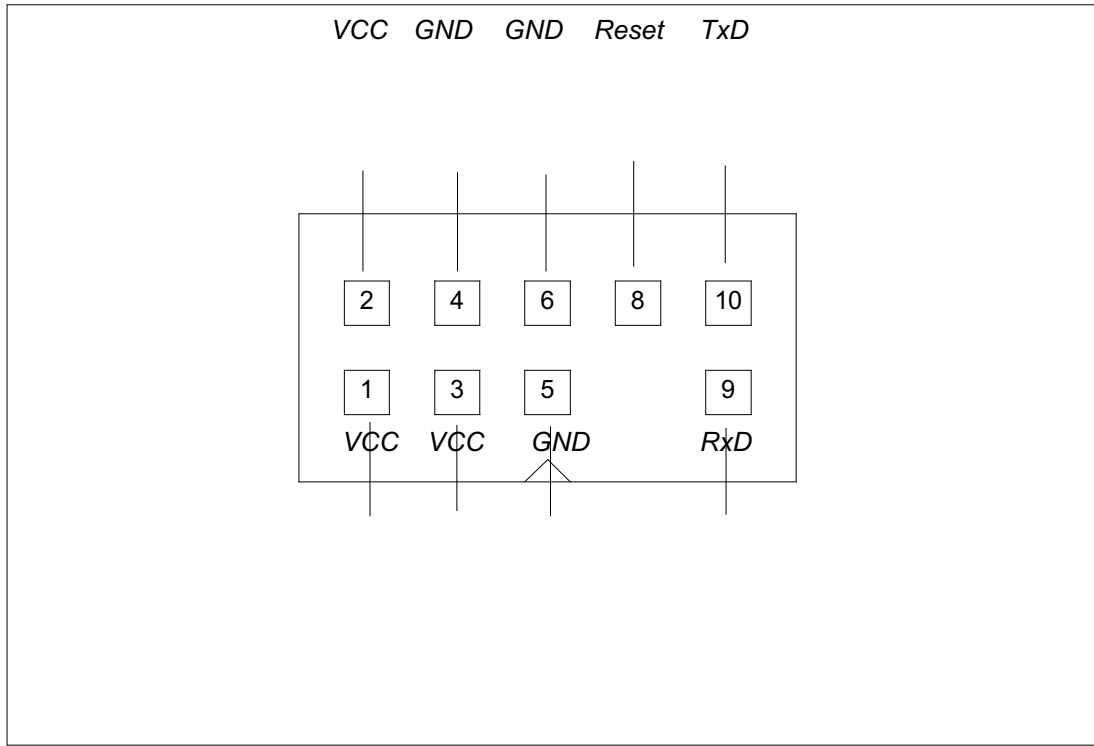
| | |
|----------------------------------|---|
| Mechanical data: | see also board drawing on previous page 4 layer PCB, thickness 1.5 mm 68 x 128 x 34 mm (width x length x max. height) |
| Attachment: | four M2.5 screws in the corners of the PCB |
| Weight: | 170 g |
| Operating voltage: | 7 Volt, +- 15% , 50...750 mA depending on state or 12 Volt, +- 15%, 50...450 mA |
| Power consumption: | < 3.50W while measuring < 0.35W during standby |
| Measurement ranges for adults: | SYS : 25 - 280 mmHg DIA : 10 - 220 mmHg MAP: 15 - 260 mmHg |
| Measurement ranges for neonates: | SYS : 20 - 155 mmHg DIA : 5 - 110 mmHg MAP: 10 - 130 mmHg |
| Leakage rate: | < 3 mmHg / minute |
| Overpressure limits: | 280 mmHg adult mode and 150 mmHg neonatal mode |
| Interface: | asynchronous, serial interface, 4800 baud, 8 data bits, 1 stop bit, no parity bit, no handshake, CMOS (0-5V) level, bidirectional |
| Protocol: | ASCII transmission, 5 frames per second during measurement. Result transmitted in a status string after host request only. |

Explanation of Terms

| | |
|------------|--|
| ASCII | Character Standard |
| Frames | Character strings which are exchanged as commands or messages between the computers. |
| Host | The computer which controls the measuring unit. Interface to the user. |
| Slave | The microcontroller on the NIBP board |
| Cycle Mode | The measuring unit starts automatic readings. The user can select the intervals. This mode has to be set by the host computer. |

Hardware Interfaces:

Pin Connection



Interface Connector

Physical Interface

Connection to the board is done via serial, asynchronous communication with a baudrate of 4800 Baud. The interface lines operate on CMOS voltage levels (0 and 5 volts). For using real RS232 voltage levels, there is a little interface available that accepts CMOS levels on the input and can be connected to a PC's serial interface. There is a special evaluation software for PC. The connection in the customer's final system would normally be done using TTL levels, which saves parts and costs on the host side of the data stream. A bidirectional connection is necessary, since parameters like cycle rate, start of measurement also have to be transmitted to the module.

Always connect all VCC and GND pins

!

Software Interface

General Conventions

All commands and messages begin with a Start of Text character, ASCII 02, and close with an End of Text character, ASCII 03. In this document the designation for Start of Text is: <STX> and End of Text <ETX>. The frames from slave to host are terminated by a carriage return, CR=ASCII 13.

Checksum

All checksums are generated by a modulo 256 addition of all the characters in the corresponding frame, with the STX and ETX characters not included.

Protocol Direction from Host to Board

General

The measuring unit is controlled by the host via command frames. Should the slave receive unexpected commands these will be ignored. In addition to this, false or unknown commands as well as violations of the time-out criteria will abort the current session in progress. All data and commands are verified via checksum.

Commands

A command consists of an 8 ASCII character frame. This includes a Start of Text and an End of Text character as well as 2 characters for the checksum.

Frame Schema:

| Char 1 | Char 2 | Char 3 | Char 4 | Char 5 | Char 6 | Char 7 | Char 8 |
|--------|--------|--------|--------|--------|--------|--------|--------|
| STX | c0 | c1 | `,` | `,` | x0 | x1 | ETX |

STX = "Start of Text" (0x02)

ETX = "End of Text" (0x03)

- c0 and c1 = command code (2 ASCII characters. Range of values 0 - 99)
- `,` = 2 semicolons (0x3B)
- x0 and x1 = checksum (2 ASCII characters)

Example (all characters in inverted commas) for command code 01:

| | | | | | | | |
|-------|------|------|------|------|------|------|-------|
| <STX> | "0" | "1" | `,` | `,` | "D" | "7" | <ETX> |
| 0x02 | 0x30 | 0x32 | 0x3B | 0x3B | 0x44 | 0x38 | 0x03 |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

Command Codes

| Command Code | Checksum | Function |
|--------------|----------|---|
| 00 | D6 | Reserve |
| 01 | D7 | Start measuring |
| 02 | D8 | Reserve |
| 03 | D9 | Select manual measuring mode |
| 04 | DA | Cycle mode 1 minute |
| 05 | DB | 2 minutes |
| 06 | DC | 3 minutes |
| 07 | DD | 4 minutes |
| 08 | DE | 5 minutes |
| 09 | DF | 10 minutes |
| 10 | D7 | 15 minutes |
| 11 | D8 | 30 minutes |
| 12 | D9 | 60 minutes |
| 13 | DA | 90 minutes |
| 14 | DB | Select manometer mode |
| 15 | DC | Start reboot |
| 17 | DE | Start leakage test |
| 18 | DF | Read status from slave |
| 19 | E0 | Set start pressure to 100mmHg (only neonatal) |
| 20 | D8 | Set start pressure to 120mmHg (only neonatal) |
| 21 | D9 | Set start pressure to 140mmHg |
| 22 | DA | Set start pressure to 160mmHg (only adult) |
| 23 | DB | Set start pressure to 180mmHg (only adult) |
| 24 | DC | Select adult measuring mode |
| 25 | DD | Select neonatal measuring mode |
| 26 | DE | Reserve |

Remarks:

- Commands 19, 20, 22, 23 are ignored if not appearing in the corresponding measuring mode (adult/neonatal).
- During measuring or leakage test or during the manometer mode all commands are ignored. Exception: Abort command ASCII X (see Abort Command)
- In order for cycle mode to start working, one successful measurement has to be started manually using command 03.
- Should the measuring unit receive command code 15, then a complete initialisation is carried out. Subsequently the measuring unit assumes the mode as described in the paragraph describing the "Abort" Command.

Abort Command

Regardless of the operational mode, the measurement can be terminated by pressing the „X“ (character). The measuring unit immediately reverts to standby mode. The pneumatic system discharges.

Example: <STX> „X“ <ETX>

Sending „X“ alone also is sufficient

Timing and Error Correction

During all operational modes the excess pressure detection and system error detection are activated. In the following cases the measuring unit reacts as under the item „abort command“

Reception of:

- Mutilated frames
- Erroneous checksum
- Unknown command
- Violation of time-out criterion.
- The period between two characters of a receive frame exceeds 10ms.

In the following cases a hardware reset or a reboot command is necessary :

All errors in autotest and manometer mode, in leakage test and after system errors.

! ■

After power on, always first transmit a "read status from slave" (18) command

Direction from Board to Host

General Conventions

There are three types of frames which, in different states, are generated by the slave.

- Cuff pressure transmission (5 times per second)
- End of cuff pressure transmission
- Status transmission

Depending on the operational status the status frame shows the version number or the error code in message code (see next paragraph).

Initialisation Message

On power up, the slave always generates a status frame within a few seconds. Immediately thereafter the host can initialize the NIBP board.

Frame example (boot ok):

<STX>;S0;A0;C00;Mxx;P-----;R---;T-----;;AF<ETX>CR

Remark :

Here Mxx represents the version information and not the error messages as in other operational modes. Example: M10 then means Version V 1.0.

Cuff Pressure Transmission

This frame is permanently transmitted five times per second during an ongoing measuring, e.g. when the cuff is pressurized.

Basic frame structure (real ASCII in inverted commas):

<STX>, d0, d1, d2, "C", c0, "S", a0, <ETX>, <CR>

Explanation of bytes:

STX = Start of Text (0x02)

ETX = End of Text (0x03)

CR = carriage return (0x0D)

d0, d1, d2 = 3 ASCII digits which represent the current cuff pressure in mmHg. Leading zeros are transmitted.

The **Caution** bit "c0" is used during a measurement to signal potential problems:

c0 = "1" module recognized the neonatal cuff in adult mode

c0 = "2" module recognized the adult cuff in neonatal mode

c0 = „0“ all other cases

The **Status** bit "a0" displays the current operational mode:

a0 = „3“ measuring

a0 = „4“ manometer operation

a0 = „7“ leakage test

Example:

<STX>035C0S3<ETX><CR>

Cuff pressure: 35mmHg

C0: normal mode, no problems detected

S3: normal measurement in process

End of Cuff Pressure Transmission

This message is generated after a measurement has been completed. The frame is transmitted if measurement completed successfully and also if there are errors. The modules then goes into idle mode, the pump is stopped and all valves are opened.

Basic frame structure (real ASCII in inverted commas):

<STX>, "9", "9", "9" <ETX>, <CR>

After this frame, only status frames are sent on host request, until the next measurement is started, either automatically (cycle mode) or manually.

Status Transmission

After booting, the leakage test and a measurement, results can be read by requesting a status frame by sending command code 18.

The status frame is transmitted after a host request only.

Frame structure (real ASCII in inverted commas, all lines consecutive)

<STX>"S",a0,";A",b0,";C",c0,c1,";M",d0,d1,";P",e0,e1,e2,e3,e4,e5,e6,e7,e8,";R",f0,f1,f2,";T",g0,g1,g2,g3,";";h0,h1,<ETX><CR>

a0 = ASCII digit

a0 = "0" auto - test in progress (only during booting)

a0 = "1" waiting for commands (standby), cycle counter stopped

a0 = "2" error (evaluation of error bits), cycle counter stopped

a0 = "3" measuring in progress

a0 = "4" manometer mode

a0 = "5" initialization (reboot) in progress

a0 = "7" leakage test

a0 = "8" reserved

b0 = ASCII digit for the operational mode

b0 = "0" adult mode

b0 = "1" neonatal mode

c0-c1 = 2 ASCII digits for indication of the selected cycle

c0-c1 = "00" no cycle selected

c0-c1 = "01" one minute cycle selected
 c0-c1 = "02" two minutes cycle selected
 c0-c1 = "03" three minutes cycle selected
 c0-c1 = "04" four minutes cycle selected
 c0-c1 = "05" five minutes cycle selected
 c0-c1 = "10" ten minutes cycle selected
 c0-c1 = "15" fifteen minutes cycle selected
 c0-c1 = "30" thirty minutes cycle selected
 c0-c1 = "60" sixty minutes cycle selected
 c0-c1 = "90" ninety minutes cycle selected

d0-d1 = 2 ASCII digits for messages (after boot version number)

d0-d1 = "00" uninterrupted operation
 d0-d1 = "02" autotest failed (during initialisation)
 d0-d1 = "03" uninterrupted operation
 d0-d1 = "06" cuff fitted too loosely or not connected
 d0-d1 = "07" leakage (including sudden occurrence)
 d0-d1 = "08" faulty slow loss of pressure
 d0-d1 = "09" pulse not recognisable (cuff incorrectly fitted)
 d0-d1 = "10" measurement range exceeded (physiological)
 d0-d1 = "11" too strong movement artefact
 d0-d1 = "12" excess pressure (in accordance with IEC limits)
 d0-d1 = "13" pulse signal saturated (too large)
 d0-d1 = "14" leakage determined during leakage test
 d0-d1 = "15" system error in measuring unit

e0-e2 = 3 ASCII digits for systolic pressure in mmHg

invalid values are shown by dashes

e3-e5 = 3 ASCII digits for mean arterial (MAP) pressure in mmHg

invalid values are shown by dashes

e6-e8 = 3 ASCII digits for diastolic pressure in mmHg

invalid values are shown by dashes

f0-f2 = 3 ASCII digits for the pulse rate in min⁻¹

g0-g3= 4 ASCII characters for the period in seconds until the next measurement

Only in cycle mode. If cycle mode is not active, blanks are displayed

h0-h1 = 2 ASCII digits for the checksum

Example:

<STX>S1;A0;C03;M00;P---120080100;R075;T0005;;D2<ETX><CR>

After power on, always first transmit a "read status from slave" (18) command

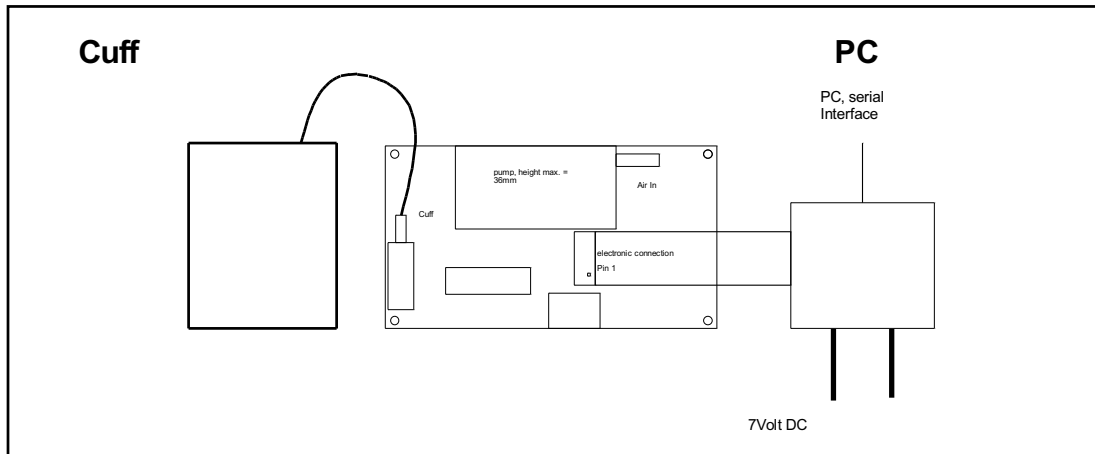


Plug and Play Testkits

To enable evaluation of the board, there is a testkit available:

The NIBP board, with a PC software for evaluation of the module.

Also included is a complete set of cables and a small serial adapter, together with one cuff, for adults, normal size.



Connection of the board, the cuff and the power supply to the PC adapter

Usage

- Install the software on your computer by copying all files into one directory
- Connect the serial cable to a serial port on your computer
- Connect the serial cable to the small adapter PCB
- Connect the the small adapter PCB to the NIBP board with the ten pin cable
- connect the cuff to the board
- connect the DC cables to a lab power supply that can deliver approx. 1A
- connect the DC cables to the adapter PCB
- turn on the power supply
- start the program on the PC and select the correct serial port in the menu
- press the "Read State" button, then "Start"

Regulatory Considerations

The device that has been described in this document is not a final medical product. The customer has to undertake the procedure of CE-marking the final product that he builds using the blood pressure module.

Second, the device is not FDA approved, which is also not possible for a module. Only final products that will be sold in the USA have to and can undertake the process of a 510K registration.

Transport and Storage Conditions

Temperature range: -40°C...+70°C
Relative humidity: 10...95%, non condensing
Atmospheric pressure: 500...1060 mbar

Compliance with Harmonized Standards

EN 60601-1:1990 + A1:1993 + A2:1995
EN 60601-2-30:2000
EN 1060-1:1995
EN 1060-3:1997
EN 1060-4:2004

Ordering Information:

12 Volt version: NIBP2000-12

7 Volt version: NIBP2000-07