medlab
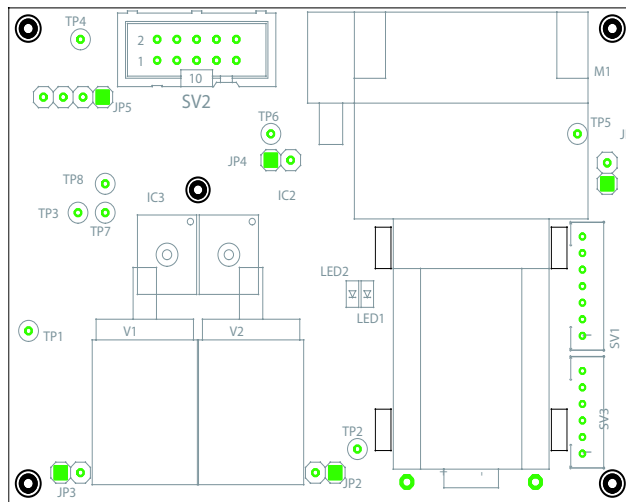
Hospital Grade Miniature Non-Invasive Blood Pressure OEM Module for Professional Applications
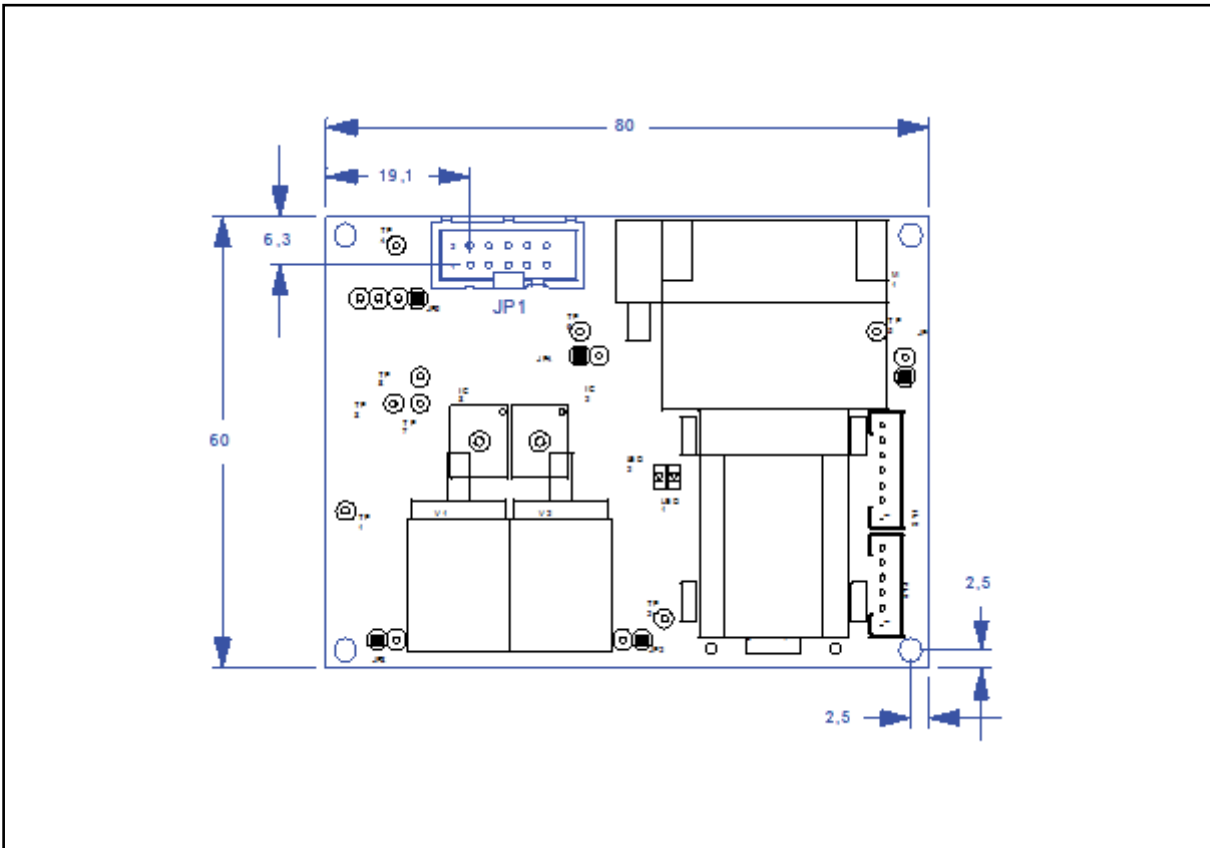
NIBScan

Technical Manual

Version 1.8

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Contents:

Mechanical Dimensions

Mechanical drawing of the PCB (top view)

Overview:

The scope of this document is the description and specification of Medlab's NIB*Scan* noninvasive blood pressure board. It should help anybody who is familiar with program-ming 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 electromedical system. The module is software compatible to the NIBP2000 and the MNIBP modules. The NIB*Scan* module replaces the MNIBP modules. It features a new powerdown mo-dus and a better suppression of artefacts. The measuring time of the system (cuff infla-ted time) and the generated noise has been reduced to a minimum.

The NIB*Scan* 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 measu-rement after a given time. The intervals of these cycles are adjustable by commands sent by the user. It is also possible to start the measurements directly ("manually") by transmitting the "start" command.
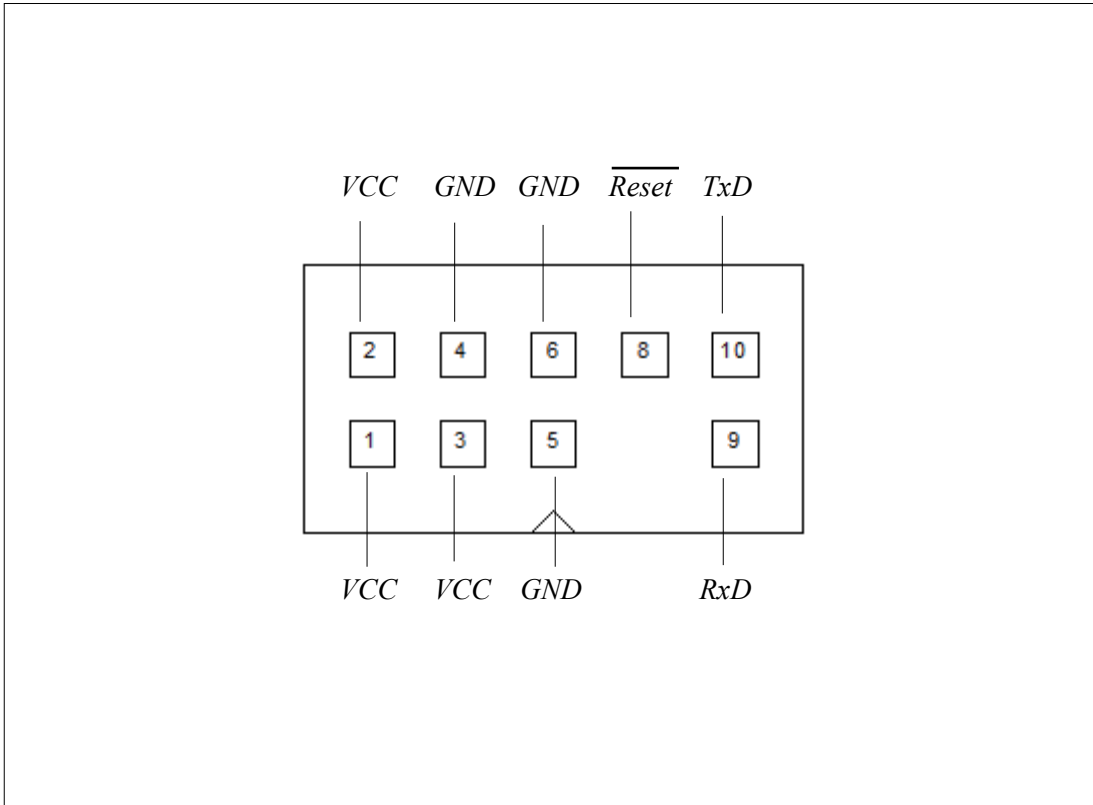
Technical Data (Specifications):

Mechanical data:	see also board drawing on previous page 4 layer PCB, thickness 1.5 mm 80 x 60 x 26 mm (width x length x max. height)
Attachment:	four M3 screws in the corners of the PCB
Weight:	120 g
Operating voltage:	5.5 - 15 Volt DC, 50 ... 750 mA
Power consumption:	< 2.50 W typically while measuring < 0.1 W during standby
Measurement ranges for adults:	SYS : 25 - 280 mmHg DIA : 10 - 220 mmHg MAP: 15 - 260 mmHg
Measurement ranges for neonates:	SYS : 20 - 150 mmHg DIA : 5 - 110 mmHg MAP: 10 - 130 mmHg
Pulse rate:	30 - 230 bpm
Leakage rate:	< 3 mmHg / minute
Overpressure limits:	300 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. (Option: "even" parity bit, other baud rate)
Protocol:	ASCII transmission, 5 frames per second during measurement. Result transmitted in a status string.

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

VCC   GND   GND $\overline{Reset}$ TxD

```
  ┌───┐ ┌───┐ ┌───┐ ┌───┐ ┌───┐
  │ 2 │ │ 4 │ │ 6 │ │ 8 │ │10 │
  └───┘ └───┘ └───┘ └───┘ └───┘
  ┌───┐ ┌───┐ ┌───┐       ┌───┐
  │ 1 │ │ 3 │ │ 5 │       │ 9 │
  └───┘ └───┘ └───┘       └───┘
```

VCC   VCC   GND   RxD

Interface Connector JP1

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 3.3 volts, 5 volts tolerable). For using real RS232 voltage levels, there is an 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 typically be done using TTL (0 / 3.3 V) 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 aso. have to be transmitted to the module. The module can also be reset over the connnector, the reset pin is active low.

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" is <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 they 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. 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        xl        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      0x31      0x3B      0x3B      0x44      0x37      0x03
  1        2         3         4         5         6         7         8
```

Command Codes

Command Code	Checksum	Function
00	D6	Reserved
01	D7	Start measuring
02	D8	Reserved
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	Reserved
16	DD	Start reboot
17	DE	Start leakage test
18	DF	Read status from slave
19	E0	Set start pressure to 100 mmHg (only neonatal)
20	D8	Set start pressure to 120 mmHg (only neonatal)
21	D9	Set start pressure to 140 mmHg
22	DA	Set start pressure to 160 mmHg (only adult)
23	DB	Set start pressure to 180 mmHg (only adult)
24	DC	Select adult measuring mode
25	DD	Select neonatal measuring mode
26	DE	Reserved
27	DF	Reserved
28	E0	Request initial message

Remarks:

- Commands 19, 20, 22, 23 are ignored if they do not appear 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 the cycle mode to start working, one successful measurement has to be started manually using command 01.
- Should the measuring unit receive command code 16, 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 is sufficient also.

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 stated in „Abort Command"
Reception of:

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

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 the 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 send commands to 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 being 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 **C**aution 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 **S**tatus 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: 35 mmHg
C0: normal mode, no problems detected
S3: normal measurement in progress

End of Cuff Pressure Transmission

This message is generated after a measurement has been completed. The frame is transmitted both if measurement completed successfully and if there were errors. The module then goes into idle mode, the pump stops, and all valves are opened.
Basic frame structure (real ASCII in inverted commas):
<STX>, "9", "9", "9" <ETX>, <CR>

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

Status Transmission

After booting, the leakage test, and one 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, except for one transmission after a measurement has been completetd.
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 indicating 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" movement artefact too strong
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 diastolic pressure in mmHg
invalid values are shown by dashes

e6-e8 = 3 ASCII digits for mean arterial (MAP) 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;P120080100;R075;T0005;;D2<ETX><CR>`

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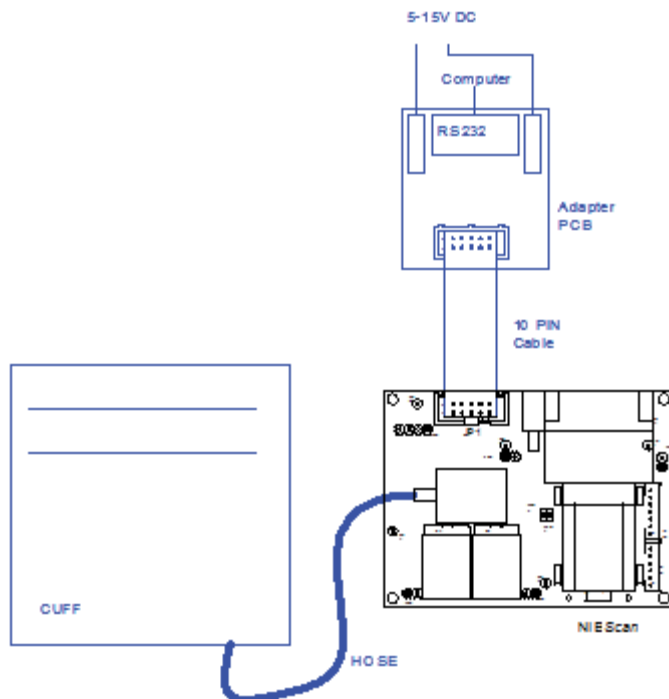

Plug and Play Testkits

There is a testkit available to ease the evaluation of the board:
The NIB*Scan* board, an adapter, all necessary cabling, and a PC software for evalua-
ting the module. The source code of this test software (Visual Basic 6) is available upon
request.
Also included are a hose and a cuff for normal adult arm 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 adapter PCB
- • connect the the small adapter PCB to the NIBP board with the 10 pin cable
- • connect the hose with cuff to the board
- • connect the DC cables to a lab power supply that can deliver approx. 1 A
- • 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

Regulatory Considerations

The device 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.
The NIBScan module is not FDA approved, which is 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 IEC 60601-1:1990 + A1:1993 + A2:1995
EN 60601-1:2006+Cor.:2010+A1:2013
EN IEC 60601-2-30:2000
EN 80601-2-30:2010+A1:2015
EN ISO 1060-1:1995
EN ISO 81060-1:2012
EN ISO 1060-3:1997
EN ISO 1060-4:2004
EN ISO 81060-2:2014

Ordering Information:

5-15 volts DC version: NIB*Scan* Module   Order number: 02050

5-15 volts DC version: Testkit NIB*Scan*   Order number: 02025

History

Rev. 0.9:	Preliminary Version
Rev. 1.0:	First Revision
	Correction of typing errors
Rev. 1.1:	Correction of several errors in protocol description
Rev. 1.2:	Correction of typing errors
Rev. 1.3:	Added Pulse rate range
Rev. 1.4:	Changed manufacturer address
Rev. 1.5:	Corrected typing errors
Rev. 1.6:	Corrected typing error
Rev. 1.7:	Corrected Neonatal Range
Rev. 1.8:	Corrected layout