

Non Invasive Blood Pressure OEM board

NIBP 2010



Hardware-Release : C
Software-Version : 3.4

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General

- New power down modus and resistant against artifacts
- CE-certification of the NIBP2010 Module
- the NIBP2010 operates very reliably and extremely patient-safe in the adult and neonatal mode (dual safety circuits for pumps, valves and pressure sensors)
- the accuracy and reproducibility of the measuring results is very good and has been demonstrated by extensive clinical tests:
 - the uniformity of results in the neonatal mode is very high through calibration with arterial reference measurements (clinical trials in the Charité hospital Berlin)
 - in the adult mode accuracy was achieved through a large number of test candidates with comparative measurements (over 80 test persons each with 6 readings parallel to sphygmomanometer evaluation)
- the measuring time (patient involvement/contact) is short,
- the generated noise has been reduced to a minimum
- the long life span of the valves and pumps employed has been achieved by using tried and tested parts
- artifacts are already "recognized" during the measuring sequence and effect a further validation of the readings
- automatic adjustment of the start pressure depending on data of a previous measuring
- automatic measuring mode, in which the repetition of measurements is controlled by a counter. The user can select between various times of repetition
- continuous mode, in which measurements will be carried out so much as possible within 5 minutes
- determination of the heart rate from the oscillations transferred by the cuff
- Software compatible to NIBP2000



Pressure range:	0...300 mmHg	
Measurement ranges:	adults	neonates
pSYS:	25 - 280 mmHg	20 - 150 mmHg
pDIA:	10 - 220 mmHg	5 - 110 mmHg
pMAP:	15 - 260 mmHg	10 - 130 mmHg
Resolution:	1 mmHg	
Measurement accuracy:	mean deviation within ± 5 mmHg standard deviation within 8 mmHg	
Leakage rate of the system:	< 3 mmHg / minute	
Overpressure limits:	300 mmHg adult mode and 150 mmHg neonatal mode	
Shutdown and pressure release after exceeding (first fault condition):	330 mmHg adult mode and 165 mmHg neonatal mode	
Time required for BD measurement:	typical (normal) 20s max.: adults 90s, max.: neonates 60s	
Heart rate range/accuracy:	30 ... 240 bpm / ± 2 bpm	
MTBF :	250.000 cycles of blood pressure measurements	
Interface to monitor:	RS232-TTL level, 4800 baud with standard protocol (CAS), also other baud rates and protocols available (e.g. Colin), hardware reset	
Calibration interval:	2 years	

Transport and Storage Conditions

Temperature range:	-20°C to +70°C
Relative humidity:	95% max, no condensing

Standards

EN 60601-1 + A1 + A2	EN 1060-1
EN 60601-1-2	EN 1060-3
EN 55011, Class B	DIN 58130
EN 60601-2-30	ANSI/AAMI SP-10

Measuring Modes

The NIBP2010 module carries out blood pressure measurements at adults and neonates according to the oscillometric measuring method in 3 different modes.

Manual mode: The user decides when he would like to trigger a measuring and starts a single measuring. If a current regular measuring isn't finished yet, a new manual measuring is carried out after completion of the regular.

Cycle mode: The user selects the temporal distance between the single measurements and starts a measuring row. The module provides automatically a minimum distance of 30 seconds between the single measurements. This mode can be stopped with a command (Abort Command "X").

Continuous mode: The user starts this mode and the module carries out so many measurements within 5 minutes as possible. A distance of 5 seconds is provided between the single measurements. This mode can be stopped with a command (Abort Command "X"). After 5 minutes the module leaves the continuous mode automatically and goes into a standby-mode.

In all three modes the user selects the start inflation pressure for the first measurement. For the following measurements (in the cycle and continuous mode) the module sets automatically the inflation pressure to the last measured systolic value plus 15 mmHg.

Safety/Calibration

The safety for the patient and user is achieved by several measures at the NIBP2010 module.

- Two independent pressure measuring channels on the circuit board are permanently compared against each other.
- There are two valves on the module, if the deflation valve fails, a second valve (safety valve) deflates the cuff. The function of the safety valve is supervised separately from the deflation valve.
- The driving circuits of the pump are supervised.
- After power on or reset the module the program is verified by a self test with calculating a checksum.
- The program flow is supervised by a watchdog.

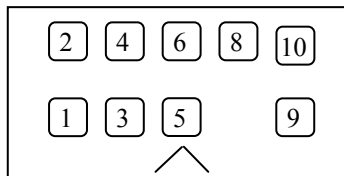
In order to achieve a steady safety, effectiveness and accuracy the user should let calibrate the module every two years. The calibration can be done automatically with commands or manually. A detailed description for calibrating the module is available.

Hardware Interface

Serial Transmission

The normal connection to the board is done via serial, asynchronous communication with a baud rate of 4800 baud. The interface lines operate on TTL voltage levels (0 and 5 volts). A bidirectional connection is necessary, because commands like cycle mode or start a measurement have to be transmitted to the module.

Interface Connector



Pin 1 Power supply Pump : + 5VDC **or** + 12VDC

Pin 2 Power supply Pump : + 5VDC **or** + 12VDC

Pin 3 Power supply Logic : + 5VDC **or** + 12VDC

Pin 4 GND

Pin 5 NC

Pin 6 NC

Pin 8 Reset (TTL – Logic, High or Low, changeable)

Pin 9 RxD, TTL – Logic

Pin 10 TxD, TTL – Logic

DIL-Switch

The position of the 8 switches depend on the operation voltage and on the hardware reset logic:

SW1 and SW3 have always to be **off**

Operating voltage 5 V: SW2 = **on** SW4 = **on** SW5 = **on**

Operating voltage 12 V: SW2 = **off** SW4 = **off** SW5 = **off**

Reset logic active high: SW6 = **on** SW7 = **off** SW8 = **off**

Reset logic active low: SW6 = **off** SW7 = **on** SW8 = **on**

Software Interface

The following description is valid for software version 3.4 and higher.
It is described the standard protocol.
There are also other protocols available.

Explanation of Terms

ASCII	Character Standard
Frames	Character strings which are exchanged as commands or messages between the computers.
Cycle Mode	The measuring unit starts automatic readings. The user is free to select the readout intervals. This mode is controlled solely by the monitor.

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 NIBP module to monitor are terminated by a carriage return, CR=ASCII 13.

Checksum

The checksum is achieved via a modulo 256 summation through all the previous characters of both checksum characters in the corresponding frame (string). The STX character is not included.

Protocol Direction from Monitor to NIBP2010

General Conventions

The measuring unit is controlled by the monitor via command frames. Should NIBP2010 receive unexpected commands these will be ignored. In addition to this, false or unknown commands as well as violations of the timeout 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,

c0 and c1 = command code (2 ASCII characters. Range of values 0 - 99)
 ; and ; = 2 times semicolon
 x0 and x1 = checksum (2 ASCII characters)

ETX (End of Text) = 0x03,

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

<STX> "0" "1" ";" ";" "D" "7" <ETX>

the same in hex- notation:

0x02 0x30 0x31 0x3B 0x3B 0x44 0x37 0x03

Command Code	Checksum	Function
--------------	----------	----------

- It is not recommended to send commands during blood pressure measuring or leakage test or during the manometer mode.
Exception: Abort Command ASCII X (see "Abort Command")
- ¹⁾ For the first measurement the start pressure is 160 mmHg (adult) and 120 mmHg (neonate), unless a "set start pressure" command is sent before. For a following measurement the start pressure is calculated to "last systolic value plus 15 mmHg".
 - ²⁾ Power down mode is not possible in the cycle mode. Power down mode can be terminated by sending the "**Abort Command**". NIBP2010 response with sending a status frame, see "**Status Transmission**".
 - ³⁾ Important: wait for an answer of the module before sending another command

Abort Command

Regardless of the operational mode, the session can be terminated by sending (the) "X" (character). The measuring unit immediately reverts to the mode : Standby. The pneumatic system discharges.

Example : "X"
or : <STX>"X" <ETX>

Software Reset Command

The software reset command does the same as the power-on reset and the hardware reset. The software starts to run at the beginning. The module is set to the adult mode and the start pressure is set 160 mmHg. Finally the module is in the standby mode and is ready to receive and answer further commands, e. g. start a measurement.

If the module has detected an incorrect checksum of the program (then the module transfers the error message M15, see chapter "Error Messages"), the software reset does not work. In this case the module resets only by a power-on reset or hardware reset.

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 timeout criterion.
- The period between two characters of a receive frame exceeds 10ms.

Direction from NIBP2010 to Monitor

General Conventions

There are three types of frames which, in the different situations, are generated by the NIBP2010.

- 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 under remarks of the various points).

Initialization Message

On power up the NIBP module always generates a status frame within a few seconds. Immediately thereafter the monitor can communicate with the module.

Frame example: <STX>,S0;A0;C00;M10;P-----;R---;T ;;AF<ETX>CR

Cuff Pressure Transmission

This frame is permanently displayed during a current measuring.

Basic frame structure (real ASCII in inverted commas):

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

Explanation of dummies:

STX = Start of Text

ETX = End of Text

CR = carriage return

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

The 'C' caution bit "c0" is used during a current measuring for the display of the cuff and corresponding measuring mode:

c0 = "1" module recognized the neonatal cuff in adult operation
c0 = "2" module recognized the adult cuff in neonatal operation
c0 = "0" correct cuff

The „S“ status bit „a0“ displays the current operational mode:

a0 = "3" measuring
a0 = "4" manometer operation
a0 = "7" leakage test

Example: <STX>035C0S3<ETX>CR

<STX> start of Text: "0x02"
035 current cuff pressure 35 mmHg
C0 correct cuff is connected
S3 module is in the measuring mode
<ETX> end of Text: "0x03"
CR carriage return

End of Cuff Pressure Transmission

This message is generated after the cuff pressure transmission has been completed and thus after the blood pressure has been measured. The measuring unit then reverts to standby.

Frame structure (real ASCII in inverted commas) :

<STX>"999"<ETX>CR

Status Transmission

After booting, the leakage test and the measurement, it may be recognized from this frame, whether it was a successfully or unsuccessfully completed action. This is expressed in the error code field.

The status is displayed on request by the monitor by sending command code 18.

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
```

Explanation:

STX = Start of Text
ETX = End of Text
CR = carriage return

a0 = ASCII digit

a0 = "0" auto - test in progress (immediately after reset)
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 (immediately after reset) in progress
a0 = "6" cycle-/continuous- mode
a0 = "7" leakage test
a0 = "8" reserve

b0 = ASCII digit for the operational mode

b0 = "0" adult mode
b0 = "1" neonatal mode

c0 and c1 = 2 ASCII digits for cycle mode in minutes.

c0-c1 = 00 , no cycle selected

d0 and d1 = 2 ASCII digits for messages (after reset 10 appears here)

d0-d1 = 00	uninterrupted operation
d0-d1 = 02	receiving invalid command
d0-d1 = 03	uninterrupted operation
d0-d1 = 06	cuff fitted too loosely or is not connected, time for pumping exceeded
d0-d1 = 07	cuff leakage
d0-d1 = 08	pneumatics faulty
d0-d1 = 09	measuring time exceeded, current pressure smaller than the lower limit of diastole, too less oscillations detected
d0-d1 = 10	systolic and diastolic value are outside the pressure range
d0-d1 = 11	too strong movement artefact
d0-d1 = 12	maximum pressure exceeded
d0-d1 = 13	two saturated oscillation amplitudes are detected
d0-d1 = 14	leakage during the leakage test
d0-d1 = 15	system error

e0 to e8 = each 3 ASCII digits represent the values for pSystole, pDiastole, pMean.

If the last measurement did not succeed in determining values, these digits will be reported as dashes.

f0, f1, f2 = 3 ASCII digits for the heart rate. If there is no heart rate determined, these digits will be reported as dashes.

g0 to g3 = 4 ASCII digits for the period in seconds until the next measurement starts (only in cycle- or continuous mode). If the cycle- or continuous mode has finished or is not active, 4 blanks are displayed.

h0 and h1 = ASCII digits for the checksum

Example :

<STX>S1;A0;C03;M00;P125090080;R075;T0005;;D2<ETX>CR

<STX>	start of Text: "0x02"
S1	waiting for commands, module is in the standby mode,
A0	adult mode,
C03	cycle mode with 3 minutes,
M00	uninterrupted operation, no errors,
125	last pSystole: 125mmHg,
080	last pDiastole: 80mmHg,
090	last pSystole: 90mmHg,
R075	last heart rate: 75mmHg,
T0005	the next measurement begins in 5 seconds,
D2	checksum.
<ETX>	end of Text: "0x03"
CR	carriage return

Error Messages

If a fault appears during or between the blood pressure measurements, an error message will be sent upon request. The following error messages can occur:

M00,
M03 = Uninterrupted operation

The module continues its measuring in the selected mode.

M02 = Receiving invalid command

An invalid command can be

- an interrupted command or
- a command with a wrong format or
- a wrong timing of the bytes within a command

After appearing M02 the module resets automatically, then the module goes into the standby-mode and is ready to receive and answer further commands.

M06 = 1. Cuff fitted too loosely or is not connected
2. Time for pumping exceeded

This error message occurs when inflating, a pressure must achieve at least 20 mmHg after 20 sec., and after 60 sec. the final pressure must be reached.

M07 = Cuff leakage (including sudden occurrence)
Appears when inflating.

M08 = Pneumatics faulty, because of:

1. Faulty slow loss of pressure
Occurs, if the pressure deflation is too small in the deflation phase (e. g. because of a faulty deflation valve or because of a blockage).
2. Faulty high loss of pressure
Occurs, if the pressure deflation is too big (> 50 mmHg e.g. because of a leakage).
3. Offset pressure has changed too much.
The offset pressure is measured always shortly before the pump starts for a new blood pressure reading. M08 occurs if this offset pressure has changed too much against the initial offset reading (the initial offset pressure reading is done after power on the module or after a hardware reset or after a software reset, therefore it is recommended to eliminate this error with a reset).

M09 = 1. Measuring time exceeded (adult: 90 sec/neo: 60 sec)
2. The current pressure is smaller than the lower measuring range limit for the diastole pressure limit
3. Too less oscillations detected (cuff incorrectly fitted)

M10 = Systolic and diastolic value are outside the pressure range (observed when deflating).

M11 = Too strong movement artefacts

M12 = The permitted maximum pressure is exceeded
(Adult: 300 mmHg, Neo: 150 mmHg, in accordance with IEC limits)

M13 = Two saturated oscillation amplitudes are detected

M14 = Leakage during the leakage test

M15 = System error, because of:

1. Faulty safety valve
2. Pump driving circuits faulty
3. Pressure channel faulty
4. In this leakage test the pressure increases for 30 seconds

5. Check sum of the program incorrect

The check sum will be checked after the module is powered on or after a hardware reset or after a software reset. If the check sum is incorrect the module goes into the sleep mode. The module is not ready to receive and answer further commands, therefore a blood pressure measurement is not possible and a software reset will not work.

The module will leave the sleep mode after power off/on or after a hardware reset.

At the appearance of M02 to M15 (except case 5. of M15) the NIBP2000 module goes into the standby-mode. The module is ready to receive and answer further commands.

Manometer Mode (extended version)

For this manometer mode send the commands:

1. <STX>51;;DC<ETX>
2. <STX>14;;DB<ETX>

The module answers with the following "Status Transmission":

```
<STX>,S4;A0;C00;M00;P-----;R---;T ;;B2<ETX>CR
```

Then the module transmits the offset pressure.

Example: offset for channel 1: 70 steps and channel 2: 75 steps

```
"Offset [0] : 70 [Stufen] Offset [1] : 75 [Stufen ] <CR>"
```

- "Stufen" means "steps".

The offset pressure range should be between 50 and 90 steps.

After sending the **Abort Command: <X>**, the module sends the pressure of channel 1 and channel 2. Connect the pressure indicator and pump up to pressure around 250 mmHg.

Example: for 250 mmHg "<CR> 1. : 250 [mmHg] 2. : 250 [mmHg]"

Remark : If pressing over 300 mmHg the valves will be opened and the module leaves the manometer mode by sending the "End of Cuff Pressure Transmission"- message. If the module receives the command "Request data from module" the module will answer with a "Status Transmission", which shows an error (S2: an error has occurred, M12: the error is maximum pressure exceeded, see "Technical Description NIBP2010" chapter "Error messages" and chapter "Status Transmission").

Leaving the manometer mode:

After sending the **Abort Command: <X>** once more, the module leaves the manometer mode by answering with the "End of Cuff Pressure Transmission"-message.

After 10 min without sending the Abort Command the module will leave the manometer mode automatically also by answering with the "End of Cuff Pressure Transmission"-message.

After leaving the manometer mode and before sending new commands, a "Power off and on" or a "Hardware-Reset" or a "Software-Reset" has to be done. Notice, that the cuff pressure is 0 mmHg at this moment.

Manometer Mode (short version)

For the manometer mode (short version) send the command:

`<STX>14;;DB<ETX>`

The module sends permanently the "Cuff Pressure Transmission" - string, according to the pressure only of channel 1.

Remark : If pressing over 300 mmHg the valves will be opened and the module leaves the manometer mode by sending the "End of Cuff Pressure Transmission"- message. If the module receives the command "Request data from module" the module will answer with a "Status Transmission", which shows an error (S2: an error has occurred, M12: the error is maximum pressure exceeded, see "Technical Description NIBP2010" chapter "Error messages" and chapter "Status Transmission").

Leaving the manometer mode:

After sending the **Abort Command:** `<X>`, the module leaves the manometer mode by answering with the "End of Cuff Pressure Transmission"- message.

After 10 min without sending the Abort Command the module will leave the manometer mode automatically also by answering with the "End of Cuff Pressure Transmission"-message.

After leaving the manometer mode and before sending new commands, a "Power off and on" or a "Hardware-Reset" or a "Software-Reset" has to be done. Notice, that the cuff pressure is 0 mmHg at this moment.

Leakage Test

Wind a cuff around a solid body with a diameter of about 7,5cm and connect it with NIBP2010.

Send the command for leakage test: <STX>17;;DE<ETX>.

NIBP2010 inflates to 200mmHg and after 60 Seconds NIBP2010 sends the "End of Cuff Pressure Transmission"- message, leaves the leakage test and returns to the standby mode. In order to get a result of the leakage test, send to the module the command "Request data from module". The module will answer with one of the following "Status Transmission":

<STX>,S1;A0;C00;M00;P-----;R---;T ;;AF<ETX>CR

S1: the leakage test has detected no leakage error

M00: the result of the leakage test is **ok** (leakage is \leq 3 mmHg/minute)

<STX>,S2;A0;C00;M14;P-----;R---;T ;;B5<ETX>CR

S2: the leakage test has detected a leakage error

M14: the result of the leakage test is **not ok** (leakage is $>$ 3 mmHg/minute)