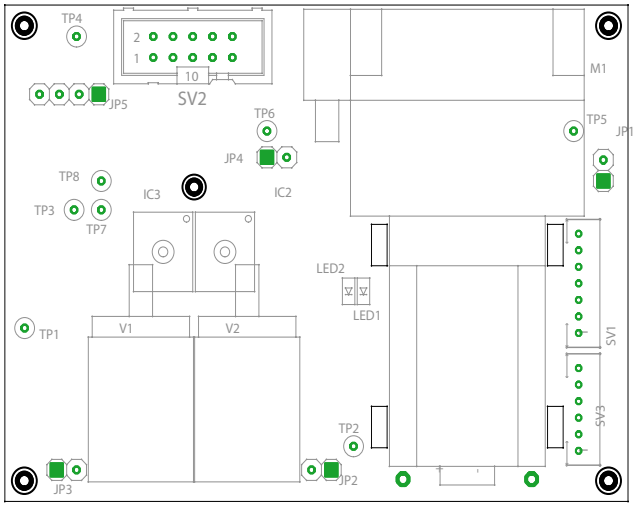
medlab

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

NIB*Scan*

Technical Manual



Version 2.2

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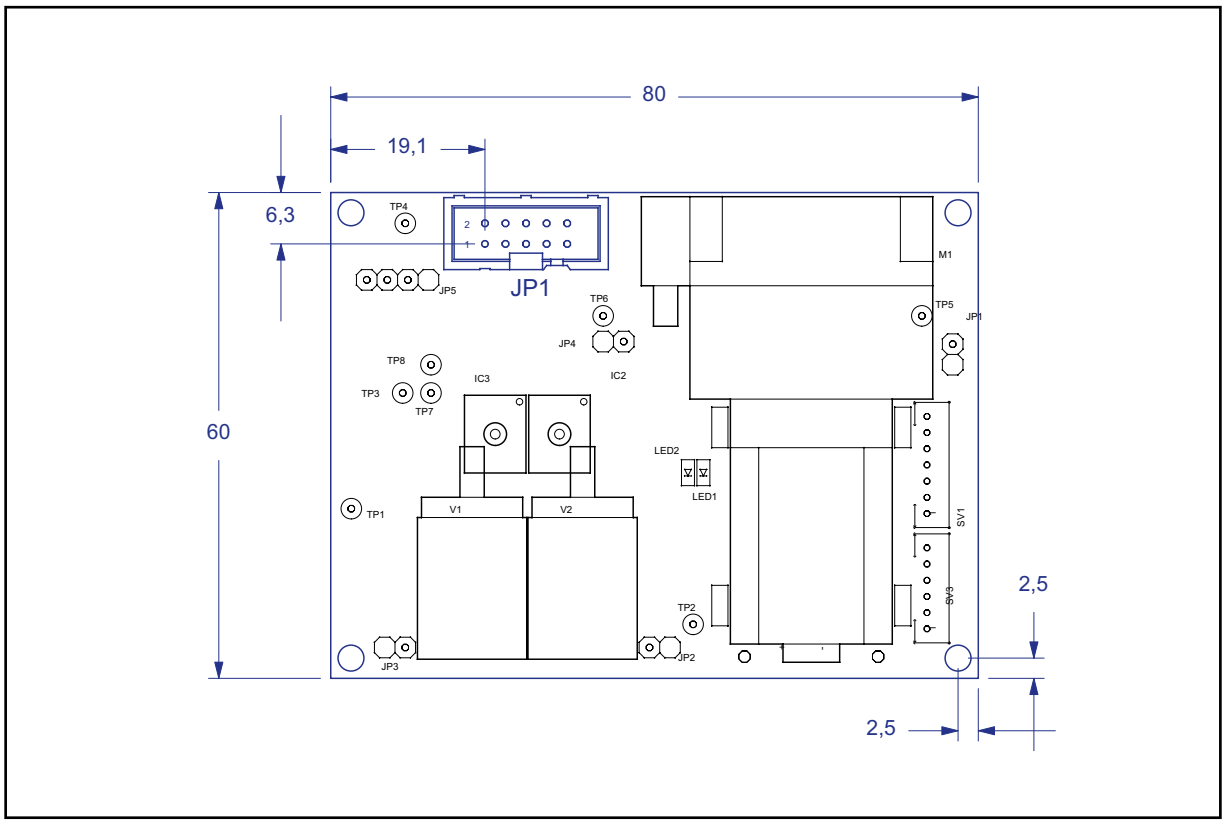
Mechanical Dimensions



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. This OEM module is intended for medical device manufacturers and for deviceces intended for professional healthcare environments. The users of this devices are intended to be trained medical personal. Its patient group ranges from neonates to adults.
It features a new power down mode and a better suppression of artefacts. The measurement time of the system (cuff inflated time) and the generated noise have been reduced to a minimum.

The NIB*Scan* uses the oscillometric method for measuring a person's systolic, mean and diastolic blood 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 can then start another cycle if necessary. 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, which automatically starts a new measurement 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)

Weight: 85 g

Attachment: four M3 screws in the corners of the PCB

Operating temperature: 0 °C ... +60°C

Transport and storage conditions:
- Temperature range: -20 °C ... +70 °C
- Relative humidity: 10 ... 95 %, non condensing
- Atmospheric pressure: 500 ... 1060 mbar

Operating voltage: 5.5 ... 15 Volt DC

Current: Max. 400 mA

Typical current values over the voltage range in Adult mode:

	Single valve version			Twin valve version		
	Standby	Inflation	Measurement	Standby	Inflation	Measurement
5,5 V	25 mA	300 mA	70 mA	30 mA	330 mA	120 mA
6,0 V	25 mA	315 mA	70 mA	30 mA	345 mA	125 mA
9,0 V	20 mA	235 mA	50 mA	25 mA	280 mA	90 mA
12,0 V	17 mA	175 mA	45 mA	20 mA	210 mA	75 mA
15,0 V	17 mA	145 mA	35 mA	20 mA	170 mA	60 mA

Operating modes: Adult and neonate

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

Accuracy:
- Mean value of differences: < +/- 5 mmHg
- Standard diviation: < +/- 8 mmHg

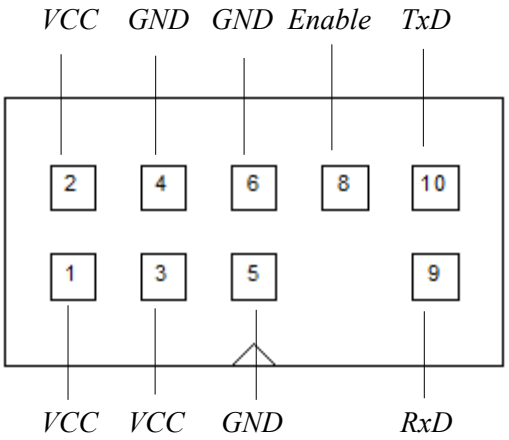
Pulse rate:	30 - 230 bpm
Leakage rate:	< 6 mmHg / minute at 280 mmHg air pressure for 500 ml air tank volume
Overpressure limits:	300 mmHg adult mode and 150 mmHg neonatal mode
Interface:	asynchronous, serial interface, 4800 baud, 8 data bits, 1 stop bit, no parity bit, no handshake, CMOS (0-5V) level, 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 host and the slave.
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 JP1

Physical Interface

Connection to the module is done using serial, asynchronous communication, with a baudrate of 4800 Baud. The interface lines operate on CMOS voltage levels (0 Volts and 3.3 Volts, 5 Volts tolerant).

For using RS232 voltage levels, a separate adapter is available which converts between CMOS levels and the serial RS232 interface levels of a PC or other device. A test and evaluation application software for Windows is available as well.

The connection in the customer's final system would typically be done using CMOS 0 V / 3.3 V levels. A bidirectional connection is necessary, since parameters like cycle rate, start of measurement etc. have to be transmitted to the module.

While the enable pin is pulled down to GND, the module is held in power down mode and voltage regulators of the module are disabled. To reset the module, power cycle it by pulling down the enable pin for a few seconds.

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 measurement
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 measurements, during leakage test and while in 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 sending the „X“ (character). The measuring unit immediately reverts to standby mode. The pneumatic system discharges.

Example: <STX> „X“ <ETX>
Sending „X“ alone is sufficient as well.

Timing and Error Correction

In 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 frames
- 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 continuously transmitted five times per second during an ongoing measurement, 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" measurement 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:

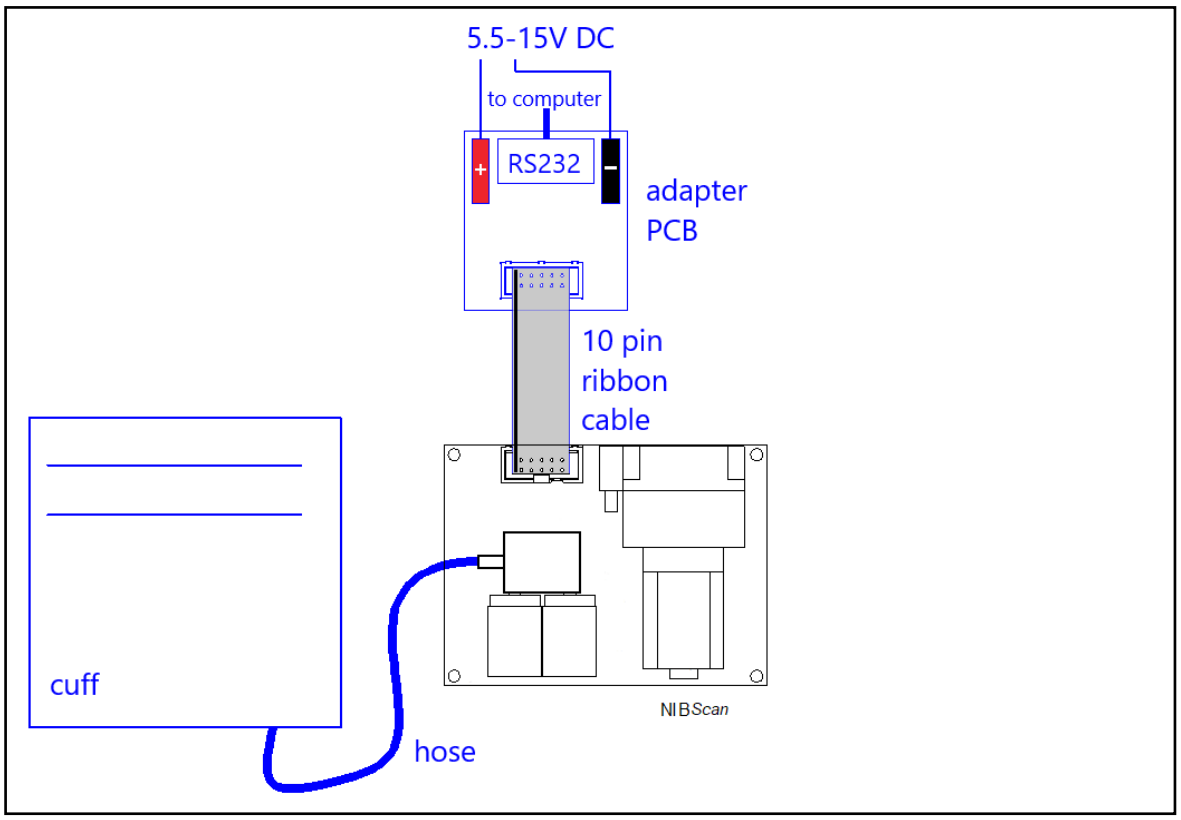
```
<STX>S1;A0;C03;M00;P120080100;R075;T0005;;D2<ETX><CR>
```

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

!

Plug and Play development kit

There is a development kit available to ease the evaluation of the board:
The NIB*Scan* board, an adapter, all necessary cabling, and a Windows application software for evaluation of 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 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
- press the "Read State" button, then "Start"

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 NIB*Scan* 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.

Compliance with Harmonized Standards

The OEM module is developed to fulfil the following standards as far as possible for an OEM module:

Basic standard:
- IEC 60601-1:2005 + Cor1:2006 + Cor2:2007 + A1:2012 + A1:2012/ Cor1:2014 + A2:2020
  (EN 60601-1:2006 + Cor.:2010 + A1:2013 + AC:2014 + A1:2013/AC:2014 + A12:2014 + A2:2021)*
- IEC 80601-2-30:2018
  (EN IEC 80601-2-30:2019)*
- ISO 81060-2:2018 + Amd. 1:2020 + Amd. 2:2024
  (EN ISO 81060-2:2019 + A1:2020 + A2:2024)*

RISK management:
- ISO 14971:2019
  (EN ISO 14971:2019 + A11:2021)*

Software-Lifecycle-Process:
- IEC 62304:2006 + A1:2015
  (EN 62304:2006 + Cor.:2008 + A1:2015)*

( )*: corresponding European standard

Ordering Information

OEM modules:

Single valve NIB*Scan* module:	Order number: 02050-00-04-01
Twin valve NIB*Scan* module:	Order number: 02050-00-04-00

development kits:

Single valve NIB*Scan* development kit:	Order number: 02050-00-04-98
Twin valve NIB*Scan* development kit:	Order number: 02050-00-04-99

In case customization is required, please contact us.

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
Rev. 1.9:	Storage and transport conditions moved and minimal storage temperature changed, operational temperature added, technical data redesigned, small design changes, ordering information reworked, power consumption removed, current changed and table of typical currents added, testkit renamed to development kit, user added, accuracy added, special point with operating modes added, harmonized standards reworked
Rev. 2.0:	Second development kit and possibility of individual version added, small design rework
Rev. 2.1:	Description of power down / reset functionality, description of physical interface updated, correction of language errors, updated and higher resolution graphics. Update weight.
Rev. 2.2:	Updated leakage information, and 81060-2 standard version