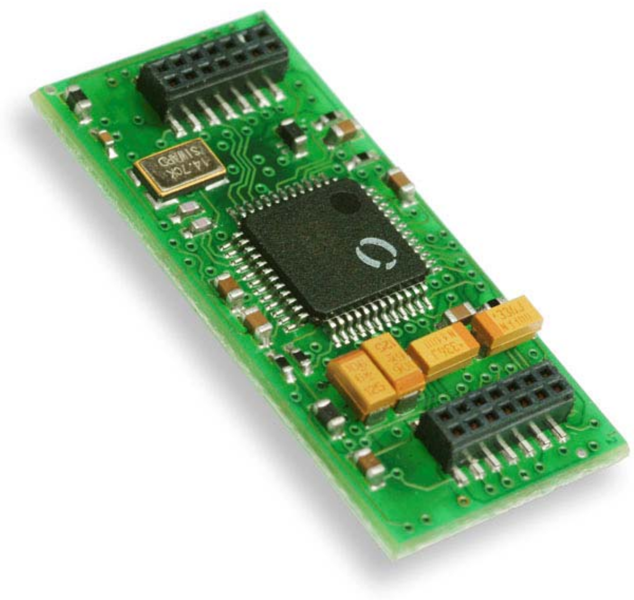
User Manual

Digital Pulse Oximeter Module ChipOx®



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Contents

1 Description

1.1 Intended use

ChipOx® is a pulse oximeter module for the non-invasive determination of the functional oxygen saturation in human arterial blood (SpO_2) and for measuring the pulse frequency. ChipOx® can be installed as an OEM module in medical products or other applications for humans.

The parameters for pulse oximetry are measured using the sensors listed under the accessories, which contain two LEDs of different wavelengths and a photodiode. The sensors, depending on type, are applied to various parts of the patient's body, e.g. the finger. The signals are measured with 300 Hz to efficiently suppress noise . From these values, the pulse oximetry parameters: oxygen saturation (SpO_2), pulse frequency, pulse wave, and the quality of these signals, are calculated using various digital filters, novel signal processing methods and calibration curves, which are then made available to various on-line interfaces.

The patient benefit of ChipOx® is the information obtained about the oxygen saturation of his arterial blood and his pulse frequency (can help with his therapy).

ChipOx® is intended for installation in devices of the following application areas, taking safety instructions into account:

- anesthesia
- pre- und postoperative monitoring
- intensive care
- emergency medicine
- sleep medicine
- ambulance service
- pulmonology
- therapeutic exercises, sports medicine
- subactute care centers
- home monitoring

1.2 Functional Principle of Pulse Oximetry

The technique of pulse oximetry is based on two principles. First, the color of blood, which depends on the oxygen saturation, is determined using two wavelength ranges, red and infrared (spectrophotometry). Second, the amount of arterial blood in tissue (and thus also the light absorption due to this blood) changes during pulsation, caused by the blood being pumped from the heart into the arteries (plethysmography).
The color difference, caused by oxygen saturation, is due to the optical properties of the hemoglobin molecule, or, to be more specific, the organic heme component. Hemoglobin is responsible for transporting oxygen in blood through oxygenation (O2Hb). The oxygen is released again later, i.e. the blood is deoxygenated (oxygen saturation goes down) and loses its red color, accordingly. This influences the absorption of red light more, and that of infrared light less.
To determine the *arterial* oxygen saturation, the *pulsation* of the arterial blood flow is used. The blood volume changes during the systole and diastole, which has an effect on the light absorption. Since only the change in light absorption is evaluated, the non-pulsating absorbing matter, such as tissue, bone and venous blood (conditionally, see Section 3.4.5), has no effect on the measurement.
The light sources for this measurement are a red and an infrared LED, and a photodiode acts as detector. The pulse oximeter measures the ratio of red to infrared pulsating absorption, which is directly proportional to the oxygen saturation. In addition, the time interval between pulsations is converted into the pulse frequency.

1.3 Special Features of ChipOx®

ChipOx® has very small dimensions (31mm x 14mm x 5mm), which allows it to be easily installed in medical products. It also has low energy consumption, is equipped with ESD and EMC protection and can be easily mounted on a carrier printed circuit board (host PCB).
ChipOx® also offers the following extra options and functions, in addition to the pulse oximetric functions.

1.3.1 Warning and error reporting system

If the measurement and operating conditions aren't met, then ChipOx® reduces its measurement operation and sends a message (see Section 5.1.2), if values are outside the limits which allow low-error measurement. In this way, the user is requested to improve the measurement conditions. The values determined under the measurement conditions for pulsation, operating temperature and operating voltage are made available to the user as a check. System errors (e.g. sensor errors) are also reported.

A loose connection can lead to false measurements or to the following error messages:
"Vital parameters outside of measurement range, "Pulse search time-out", "Motion artifacts".

1.3.2 3 freely configurable, analog inputs

ChipOx® offers 3 inputs for the measurement of other parameters, which are each sampled with a maximum of 100 Hz and 12 Bits. The sampling rate and the input voltage ranges are freely configurable over the communication protocol (see Section 5.1.2.2).

1.3.3 Multiplexed analog output

ChipOx® offers the option of outputting the vital parameters and other measurements as analog, multiplexed signals on up to 8 channels. ChipOx® can then be either directly connected to a system with an AD converter or to a recorder over a demultiplexer.

1.3.4 Serial interface for data exchange

A serial UART interface is available as a digital output and for all settings, which allows data to be exchanged over a secure protocol.
The standard protocol used here has a very versatile design, so that most requirements are taken into account over a large selection of set parameters (see Section 5.1.2.2).

1.3.5 Other digital I/O functions

Most of the digital I/O lines are occupied by the standard serial interface and the multiplexed analog output. One of the pins (I/O-INT) is still free and can be used as an event input signal. Its input is sampled with 100 Hz and can be polled over the communication protocol (see Section 5.1.2.2).

1.3.6 Signal quality

ChipOx® supplies a value which represents the signal quality. This is an index for the SpO_2 value computing power. ChipOx® calculates the SpO_2 value not only once per pulse wave (FPWA = Full Pulse Wave Algorithm), but several times; the pulse wave is split up (SPWA = Splitted Pulse Wave Algorithm). ChipOx® splits the pulse wave as frequently as possible. The SpO_2 computing power (splitting and SpO_2 determination frequency per unit time) depends on the signal quality. The better the signal is (high amplitude due to stronger pulsation, fewer motion artifacts), the higher the computing power and the associated output value is for the signal quality.

1.3.7 Plethysmogram

If possible, ChipOx® normalizes the plethysmogram, which is output as a curve, so that the amplitude makes up 75 % of the display range. This way, it's independent of the pulse volume. A signal proportional to the pulse volume can more likely be determined over the pulsation strength (see Section 3.4.5).

1.3.8 Flexible Artifact Leveling (FAL)

Flexible artifact leveling (FAL) is used to suppress motion artifacts in the measurement of the SpO_2 and pulse frequency parameters.

For SpO_2:

The lower the setting, the faster the reaction is for desaturation. The artifact stability is weaker, however (more suitable for desaturation during sleep). The higher the setting, the more stable the value, but the reaction time is then longer (suitable for restless/jittery measurement conditions, for example). The setting should be chosen according to case. The standard setting 'Normal' is a compromise between the two.

For pulse frequency:

The lower the setting, the faster the reaction when the pulse frequency changes. The artifact stability, however, is weaker (suitable for the measurement of HF variations, for example). The higher the setting, the more stable the value, but the longer the reaction time (suitable, i.e., for bumpy ambulance transportation).

In addition, a plausibility check is installed for the pulse frequency measurement: variance suppression (VS) in percent.
It evaluates the distance between two consecutive beats and considers the new value to be implausible as soon as it deviates from the old value by more than the VS value (plausibility control value). At the same time, the plausibility control value is adapted to the new value.
The standard setting 'Normal' is a compromise between the two.

1.3.9 Adjustable sampling rate

To reduce the power consumption of ChipOx® further more, there is the facility to reduce the standard sampling rate of 300 Hz down to 75 Hz. In this case it has to be considered, that parasitic frequencies around 75 Hz can disturb the signal. Frequencies lower than 61 Hz or higher than 91 Hz will still be suppressed effectively.

2 Safety Information

ChipOx® was tested and qualified according to the standards listed in Chapter 6.5. (insofar as these are applicable for an OEM module). When being integrated in a host system, all corresponding standards are to be taken into consideration by the user. Any influences on or from the host system are <u>not</u> taken into consideration here.

- These user instructions are a component of ChipOx®. Any action taken with ChipOx® requires that the user is aware of the user instructions in all chapters and that they are observed.
- ChipOx® is only intended for the described purpose.
- ChipOx®, as well as all accessories, may only be used by persons with sufficient expertise.
- ChipOx® is delivered in high-quality packaging. Do not use ChipOx® or the sensors used with it if one of the parts shows damage from transportation or other damage.
- ChipOx® is only to be integrated in a host system and operated by qualified personnel.
- Before ChipOx® is installed, it isn’t protected from ESD and has to be handled accordingly.
- As part of a system, the host must be electrically insulated from the patient according to EN 60601-1 and other regulations regarding electrical safety. ChipOx® is in no way insulated, and all parts should be considered to be galvanically connected. This is also true for the connected sensors. The silicon layers on the LEDs and receiver do not qualify as insulation, since they can be damaged if not used as intended.
- ChipOx® may not be submerged in liquids, have liquids poured on it or be cleaned with liquid detergents. ChipOx® should also be protected from condensation and humidity.
- ChipOx® is not suitable for operation near MRI or NMR devices or x-ray machines, and may not be operated in such an environment.
- If the Operating Parameters are exceeded or the measurement conditions are disregarded, this can lead to faulty measurements, and can lead to damage to ChipOx® in an extreme case.
- If the sensors are applied in the wrong place, or if the wrong types of sensors are applied, the measurements can be falsified. Body parts may also be pinched off by the sensor cable, or the skin could be torn by the finger clip sensor, etc.
- Only the sensors and accessories offered by EnviteC for ChipOx® may be used. Sensors and accessories must be in perfect condition. If other sensors and accessories are used, it could lead to malfunctions and problems with biocompatibility.
- Taking medicine or other preparations which change blood color, the administration of intravascular dyes (such as methylene blue or indocyanine green, etc.) or a high concentration of dysfunctional hemoglobin can drastically falsify the measurement results.
- ChipOx® is intended as a support for diagnosis and monitoring. ChipOx® may only be used for making a diagnosis in connection with other clinical signs and symptoms. It is not allowed to make a clinical evaluation based only on ChipOx® results.
- If there should be any reason to doubt the exactness of the measurement, then the vital functions of the patient should first be investigated with other means. Afterwards, the functionality of ChipOx® should be checked.

3 Measurement Conditions

For successful ChipOx® application, please make sure you observe the following:

- safety information in Chapter 2.
- operating and environmental conditions in this chapter and in Chapter 6
- ChipOx® application and integration instructions in Chapter 4 and the connection between ChipOx® and the sensor
- interface specifications in Chapters 5 and 5.2
- the use of the approved sensors and accessories described in Section 10.2.1 and their correct application according to the included user instructions

3.1 Power Supply

The power supply (see Section 6.1) corresponds to the EN 60601-compatible low-voltage supply (medical safety extra-low voltage MSELV).
Please observe that if the voltage is too high, it can lead to defects.
We recommend a linear regulator be used to stabilize the power supply, since a chopper-type regulator can have a negative effect on the signal quality (see Section 4.3.2).
ChipOx® monitors the power supplies. If the power supplies are determined to be outside the limits which allow low-error measurement, ChipOx® cuts down measurement operation and sends an error message.
ChipOx® restarts its program if the power supply is briefly interrupted.

3.2 Operating and Storage Temperature / Humidity

The following temperatures and humidity should be observed:

	Ambient temperature	Humidity, no condensation
Storage	between -30°C and +70°C	between 0% ... 90%
Operation	between -20°C and +60°C	between 0% ... 90%

Operation or storage outside of these ranges implies improper handling.
ChipOx® monitors the ambient temperature. ChipOx® cuts down measurement operation and sends a message if the temperature is determined to be outside the limits which allow low-error measurement.

3.3 Sensors and Accessories

Please use only one of the approved sensors included in the accessories given in Section 10.2.1 and make sure it is applied correctly according to the included user instructions.
Make sure that neither the LEDs nor the detector in the sensor are dirty or wet.
ChipOx® monitors the connected sensor. ChipOx® will not allow measurements to be made if a defective sensor or a non-specified sensor is detected, and informs the user of this.
The thermal output of the sensor is so low that no injuries are caused where it is applied.
Only one of those extension cords included in the specified accessories may be used. Further extension cords could reduce the quality of the measurement results.

3.4 Factors Which Influence Measurement

3.4.1 Electromagnetic interference immunity, EMC, disturbance signals

The compatibility with electromagnetic radiation according to EN 60601-1-2 and interference immunity according to EN 61000-4-3 has been pretested.
ChipOx® is not suitable for operation near MRI, NMR or x-ray machines.
ChipOx® monitors disturbances in the measurement signal. ChipOx® cuts down measurement and sends a message if it detects that the signal is outside of the limits which allow low-error measurement.

3.4.2 Ambient light

A normal amount of ambient light on the sensor can be compensated by ChipOx®. Strong or fluctuating ambient light (e.g. direct sunlight or OR lamps) can falsify measurements.
ChipOx® monitors the ambient light. ChipOx® cuts down measurement and sends a message if it detects that the ambient light is outside of the limits which allow low-error measurement.

3.4.3 Motion artifacts

ChipOx® checks for motion artifacts, and suppresses them for the most part with various algorithms, and indicates when they get too high. Still, false data due to motion artifacts can't be ruled out (especially ones of long duration).

3.4.4 Dysfunctional hemoglobin, intravascular dyes

If the concentration of dysfunctional hemoglobin (e.g. carboxyhemoglobin or methemoglobin), which can't transport oxygen, is too high, the measurement can indicate a normal result, although the patient is hypoxic, since less hemoglobin is available to transport oxygen. In such cases, a pulse oximeter, which uses two wavelengths to measure the functional oxygen saturation (like ChipOx®), cannot be used.
Intravascular dyes, such as methylene blue, indocyanine green or other dyes, falsify the measurement dramatically.

3.4.5 Pulsation strength (perfusion)

Sufficient pulsation is essential for a good measurement.
In many cases the term perfusion is used misleadingly. By perfusion we understand the blood circulation whereat the flow of blood through the capillaries is meant. The arterial pulsation (for which a pulse oximeter is sensitive) can be high whereas the perfusion is low simultaneously at contracted capillaries. The vice-versa case is cogitable likewise.
ChipOx® measures the pulsation strength continuously as the photodiode current caused by the pulse wave ΔIAC/IDC (total pulse modulation) and registers a weak pulsation when the pulsation is less than 1% (which is usually the case, e.g., when non-prepared earlobe used as application place). Then, measurement falsification is to be expected.
The pulsation strength is negatively influenced by the use of blood pressure cuffs or arterial catheters, arterial occlusion or if the sensor is applied too tightly.
Venous pulsation or defibrillation can also falsify the measurement.

3.5 Connection of Free Inputs

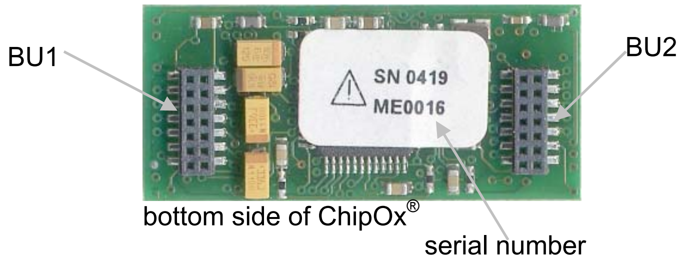
Please observe that if the voltage of external devices connected to the free analog or digital inputs is too low or too high (see Section 6.4), this can lead to defects.

4 Dimensions / Connections / Mounting

4.1 Dimensions

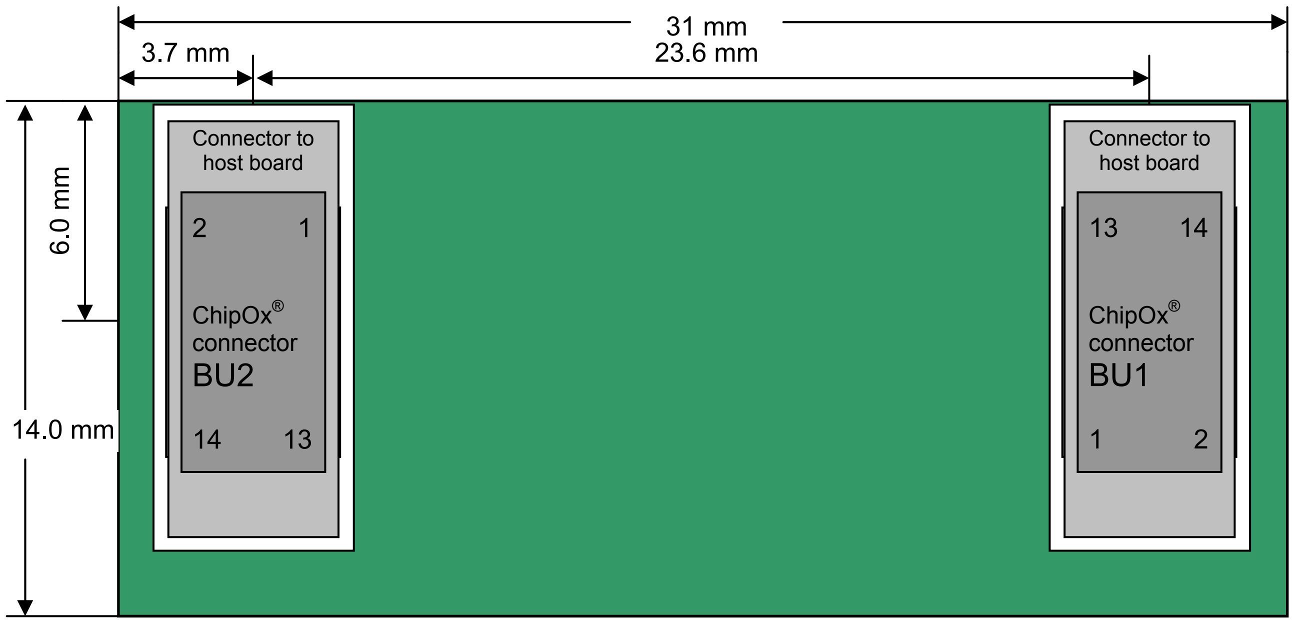
31 mm * 14 mm * 5 mm

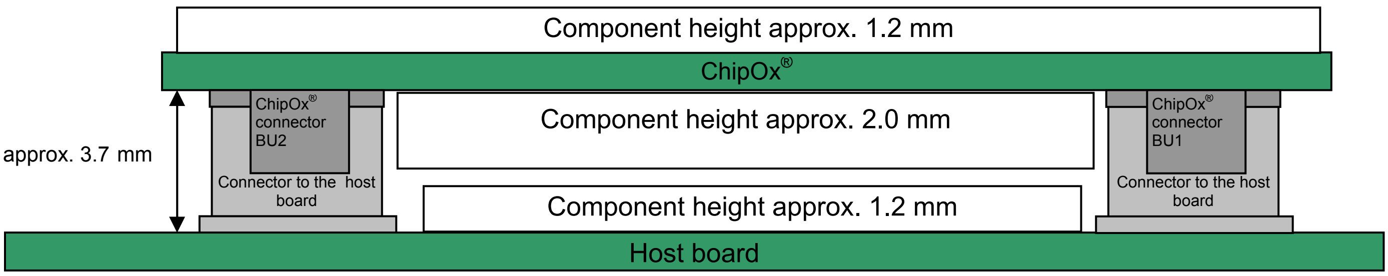
top side of ChipOx®



bottom side of ChipOx®

View of bottom side (connector side) of ChipOx® (scale: ca. 5:1)





Please make sure that ChipOx® is installed in suitable housing so that the safety information (Chap. 2), measurement conditions (Chap. 3) and hygiene specifications (Chap.9.4) are observed.
ChipOx® is to be plugged in/out plane-parallel and without tilting when it's being mounted or dismounted.
We emphasize here again that ChipOx® is vulnerable to ESD if it's not in its installed state.

4.2 ChipOx® Pin Allocation

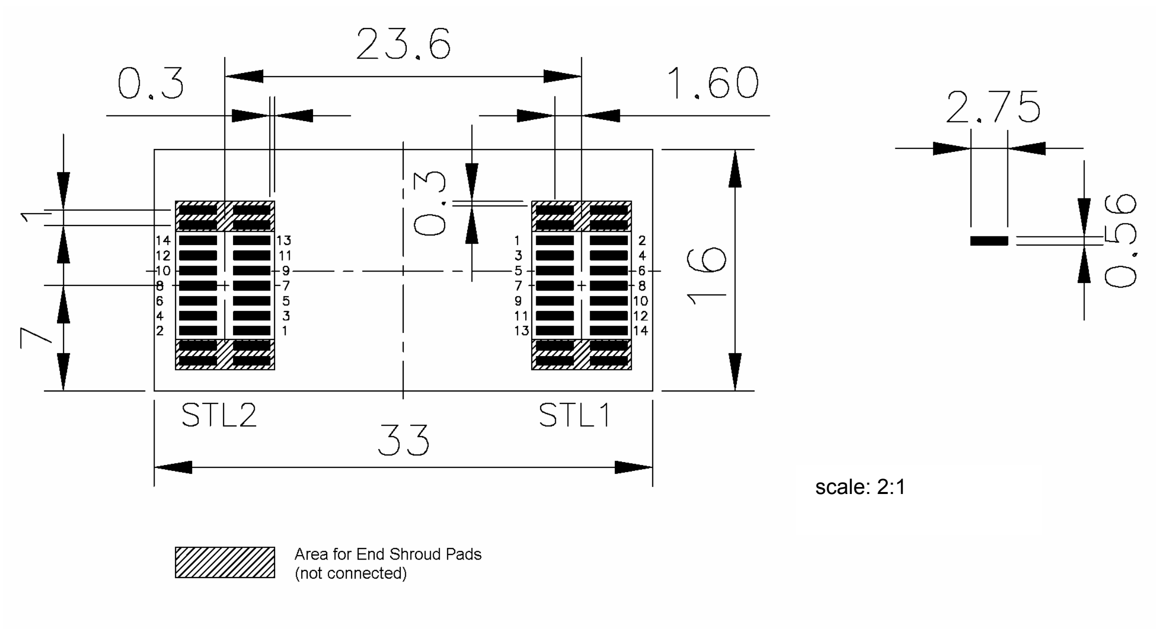
Number	Host side BU1	Sensor side BU2
1	+3V3	Free, do not contact!
2	GND	Shield
3	RESET	SENSOR_ID
4	I/O-0 (TXD)	IN_A
5	I/O-1 (RXD)	IN_K
6	I/O-2 (Adr-AO-0)	LED_AIR
7	I/O-3 (Adr-AO-1)	LED_ART
8	I/O-4 (Adr-AO-2)	AIN-0
9	I/O-5 (AO-Strobe)	AIN-1
10	I/O-INT	AIN-2
11	Analog Out	Do not contact!
12	Do not contact!	Do not contact!
13	Do not contact!	Do not contact!
14	Do not contact!	Do not contact!

4.3 PCB Layout Recommendation

4.3.1 Footprint

The plug connections are asymmetrically arranged along the longitudinal axis so that it is mechanically impossible to plug them in incorrectly when relatively high components are placed in the direct vicinity of ChipOx® in a way that they prevent incorrect plugging.

We recommend that the counterparts to the connectors of ChipOx® included in the accessories (Chap. 10.2.2) be used.
This includes the following layout recommendation (dimensions in mm). The datasheet to the counterparts should be observed in any case:



ChipOx® is to be secured against falling out of the plug contacts by an additional fixture.

4.3.2 Special line wiring

The electric wiring of the two sensor lines IN_A and IN_K require special care since the currents in these lines are processed in the nA range with a resolution up to the pA range via a differential amplifier. Disturbances due to inductive coupling on these lines have a direct effect on the measurement quality. For this reason, the following applies for these lines:

- They should be kept as short as possible up to the sensor connection.
- They should be wired exactly parallel a short distance from each other.
- They are to be kept away from electromagnetic noise sources (e.g. caused by chopper-type regulators).
- They should be flanked around the outside by GND lines.
- The same applies for any adapter cables from the host PCB to the sensor connection. For lengths longer than 10 cm, a shielded cable should be used.

The success of the measure can be checked. To do this, a finger sensor is to be preferably used, which can be applied across the thumb, for example (this unfavorable application is intentional, so as to get a small useful signal). Via the communication protocol (see Chap. 5.1.2.4), dynamic disturbances can be measured with the identifier value 0x0b and a sampling rate of min. 10 Hz. If successful, the read off value should then fluctuate between 10 and 20 or less.

4.3.3 EMC measures

ChipOx® itself is already provided with measures for better electromagnetic compatibility with ferrite in all sensor lines. However, the EMC always additionally depends on the further integration of the module.

For better EMC, we recommend that the sensor lines be wired through ferrite. The EMC measurements with ChipOx® have been passed through ferrite of type WE7427221 from Würth Elektronik.

Despite the EMC measures taken on ChipOx®, it is a good idea to wire a 100 pF capacitor to GND at each sensor line.

The signal shield:

- <u>For devices lacking ground connections (usually small battery-operated ones):</u>
  There must be no AGND/DGND/GND from an external circuit connected to the signal shield, but only to the shield of the sensor.
- <u>For devices with further cable-bound interfaces, such as a power supply or PC connection:</u>
  The shield connected to ChipOx® is to be connected to GND in order to realize a large-area ground connection with low NF and HF impedance from the input socket to ChipOx®.
  Furthermore, it is to be made sure that the further circuit on the host PCB doesn't spread disturbances over the grounding surface, since these can then be radiated over the sensor lines.
  Furthermore, it is to be made sure that no remarkable parasitic current can flow through this grounding surface, e.g. from chopper-type regulators or digital circuits.

4.3.4 Lines which are not standardly used

Non-used lines are to be handled as follows:

- The analog inputs AIN0 to AIN2 are to be wired over a resistance of 1 kOhm to GND.
- The signal I/O-INT is an output, lies at logical 0 and is to be left open.
- The Signal $\overline{\text{RESET}}$ is to be left open, or, if used, is to be coupled to an open collector or open-drain circuit.

5 Operation

ChipOx® has two interfaces available for operation:
- a serial UART interface for communicating with ChipOx® for setting parameters and for data output
- a multiplexed analog output for data output.

5.1 Communication with ChipOx®

The serial UART protocol for ChipOx® is divided into the communication layer and the transfer layer. The transfer layer contains error detection and corresponds to the “Data Link Layer” of the OSI model.

5.1.1 Transfer layer

The transfer layer is an asynchronous, bit-serial, packet-oriented, secure transmission method , in which control and user information characters are transferred over the connecting lines. The transfer layer establishes a full-duplex communication transfer layer of a point-to-point connection, preferably between PCBs. It is meant for systems with several independent hardware components, which communicate with each other. The communication paths are short.
The transfer layer structure is kept as simple as possible to allow its implementation in devices with relatively low computing power. It is a simple polling transfer protocol. Data from the host to the client (ChipOx®) and from client to host are grouped in packets.

The error protection does not allow errors to be corrected autonomously. Due to the dynamic changes in the data and the corresponding packet lengths, the packets are not acknowledged. Because the communication layer of the client doesn’t receive any information from the transfer layer if there’s an error in the packet (e.g. incorrect checksum), and therefore doesn’t reply to the host, the communication layer of the host, which lies above the transfer layer, must monitor the client reply time and, if necessary, resend the last packet. The recommended monitoring time is usually 100 ms, after which ChipOx® should reply in any case. Exceptions are the channels ‘real-time data format’ and the ‘periodical response time’ on all channels whose reply is expected after the correspondingly configured time + 100 ms. The probability of a transmission error caused by the path can be estimated to be very low, which justifies the lack of error correction.

Because data packets are sent without receiving an acknowledgement, the addressee must always have its receiving equipment on. Data packets not picked up by the addressee are lost.

5.1.1.1 Hardware protocol of the transfer layer

Serial UART interface: variable Baud rate, 1 start bit, 8 data bits, 1 stop bit, no parity bits.

5.1.1.2 Packet structure

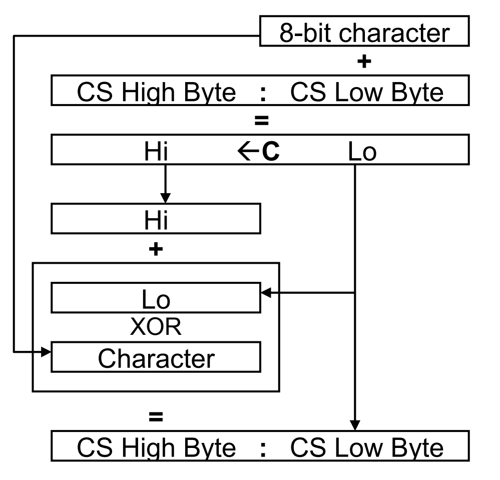
Every packet has the following structure:

Flag	Data	Checksum	Flag

Identifier	Description	Size
Start flag	Indicates the beginning of a packet: 0xa8	1 byte
Data	Data packets	variable
Checksum	Checksum as below from all characters in the field 'Data'. Send: High byte first	2 bytes
End flag	Indicates the end of a packet: 0xa8	1 byte

The transfer layer divides its work into two layers. The first layer conducts the data and the calculated checksum to the frame layer, which is directly connected to the hardware UART.

Calculation of the 16-bit checksum from the 'Data' block, 0 is the starting value:



<u>Example in C:</u>

```
wChecksum+=byChar;
HI_BYTE(wChecksum)+=
  LO_BYTE(wChecksum)^byChar;
```

<u>Example in Assembler for the µC-8051:</u>

```
MOV   A,byChar
ADD   A,wChecksum+01H; Low-Byte
MOV   wChecksum+01H,A; Low-Byte
XRL   A,byChar
ADDC  A,wChecksum; Hi-Byte
MOV   wChecksum,A; Hi-Byte
```

The frame layer sends the packet, consisting of data and a checksum between the start and end flag (frame), using a byte-stuffing algorithm. With this algorithm, the addressee can detect the packets securely without losing the synchronization due to extraneous data traffic. The reserved value 0xa8 is used for the start and end flags . The second reserved character is the control byte with value 0xa9. If in the block "data" or "checksum" a character appears which is the same as one of the flags of the control byte, it's coded with two bytes. First, the control byte is transmitted, and the second byte is the original data byte AND-linked with 0xdf (byte-stuffing).

0xa8 is coded as 0xa9, 0x88.
0xa9 is coded as 0xa9, 0x89.

The addressee can then clearly detect where one packet ends and the next one begins with the start and end flags. If in the received data stream a control byte is detected, it is to be ignored and the following byte is to be linked with 0x20 OR (destuffing).

5.1.2 Communication layer

The communication layer is one layer above the transfer layer and is completely contained in the 'data' block of the transfer layer.

Transfer layer:	Flag	Data		Checksum	Flag
or	Flag	Data channel-ID	User Data	Checksum	Flag

If the transfer layer of ChipOx® receives faulty data packets, this is reported to the communication layer, which in turn sends the corresponding error message to the distant end.

5.1.2.1 Structure of a communication data packet

In order to be able to put the individual data packets together to form a block at the distant end or in order to be able to allocate the data packets to certain channels, each packet consists of a data channel ID and the following user data:

Data channel ID	User data (N bytes)

The data channel ID defines the type of user data. For ChipOx®, the following channels are used:

Data channel	Name	Meaning	Length of user data
13	*SYSTEM_ERROR*	system error	variable
127	*CHIPOX*	communication specific to ChipOx®	variable

The user data are differentiated by the protocol using the data channel ID.

5.1.2.2 Communication data channel 127

Most of the user data for ChipOx® is transmitted on channel 127 (*CHIPOX*). The simplest procedure is the polling transmission, where the host polls the individual data from ChipOx®.

Data channel ID 127	Identifier	Data

The 'identifier' is used to allocate the data within the data channel 127 to a task.

For commands from the host to ChipOx® regarding data requests or parameterization (request/setting), the identifier is linked with the attribute 0x80 OR. Afterwards, further bytes will follow the identifier, accordingly. For messages from ChipOx® to the host (reply), the identifier doesn't come with an attribute and the corresponding information comes in the following bytes.

Identifier		**Length of the data**	
Value	**Description** [reply value range]	**For replies**	**For request/ setting**
	Vital parameters		
0x01	SpO_2 value [0...100%]	1 byte	1 byte(1)(6)
0x02	Pulse [0...300 bpm]	2 bytes(2)	1 byte(1)(6)
0x03	Signal quality [0...100%] (more about this in Section 1.3.6)	1 byte	1 byte(1)(6)
0x04	Plethysmogram [0...255], resolution max. 100 Hz	1 byte	1 byte(1)(6)
0x05	Pulsation strength (perfusion) $\Delta I_{AC}/I_{DC}$ in [0...255]/1000	1 byte	1 byte(1)(6)
0x08	Status Information: Bit 0: Sensor is off Bit 1: Finger is out Bit 2: Pulse wave detected Bit 3: Searching for pulse Bit 4: Pulse search takes too long (pulse can't be found within 15 s) Bit 5: Low pulsation strength (low AC/DC ratio) Bit 6: Low signal (low AC and low DC signals) Bit 7: Too much ambient light Bit 8: Too many disturbances Bit 9: Many motion artifacts Bit 10: Sensor defective Bit 11: Power supply outside of tolerance Bit 12: Operating temperature outside of tolerance Bit 13: Wrong sensor Bit 14: Vital parameter data outside of measurement range Bit 15: -	2 bytes(2)	1 byte(1)(6)
0x0b	Dynamic disturbances, e.g. fluorescent lamps, EM interference fields, etc. [0...255]	1 Byte	1 Byte(1)(6)
	Additional Measurements		
0x11	Signal amplification [0...255]	1 byte	1 byte(1)(6)
0x12	Analog input channel 1 [0...4095]	2 bytes(2)	1 byte(1)(6)
0x13	Analog input channel 2 [0...4095]	2 bytes(2)	1 byte(1)(6)
0x14	Analog input channel 3 [0...4095]	2 bytes(2)	1 byte(1)(6)
0x15	I/O port pins	1 byte	1 byte(1)(6)
0x16	Chip core temperature as signed int in 0.1°C steps	2 bytes(2)	1 byte(1)(6)
	Module Data		
0x21	Firmware version [SW#### Vx.yy.zzzz]	17 bytes	0 bytes
0x23	Serial number (3)	10 bytes	0 bytes
0x25	Sensor type	variable	0 bytes
	Commands / Settings		
0x31	Reset hardware (ChipOx reset pin is set to Low for 100 ms)	n. a.	0 bytes
0x32	Reset software (ChipOx reset pin not influenced)	n. a.	0 bytes

Identifier		Length of the data	
Value	**Description** [reply value range]	**For replies**	**For request/ setting**
0x33	Set idle mode (for saving energy during time between measurements): 0=wake up 1=sleep (no measurements or messages) 2=deep sleep (wake up only possible over Low at reset pin)	1 byte(5)	1 byte
0x3a	For testing purposes, any data package which originates within the transfer layer of ChipOx® can be generated. The data transmitter is responsible for the content and further use.	variable	variable
0x41	Set Baud rate: 0= Baud rate inquiry 24= 2400 48= 4800 96= 9600 (default) 19= 19200 38= 38400 57= 57600 115= 115200 23= 230400	1 byte(5)	1 byte
0x42	Sensitivity for SpO_2 (SpO_2-FAL) (7) [0...3]: 0=inquiry of sensitivity for SpO_2 1=sensitive 2=normal (default) 3=stable	1 byte(5)	1 byte
0x43	Pulse frequency sensitivity (PF-FAL) (7) [0...5]: 0=inquiry of the pulse frequency sensitivity 1=beat-to-beat with 10% VS (8) 2=sensitive and 33% VS 3=sensitive and 10% VS 4=normal and 10% VS (default) 5=stable and 10% VS	1 byte(5)	1 byte
0x44	Sampling rate (effective from firmware version V1.02.0007): 0= inquiry of the sampling rate 75= 75 Hz 30= 300 Hz (default)	1 Byte(5)	1 Byte
0x45	12-bit measurement range analog channel 0 (AIN-0): 0=inquiry of the12-bit measurement range 1= 0 to150mV 2= 0 to 300mV 3= 0 to 600mV 4= 0 to 1200mV 5= 0 to 2400mV (default)	1 byte(5)	1 byte
0x46	Meas. range analog channel 1 (AIN-1) (see analog channel 0)	1 byte(5)	1 byte
0x47	Meas. range analog channel 2 (AIN-2) (see analog channel 0)	1 byte(5)	1 byte

<table>
<tr><th colspan="2">Identifier</th><th colspan="2">Length of the data</th></tr>
<tr><th>Value</th><th>Description [reply value range]</th><th>For replies</th><th>For request/ setting</th></tr>
<tr><td>0x51</td><td>
Real-time data channel (sending selected data in a block):

Data format at setting:
1st byte: block interval in steps of 100 ms (0=off)
2nd byte: channel 1: identifier, 3rd byte: number of values per block
4th byte: channel 2: identifier, 5th byte: number of values per block
…
20th byte: channel 10: identifier, 21st byte: no. of values per block

Identifiers of 0x01 to 0x1F are possible.
When less than 10 channels are transmitted, only the set ones are taken into consideration. When the real-time data channel is configured, all following bytes are discarded if “Number of values per block” is sent with 0 one time.

Due to the internal data processing, not every combination of block intervals (Bi) and number of values per block (NVpB) lead to the desired result.
Example:
The channel 0x04 (Plethysmogram) should be transmitted at 32 Hz in one block to 1 s (Bi = 10 and NVpB = 32). Due to rounding errors, ChipOx® calculates a sampling interval (SI) of 30 ms based on the internal processing frequency of 100 Hz, which leads to an actual sampling frequency of 33.333 Hz instead of 32 Hz. The 32 sampled values then lead to the block being sent already after 960 ms instead of after 1 s.
Correct sampling frequencies (Sf) are only reached by selecting Bi and NVpB so that the following relationships are valid, whereby the units for Sf, Si and Bi refer to the following exemplary table:

$Si = \frac{100}{Sf}$. When Si is an integer, then
$Bi = n * \frac{Si}{10}$. If n as an integer is chosen so that Bi becomes an integer, then
$NVpB = \frac{Sf * Bi}{10}$.

Exemplary table:
<table>
<tr><th>Sf / Hz</th><th>Si / 10ms</th><th>Bi as steps of 100ms</th><th>NVpB</th></tr>
<tr><td>100</td><td>1</td><td>1;2;3;4;...</td><td>10;20;30;40;...</td></tr>
<tr><td>50</td><td>2</td><td>1;2;3;4;...</td><td>5;10;15;20;...</td></tr>
<tr><td>33,333</td><td>3</td><td>3;6;9;12;...</td><td>10;20;30;40;...</td></tr>
<tr><td>25</td><td>4</td><td>2;4;6;8;...</td><td>5;10;15;20;...</td></tr>
<tr><td>20</td><td>5</td><td>1;2;3;4;...</td><td>2;4;6;8;...</td></tr>
<tr><td>10</td><td>10</td><td>1;2;3;4;...</td><td>1;2;3;4;...</td></tr>
<tr><td>5</td><td>20</td><td>2;4;6;8;...</td><td>1;2;3;4;...</td></tr>
<tr><td>2</td><td>50</td><td>5;10;15;...</td><td>1;2;3;...</td></tr>
<tr><td>1,25</td><td>80</td><td>8;16;24;...</td><td>1;2;3;...</td></tr>
<tr><td>1</td><td>100</td><td>10;20;30;...</td><td>1;2;3;...</td></tr>
</table>
Bi is in one block of parameters when several channels of different sampling frequencies are transmitted, which must be selected the same for all channels.

<u>Data format in replies</u> (max. of 130 bytes per data packet, max. 200 bytes per s) (6):
Values for channel 1, values for channel 2, ...

Example: see Section 5.1.2.4 - Standard settings
</td><td>variable: (2)</td><td>variable: (6)
1+
2 bytes per channel</td></tr>
</table>

Identifier		Length of the data	
Value	**Description** [reply value range]	**For replies**	**For request/ setting**
0x52	Real-time data format: Delivers current data format, the way it has been set by 0xD1.	as by 0xD1	0 bytes
0x61	Configuration of the multiplexed analog output: 0 = configuration inquiry, further bytes are ignored Configuration settings: Channel 0: identifier (up to 0x1F), [Channel 1: identifier (up to 0x1F),... Channel 6: identifier (up to 0x1F), Channel 7: identifier (up to 0x1F)] 255 = turn off analog output (default), further bytes are ignored	1 byte per channel(5)	1 byte per channel
0x62	Calibration signal at all multiplexed analog outputs: The first byte refers to the current calibration signal. The second byte refers to the calibration signal behavior after reset. For both: 0 = inquiry 1...15 = period in seconds and activate 255 = calibration signal off	2 bytes(5)	2 bytes
0x6F	All settings are deleted and the factory settings described below are made. This is only done when the security byte 0xF6 is transferred as a parameter. ChipOx® then carries out a software reset (0xB2).	n.a.	1 byte
	Error messages		
0x71	Unknown data channel ID	2 bytes(4)	n. a.
0x72	Unknown identifier	2 bytes(4)	n. a.
0x73	Corrupt parameter	2 bytes(4)	n. a.
0x74	Transfer protocol on receiving with number: 0x80: internal error 0x81: checksum error 0x82: overflow error 0x83: frame error	1 byte	n. a.

(1) Data request: The character after the identifier indicates the reply period in steps of 100 ms.(6)
The maximum value of the period is 250, which corresponds to 25 s.
The value 251 for the period is reserved for 'automatic transmission if change', minimum time interval between two messages is 100 ms (for 'Status information: pulse wave detected' it can be less).
The value 252 turns off the periodical reply process.
The value 0 delivers the current measurement and has no influence on the periodical reply process.
(2) For 16-bit values, the high byte is sent first.
(3) Is automatically sent once after a reset.
(4) Both bytes correspond to the first 2 bytes of the received telegram.
(5) After receiving the command, ChipOx® sends a reply in any case, the contents of which is identical with the command itself. This way the host can check whether the command was correctly understood.
(6) In order to avoid system overload, the entire data rate for real-time data and periodical reply processes is limited to an average of 250 bytes/s. Attempts to generate a data rate beyond this will be answered with the error value 0x73 (=faulty parameter).
(7) FAL stands for Flexible Artifact Leveling. More details can be found in Section 1.3.8.
(8) VS stands for variance suppression. More details can be found in Section 1.3.8.

All setting changes (identifiers 0x41 to 0x6F) are permanently saved, so that after ChipOx® is reset, it works with the last made settings. The number of setting changes is limited to a total of 10000 times.
If this is exceeded, or if there was an error during saving, ChipOx® will bring out a system error message. In this case, it must be checked whether the settings really had to be changed that often (host algorithm).
The repetition of a setting does not count as a setting change. In other words, if the setting doesn't change due to an identifier of 0x41 to 0x6F, this is detected by ChipOx®.
Example:
An unfavorable algorithm would be, for example, when the host always resets the settings to ChipOx® factory settings after every restart and then individually sets the response times of SpO_2, pulse and signal quality. In this case, this would correspond to 4 setting changes.
It would be better if these means were only taken if not yet done by ChipOx®. A change by ChipOx® or a new ChipOx® can be detected by means of the serial number.

5.1.2.3 Communication data channel 13

System errors are transmitted on data channel 13 (*SYSTEM_ERROR*). Telegrams on this channel are sent independently, without request, by ChipOx®. ChipOx® does not accept any telegrams on this channel.

Data channel ID 13	32-bit error number (high order first)	optional error text of variable length

It is possible for ChipOx® to announce the following system errors:

Number	Meaning
2[(1)] or 3[(1)]	RAM error
7[(1)]	Program memory: checksum error
8	EEPROM: Integrity faulty (configuration faulty, factory settings made)
10	Code number faulty (the code number is a kind of internal serial number)
20	Serial interface (paradox for exclusively serial data transmission)
51[(1)]	Ox-Sensor: Red LED defective
52[(1)]	Ox-Sensor: Infrared LED defective
53[(1)]	Ox-Sensor: Photodiode defective
55[(1)]	Ox-Sensor: Error can't be determined specifically
70	Stack overflow, run-time error, ChipOx® restarts
71	Watchdog reset (ChipOx® restarted due to run-time error)

[(1)] If this error occurs, ChipOx® cannot continue to operate properly.

5.1.2.4 Standard settings

At delivery, ChipOx® standard operation is as if the following commands have been sent to ChipOx® (factory settings correspond to the execution of request identifier 0xEF):

Parameter	Description	Request sequence
Status information	Sent any time there's a change	0x88; 251
Baud rate	9600 Baud	0xC1; 96
SpO_2 sensitivity	normal	0xC2; 2
Pulse frequency sensitivity	normal and 10% variance suppression	0xC3; 4
Analog sampling rate	300 Hz	0xC4; 30
Range analog- input channel 0	0 to 2400 mV	0xC5; 5
Range analog- input channel 1	0 to 2400 mV	0xC6; 5
Range analog- input channel 2	0 to 2400 mV	0xC7; 5
Real-time data	Every second: SpO_2, pulse frequency and signal quality	0xD1; 10; 1;1; 2;1; 3;1
Analog output	SpO_2, pulse frequency, signal quality and plethysmogram	0xE1; 1; 2; 3; 4
Calibration at analog output	Period after reset: 10 s	0xE2; 255; 10

5.1.3 Examples

Examples on the communication level:

a) Host requests the pulse frequency from ChipOx® with: 127; 0x82; 0;
For a pulse frequency of 168, ChipOx® replies with:127; 0x02; 0x00; 0xa8

b) Host requests the automatic transmission of the saturation every second from ChipOx®: 127; 0x81; 0x0a
For a saturation of 97%, ChipOx® replies automatically every second with:127; 0x01; 0x61

c) Host requests the plethysmogram with 20 Hz and the pulse frequency with 1 Hz in the real-time data channel, whereby the real-time data packet is sent every second by ChipOx®:
127; 0xd1; 0x0a; 0x04; 0x14; 0x02; 0x01
Reply from ChipOx® automatically after every second for a pulse frequency of 100 : 127; 0x51; 20 Bytes for plethysmogram; 0x00; 0x64

Example, answer a) for calculating the checksum character by character:

Again, the program sequence:

```
CS=CS + character;                          // 16-bit operation
CS-Hi=CS-Hi + (CS-Lo XOR character);
```

State	Character	CS-Hi	CS-Lo
Start	0x00	0x00	0x00
Character 1	0x7f	0x00	0x7f
Character 2	0x02	0x83	0x81
Character 3	0x00	0x04	0x81
Character 4	0xa8	0x86	0x29

Transfer layer level

In connection with the transfer layer, the complete ChipOx® data packet looks like:

Flag	Data channel ID	User data	Checksum	Flag

Correspondingly, on the hardware protocol level based on the transfer layer protocol, the example a) from above looks like (physical data on transmission line):

Request: Host to ChipOx®:

0xa8;	0x7f;	0x82;	0x00;	0x85;	0x01;	0xa8;
start flag;	*CHIPOX*;	Identifier for pulse	date	CS-Hi;	CS-Lo	end flag;

Reply: ChipOx® to Host:

0xa8;	0x7f;	0x02;	0x00	0xa9; 0x88;	0x86;	0x29;	0xa8;
start flag;	*CHIPOX*;	Identifier for pulse	HiByte;	LoByte + byte stuffing	CS-Hi;	CS-Lo	end flag;

5.2 Analog Output of ChipOx®

ChipOx® offers up to 8 channels for outputting vital parameters and other measurements as analog multiplexed signals.

5.2.1 Possible parameters

The output range lies from 0...1000mV, whereby the following channels have the resolutions indicated in the table below:

Parameter	**Range**	**Resolution 1)**
SpO_2	0...100%	10mV / $\%_{SpO2}$
Pulse frequency	0...300 bpm	3.33mV / bpm
Signal quality	0...100 in 10 steps	100mV / step
Plethysmogram	0...255	3.9mV / LSB
Pulsation strength	0...255$^{o}/_{oo}$	3,9mV / $^{o}/_{ooTPM}$
Signal amplification	0...255	3.9mV / LSB
Analog input channel 1	0...4095	244µV / LSB 1)
Analog input channel 2	0...4095	244µV / LSB 1)
Analog input channel 3	0...4095	244µV / LSB 1)
Chip temperature	-20°C...+80°C	200 mV +10mV / °C

1) The highest resolution of the analog output is 590µV / LSB

The output analog signals can be selected over a serial interface (see communication protocol).

5.2.2 Decoding

The signals are output multiplexed at the pin “Analog Out”.

Caution: Voltages to the pin Analog Out must not be applied!

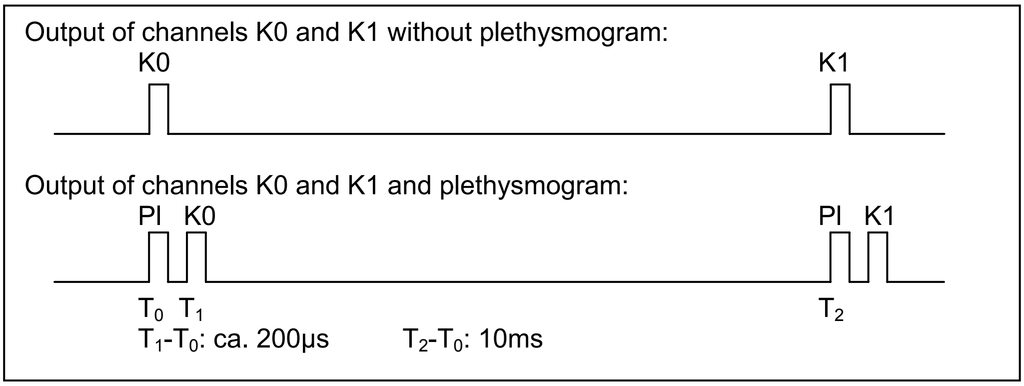
The signals are to be decoded over the output address at pins I/O2 to I/O4 and the pin I/O-5 as sample/hold controller. The pins I/O-2 to I/O-5 are outputs and can’t be influenced. The function of this control has been tested with the sample/hold device SMP08 from the manufacturer Analog-Devices.

The allocation is as follows:

Analog channel	I/O-5 (Addr.AO-Strobe)	I/O-4 (Addr.AO-2)	I/O-3 (Addr.AO-1)	I/O-2 (Addr.AO-0)
No output	1	X	X	X
0	0	0	0	0
1	0	0	0	1
2	0	0	1	0
3	0	0	1	1
4	0	1	0	0
5	0	1	0	1
6	0	1	1	0
7	0	1	1	1

5.2.3 Timing

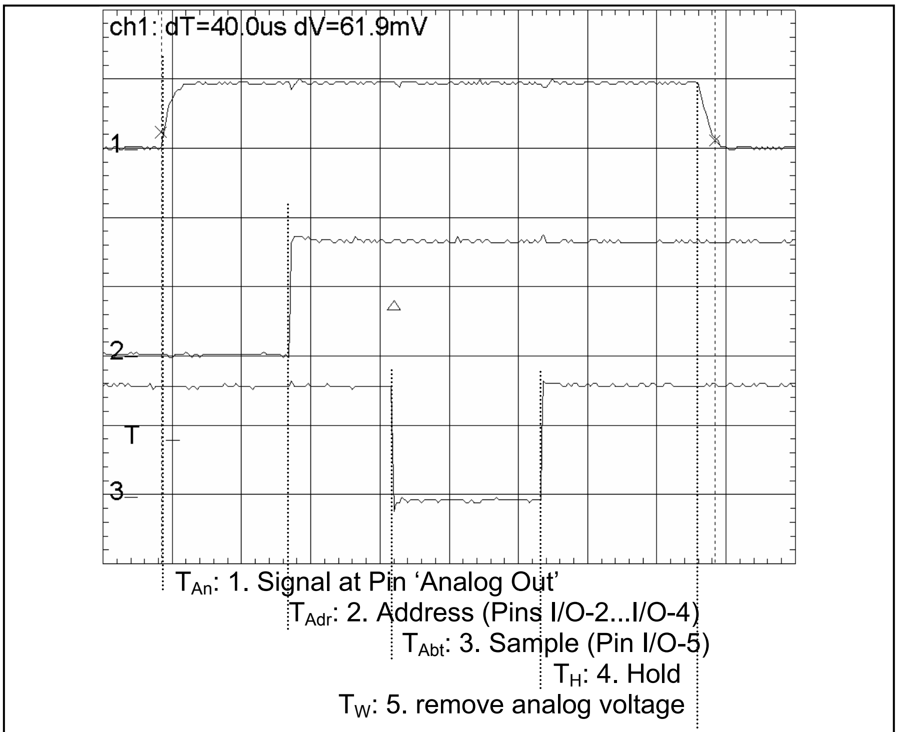
The output frequency is 100Hz, i.e. one channel is output every 10ms. Therefore, the output frequency per channel is divided into 100Hz / number of activated channels.
If the plethysmogram is included among the activated analog channels, then it is always output with 100Hz and additionally (ca. 200µs later), one of the other channels is output. In this case, the 100 Hz are distributed among all other channels.



In the standard settings of ChipOx®, the channels SpO_2, pulse frequency, signal quality and plethysmogram are output. This results in the following output frequencies:

- Plethysmogram: 100 Hz
- SpO_2, pulse frequency and signal quality: each 33.333Hz

Output timing of a single channel:



The following times are typical:

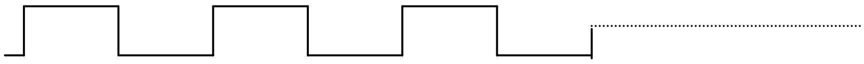
- T_{Adr} - T_{An}: 8 µs
- T_{Abt} - T_{Adr}: 7µs
- T_H - T_{Abt}: 10...12µs
- T_W - T_H: 10...12µs
- Overall duration: T_W - T_{An}: 35...40µs

5.2.4 Calibration signal

In order to compensate for offset, amplification and linearity errors, and therefore to get the most exact analog output result possible, there is the option of having a calibration signal output.
The calibration signal alternately outputs the maximum and minimum values of the corresponding channel.

The standard option:

Output of the calibration signal on all channels:



The calibration signal's period after a reset can be changed over the serial interface (see communication protocol in Section 5.1.2.2). A spontaneous calibration signal can also be output.

6 Technical Data

6.1 Operating Parameters

Parameter	Value range		units	Accuracy / Comments
	min.	max.		
Power supply V+ vs. GND	3.3 Tol.: - 0.3 / + 0.1		V	Ripple: < 100mV$_{SS}$ (linearly regulated).
Current consumption at 300Hz at 75Hz sampling rate	12 12	25 16	mA	Additionally depending on whether measurements are being carried out or not and on the regulated LED current
Allowed operating temperature	-20	+60	°C	See also Section 3.2

6.2 Pulse Oximetry Parameters

Parameter	Value range		units	Accuracy / Comments
	min.	max.		
Analog signal sampling rate	75 or 300		Hz	Better than 100 ppm
Sensor: wavelengths	660 / 905		nm	→ maximum temperature increase by 2°C at point of application
Thermal output	0	20	mW	
SpO_2 measurement: Measurement dynamics: for FAL[(1)]	45	100	%	70% < SpO_2 < 100%: better than 2% accuracy (see Chapter 7) SpO_2 < 70% not validated
sensitive: First reaction after final value reached after	ca. 1 ca. 4		s	Measured at desaturation / resaturation between 96% and 84% SpO_2 under favorable measurement conditions. The values can be extended by a bad pulsation strength or motion artifacts.
normal: First reaction after final value reached after	ca. 2 ca. 8		s	
stable: First reaction after final value reached after	ca. 4 ca. 12		s	
First displayed value after application	3	6	s	Measured at default settings. The worse the measurement conditions, the less reliable the first displayed value.
Pulse frequency measurement: Measurement dynamics: for FAL[(1)]	20	300	Bpm	1 bpm up to 2% of displayed value
Beat to Beat - 10% VS[(2)] : Reaction after	1	7	s	Maximum values measured with sudden change of 40 to 200 bpm and vice-versa. The reaction depends on the difference (variance) of the beats among themselves.
sensitive-33% VS: First reaction after final value after further	1 1	5 4	s	
sensitive-10% VS: First reaction after final value after further	1 1	7 4	s	
normal-10% VS: First reaction after final value after further	1 1	7 6	s	
stable-10% VS: First reaction after final value after further	1 1	7 8	s	
First displayed value after application	5	8	s	Measured at default settings. The worse the measurement conditions, the less reliable the first displayed value.
Signal quality	0	100	%	A signal quality of > 90% is good, below this the SpO_2 values and pulse frequency can be unreliable.
Plethysmogram	0	255	LSB	> 6 ppm / LSB
Pulsation strength (Perfusion) $\Delta I_{AC}/I_{DC}$ (see Section 3.4.5)	0	250	$^{o}/_{oo}$	The pulsation strength is low if the value is under $10^{o}/_{oo}$ and is sufficient if this value is $15^{o}/_{oo}$. This is also displayed by the status flag on the communication channel 127 identifier 0x08.
Ambient light suppression	Up to 14 x the measurement signal			
Signal amplification	0	255	1	The pulse oximetry signal is low if the signal amplification is over 160. This is also displayed by the status flag on the communication channel 127 identifier 0x08.

(1) FAL stands for Flexible Artifact Leveling. For details, see Section 1.3.8.
(2) VS stands for Variance Suppression. For details, see Section 1.3.8.

6.3 Analog Output

Measured at V_{+3V3} = 3.3V, over the entire temperature range

Parameter	**typ. value**	**units**
Resolution	586	µV / LSB
Minimum output voltage	0	mV
Maximum output voltage (measurement range)	1000	mV
Maximum output voltage which can be applied at the analog output outside of sampling time	2400	mV
Offset error	max. ±30	mV
Integral non-linearity	±1200	µV
Differential non-linearity	±600	µV
Amplification error	max. ±50	mV
Output resistance R_A at the pin 'Analog Out'	22	kΩ
Time until output voltage is reached with a accuracy of ±1/2 LSBs	10	µs
Refresh cycle for all channels together except for plethysmogram	10	ms
Refresh cycle for plethysmogram	10	ms
Overall duration for the output of a channel	max. 40	µs
Calibration signal duration after reset (can be deactivated)	30	s
Minimum period for calibration signal	1	s
Maximum period for calibration signal	15	s

Caution: Voltages to the pin Analog Out must not be applied!

6.4 Other Parameters

Parameter	**Value range**		**Units**	**Accuracy / Comments**
	min.	**max.**		
Measurement of analog inputs: Maximum settable input voltage:	0	150 300 600 1200 2400	mV	
Resolution	12		Bit	overall error: -3 ±2 LSB
Sampling rate	100		Hz	better than 1 $^{o}/_{oo}$
Measurement of chip core temp.	-25	+80	°C	±3°C
Digital I/O's as input	0.8 x V+	0.2 x V+	V	for logical Hi / Lo, 5V-tolerant
Digital I/O's as output (high voltage)	V+ -0.1		V	I_{OH} = -10 uA, port I/O push-pull
	V+ -0.7		V	I_{OH} = -3 mA, port I/O push-pull
Digital I/O's as output (low voltage)				
		0.1	V	I_{OL} = 10 uA
		0.6	V	I_{OL} = 8.5 mA
$\overline{\text{RESET}}$ pin, low active	0.8 x V+	0.2 x V+	V	Input current I_{Rst}=60µA_{typ} / 100nF

Parameter	Value range		Units	Accuracy / Comments
	min.	max.		
Dimensions	31 x 14 x 5		mm	
Weight	ca. 1.9		g	

6.5 Standards

In the design and validation of ChipOx®, the standards in the table below were observed, if applicable, whereby the remaining risk of any errors was reduced to a minimum.

Standard / Regulations	Content
EG Guideline 93/42/EWG: 1993-06-14	Medical products (basic requirements)
MPG: 2002-08-07	Medical product law
DIN EN 60601-1: 1990 + A1: 1993 + A2: 1995	Medical electrical devices General safety definitions
DIN EN ISO 1441: 1998-01	Risk analysis
DIN EN 865: 1997-05	Pulse oximeter – special requirements
ISO/WD2 9919 (IEC/WD2 60601-2-54): 2002	Medical Electrical Equipment -- Part 2-54: — Particular requirements for the basic safety and essential performance of pulse oximeters for medical use
DIN EN ISO 60601-1-2: 2002-10	Electromagnetic compatibility
DIN EN ISO 60601-1-4: 2001-04	Programmable electrical medical systems
DIN EN ISO 61000-4-2: 2001-12	Immunity to static electricity
DIN EN ISO 61000-4-3: 2003-11	Immunity to HF EM fields
DIN EN 1041: 1998-04	Availability of information

7 Calibration

Studies carried out by: University of Lübeck, Institute for Anesthesiology / Institute for Medical Technology

7.1 Evaluation

The evaluation complies with the definitions in ASTM F1415, as well as those in ISO/WD2 9919 and IEC 60601-2-54.

According to this standard, the approved pulse oximetry sensors are calibrated and evaluated against dyshemoglobin-free reference measurements, which were determined from CO oximeter data and do not contain saturation components of the hemoglobin fractions SaCO and SaMet. With these values, the functional and fractional O_2 saturation are identical. Using this method, the reference data falsification, caused by dysfunctional Hb fractions, which occurs often with smokers, is eliminated for the most part.

With this data ChipOx® has been calibrated specifically to the sensor within the range of 70% - 100% SpO_2.

The accuracy for the approved sensors according to this standard are:

Accuracy between	Precision between	Bias between
1.5% and 2.0%	1.5% and 2.0%	0.05% and 0.2%

8 Error Messages, Troubleshooting

ChipOx® is designed for safe operation, detects most error states, and passes this information on to the serial interface. ChipOx® monitors its own program sequence and restarts the program if a program flow error occurs.

In principle, all status reports and messages with error numbers for all disturbances are to be checked on the communication channel 13.

Problem	Possible cause	Remedy
No communication possible	Serial interface lines exchanged	Check and correct problem, if necessary
	Baudrate incorrectly set	Try 9600 Baud (default setting)
	Communication protocol incorrectly implemented	Check and correct problem, if necessary
ChipOx® refuses to measure	Wrong sensor connected	Check (also by requesting status report and sensor type) and use approved sensor.
	System error	Check status reports and messages on communication channel 13, try to correct, and if unsuccessful, contact the manufacturer's service representative.
ChipOx® displays 0-values during measurement	Operating voltage too high or too low	Check (also over ChipOx® status report) and correct, if necessary.
	Operating temperature too high or too low	Check (also over ChipOx® status report) and correct, if necessary.
	Disturbances due to electrical AC voltage	Check (also over ChipOx® status report) and shield, if necessary.
	Too much ambient light	Check (also over ChipOx® status report) and shield, if necessary.
Error message 'Sensor off', although sensor is still connected	Wire SENS_ID connected to wrong sensor pin	Check against the sensor datasheet and correct, if necessary.
Error message 'Photodiode is defective', although the sensor is OK.	Photodiode wires exchanged.	Check and correct, if necessary.
SpO_2 value shows values around 50% in the normal saturation range	LED wires exchanged	Check and correct, if necessary.
Values at analog output too low	Output load too high	Insert impedance converter with high-ohm input

9 Maintenance, Service

9.1 Maintenance

ChipOx® maintenance or recalibration is not necessary.

9.2 Function Check

If ChipOx® detects an error or non-allowed states, these are reported.
After installation, ChipOx® should be given a function check at least once a year or if malfunctioning is suspected. A function test should be carried out with a finger sensor within the normal saturation range (95% to 98% SpO_2). Alternatively, a simulation device (e.g. BIO-TEK Index 2 or METRON deag) can be used for the saturation range from 70% to 99% SpO_2 and for a pulse frequency range from 45 bpm to 250 bpm. The necessary settings for ChipOx® are closest to the settings of the pulse oximeter manufacturer BCI. The entry of ChipOx® into the settings is pending.

9.3 Technical Service

9.3.1 Repair service

Modules needing repair should be sent to the following address:

EnviteC-Wismar GmbH

Alter Holzhafen 18
23966 Wismar
Germany

If the error message indicates a defective sensor, please only send the defective sensor with the error message information.

9.3.2 Implementation support

We can help you with implementation if you send your request to EnviteC:
info@envtec.com

9.4 Hygiene

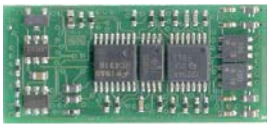
ChipOx® is to be kept free of contaminants, such as dust, grease, smoke particles and dampness, during and after installation. Contaminants can negatively influence the measurement. ChipOx® can only be cleaned in its uninstalled state with a circuit board cleaner. ChipOx® should not be installed unless it is completely dry, and then, only with regard to the information in Chapter 4.
Cleaning and disinfection instructions for the sensors can be found in the package inserts.

9.5 Disposal

ChipOx® can be disposed of as electronic scrap.
Alternatively, ChipOx® can also be sent to the ENVITEC's Technical Service (address see above).

10 Scope of Delivery

10.1 Standard Delivery / Replacement Parts

Article		Order-No.
	ChipOx® OEM module in standard high-quality packaging In one package, there can be up to 10 articles.	47-00-0033
User instructions in German. The current version is available on the internet under: http://de.envitec.biz/download/?47-07-00330001-a-www.pdf		47-07-00330001
User instructions in English. The current version is available on the internet under: http://de.envitec.biz/download/?47-07-00330002-a-www.pdf		47-07-00330002

10.2 Accessories

10.2.1 SpO_2 sensors

The SpO_2 sensors are transmission sensors and include two LEDs with the wavelengths 660 nm and 905 nm, as well as a photodiode for this spectrum. The sensors are detected individually by ChipOx® to the best possible accuracy or measurement.

10.2.1.5 Overview of cables and sensors

ENVITEC sensors:

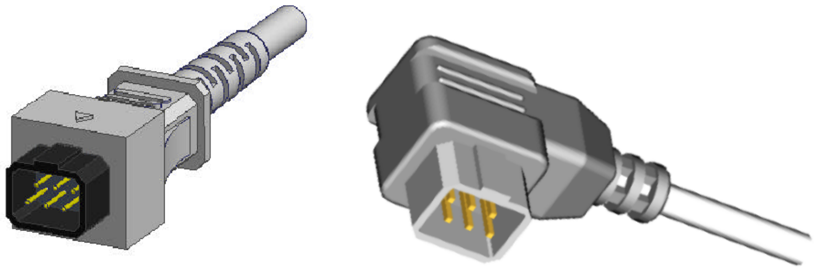
Item	length	plug	Order No.
SpO_2 finger clip sensor	120 cm	MiniMed	F-3227
		MiniMed-90°	F-3225
		Sub-D	F-3226
Small SpO_2 ear sensor	120 cm	MiniMed	
		MiniMed-90°	
		Sub-D	
Disposable SpO_2 sensor for adults	20 cm	MiniMed	2311-1
		MiniMed-90°	2311-1
		Sub-D	2310-1
All-purpose SpO_2 Y sensor	120 cm	MiniMed	
		MiniMed-90°	
		Sub-D	
Small SpO_2 finger clip sensor	120 cm	MiniMed	
		MiniMed-90°	
		Sub-D	

ENVITEC sensor cable:

Item	Connections	Length	Order No.
SpO_2 adapter cable	MiniMed – MiniMed	120 cm	X-3227-12
	MiniMed – MiniMed	240 cm	X-3227-24
	Sub-D – Sub-D	120 cm	X-3226-12
	Sub-D – Sub-D	240 cm	X-3226-24

10.2.1.6 Details

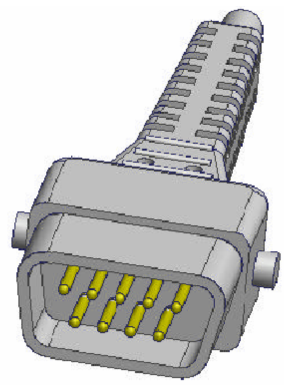
Sensor connection allocation with 6-pole MiniMed plug:

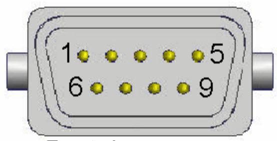


MiniMed	ChipOx® BU2	Signal
1	3	SENSOR_ID
2	7	LED_ART
3	6	LED_AIR
4	2	Sensor shield
5	4	IN_A
6	5	IN_K

Front view

Sensor connection allocation with 9-pole Sub-D plug:





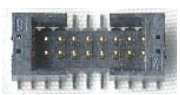
Front view

Sub-D	ChipOx®-BU2	Signal
1, 6, 7	2	Sensor shield
2	6	LED_AIR
3	7	LED_ART
5	4	IN_A
8	3	SENSOR_ID
9	5	IN_K

Sensor selection:

Sensor type:	Finger Clip	Small Ear	Y-Sensor	Small Finger	Disposable
Picture:					
Recommended for use on patients with a weight of	more than 20 kg	more than 30 kg	more than 20 kg	more than 20 kg	more than 30 kg
	F-3227	ES-3227	Y-3227	FS-3227	2311-1
	F-3225	ES-3225	Y-3225	FS-3225	2311-1
	F-3226	ES-3226	Y-3226	FS-3226	2310-1

10.2.2 Other accessories

Picture	Article	Best.-No.
	**Development Kit** ChipOx® introduction kit, consisting of: - development board - ChipOx® - fingerclip sensor F-3226 - serial interface cable User instructions: In Chapter 12	47-00-0034
	**Development Board**, The circuit board from the Development Kit	47-00-0050
	**Connector** for connecting ChipOx® with the host circuit board. For 1 ChipOx®, 2 of these are needed. Manufacturer: Samtec; Type: FTM-107-03-L-DV-S	47-000001
	**Panel jack MiniMed** For connecting the sensors with the MiniMed plug	06-024193

10.3 Customer-specific Options

A serial UART interface is available as a digital data output and for all settings. It allows data to be exchanged over a secure protocol.
Instead of the serial UART interface for data exchange and the multiplexed analog output, which both have the standard set-up, I/O lines can also be otherwise allocated. Some possibilities would be:

- other serial protocols
- SPI interfaces
- I²C-bus interface

For customer-specific options, please contact ENVITEC: info@envitec.com.

11 Guarantee

ENVITEC does not guarantee the functionality of ChipOx® if the owner or operator handles ChipOx® in a manner not intended, as described in these user instructions.

Please note that any guarantee claims become invalid if neither the recommended accessories in the user instructions are used nor the original replacement parts.

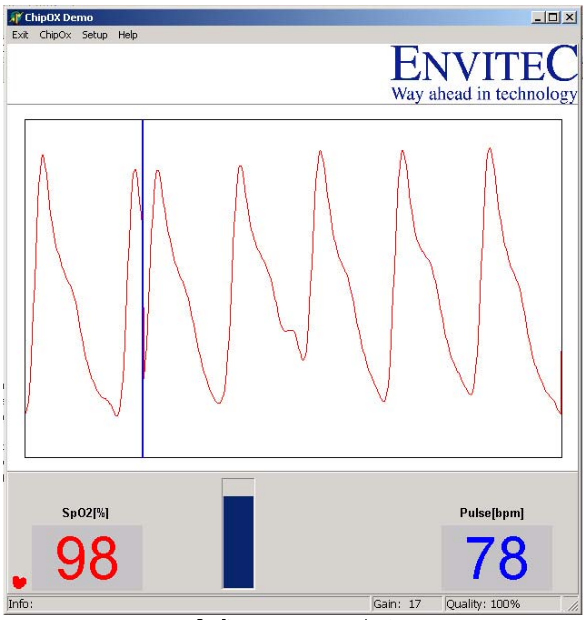
ENVITEC guarantees that ChipOx® is free of defects or faults for a period of 24 months after the date of purchase if used as intended.

- To make any guarantee claims, it is required that you present the receipt of purchase, which includes the vendor and the date of purchase.
- We don't make any guarantees when:
  – the user instructions weren't completely observed
  – operating errors were made
  – the device was handled or used in a way not intended
  – non-authorized personnel have manipulated the module
  – forces of nature, such as lightning, etc.
  – transportation damage due to inexpert packaging when being returned
  – operational and normal wear.
- ENVITEC is not liable for consequential harm caused by a defect if it is not based on intention or gross negligence. ENVITEC is also not liable for minor physical injury to life or limb resulting from negligence.
- ENVITEC reserves the right to eliminate defects or faults, to deliver a defect-free product or to reduce the price, as it so chooses.
- If we reject the guarantee claim, we will not shoulder the transportation costs.
- The legal guarantee claims are not effected by this.
- We recommend that our customers pass on the 2-year guarantee on to their customers.

The guarantee conditions for the SpO_2 sensors can be found in the package inserts included with delivery.

12 Development Kit

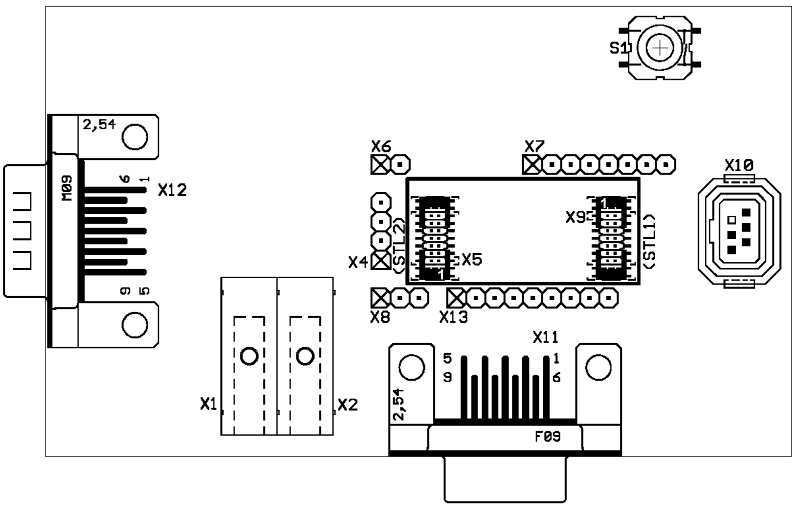
12.1 Description



Software screen shot

The Development Kit is for testing ChipOx®. It offers the possibility to immediately put ChipOx® into operation in connection with the associated PC software, and to test it.

The Development Kit offers:
- the option to accommodate ChipOx®
- direct sensor connections
- an RS232 interface to be directly connected to a PC
- the possibility for analog outputs in continuous (demultiplexed) form to be made available
- a power supply of 7V to 16V,
- PC software for visualization. It can be downloaded from: http://de.envitec.biz/download/?chipoxV2_4.zip
- The Development Kit with its standard connections, actual size:



12.2 Connection Configuration

12.2.1 Connectors to accommodate ChipOx®

ChipOx® is accommodated over 2 plug connections X5 (=BU2 on ChipOx®) and X9 (=BU1 on ChipOx®).

Plug / Pin	**Signal**	**Function**
X5 / 1	N.C.	Not connected
X5 / 2	SHIELD	Sensor shield
X5 / 3	SENSOR_ID	Sensor ID
X5 / 4	IN_A	Anode of the sensor photodiode
X5 / 5	IN_K	Cathode of the sensor photodiode
X5 / 6	LED_AIR	Anode of the infrared LED
X5 / 7	LED_ART	Anode of the red LED
X5 / 8	AIN-0	Analog input AIN-0 with reference potential GND
X5 / 9	AIN-1	Analog input AIN-1 with reference potential GND
X5 / 10	AIN-2	Analog input AIN-2 with reference potential GND
X5 / 11,12,13,14	Service	For service purposes only. Don't connect!
X9 / 1	+3V3	Power supply +3.3V
X9 / 2	GND	Power supply: ground
X9 / 3	/RESET	Reset I/O low-active
X9 / 4	I/O-0 (TXD)	Digital output: UART-TXD
X9 / 5	I/O-1 (RXD)	Digital output: UART-RXD
X9 / 6	I/O-2	Digital output: Analog-Signal-MUX: A0
X9 / 7	I/O-3	Digital output: Analog-Signal-MUX: A1
X9 / 8	I/O-4	Digital output: Analog-Signal-MUX: A2
X9 / 9	I/O-5	Digital output: Analog-Signal-MUX: Hold / Sample
X9 / 10	I/O-INT	Digital input for free use
X9 / 11	ANALOG-OUT	Multiplexed analog output vs. GND
X9 / 12,13,14	Service	For service purposes only. Don't connect!

12.2.2 Sensor connection

The sensor is either connected using the MiniMed plug connector X10 or the female SUB-D-9-plug connector X11 (not both at the same time!):

Pin X10	**Pin X11**	**Signal**	**Function**
1	1 / 8 [1)]	SENSOR_ID	Sensor ID
2	3	LED_ART	Anode of the red LED
3	2	LED_AIR	Anode of the infrared LED
4	7	SHIELD	Sensor shield
5	5	IN_A	Anode of sensor photodiode
6	9	IN_K	Cathode of sensor photodiode

[1)] In the standard case, the sensor ID is on Pin 8 and is selected over a jumper connection on the pin header connector X8 from Pin 1 to Pin 2. The connection X8 Pin 2 to Pin 3 selects Pin 1 from X11 as SENSOR_ID.

12.2.3 RS232 connection

The male SUB-D9 connection is configured according to the standard for data terminal equipment (DTE) without handshake lines.

Pin	Signal	Function
1	N.C.	Not connected
2	RX-IN	RS232-RxD input
3	TX-OUT	RS232-TxD output
4	N.C.	Not connected
5	GND	Reference potential: ground
6	N.C.	Not connected
7	N.C.	Not connected
8	N.C.	Not connected
9	N.C.	Not connected

12.2.4 Pin header connector

The following connections are available for feeding and receiving certain signals:

Pin	X4: Analog input signals	X7: Digital I/O-Signals	X13: Continuous analog output signals
1	AGND (SHIELD)	GND	AGND (SHIELD)
2	AIN-0	I/O-0 (TXD)	AOUT-0
3	AIN-1	I/O-1 (RXD)	AOUT-1
4	AIN-2	I/O-2 (Addr-AO-0)	AOUT-2
5		I/O-3 (Addr-AO-1)	AOUT-3
6		I/O-4 (Addr-AO-2)	AOUT-4
7		I/O-5 (AO-Strobe)	AOUT-5
8		I/O-INT	AOUT-6
9			AOUT-7

The **Jumper X6** connects the signal 'I/O-1 (RXD)' with the RS232 interface.
The **Jumper X8** selects the sensor ID on the sensor connection X11 between Pin 1 and Pin 8.

12.2.5 Power supply

The Development Kit can be supplied over two 4mm sockets.
The green LED indicates that the Development Kit is in operation.

Plug Connection	Signal	Function
X1	UB+	Power supply: +7V...+16V
X2	GND	Power supply: ground

12.2.6 Button

The button S1 is a reset button for ChipOx®.

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