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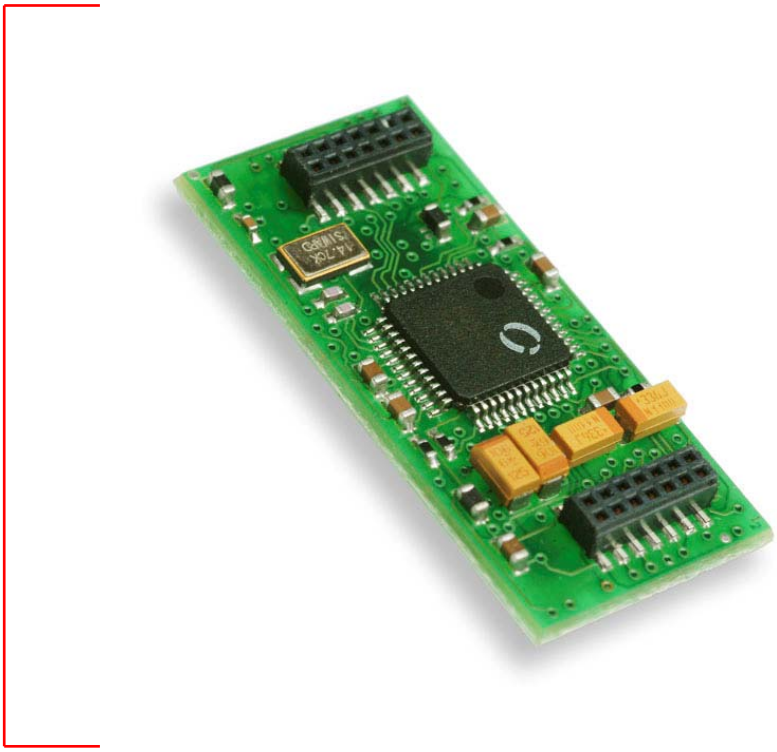
User Manual

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 **Fehler! Verweisquelle konnte nicht gefunden werden.**), 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.

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 5.1.2.6).

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 5.1.2.6).

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 5.1.2.6).

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 pulsewave (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 not 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.
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. ChipOx® measures the pulsation strength continuously as the photodiode current caused by the pulse wave $\Delta I_{AC}/I_{DC}$ (total pulse modulation) and registers a weak pulsation when the pulsation is less than 1%. In this case, 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.

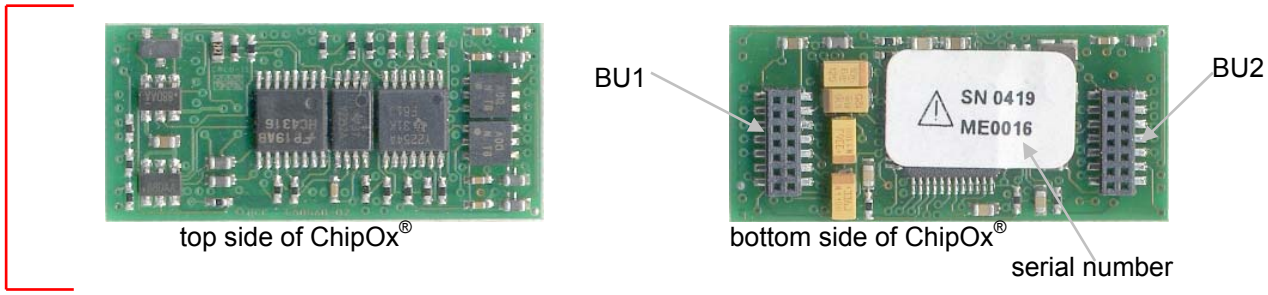
3.5 Connection of Free Inputs

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.

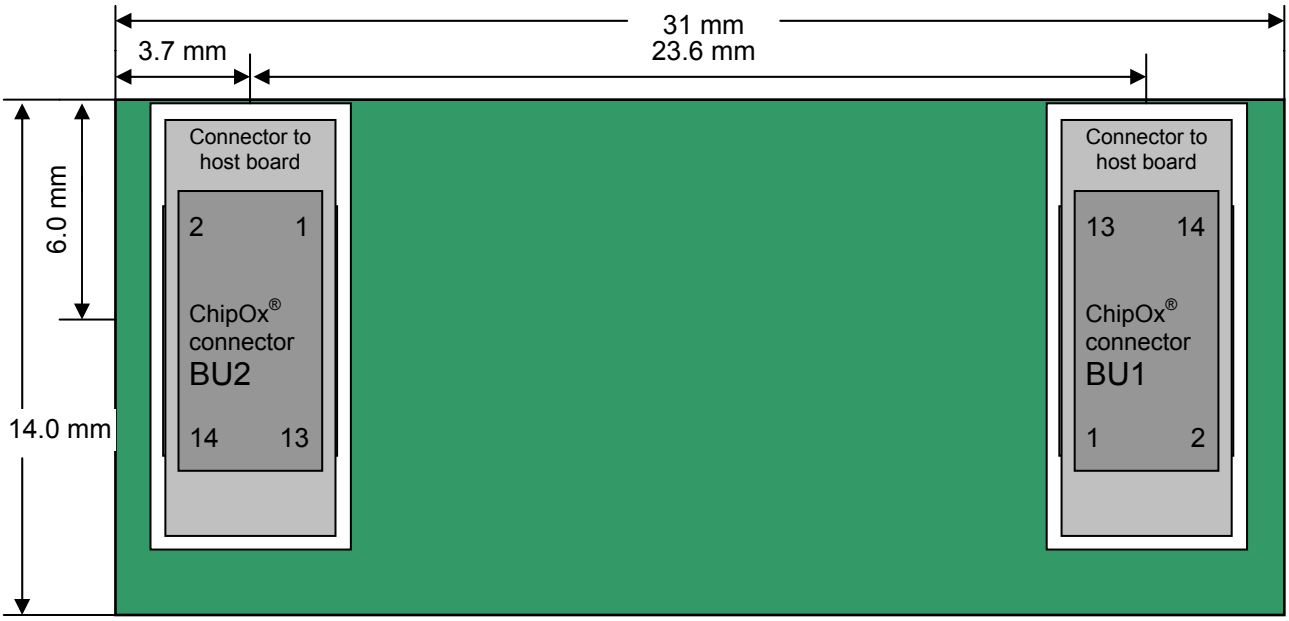
4 Dimensions / Connections / Mounting

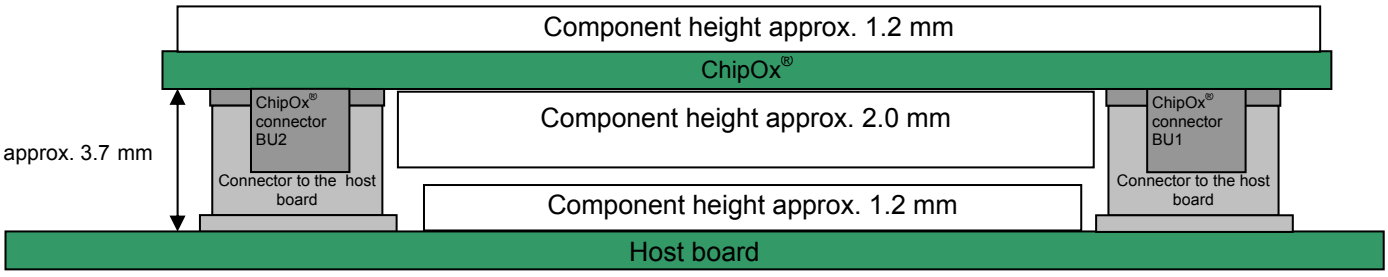
4.1 Dimensions

31 mm * 14 mm * 5 mm



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.

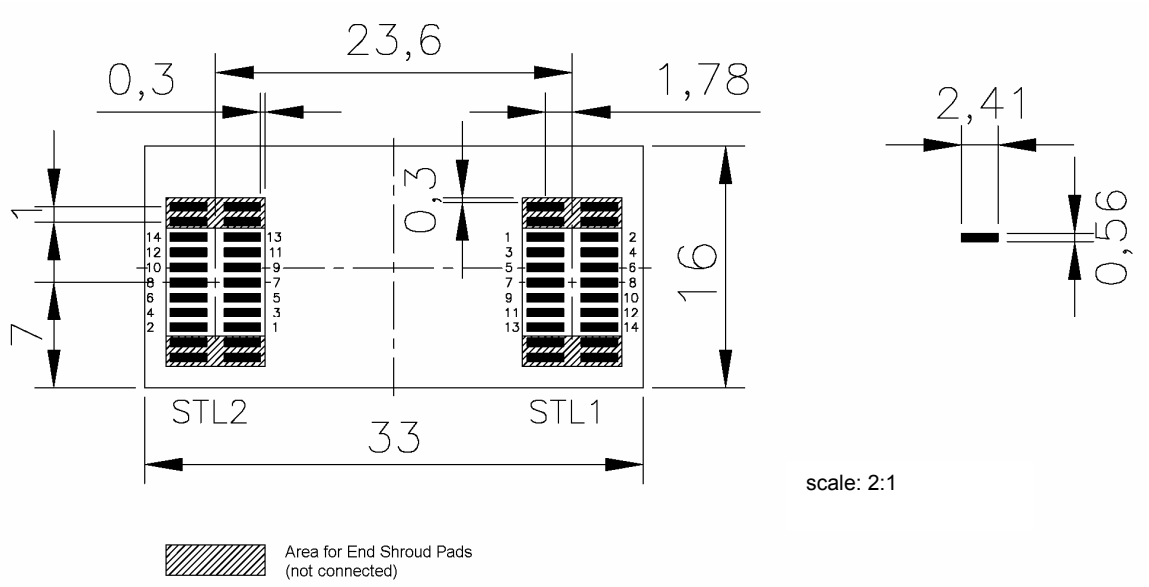
4.2 ChipOx® Pin Allocation

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!

No AGND/DGND/GND of an external circuit may be connected to the signal Shield, but only the shield of the sensor.

4.3 PCB Layout Recommendation

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:



It usually isn't necessary to fix ChipOx® to the host board in another way if the recommended counterparts are used.

For better EMC, we recommend the sensor cables be passed through a ferrite. The EMC measurements with ChipOx® were carried out with a ferrite of type WE7427221 from Würth Elektronik.

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 complete description of the communication protocol will be delivered together with ChipOx®.
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5.1.2.6 Communication data channel 127

The complete description of the communication protocol will be delivered together with ChipOx®.

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Identifier		Length of the data	
Value	**Description** [reply value range]		
	Vital parameters		
	SpO_2 value [0...100%]		
	Pulse [0...300 bpm]		
	Signal quality [0...100%] (more about this in Section 1.3.6)		
	Plethysmogram [0...255], resolution max. 100 Hz		
	Pulsation strength (perfusion) $\Delta I_{AC}/I_{DC}$ in [0...255]/1000		
	Status Information:		
	Additional Measurements		
	Signal amplification [0...255]		
	Analog input channel 1 [0...4095]		
	Analog input channel 2 [0...4095]		
	Analog input channel 3 [0...4095]		
	I/O port pins		
	Chip core temperature as signed int in 0.1°C steps		
	Module Data		
	Firmware version [SW#### Vx.yy.zzzz]		
	Serial number [3]		
	Sensor type		
	Commands / Settings		
	Reset hardware (ChipOx reset pin is set to Low for 100 ms)		
	Reset software (ChipOx reset pin not influenced)		
	Set idle mode (for saving energy during time between measurements):		
	Set Baud rate from 2400 to 230400 Baud:	1 byte[5]	1 byte
	Sensitivity for SpO_2 (SpO_2-FAL) [7] [0...3]:	1 byte[5]	1 byte
	Pulse frequency sensitivity (PF-FAL) [7] [0...5]:	1 byte[5]	1 byte
	Sampling rate (effectife3 from firmware version V1.02.0007)		
	12-bit measurement range analog channel 0 (AIN-0):	1 byte[5]	1 byte
	Meas. range analog channel 1 (AIN-1) (see analog channel 0)	1 byte[5]	1 byte
	Meas. range analog channel 2 (AIN-2) (see analog channel 0)	1 byte[5]	1 byte
0x51	Real-time data channel (sending selected data in a block):	variable:[2]	variable: [6] 1+ 2 bytes per channel
0x52	Real-time data format: Delivers current data format, the way it has been set by 0xD1.	as by 0xD1	0 bytes
	Configuration of the multiplexed analog output:	1 byte per channel[5]	1 byte per channel
	Calibration signal at all multiplexed analog outputs:	2 bytes[5]	2 bytes
	All settings are deleted and the factory settings described below are made.	n.a.	1 byte

Identifier		Length of the data	
Value	**Description** [reply value range]		
Error messages			
	Unknown data channel ID	2 bytes(4)	n. a.
	Unknown identifier	2 bytes(4)	n. a.
	Corrupt parameter	2 bytes(4)	n. a.
	Transfer protocol on receiving with number:	1 byte	n. a.

5.1.2.6 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	
Status information	Sent any time there's a change	
Baud rate	9600 Baud	
SpO_2 sensitivity	normal	
Pulse frequency sensitivity	normal and 10% variance suppression	
Range analog- input channel 0	0 to 2400mV	
Range analog- input channel 1	0 to 2400mV	
Range analog- input channel 2	0 to 2400mV	
Real-time data	Every second: SpO_2, pulse frequency and signal quality	
Analog output	SpO_2, pulse frequency, signal quality and plethysmogram	
Calibration at analog output	Period after reset: 10 s	

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..10	100mV / point
Plethysmogram	0...255	3.9mV / LSB
Pulsation strength	0...25.5%	39mV / $\%_{TPM}$
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).

The complete description of the communication protocol will be delivered together with ChipOx®.
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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	12	25	mA	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	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:	45	100	%	70% < SpO_2 < 100%: better than 2% accuracy (see Chapter 7) SpO_2 < 70% not validated
Measurement dynamics: for FAL[1] sensitive: reaction and final value	ca. 1 and 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: reaction and final value	ca. 2 and 8		s	
stable: reaction and final value	ca. 4 and 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:	20	300	bpm	1 bpm up to 2% of displayed value
Measurement dynamics: for FAL[1] Beat to Beat - 10% VS[2] : Reaction	1	7	Pulse	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: reaction & final value	max. 5 pulses & 4 s			
sensitive-10% VS: reaction & final value	max. 7 pulses & 4 s			
normal-10% VS: reaction & final value	max. 7 pulses & 6 s			
stable-10% VS: reaction & final value	max. 7 pulses & 8 s			
First displayed value after application	5	8	pulses	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 OT 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 °/oo
Measurement of chip core temperature	-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
Reset-Pin	0.8 x V+	0.2 x V+	V	input current I_{Rst}=60µA_{typ} / 100nF
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. 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
D – 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@envitec.com

9.4 Hygiene

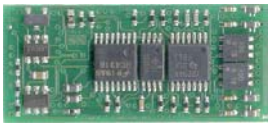
ChipOx® is to be kept free of contaminants, such as dust, grease, smoke particles and dampness, during and after installation. Contaminants can negatively influence the measurement. ChipOx® can only be cleaned in its uninstalled state with a circuit board cleaner. ChipOx® should not be installed unless 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://www2.envitec.com/download/?47-07-00330001-a.pdf		47-07-00330001
User instructions in English. The current version is available on the internet under: http://www2.envitec.com/download/?47-07-00330002-a.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.

10.2.2.6 Overview of cables and sensors

ENVITEC sensors:

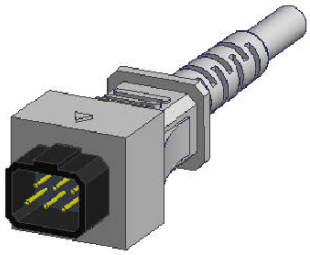
Item	length	plug	Order No.
SpO_2 finger clip sensor	120 cm	MiniMed	F-3227
		MiniMed-90°	F-3225
		Sub-D	F-3226
Small SpO_2 ear sensor	120 cm	MiniMed	
		MiniMed-90°	
		Sub-D	
Disposable SpO_2 sensor for adults	20 cm	MiniMed	2311-1
		MiniMed-90°	2311-1
		Sub-D	2310-1
All-purpose SpO_2 Y sensor	120 cm	MiniMed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

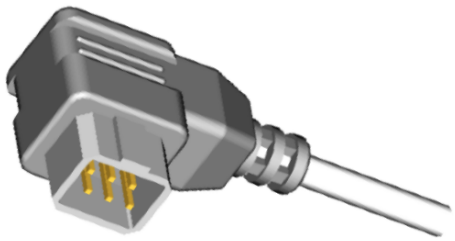
ENVITEC sensor cable:

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

10.2.2.6 Details

Sensor connection allocation with 6-pole MiniMed plug:

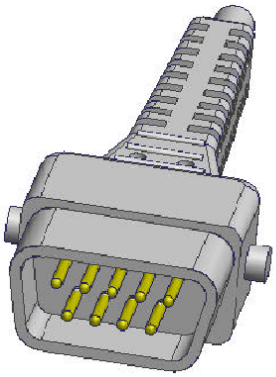


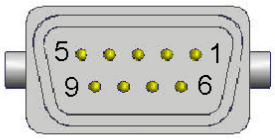


MiniMed	ChipOx® BU2	Signal
1	3	SENSOR_ID
2	7	LED_ART
3	6	LED_AIR
4	2	Sensor shield
5	4	IN_A
6	5	IN_K

Front view

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





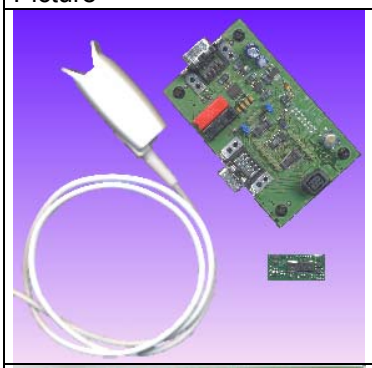
Front view

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.

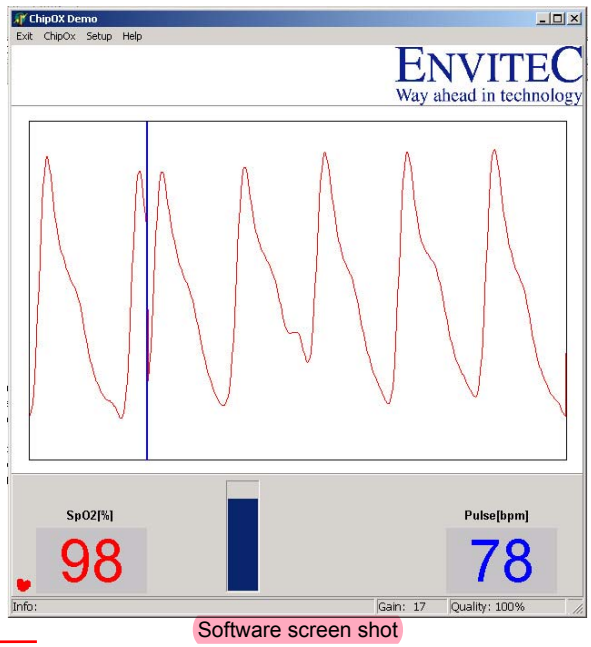
ENVITEC guarantees that ChipOx® is free of defects or faults for a period of 24 months after the date of purchase if used as intended.

- 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

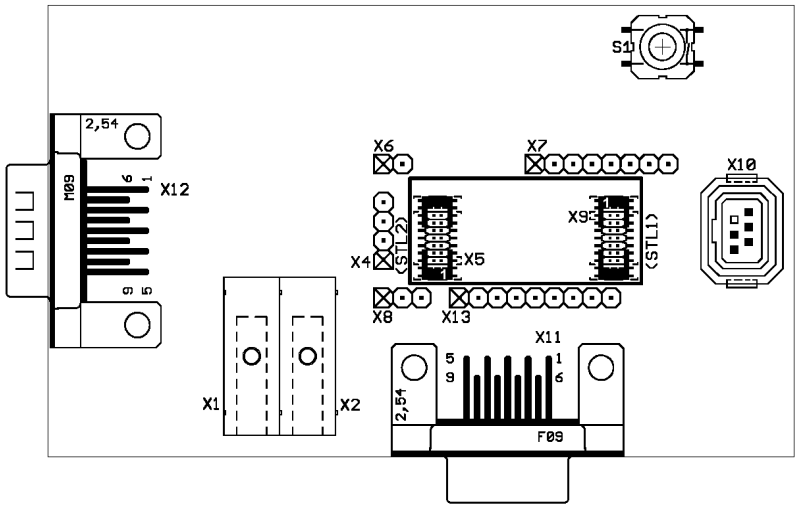
12.1 Description



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 Safety Information

The Development Kit is not galvanically isolated, neither from ChipOx® nor from the PC. It may not be used on patients or in a clinical environment, but only is intended for testing purposes

12.3 Connection Configuration

12.3.1 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!

12.3.2 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.

12.3.3 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

12.3.4 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.

12.3.5 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

12.3.6 Button

The button S1 is a reset button for ChipOx®.

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