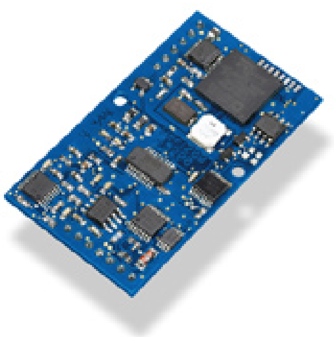
medlab

Pulse Oximeter OEM Board

PEARL200™

Technical Manual



Version 1.05

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PEARL = **P**ulse **E**nhancement **A**rtefact **R**ejection **L**ogic

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Contents:

Overview

The PEARL200 module is a pulse oximetry OEM module. It non-invasively determines the functional oxygen saturation of arterial blood (the SpO_2 value) by emitting red and infrared light into an arteriolar bed and measuring the change in light absorption during the pulse cycle. Red and infrared light emitting light emitting diodes (LEDs) in the pulse oximeter sensor serve as light sources, and a photodiode serves as a photodetector. The Pearl200 module can be used in conjunction with the transmission as well as the reflection method. It has control for 2 LEDs, regulating their brightness, and a measuring input for a detector.
Compatible sensors can be found on the Medlab homepage (www.medlab.eu).

The optical measurement principle is based on the fact that hemoglobin loaded with O_2, so-called oxygenated hemoglobin (HbO_2), shows a significantly different absorption curve at optical wavelengths than deoxygenated hemoglobin (Hb). Medlab probes use the classical transmission method with two wavelengths.

Two values are measured, the absorption of the light in the 660 nm range (red), and in the 890 nm range (infrared). The difference in the absorption of the light, which takes place due to the blood pressure between systole and diastole, results in a difference. Thus, the measurement is made by the pulsating blood; the tissues and vessels have no influence on the measurement. By comparing the measurement result with a reference table specially adapted to Medlab, the software determines what percentage of the red blood cells is saturated with oxygen.

The used PEARL software decreases the influence of artefacts on the measure. The influence of ambient light is decreased by the use of a lock in amplifier.

Communication with the host device is handled by a serial interface on TTL-Level.

Use restrictions

- The PEARL200 as developed and shipped isn’t able to be operated close to MRT’s.
- In order to measure oxygen saturation correctly the used LED’s in the probes must have 660 nm and 890 nm wavelengths. To secure this we recommend to use Medlab probes. The use of other probes with different wavelengths may re sult in inaccurate SpO_2 values.
- Medlab probes are intended for use in the clinical environment. For use in other areas (homecare, emergency medical services environment), the customer can use the Medlab desaturation study; however, it is his responsibility to ensure conformity with the respective requirements. This also explicitly applies to the accompanying documents.

Contraindications

- Pulse oximetry is a non-invasive diagnostic procedure resulting in no contraindications to be mentioned.

PEARL Algorithm

PEARL is an acronym for “Pulse Enhancement Artefact Rejection Logic”.

The PEARL200 module uses the proprietary PEARL algorithm that constantly shifts a time window of six seconds over a data buffer that contains samples of the red and infrared waveforms. The algorithm detects the correct pulse rate by convoluting a template over the waveform at different phase angles, which leads to the wanted effect of artefact rejection. On the analog side, the PEARL uses a lock-in amplifier that enables the module to work even under extreme conditions, as high ambient light and low signal strength (0.025%). The basic operation frequency of that amplifier is 20 kHz, and the used analog front end very effectively suppresses noise by using a lock-in signal recovery scheme.

The PEARL algorithm leads to the effect that real time pulse detection is not coupled directly to calculation of correct saturations any more, since the mentioned six second buffer is used for all calculations.

Since the algorithm itself does not detect the pulse in real time, a traditional pulse detector is applied to the input signal and is responsible for the realtime pulse detection which can be used by the host system to generate a pulse tone.

Once per detected pulse, the current calculated SpO_2 and pulse values are transmitted to the host system. If an audible signalization is needed, this point in time of data transmission can be used to generate the mentioned pulse tone.

Technical Data (Specifications)

Mechanical Data:

General:	Size of board: 55mm x 31.5mm Maximum thickness of the board: 4mm PCB thickness: 1mm (6-layer PCB)
Attachment:	Two 2.6mm holes in the middle of the PCB
Weight:	15 g

Power Suppy:

Operating Voltage:	3.3 Volt DC, ± 5%,
Current:	max. 45 mA during startup 20...40 mA during standard operation depending on interface and LED brightness. (LED brightness depends on finger thickness)

Environmental:

Temperature:	Storage	-30 °C to 70 °C
	Operation	-20 °C to 50 °C
Humidity:	Storage	0 .. 95 %, non condensing
	Operation	5 .. 95 %, non condensing

SpO_2:

Measuring range:	0%..100% of SpO_2	
Accuracy:	Standard	± 2 %
	Movement artefacts	± 3 %
	Low perfusion	± 3 %
	(70-100 %, below 70 % not specified)	
Averaging:	Fixed to 8 beats	

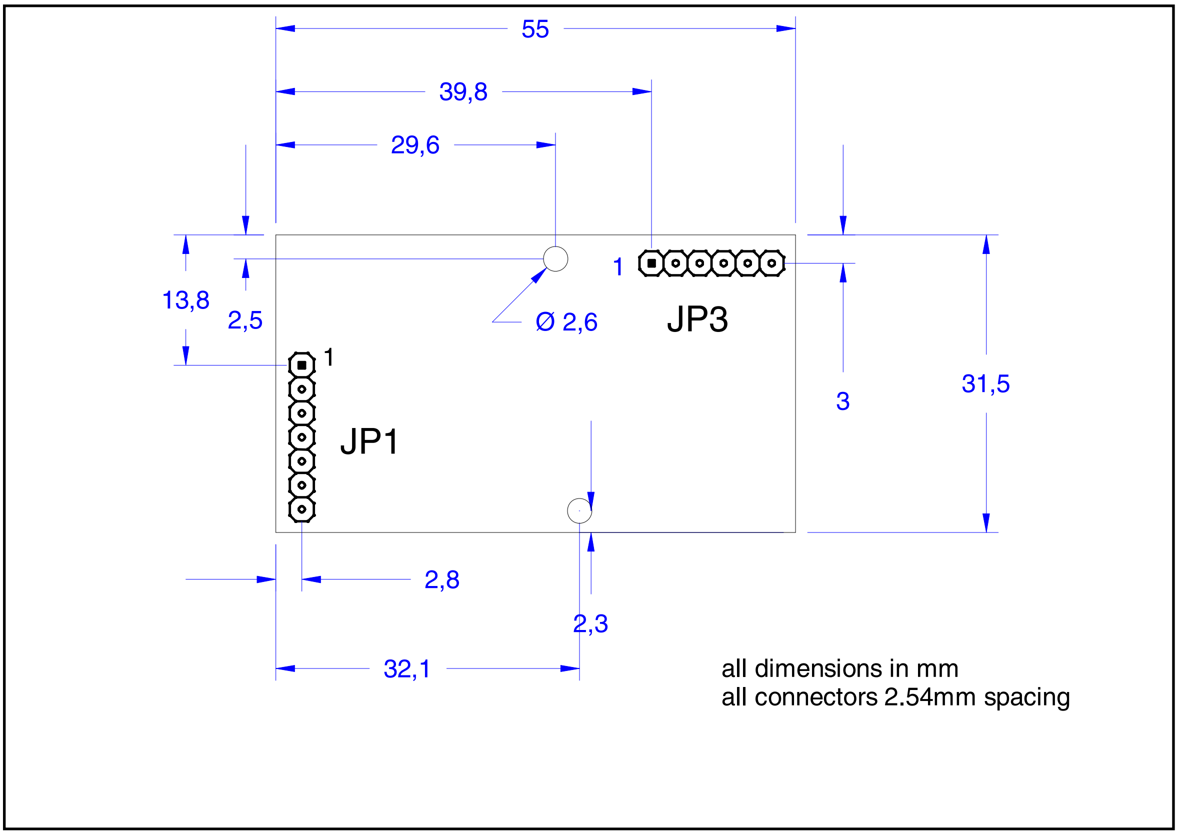
Pulse Rate:

Measuring range:	30 .. 250 min^{-1}
Accuracy:	± 3 min^{-1}
Averaging:	Fixed to 8 beats

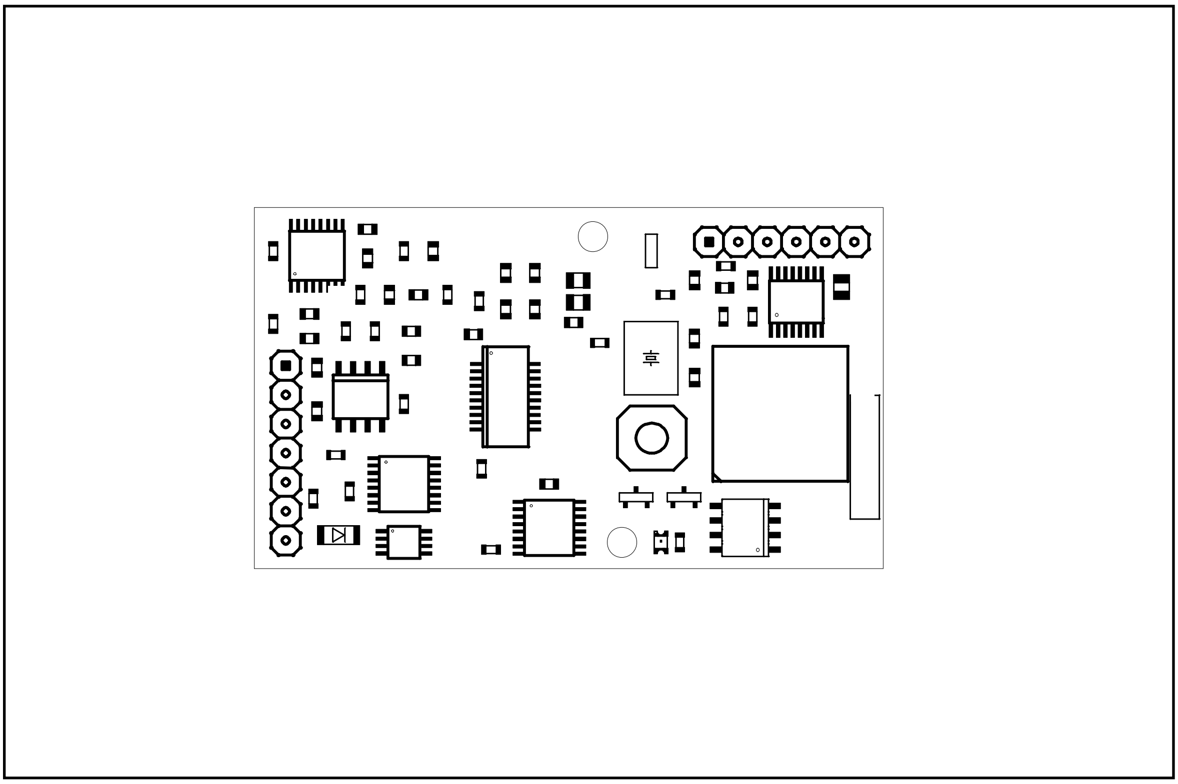
Interface:

Asynchronous, serial interface with CMOS levels
data format depending on protocol.

Mechanical Dimensions



Mechanical drawing of top view of the PCB (original size)



Part position top view of the PCB

Connectors Pin Assignment

(for location, see drawing on page 7)

Header for Probe Connection:
(pin number of probe DSUB connector to connect to in parentheses)

JP1:	1	Input Photodiode 1 (DSUB 5)
	2	Input Photodiode 2 (DSUB 9)
	3	Sensor Coding (DSUB 1)
	4	Agnd (DSUB 6 and 7)(1)
	5	Led Output 1 (DSUB 3)
	6	Led Output 2 (DSUB 2)
	7	Sdata (DSUB 4)

Header for Host Connection :

JP3	1	/Powerdown (Connect to 0V for power down)
	2	RxD (TTL Level)
	3	n.c.
	4	TxD (TTL level)
	5	Ground
	6	VCC input (3.3VDC)

(1) see page 9, "Mounting the PEARL200 board into your medical device"

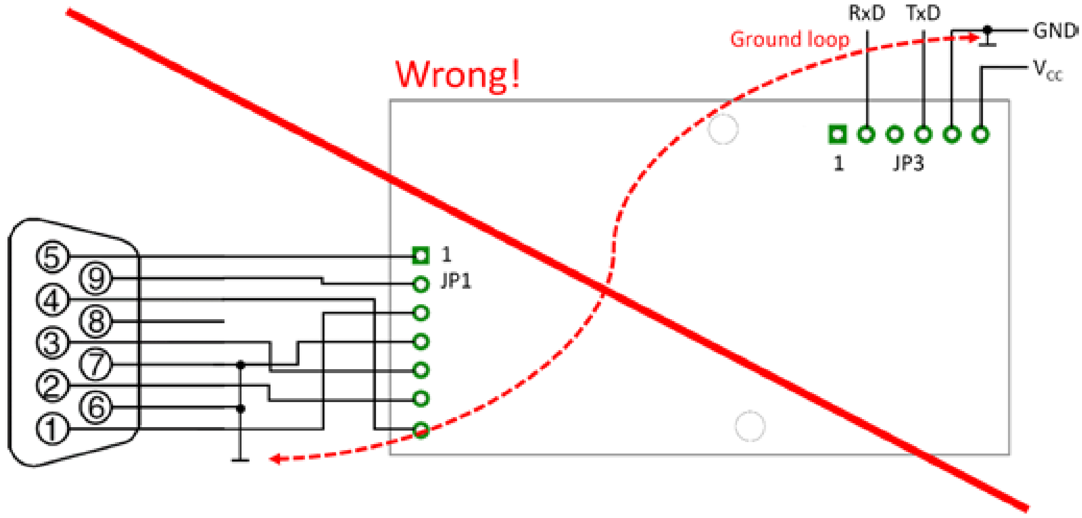
Mounting the PEARL200 into your Medical Device

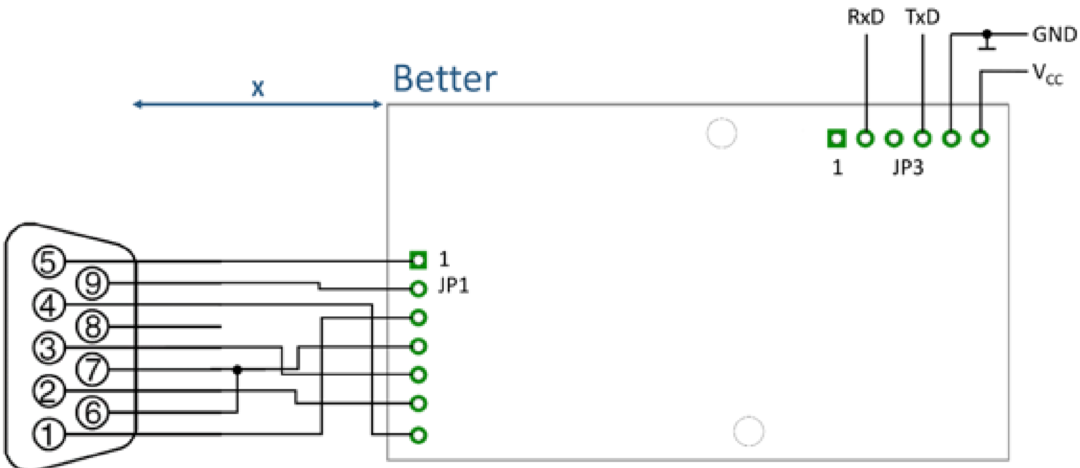
If the PEARL200 board is mounted as a piggy back on your own electronic PCB, please make sure that the "Ground" potential of your device is connected to JP3 only, and not to pin 4 of JP1, the probe connector. Pin 4 of JP1 should be connected to pin 6 and 7 of the DSUB probe connector only.

Although on the board itself, these two pins (GND and AGND) are connected at a single point, connecting of pin 4 of JP1 also to your device's ground potential would form a ground loop, that largely deteriorates RF immunity of the PEARL200.

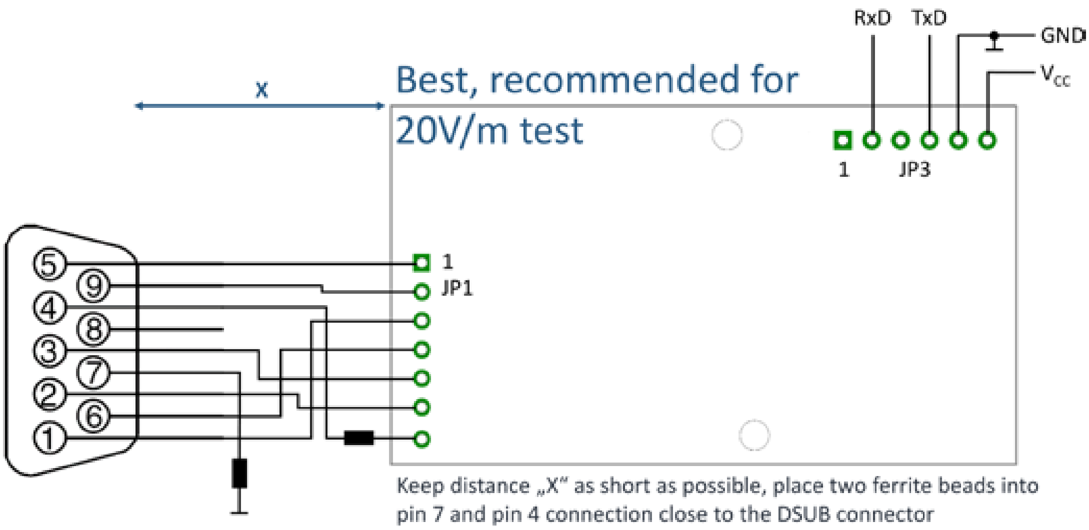
Pulse oximeters used during transport are subject to a 20V/m RF immunity test, instead of the 3V/m used for normal pulse oximeters. In this case, additional EMC filtering is needed, close to the DSUB connector, where the signals enter the housing of your medical device. Please contact Medlab for details.

Recommendations for the electrical integration of the PEARL200 module





Keep distance „X" as short as possible, connect device ground only to JP3



Keep distance „X" as short as possible, place two ferrite beads into pin 7 and pin 4 connection close to the DSUB connector

Serial Transmission

This protocol is the default protocol when ordering a module from Medlab.

Physical Data format:
9600 baud, 8 bits, 1 stop bit, no parity

Plethysmographic waveform data during measurement is sent at 50 Hz transmission rate. This rate was selected since higher frequencies do not produce smoother waves, lower frequencies are leading to an incorrect appearance of the waveform.

As long as there is no probe connected to the module, or no finger is detected, e.g. the module is issuing info bytes containing either 0x01 or 0x02, no waveform data is transmitted. The marker bytes and pulse and SpO_2 values of "0" are sent once per second in this state, the same is true for the info and quality/perfusion bytes with their respective markers.

During measurement, for each detected pulse, a block with new saturation, pulse rate, info and quality/perfusion information is transmitted. The pulse wave sample points are transmitted continuously at 50 bytes per second. Their values are limited to a range between 0x00 and 0xF7, so they do not interfere with the marker bytes. The point in time where the host receives a new data block of markers, SpO_2- and pulse values can be used to generate a pulse beep on the host side.

After power up, the module needs about three seconds to finalize its internal boot process. The first three data blocks sent after boot (one per second, if no measurement taking place) contain a firmware revision number in the lower five bits of the quality/perfusion byte, e.g. the byte following the 0xFC marker. As this was introduced with firmware revision 1.28, 128 has been chosen as an offset. To calculate the actual firmware revision, use the following algorithm:

revision = (128+(quality_byte & 0x1F))/100

Note: reading a value of 0x0A from the quality/perfusion byte means you missed the firmware revision, as 0x0A is the default content of this byte, when not measuring.

As mentioned before, values that are higher than 0xF7 are used for marking the following data byte as a new data value with the definitions on the next page:

Marker byte	*Definition of following byte*
0xF8	*wave sample points follow*
0xF9	*Spo_2 value follows*
0xFA	*Pulse value follows*
0xFB	*info byte follows*
0xFC	*quality/perfusion byte follows*

Definition of command bytes

Info byte	*Definition*
0x00	*OK*
0x01	*No sensor connected*
0x02	*No finger in probe*
0x03	*Low perfusion*
0x45	*Selftest Error*

Definition of info byte

```
Bit7 Bit6 Bit5 Bit4 Bit3 Bit2 Bit1 Bit0
0    A2   A1   A0   B3   B2   B1   B0
```

Bit A2 bis A0: Perfusion Info

A2	A1	A0		
0	0	0	unused	
0	0	1	< 0.25%	AC/DC ratio
0	1	0	0.25-0.5%	AC/DC ratio
0	1	1	0.5-1.0%	AC/DC ratio
1	0	0	1.0-2.0%	AC/DC ratio
1	0	1	2.0-4.0%	AC/DC ratio
1	1	0	4.0-8.0%	AC/DC ratio
1	1	1	> 8%	AC/DC ratio

Bit B3 - B0: Quality

```
10..0      0 is best quality
```

Definition of quality/perfusion byte

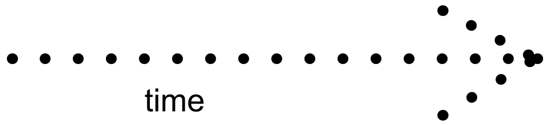
Perfusion info is a number between 1 and 7, coded into bit 6 to bit 4 of the info byte. It is an indicator for the relation of pulsating - to constant radiation through the measuring site. See table on the left for details.

Quality is a number between 0 and 10, coded into the lower 4 bits of the info byte.
If the number is 0, ten or more consecutive pulses have been detected without artefact or other problems.

Description of quality/perfusion byte

Examples of Data Transmission

0xF9, 0x61, ...	0xFA, 0x80,	0xFB, 0x00,	0xFC, 0x30,	0xF8, 0x23, 0x25, 0x26, 0x28, 0x30
Spo_2 = 97%,	*Pulse = 128,*	*Status = OK,*	*Quality = 0, Perfusion = 3*	*Waveform, sample points follow until next marker byte received*



The advantage of this protocol is the low overhead. The data type with the highest transmission rate, the waveform, is not marked in any form, leading to the smallest possible amount of transmitted data bytes.
If no finger is inserted or no probe is connected, zero is transmitted for both Spo_2 and pulse rate, once per second, while the status byte indicates either "no signal" or "no sensor".

C Source Code Examples

The following C source code is intended to help integrate the Medlab OEM pulse oximeter board into the customer's system. The first example is part of the sourcecode we used for writing our PC demo program and is written in C.
The second example was originally written for usage with a 8051-family controller using the Keil C51 compiler. The data is received in serial interrupt and the values are copied into global variables that can be processed during the main program.

```
/* getccb() returns the next serial value from a queue that is filled during the PC's serial interrupt */

while (1)
 {
  if ((val=getccb()) == 0xF8)
   {
     while((val=getccb()) < 0xF0)
        {
            /* here "val" always contains a new plethysmogram sample          */
            /* process it acccording to your needs ........                   */
        }
   }

  switch(val)    /* now val contains a marker, indicates next byte is a special value     */
   {
    case 0xF9:
          printf("%02u",getccb());                        /* print SpO2          */
          break;
    case 0xFA:
          printf("%03u",(unsigned char)getccb());         /* print pulse         */
          break;
    case 0xFB:
          switch(getccb())
          {
           case 0: gotoxy(20,23);
                printf("          OK !       ");          /* print messages               */
                break;
           case 1: gotoxy(20,23);
                printf("    No sensor connected !    ");
                break;
           case 2: gotoxy(20,23);
                printf("    No finger in probe !     ");
                break;
           case 3: gotoxy(20,23);
                printf("    Low perfusion    !     ");
                break;
           }
           break;
     case 0xFC:
            val = getccb();
            printf("%02u",getccb()&0x0F);                 /* print quality, mask perf.*/
            break;
   }
 }
```

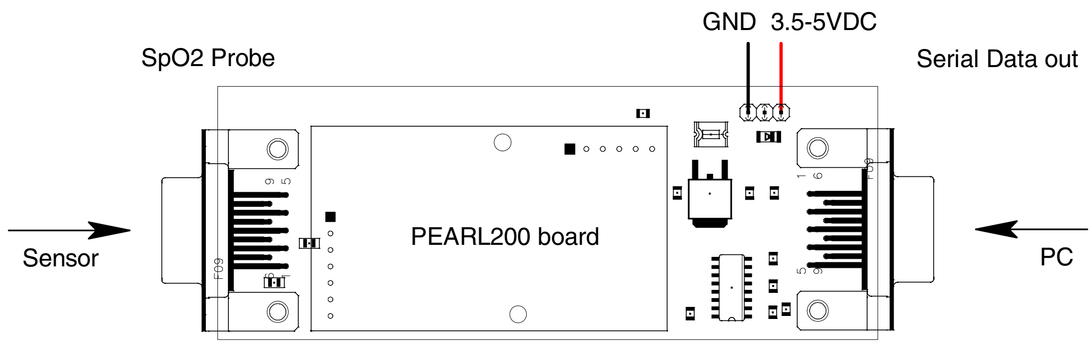
C Example for PC decoding

```
data byte data *rcvptr;
data byte Oxval;
data byte Oxgraph;
data byte Oxpuls;
data byte Oxinfo;
data byte Oxqual;

data bit Tbit;
data byte Serval;

void serial_int() interrupt 4 using 2
{

 if (TI)                                    /* transmitter int ?                    */
  {
   TI = 0;
   Tbit = TRUE;
   return;                                  /* nothing to do                        */
  }

 RI = 0;                                    /* else must be receiver int            */

  Serval = SBUF;                            /* get value from serial buffer register */
  if (Serval > 0xF5)                        /* is it a code ?                       */
   {
    switch (Serval)                         /* yes                                  */
     {

      case 0xF8:     rcvptr = &Oxgraph;     /* next time get plethysmogram          */
                     return;
      case 0xF9:     rcvptr = &Oxval;       /* next byte is get spo2 value          */
                     return;
      case 0xFA:     rcvptr = &Oxpuls;      /* next byte is pulse value             */
                     return;
      case 0xFB:     rcvptr = &Oxinfo;      /* next byte is spo2 info               */
                     return;
      case 0xFC:     rcvptr = &Oxqual;      /* next byte is quality information     */
                     return;
      default  :     return;
     }
   }
  else
     *rcvptr = Serval;                      /* byte is no code, so store it where pointer points */
  }
 return;
}
```

Code for interrupt driven decoding using an 8051 microcontroller

Plug-and-Play Development Kit

To ease the work of evaluating the unit, there is a complete, ready-to-run development kit available. It is easily possible to evaluate the module with a PC software that is adapted to the pulse oximeter's interface protocol. The software displays all relevant data that is transmitted in the protocol version.
It runs on each PC under windows. Also, a complete set of cables and a reusable P-200 fingerclip probe are included in this kit.
The source code of the PC application can be downloaded from the web.



Connection of the pulse oximeter testboard to the probe and to the PC adapter

Remarks:

There is a voltage regulator on the carrier board that produces 3.3V DC.
Only Ground, TxD, and RxD are used in the interface. The voltage levels of the serial signals are approx. +/-6.5 volts, generated by a circuit on the PCB.

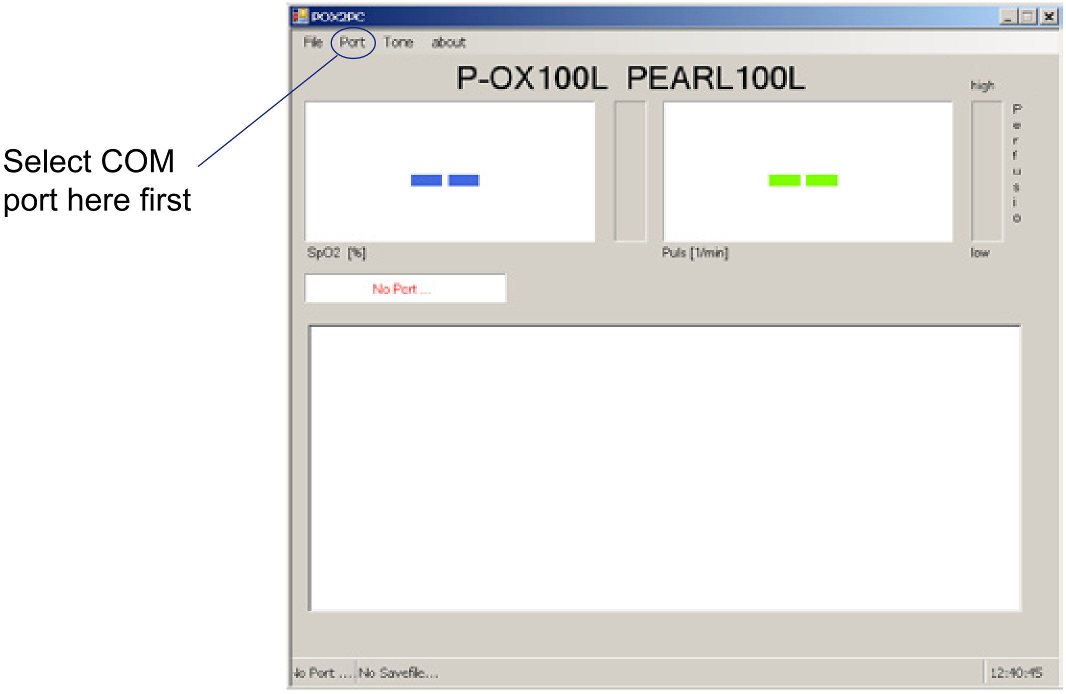
Usage:

- connect the power connector to a regulated DC supply (3.5-5.0V)
- connect the serial cable to the COM port of a PC
- connect the other side of the serial cable to the carrier PCB
- connect the probe to the carrier board
- turn on the power supply
- turn on PC
- download the test program from oem.medlab.eu
- the program does not need to be installed, you can start the "pox2pc.exe"
- the download also includes the project file in VC#
- select the correct com port in the software
- put your finger into the probe

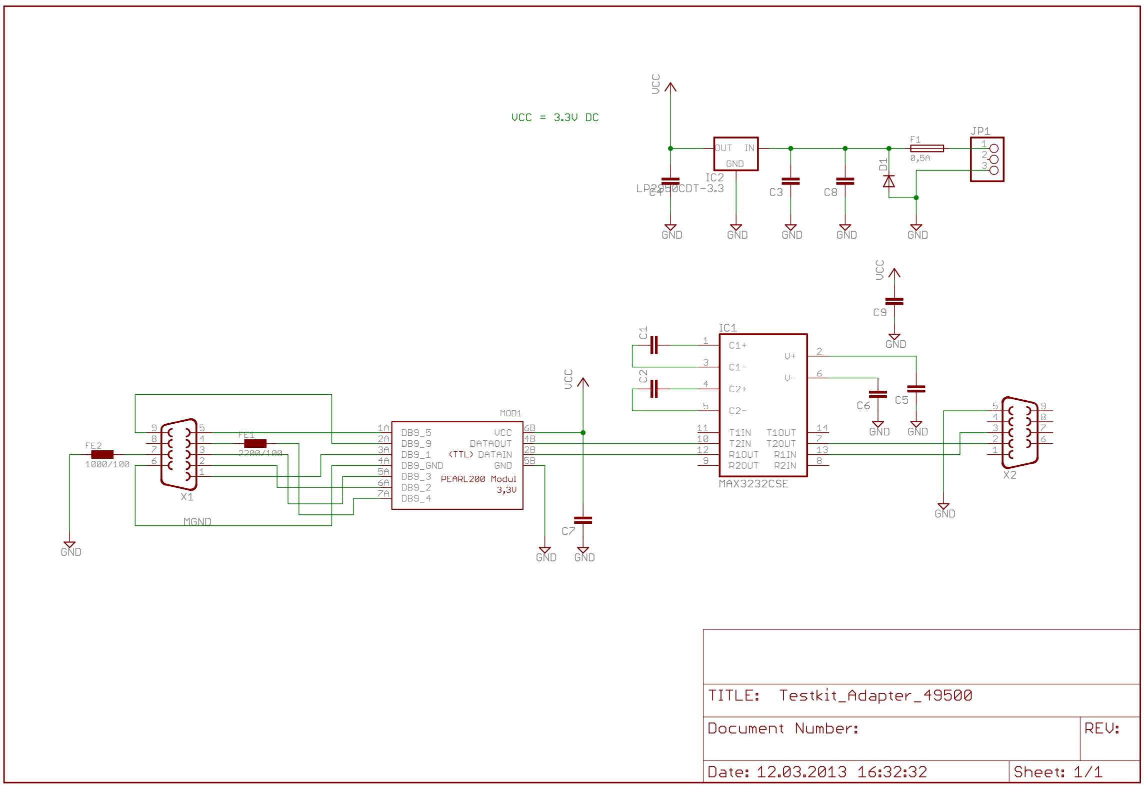
After a short time, the values and the plethysmogram will be displayed.

Note: This setup should be used for internal testing only. It does not comply to the power supply isolation requirements of IEC601 or ISO 80601-2-61 / ISO9919 (patient connection should be of type BF).

Screenshot of the PC Software:

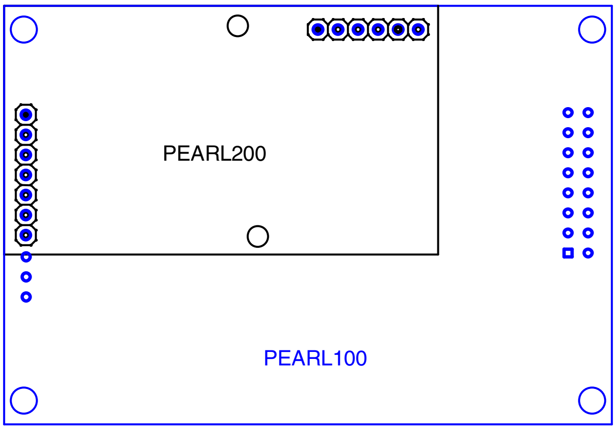


Schematic of the Development Kit:



Compatibility to PEARL100 module

The PEARL100 and PEARL200 share the same connector positions and pin assignment.



Regulatory Considerations

The PEARL200 module described in this document is not a medical product. That means that it cannot be used as a standalone unit to do pulse oximetry measurements on patients. Therefore, the module does not have to be - and cannot be CE-marked. The customer has to undertake the procedure of conformity assessment and CE-marking of the final product that will contain the PEARL200 module.

EMC testing has to be done on the complete host device, not with the module alone.

The module complies with the applicable clauses of the following standards:

ISO 9919:2005	(EN ISO 9919:2009)*
ISO 80601-2-61:2017 + COR1:2018	(EN ISO 80601-2-61:2019)*
IEC 62304:2006 + A1:2015	(EN 62304:2006 + Cor.:2008 + A1:2015)*

( )*: corresponding European standard

Note:
If the final medical device is mains powered or the device can be connected to another mains powered part while a patient is connected, an isolation is required, because ISO 80601-2-61 requires the patient connection of a pulse oximeter to be of type BF or CF. That means that the power supply and the communication channels for the PEARL200 module have to be galvanically isolated from the main electric part of the medical device. We can support our customers with the design of a simple, reliable and cost effective solution for this.

History:

Rev. 0.99:	Preliminary Version
Rev. 1.00:	First release
Rev. 1.01:	Corrected mounting instructions (p. 18)
Rev. 1.02:	Added description of version transmission (p.10)
Rev. 1.03:	Changed pulse rate accuracy to min^{-1} from %
Rev. 1.04:	Corrected layout
Rev. 1.05:	editorial changes, Recommendations for the electrical integration of the PEARL200 module added, Protocol 1 removed

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