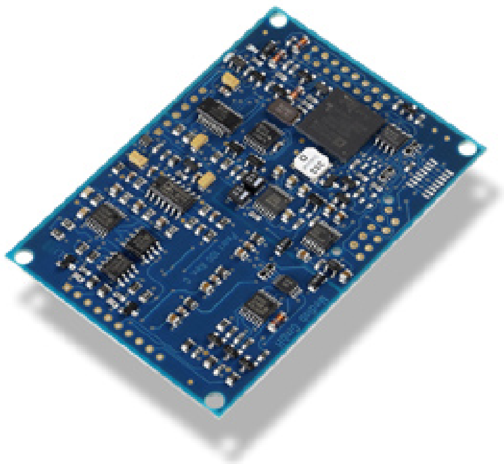
Pulse Oximeter OEM Board

PEARL100™

Technical Manual



Version 1.48

PEARL = Pulse Enhancement Artefact Rejection Logic

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Content:

Overview

The PEARL100 module is a pulse oximetry OEM module. It is intended to be used by medical device manifacturers for use in devices for trained medical personal. The patient group of the OEM module includes neonates, children and adults. Compatible sensors can be found on the Medlab homepage (www.medlab.eu).

The OEM module 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 Pearl100 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.

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 PEARL100 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

The PEARL100 module uses the proprietary PEARL algorithm, that constantly shifts a time window of six seconds over a data buffer that contain 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. This technology is also known as "cross correlating" the signal to another in digital signal processing. 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 other sources of disturbance. 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 any more coupled directly to calculation of correct saturations, 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:	6-layer PCB, thickness 1mm
Attachment:	Four 3.3mm holes in the corners of the PCB
Weight:	23 g

Power Suppy:

Operating Voltage:	3.3 - 5.5 Volt DC,
Current:	20...40 mA 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:	Depending on protocol	

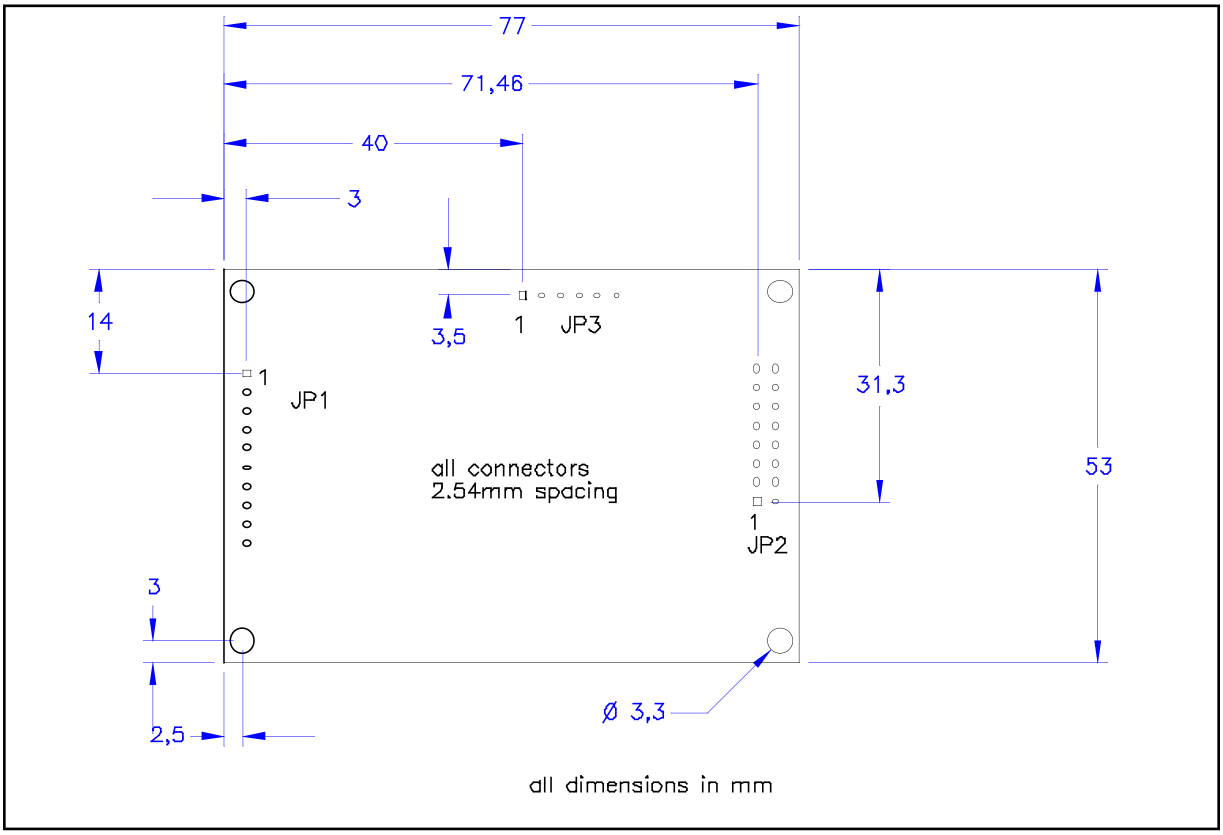
Pulse Rate:

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

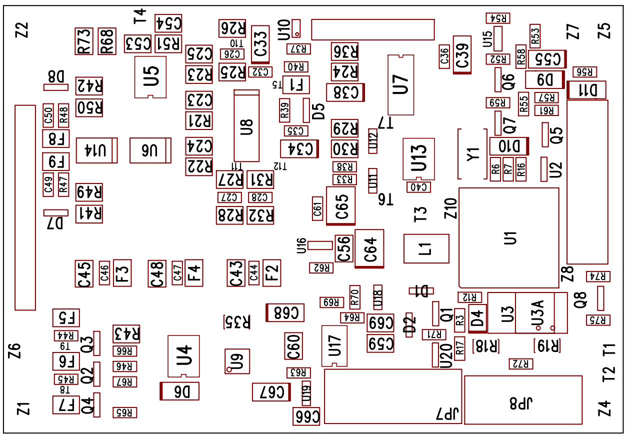
Interface:

Asynchronous, serial interface with TTL or RS232 levels
Baudrate: 9600 baud, 8 bits, 1 stop bit, no parity

Mechanical Dimensions

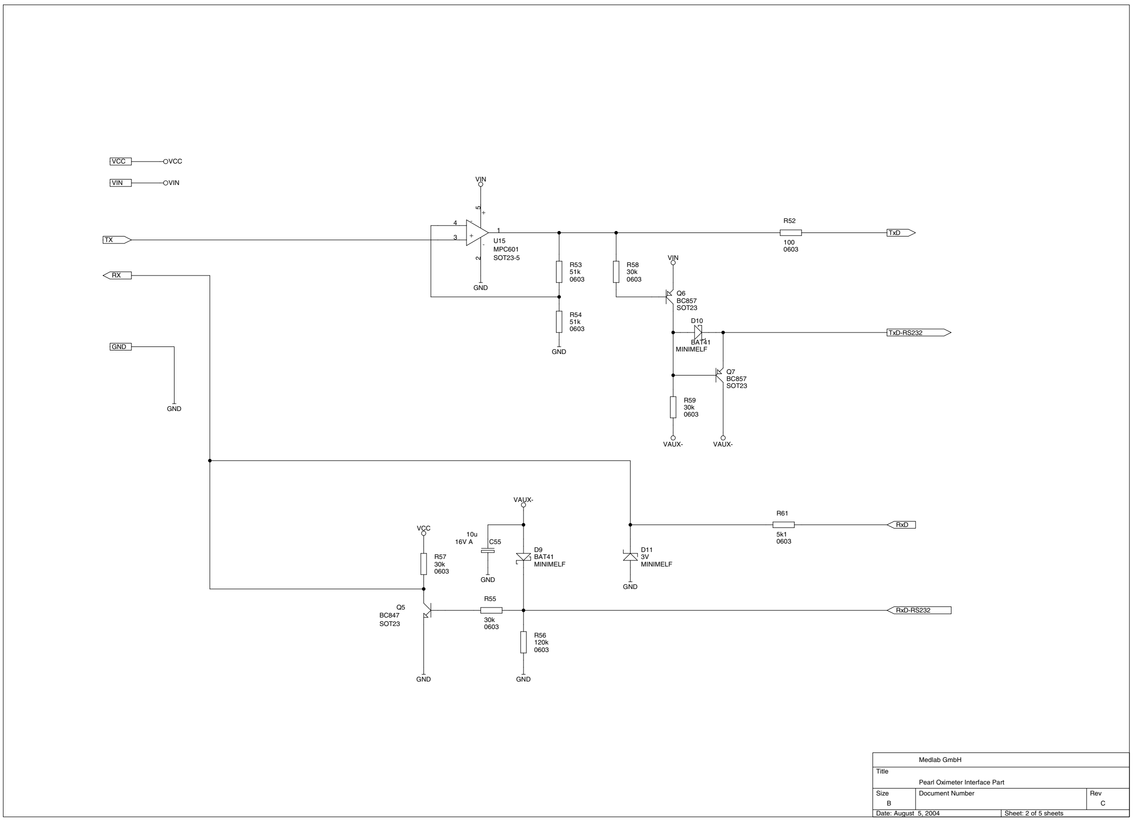


Mechanical drawing of top view of the PCB (original size)



Part position top view of the PCB

Hardware Interface



Interface part of the pulse oximeter´s electronics

Serial Interface

The host system is connected to the pulse oximeter module over a serial, asynchronous communication channel with protocol depending baudrate and transmission parameters.

Both CMOS and RS232 voltage levels are available.

As can be seen on the schematic on top of the screen, the board adapts to the input voltage of the system. That means, if the board is powered by 5 V DC, the RxD, TxD levels are 0 and 5 Volts, +/- 50 mV. If the board is powered by 3.3 V DC, the levels are 0 and 3.3 V, +/- 50 mV.

The RS232 option is in fact not a real RS232 interface, but is helpful during evaluation of the board, which can then be done using an ordinary PC and a special test software. The board uses the positive supply as the "0" output level and uses the negative voltage from the incoming RS232-RxD pin to generate the negative "1" output level. Therefore, RS232-RxD and RS232-TxD must be connected to the host, or no RS232 level output will be available. The board should be powered with 5 V DC when using this option, otherwise, the positive level is not high enough to trigger the receiving UART reliably.

The connection in the customer's final system should preferably be done through CMOS level connnection pins.

Only a unidirectional interface (PEARL100 → host system) is necessary.

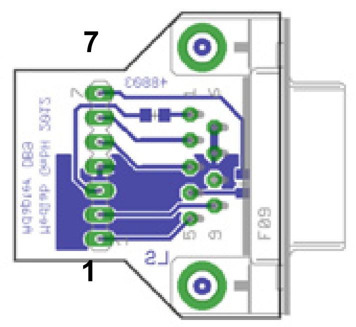
Connectors

(see drawing in chapter "Mechanical Dimension")

Header for Probe Connection:

(pin number of probe DSUB connector to connect to in parenthesis)

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)
8 don't connect
9 don't connect
10 don't connect



Adapter for DSUB 9 probe to PEARL100 board

Note: Depending on the RF immunity level your final product needs to fulfil (3V/m or 20V/m), it might be necessary to include further EMC filtering measures close to the SpO_2 connector input of your medical device. Please contact Medlab for details.

Header for Host Connection:

JP2:
1 Ground
2 Ground
3 Txd (CMOS level)
4 RS232-Txd (RS232 level)[2]
5 Rxd (CMOS level)
6 RS232-RxD(RS232 level)[2]
7 n.c.
8 n.c.
9 n.c.
10 n.c.
11 /Powerdown
12 Aux Port
13 3.3 VDC input
14 3.3 VDC input
15 VCC input, 3.3 - 5.5 VDC[3]
16 VCC input, 3.3-5.5 VDC[3]

Alternative 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 (3.3-5.5VDC)

(1) see chapter "Mounting the PEARL100 board into your medical device"
(2) see description under "Hardware Interface"
(3) use only pin 13 and 14 **OR** 15 and 16 for supply, do not use both.

Software Protocol

Serial Transmission

The serial transmission protocol used by the PEARL100 module uses the following 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*

time

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 customers 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 puls 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 of protocol 2 using an 8051 microcontroller

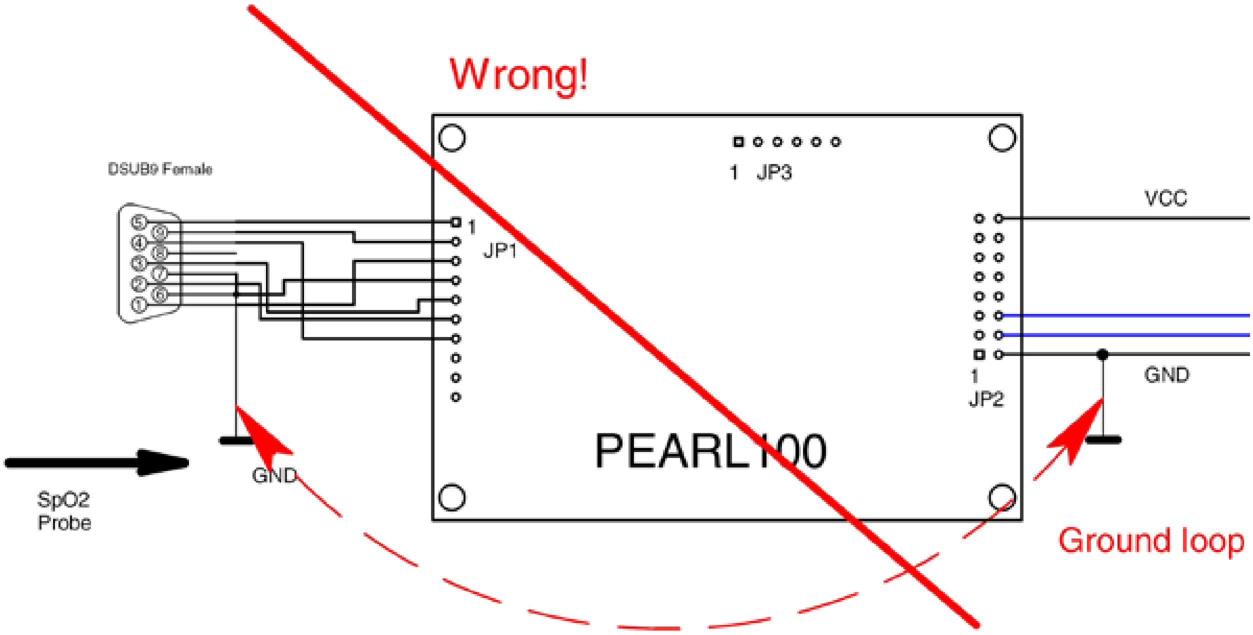
Mounting the PEARL100 into your Medical Device

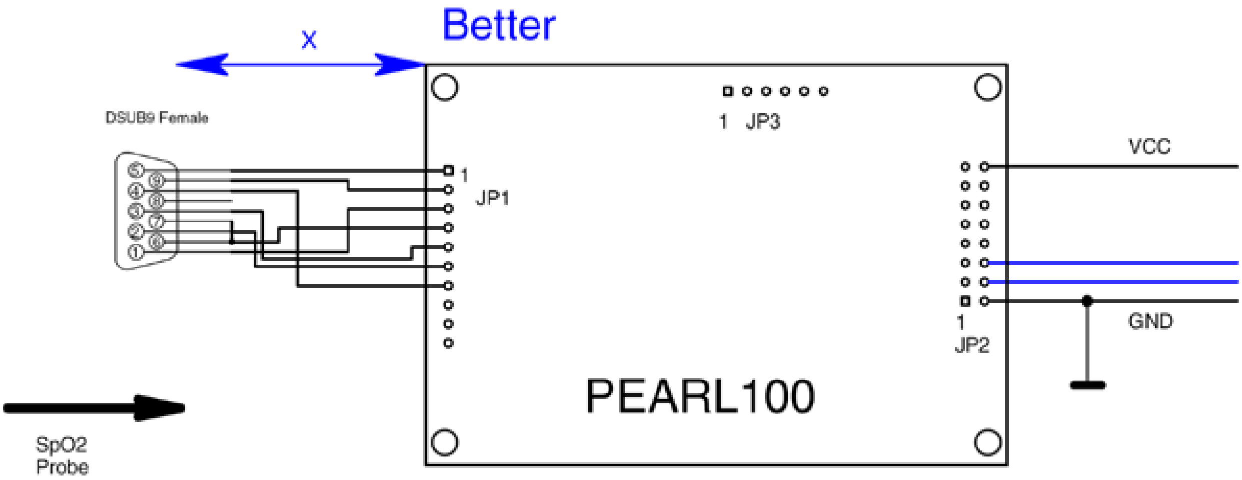
If the PEARL100 board is mounted as a piggy back on your own electronic PCB, please make sure that the "Ground" potential of your device is connected to JP2 only, and not also to pin 4 of JP1, the probe connector. Pin 4 of the probe connnector should be connected to pin 6 and 7 of the DSUB probe connector 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 PEARL100.

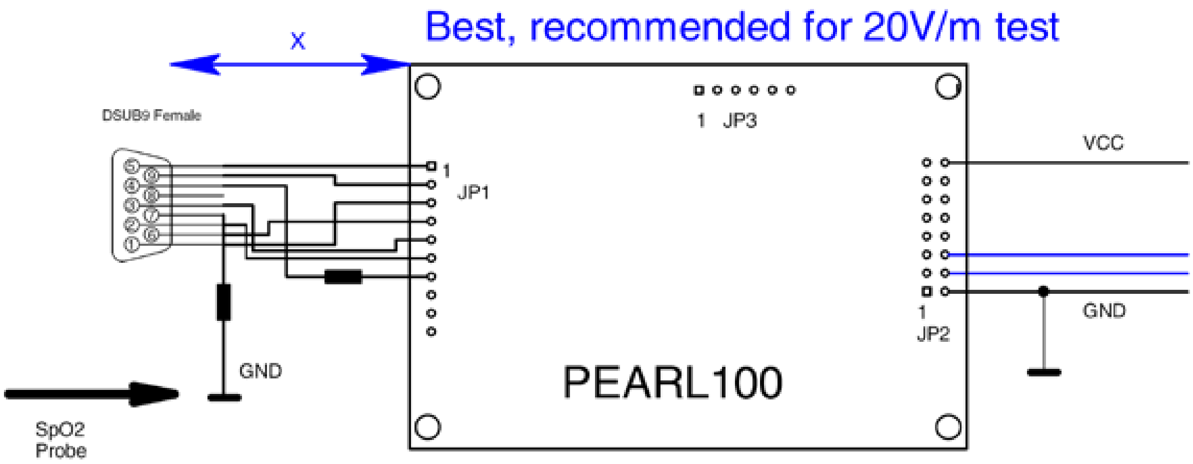
Pulse oximeters used during transport are subject to a 20V/m RF immunity test, instead of the 3V/m used for normal pulse oximeters. In this case, addtional EMC filtering is needed, close to the DSUB connector. Please contact Medlab for details.

Integrating the PEARL100 pulse oximeter OEM board into a medical device





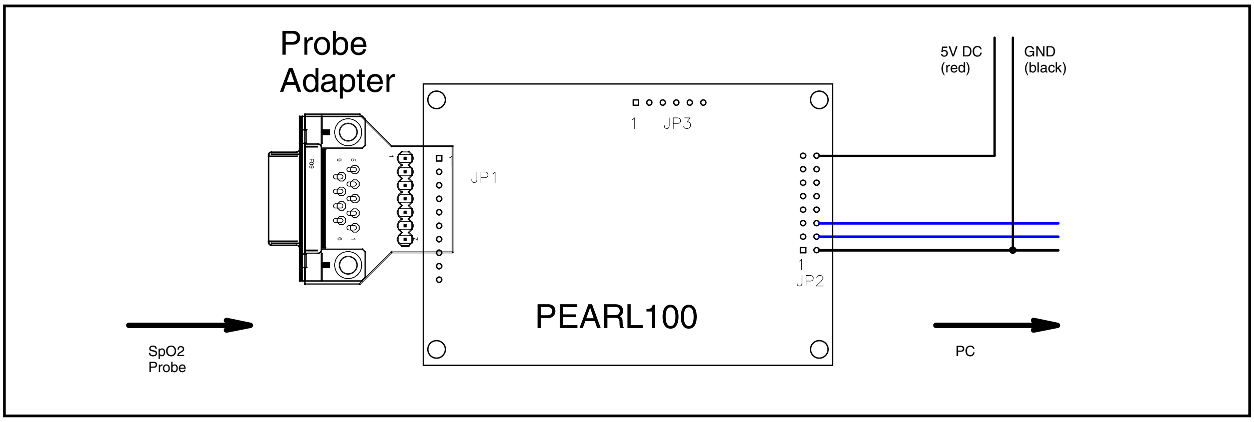
keep distance "X" as short as possible, connect device ground only to JP2



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

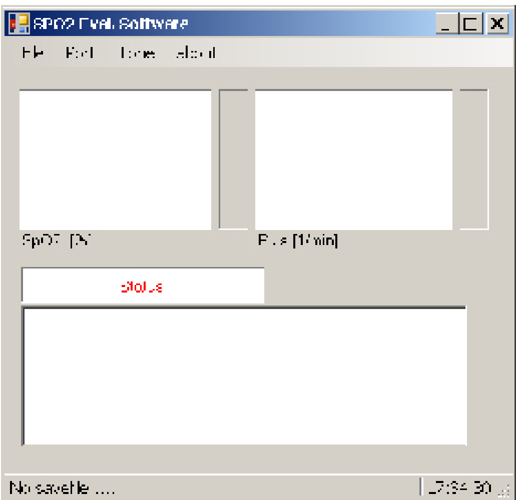
Development kit

To ease evaluation of the module, there is a complete, ready-to-run development kit available: it includes a PC software that is adapted to the pulse oximeter 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 adapters is included in this kit. It contains one fingerclip probe P-200 and an adapter to connect the probe to the PEARL100 board.



Connection of the Pulse oximeter to probe and PC adapter

Usage



Connect the red cable to a regulated 5VDC voltage source and the black cable to the power supplies GND.

Connect the serial cable to a COM port of the computer. Only Ground, TxD and RxD are used in the interface. If you use a USB-RS232 adapter, please install the "virtual serial port" driver delivered with the adapter.

Connect the other side of the cable to the PCB as shown in the drawing.

Connect the probe as shown in the drawing, using the adapter.

Turn on the power supply.

Turn on PC.

Start the software.

Regulatory Considerations

The PEARL100 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 PEARL100 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:

IEC 60601-1:2005 + Cor1:2006 + Cor2:2007 + A1:2012 + A1:2012/Cor1:2014 + A2:2020	(EN 60601-1:2006 + Cor.:2010 + A1:2013 + AC:2014 + A1:2013/AC:2014 + A12:2014 + A2:2021)*
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 PEARL100 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. 1.00:	Added DSUB-JP Adapter drawing
Rev. 1.10:	Minor changes, new probe pictures
Rev. 1.20:	Added description of perfusion info
Rev. 1.30:	changed manufacturer address
Rev. 1.40:	Edited sensor connection information
Rev. 1.41:	Corrected typing errors
Rev. 1.42:	Clearified Ground connections of probe Added mounting instructions page 19
Rev. 1.43:	Corrected mounting instructions on page 19
Rev. 1.44:	Added description of version transmission, page 12
Rev. 1.45:	Added operating temperature
Rev. 1.46:	Changed operating voltage range
Rev. 1.47:	Corrected the layout
Rev. 1.48	Overview, Storage temperature and regulatory considerations changed, chapter "probes", "section power supply" and "serial transmission protocol 1" removed, chapter "Mounting the PEARL100 into your Medical Device" moved, chapter "ground connection" added, power consumption removed, voltage and current data separated in chapter "Technical Data (Specifications)", user and patient group added in chapter "Overview"

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