medlab

Pulse Oximeter OEM Board

PEARL200™

Technical Manual

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

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Revisions:

V0.99	12.03.2013	Preliminary Version
V1.00	14.03.2013	First release
V1.01	29.01.2014	Corrected mounting instructions (p. 18)
V1.02	28.03.2014	Added description of version transmission (p.10)
V1.03	23.10.2014	Changed pulse rate accuracy to min^{-1} from %

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Contents:

Overview

The scope of this document is the description and specification of Medlab's PEARL200 pulse oximeter module. It is intended to help to integrate the board into another medical device manufacturer's electronic system.

The probes (sensors) that can be used together with the PEARL200 are described on the last pages of this document.

The document describes the basic technology used, the mechanical and power supply considerations and the software protocol for interfacing the PEARL's UART to a host system.

The PEARL is an electronic PCB, fully pre-tested, that connects to one of the different Medlab SpO_2 probes to measure a patient's arterial oxygen saturation and his pulse rate.

The interface to the host system needs a filtered and regulated DC power supply of 3.3 volts and an asynchronous, serial connection to the host system.

Depending on the selected protocols, the baud rate varies between 4800 and 9600 baud, and also depending on protocol, the connection is uni- or bidirectional.

The delivered standard is protocol number 2, this is a unidirectional connection to the host system, with a data rate of 9600 baud. Transmitted are the SpO_2 value, the pulse rate, the plethysmographic waveform and several status information, including the perfusion index.

PEARL Algorithm

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. 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 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 (protocol 2), 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, 55mm x 31.5mm Maximum thickness 4mm
Attachment:	Two 2.6mm holes in the corners of the PCB
Weight:	15 g

Power Suppy:

Operating Voltage:	3.3 Volt DC, +/- 5%,
Current:	20...40 mA depending on interface and LED brightness. (LED brightness depends on finger thickness)
Power Consumption:	70mW to 130mW

Environmental:

Temperature:	Storage	-30 °C to 90 °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 SpO2	
Accuracy:	Standard	+/- 2 %
	Movement artefacts	+/- 3 %
	Low perfusion	+/- 3 %
	(70-100 %, below 70 % not specified)	
Averaging:	Depending on protocol	

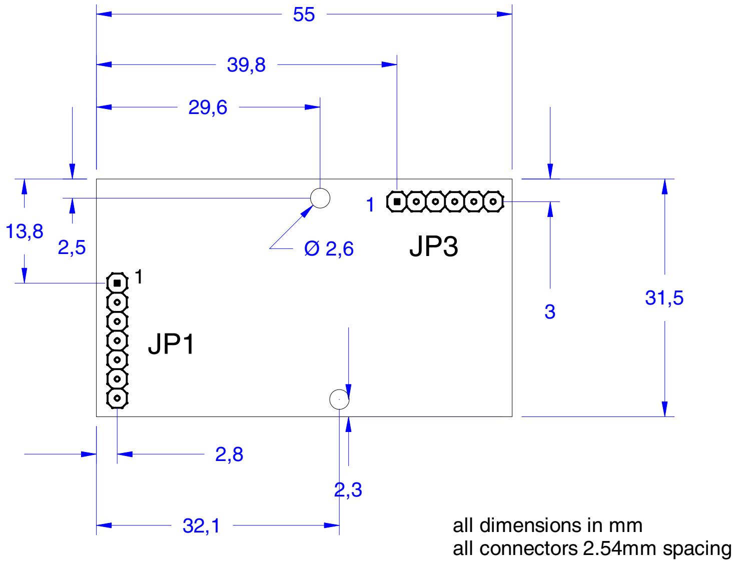
Pulse Rate:

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

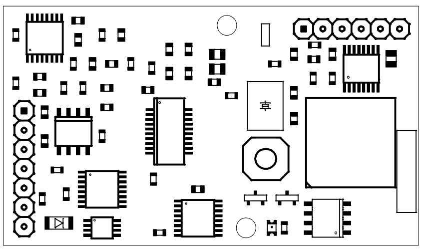
Interface:

Asynchronous, serial interface with CMOS levels
Baudrate and 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)

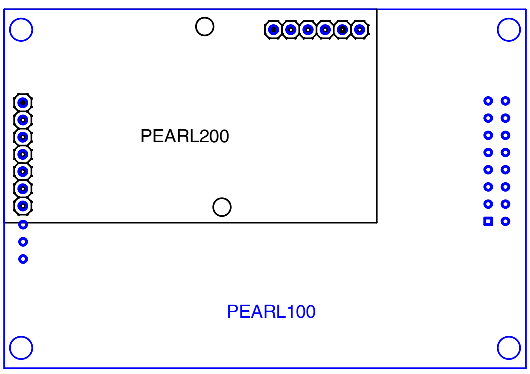
Header for Host Connection :

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 17, "Mounting the PEARL200 board into your medical device"

Compatibility to PEARL100 module

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



Serial Transmission (Protocol 1)

Transmission is not synchronized to any event in the SpO2 calculation, instead a data block is sent 60 times per second. Each data block is five bytes long. The power consumption of the PEARL is slightly higher than in other protocols, due to the relatively large amount of data that is transmitted.

Advantage:
Since the board always transmits 300 bytes per second, it is easily recognized if transmission fails for some reason. Easy to decode.
Disadvantage:
The host CPU has to process a relatively high amount of mostly redundant data because data bytes are received 300 times per second.

Data format:
4800 Baud, 1 Startbit, 8 Databits, even parity bit,1 Stopbit

Bit 7 in Byte 1 is used for synchronisation of the blocks.

```
Byte          Bit                Definition
       7 6 5 4 3 2 1 0

  1    1                         a "1" in bit 7 indicates the start of a new block
         x                       pulse trigger (1 for about 100 ms if pulse detected)
           x                     not used
             x                   not used
               x x x x           Signal strength (0..7), 0x0f is bad signal

  2    0
         x x x x x x x           Plethysmogram sample value (0..99)

  3    0
         x                       Bit 7 of Pulse
           x                     not used
             x                   problem with probe
               x x x x           Bargraph (0..15)

  4    0
         x x x x x x x           Pulse bit 0 to 6

  5    0
         x x x x x x x           Spo2 (0..99)
```

This 5 Byte block is transmitted with 60 Hz = 300 bytes/second.

Serial Transmission (Protocol 2, default)

The second protocol implements the same functionality as the first one, without the large redundant data overhead of it. 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 SpO2 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, SpO2- 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	*Spo2 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.

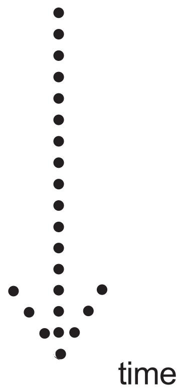
Quality is a number between 0 and 10, coded into the lower 4 bits of the info byte.
If the number is 0, ten or more consecutive pulses have been detected without artefact or other problems.

Description of quality/perfusion byte

Examples of Data Transmission

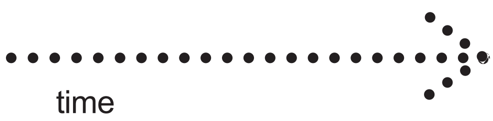
Protocol Version 1:

BLOCK n	
0xC7	*new block, pulse trigger, signal strength = 7*
0x47	*plethysmogramm sample (between 0 and 99)*
0x08	*bargraph sample point is 8, pulse bit 8 = 0*
0x60	*pulse = 96*
0x61	*spo2 = 97*
BLOCK n+1	
0x86	*new block, no pulse trigger, signal strength = 6*
0x49	*plethysmogramm sample (between 0 and 99)*
0x46	*bargraph sample point is 6, pulse bit 8 = 1*
0x30	*pulse = 48 + 128 = 176*
0x60	*spo2 = 96*
……..	
……..	
……..	



Protocol Version 2:

0xF9, 0x61, …..	0xFA, 0x80,	0xFB, 0x00,	0xFC, 0x30,	0xF8, 0x23, 0x25, 0x26, 0x28, 0x30
Spo2 = 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 Spo2 and pulse rate, once per second, while the status byte indicates either "no signal" or "no sensor".

C Source Code Examples for Protocol 1

The following C source codes are intended to help integrate the Medlab OEM pulse oximeter board into the customer’s system. The data is received in the PC's serial interrupt and the values are copied in a data queue that is processed during the main program.

```
void decode_data(void)
    {
      while (!((val = getccb()) & 0x80));    /*  wait for sync bit            */
      if (val & 0x40)
         printf(“!Puls!”);                   /*  pulse trigger active         */

      y = getccb();                          /*  get plethysmogram sample     */

      val = getccb();                        /*  get pulse bar sample         */
      puls_hbit = (val & 0x80)?1:0;          /*  store bit 7 of pulse         */
      bar_graph = val & 0x0F;                /*  store bar_graph value        */

     printf(“Puls %03u”,0x80*puls_hbit + getccb());
                                             /*  print pulse                  */

     printf(“SpO2 %03u”,getccb());           /*  print spo2                   */
   }


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

C example for decoding of data protocol 1

C Source Code Examples for Protocol 2

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;
   }
 }
```

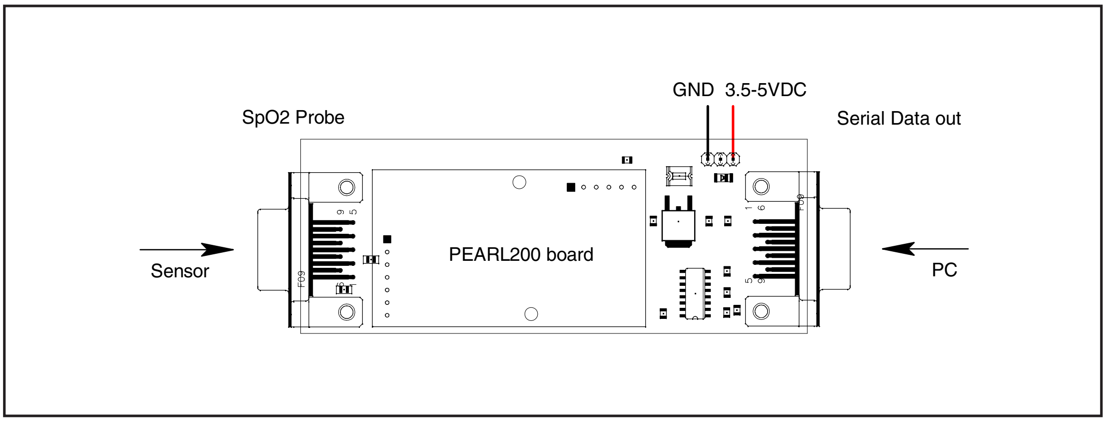
C Example for PC decoding of protocol 2

```
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 of protocol 2 using an 8051 microcontroller

Plug-and-Play Test Kit

To ease the work of evaluating the unit, there is a complete, ready-to-run testkit 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:

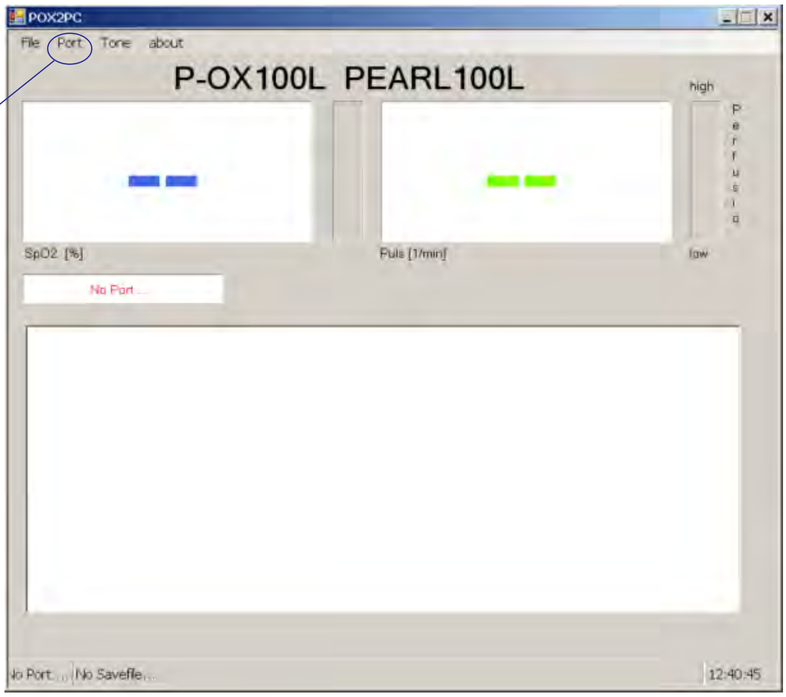
- connect the power connector to a regulated DC supply (3.5-5.0V)
- connect the serial cable to the COM port of a PC
- connect the other side of the serial cable to the carrier PCB
- connect the probe to the carrier board
- turn on the power supply
- turn on PC
- download the test program from oem.medlab.eu
- 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.

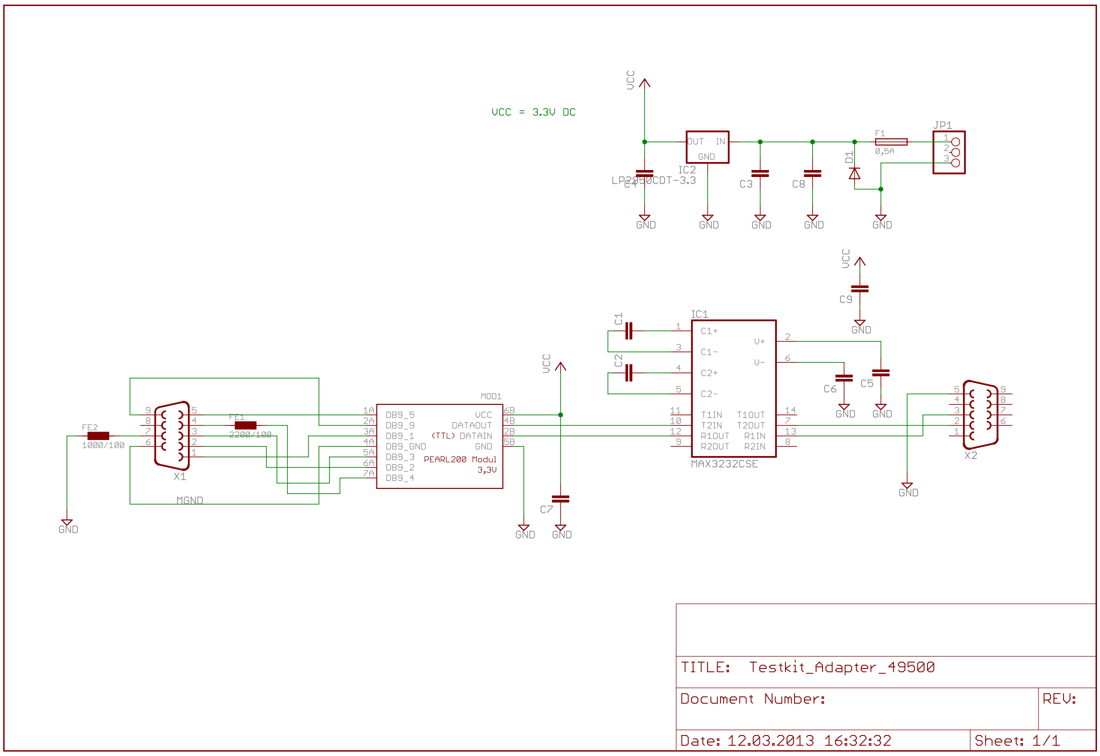
Note: This setup should be used for internal testing only. It does not comply to the power supply isolation requirements of IEC601 or ISO9919 (patient connection should be of type BF).

Screenshot of the PC Software:

Select COM port here first



Schematic of the Test Kit:



Regulatory Considerations

The PEARL200 module described in this document is not a final medical product. That means that it cannot be used as a stand alone 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 CE-marking the final product that will contain the PEARL200 module.

One important part of this is EMC testing the complete medical device. This has to be done on the complete product, not with the board alone. It is important to supply the PEARL200 with a properly filtered, stable DC voltage. The probe inputs and outputs are already fed through small ferrite beads on the module itself.

The module complies to the following standards :

IEC60601-1:1996 and 2006
ISO9919:2005 and ISO80601-2-61

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 ISO9919 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.

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 also 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, addtional EMC filtering is needed, close to the DSUB connector, where the signals enter the housing of your medical device. Please contact Medlab for details.

Available Probes

P 200
Fingerclip probe

WR 200
Wrap probe

PS 200
Small Fingerclip probe

Y 200
Universal Y-probe

R 200
Oxiflex large finger probe

RS 200
Oxiflex small finger probe

V 200
Tongue probe - for veterinary applications

Disposable probes
in 4 Sizes,
Material
plaster or Microfoam
Delivery:
Package of 24 pieces

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