Pulse Oximeter

Service Manual

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Responsibility of the Manufacturer

Our company is responsible for the safety, reliability, and performance of the referenced equipment only under the following conditions:

- all installation, expansion, change, modification and repair of this device are conducted by qualified personnel;
- applied electrical appliance is in compliance with relevant National Standards;
- the device is operated under strict observance of this manual.

⚠ **Note**

- This device is not intended for home use.

- Federal law (USA) restricts this device to sale by or on the order of a physician.

⚠ **Warning**

- This device is not intended as a device used for treatment purposes.

It is important for the hospital or organization that uses this equipment to carry out a reasonable maintenance schedule. Failure to do so may result in equipment failure, or injury to the patient or operators.

Warranty

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANT ABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

Exemptions

Our company's obligation or liability under this warranty does not include any transportation or other charges, or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product, or the substitution of parts or accessories not approved by our company, or repairs performed by anyone other than an authorized representative.

This warranty shall not apply to any instrument subjected to misuse, negligence or accidents, or any instrument from which our company's original serial number tag or product identification markings have been altered or removed, or any product from any other manufacturer.

Safety, Reliability and Performance

Our company is not responsible for the effects on safety, reliability and performance of the product if:

- assembly operations, extensions, re-adjusts, modifications or repairs are carried out by persons unauthorized by our company.
- the product is not used in accordance with the instructions for use, or the electrical installation of the product, and its location does not comply with NFPA 70: National Electric Code or NFPA 99: Standard for Health Care Facilities (Outside the United States, the relevant installation location must comply with all electrical installation regulations mandated by the local and regional bodies of government).

Return Policy

In the event that it becomes necessary to return a unit to our company, follow the instructions below.

1. Obtain a return authorization.

Contact our company to obtain a Customer Service Authorization number. This number

must be marked clearly on the outside of the shipping container. Return shipments will not be accepted if this number is not clearly visible. Please provide the model number, serial number, and a brief description of the reason for return.

2. Freight policy

The customer is responsible for freight charges when equipment is shipped to our company for service (including any relevant customs fees or other freight related charges).

⚠ **Warning**

It is important for the hospital or organization that uses this equipment to carry out a reasonable maintenance schedule. Failure to do so may result in equipment failure, or injury to the patient or operators.

Safety Symbols

⚠ **Warning**

A **Warning** indicates that failure to follow proper instructions can cause death or injury to the patient, the operator, or serious damage to the equipment.

⚠ **Caution**

A **Caution** indicates that failure to follow proper instructions may cause serious injury to the patient, the operator, or may cause damage to the equipment.

⚠ **Note**

A **Note** is an indication of supplemental information to the operation, or handling, of the equipment, or associated accessories.

This symbol indicates type BF applied part according to IEC 60601-1.

This symbol indicates the dual-purpose socket can connect with the PC communication cable.

Illustrations

All illustrations in this manual are provided as examples only. They may not necessarily reflect your setup or data displayed on your Pulse Oximeter.

Content

Chapter 1 Introduction

1.1 General

The Pulse Oximeter is a portable system using common or rechargeable batteries. It is compact, light, flexible to use and easy to learn.
Parameters monitored by the Pulse Oximeter include: arterial oxygen saturation (SpO2), pulse rate (PR) and pulse strength. The Pulse Oximeter employs a finger SpO2 sensor to measure patient's SpO2, PR and pulse strength, and all of these are displayed on the LCD screen.
The Pulse Oximeter is operated and controlled by three buttons, which are Power Button, Backlight Button and ID Confirm Button. The Pulse Oximter is also capable of data manage and exporting the patient's trend data to a PC for printing through the SpO2/communication multiplex port.

1.2 Functions

Pulse Oximeter has the functions shown as below：

1. Monitoring-----SpO_2, PR and pulse strength.
2. Printing-----patient ID, trend data, measurement time.
3. Power Saving------automatic standby, automatic shutdown.
4. Warning-----memory full, ID full, low battery, standby, technical error.

Printing is available only when the device is equipped with a communication cable and works with a PC with a printer.

1.3 Parameters Measurement

Parameters monitored by Pulse Oximeter includes: SpO2, PR and pulse strength.
Pulse Oximeter measures SpO2 by pulsating oximetry, which is a continuous and non-invasive method to determine oxygen saturation of hemoglobin.
Pulse Oximeter also can determine pulse rate and pulse strength, which are indicated on the LCD screen after processing.

Chapter 2 Circuit Principle

2.1 Overview

The Pulse Oximeter collects SpO2 data from the sensor and sends to mainboard. The maniboard processes the data and displays the results (SpO2 values) on the LCD screen. Pulse-strength bar, battery remained capacity and data export indication are also shown on the screen. Pulse Oximeter can be connected with PC through serial port for data transportation and the data can be printed out from PC.

2.1.1 Hardware Theory

Pulse Oximeter's mainboard consists of power circuit, main logic circuit, display circuit and control input circuit. The SpO2 value can be displayed on the LCD or be exported to PC through serial port. The data also can be saved in the EEPROM on the main board as history record. Watchdog circuit is used to reduce interference. Low-power design is adapted to the main board in order to saving energy.

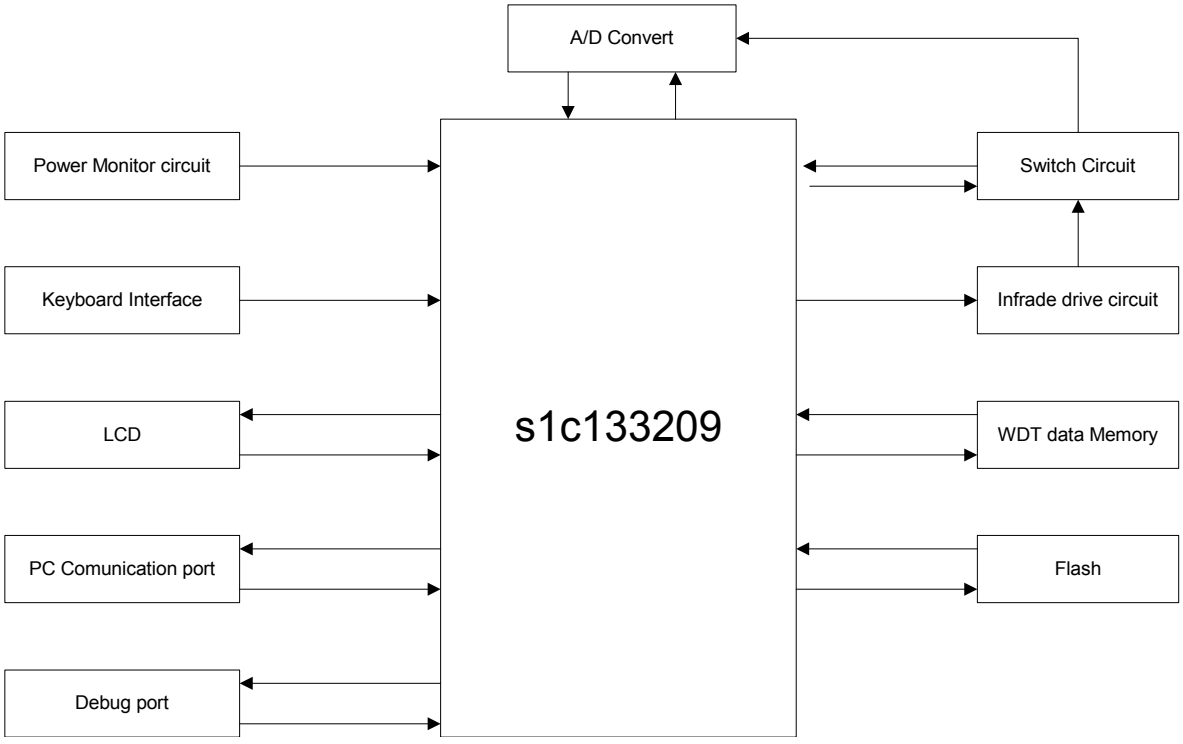

Fig 2-1 Pulse oximeter Block Diagram

2.1.1.1 CPU Power System

S1C33209 uses two voltages. VDD is used to supply the CPU and VDDE is the power

supply for IO module and analog circuit. The voltage of them is 3.3V.

S1C33209 has two crystal oscillators, OSC1 and OSC3. OSC1 supplies RTC and system clock frequency, whose frequency is 32.768KHz. OSC3 supplies work frequency to the CPU, whose frequency is 22.1184MHz.

2.1.1.2 Watchdog Circuit

The watchdog circuit control chip is MAX823. When S2 is shorted, the program will access watchdog procedure. R64 and C63 compose RC low-pass filter to reduce interference of the reset signal. R87 is a pull-up resistor. When power on or operate reset by manual, the capacitor of C54 will release its charge and become low level voltage. C54 and R59 form a RC low pass filter to reduce high frequency noise.

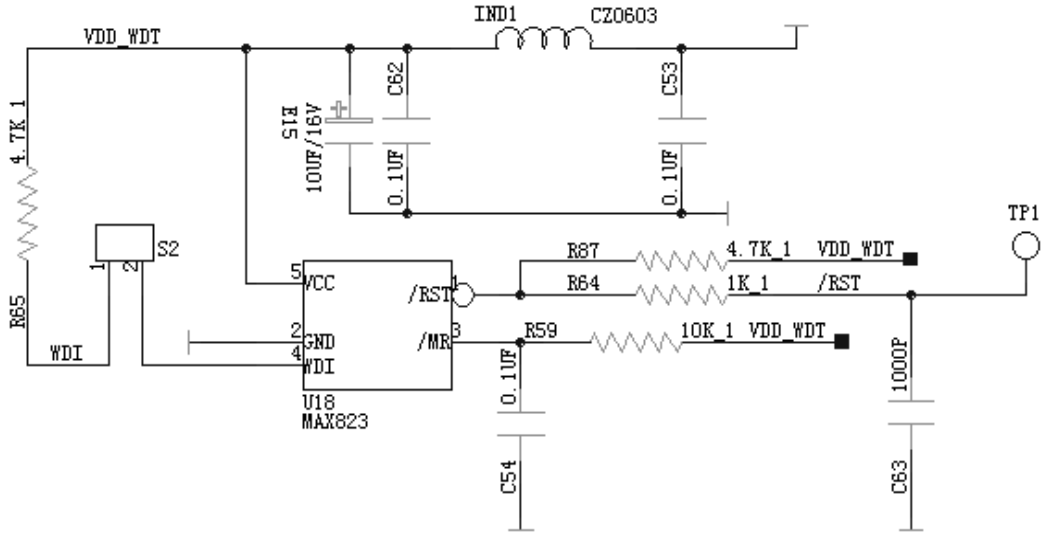

Fig 2-2 Watchdog Circuit

2.1.1.3 Data Storage

The Pulse Oximeter requires automatic data storage in case of power supply failure. 24WC64 IC with the capacity of 8K bytes was adopted. This IC uses I^2C bus.

The C111 and C112 act as filter capacitors to reduce the influence from high frequency noise. When the 24WC64's seventh pin is high level voltage, the IC is write-protected. C113 is a filter capacitor between the write-protect pin and VDD pin. It is used to set the write-protect pin to high level voltage to avoid wrong write operation. The circuit block is shown as below:

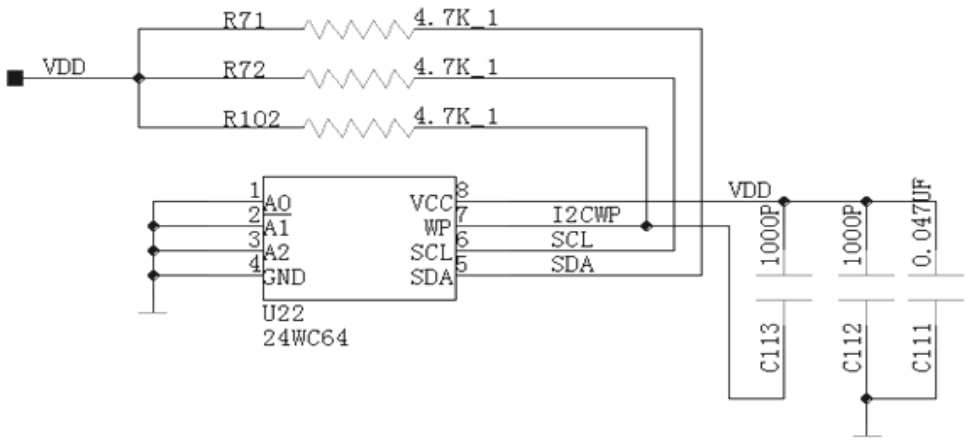

Fig 2-3 Data Storage Circuit

2.1.1.4 DAC

Pulse Oximeter's analog circuit includes two DAC channels. They are DRIVE channel and OFFSET channel.

MAX5102A is a 8-bit resolution DAC control chip. The 2.5V reference level was produced by MAX6066.

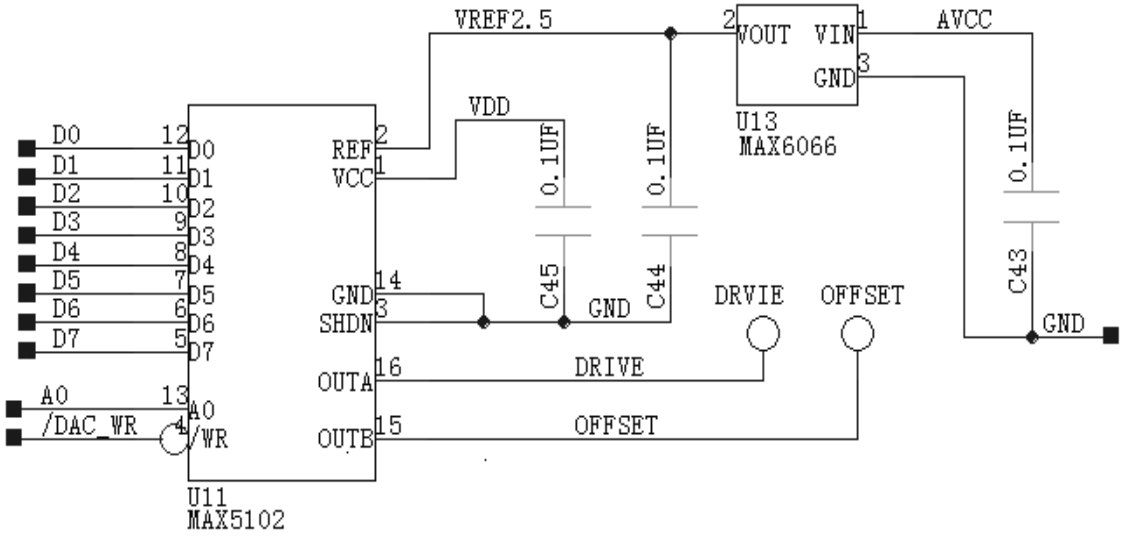

Fig 2-4 DA Circuit

2.1.1.5 ADC

Pulse Oximeter uses MAX1290 as the ADC, which of 12-bit resolution and 8 channels and parallel interface. Two signals of SIGNAL and PROBE-DET are collected by the chip. They directly enter the channel 0 and channel 1 of the ADC without analog switch.

MAX1290 uses separate power supply and the input signal should be in the range of 0V~5V. But the amplitude of the SpO2 signal is between -2.5V and +2.5V. Therefore, a

2.5V voltage shift should be required. R27-C20, R20-C30 and R23-C19 form RC low pass filters to reduce the interference from high frequency noise. C31 is used to prevent self-oscillating and enhance the reliability.

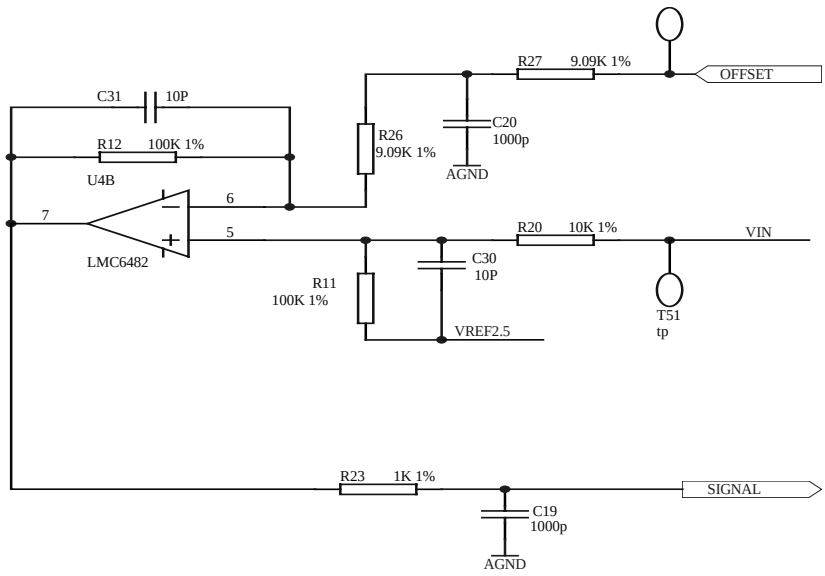

Fig 2-5 Voltage Shift Circuit

Due to the input signal limits of 0V~5V for the ADC chip, a clamp diode is used at the SIGNAL input circuit.

2.1.1.6 LCD Display Module

Pulse Oximeter uses LCD module to display data and patient information. The interface between LCD and CPU includes power line, data bus, read/write control, chip selection and address line.

Backlight of the LCD is separated from others, which is a LED and controlled by a CPU-controlled transistor or MOS transistor.

A π-type filter was adopted for this power in order to reduce the interference from the voltage multiplier circuit in the LCD module.

2.1.1.7 Switch ON/OFF Delay Circuit

Pulse Oximeter has no delay for switch on, but there is 2s delay for switch off.

In the delay circuit, a voltage of +7V is slowly supply to the Q5. The RC network on Q4's base is used to eliminate the button-press shaking and to protect the circuit from electrostatic charge. Before power on, Q5 is off and does not influence Q4. When the Vbe of Q5 goes up and over 0.7V, the Q5 will work. Additionally, the capacitance of E104 should be large enough, otherwise the time interval between 0V and 0.7V will be short. When power off, the discharge time of the 10uF capacitor will become short because the diode D7 is used to fasten the charge release. After power on, Q5 is on and the base of Q4 is 0V. When a button is pressed, Q4 is off and RST-POWER will not function. D2 and

R85 work together to prevent the locking of the CPU.

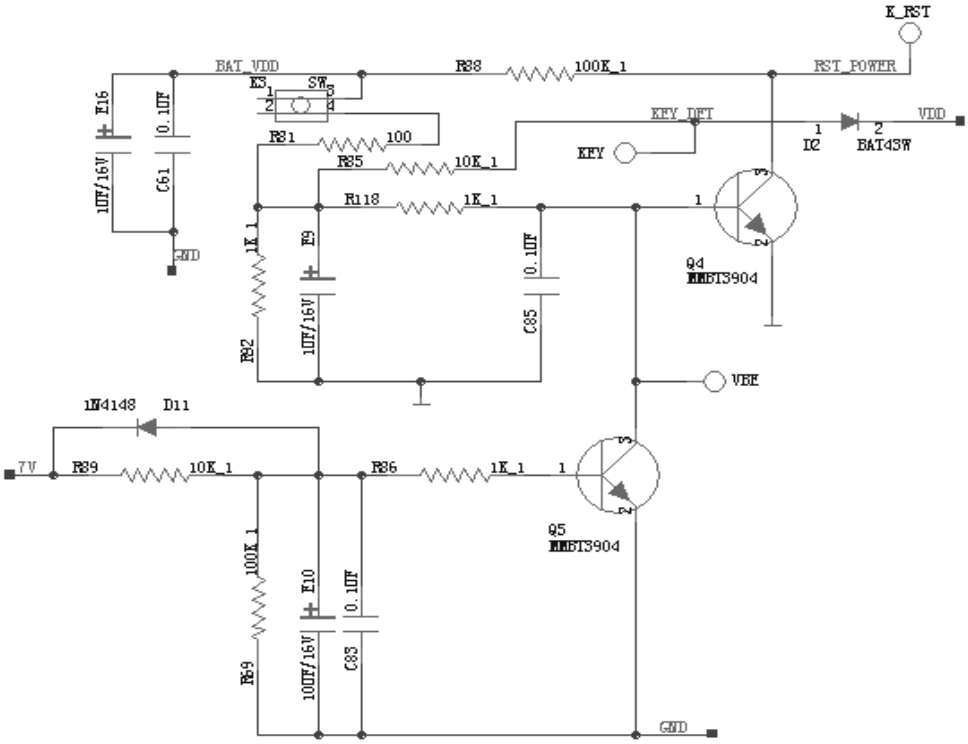

Fig 2-6 Delay Circuit Block

The power-on and power-off signals through two diodes constitute a AND logic output signal named PCON signal, which directly controls the ON/OFF. Resistor R111 is necessary for the AND logic circuit. R95, C82 and E12 form a RC filtering network to protect the circuit from electrostatic charge.

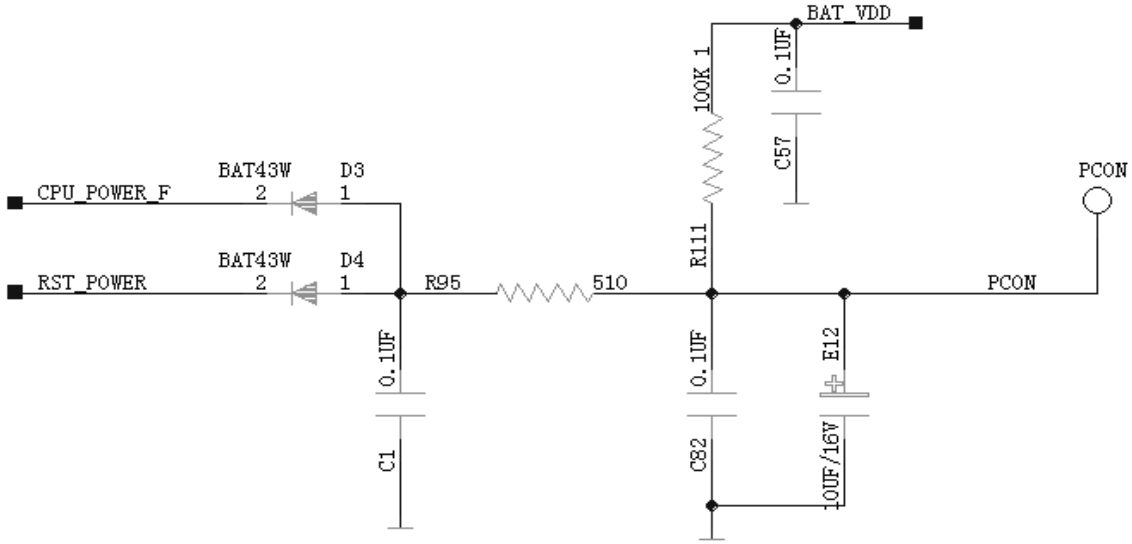

Fig 2-7 Switch On Circuit

2.1.1.8 Serial Port Signal Voltage Level Conversion Circuit

MAX202E is used for the signal voltage level conversion. The output of MAX202E is 5V TTL voltage, and the S1C33209's I/O should use 74HC32 as the voltage level convertor and driver and isolator. R116 and R115 convert the TTL level to LVTTL. R61 and R116 can prevent short-circuit and electrostatic charge damage. Circuit block is shown as below:

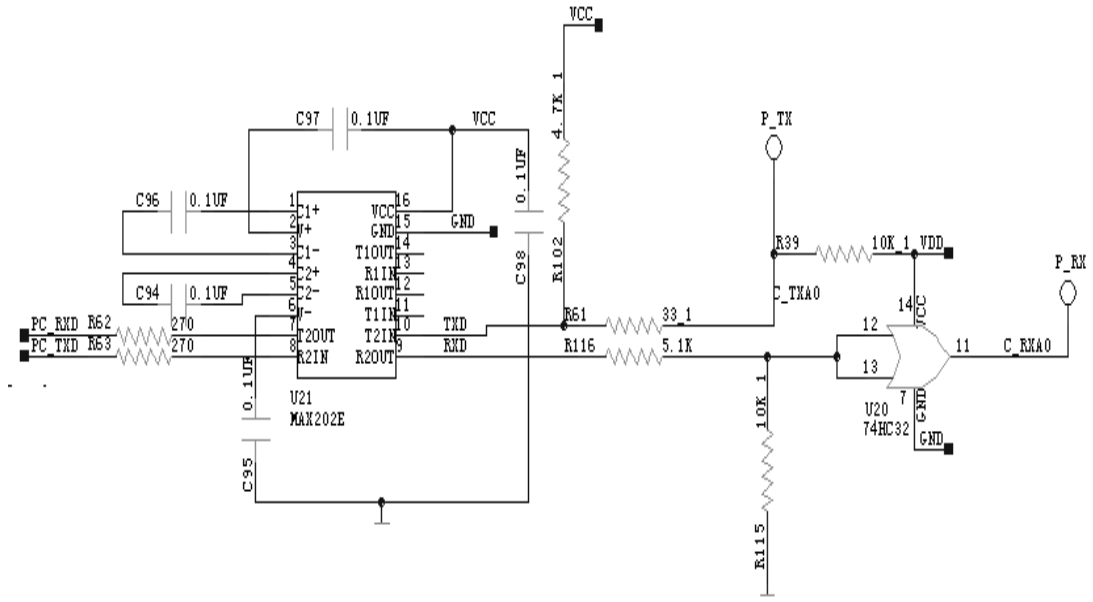

Fig 2-8 Serial Signal Voltage Level Conversion Circuit

2.1.1.9 Button Circuit

Pulse Oximeter has three buttons, Power Button, ID Confirm Button and LCD Backlight Button. The circuit is shown as below:

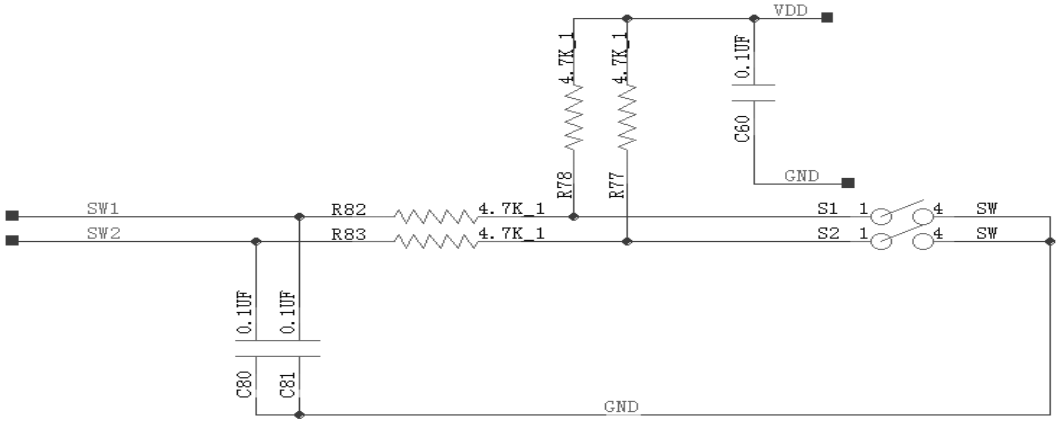

Fig 2-9 Button Circuit

R82 and C81 form RC filter circuit and can resist electrostatic charge interference. The resistance of R82 is 4.7K, which can protect the circuit with big current. RC circuit can also reduce the shaking influence.

2.1.1.10 Voltage Detect

Pulse Oximeter requires that the battery voltage and +7V be detected all the time. S1C33209 has 8 10-bit AD channels, two of which were used. S1C33209 cannot stand that high voltage, so, a voltage divider was adopted to convert the monitored voltages to the range S1C33209 can detect. The divided voltage has a RC filter, which can resist the influence from electrostatic charge.

2.1.2 Power Supply Circuit Block Diagram

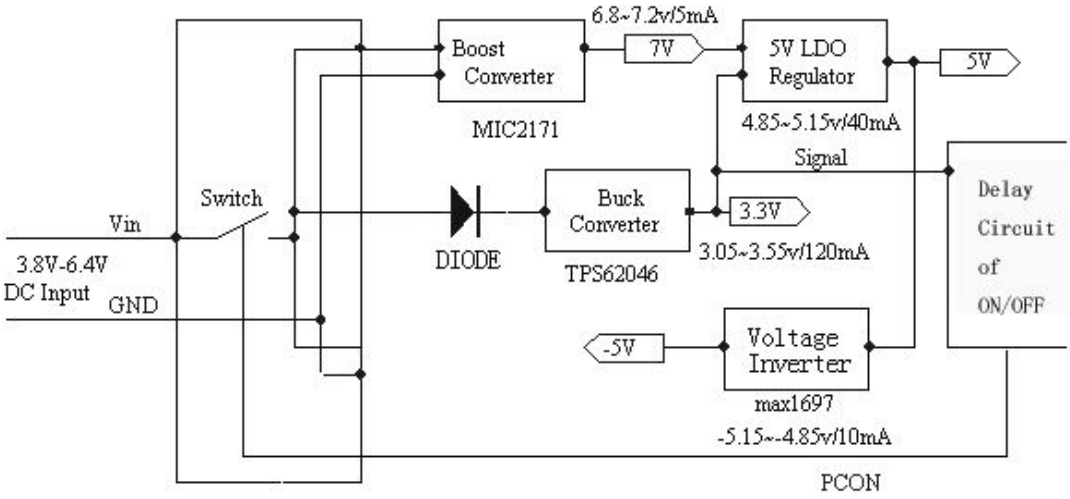

Fig 2-10 Power Supply Circuit Block Diagram

2.2 Reliability Design

The following reliability control methods are used in the Pulse Oximeter:

1. Derating for key elements;
2. Watchdog circuit, to restore the system when the software crashes;
3. By-pass capacitors for each IC, to reduce the interference from power supply;
4. Serial resistors on each line of the serial port, to avoid the destroy to devices due to unintentional short with power;
5. One I/O port to control the write protection of the FLASH, to reduce the possibility of unintentional FLASH write;
6. Monitoring the two major voltages through the CPU's AD, to prevent inaccurate measurement and unreliable data due to the voltage swing.

2.3 EMC Design

The following protections are used for EMC design in Pulse Oximeter:

1. Every IC has one by-pass capacitor, some ICs have different rating capacitors to enlarge the filter band;
2. Serial resistors on the communication lines connected with the PC, to reduce the interference propagation;
3. RC low pass filter on most low frequency signals, to reduce high frequency interference;
4. One ground plane, no discrimination between digital ground and analog ground;
5. Match resistor used on important signals, e.g. read/write, chip select etc., to prevent oscillating or overshoot

Chapter 3 Specifications

3.1 Product Classification

Type of protection against electric shock (standard)	Class IIb according to 93/42EEC
Type of protection against electric shock	Device operated from internal power
Degree of protection against electric shock	BF
Protection against ingress of liquid	Non- protection (ordinary), IPXO
Disinfection /sterilization method	TBD
Mode of operation	Continuous
EMC type	Class A

3.2 General Specifications

Type of patients	Adult, pediatrics, neonate
Parameter monitored	SpO2, pulse rate (PR) and pulse strength
Data interface	Multiplex interface: SpO2 and PC communication cable
Display screen	Dot matrix LCD
Display area	Not less than 42mm×35mm
Backlight of screen	Blue
Dimension	65mm×140mm×32mm
Weight	About 130g (without battery and SpO2 sensor）

3.3 Function Specifications

Prompt Information	Memory full, ID full, low battery, standby state, technical fault
Power saving	Auto standby, auto shut off
Print*	
Printer specification	Dependent on the PC printer
Print paper specification	A4
Content printed	Patient ID, trend data
Online Downloading*	Software update through serial port

Note: “*” only when the PC communication cable is selected.

3.4 Environment

Temperature	
Operating	0℃～50℃

Transport and storage	-20℃～60℃
Relative humidity	
Operating	15%～95%
Transport and storage	10%～95%
Pressure	
Operating	86KPa～106KPa
Transport and storage	50KPa～106KPa

3.5 Electrical Specifications

Operating voltage	4.0V～6.4V DC
Power source	Battery
Battery specification	Normal AA alkaline or rechargeable battery
Shutdown Leakage current	<200 uA
Battery run time	15h for alkaline battery

3.6 SpO_2&PR Specifications

SpO2 measurement range	0%～100%
SpO2 resolution	1%
SpO2 accuracy	Adult/ Pediatric 70%- 100%:±2%
	Neonate 70%- 100%:±3%
	0%- 69%: No specified
PR measurement range	25～254bpm
PR resolution	1bpm
PR accuracy	±2bpm

Chapter 4 Structure

4.1.1 Explosive diagram

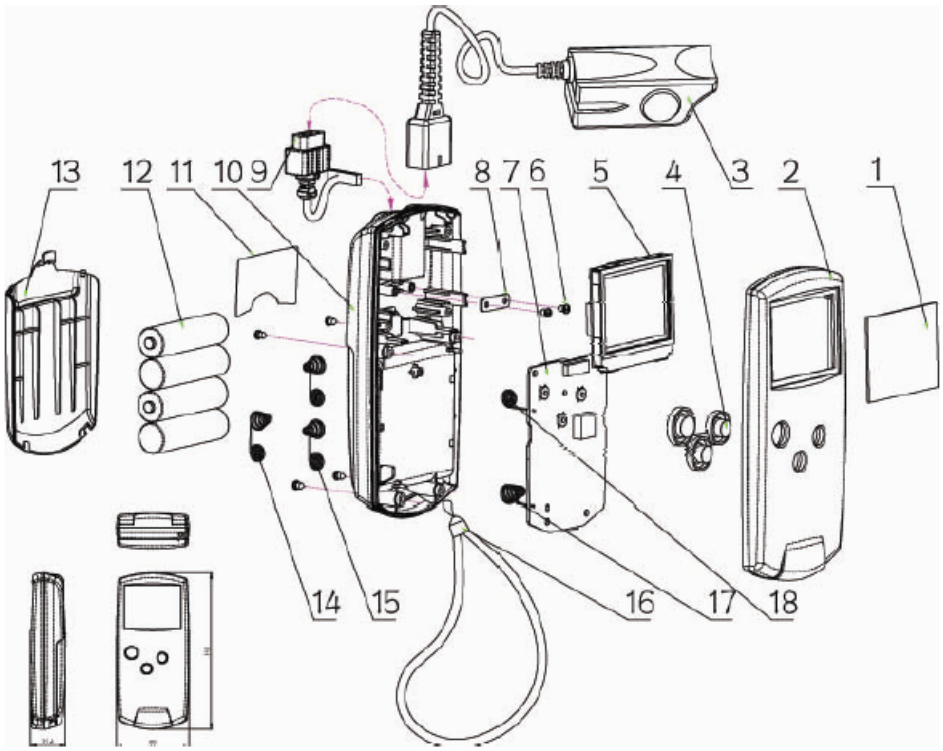

Fig 4-1 Pulse Oximeter Explosive diagram（0850-30-30752）

Table 1 Parts list

#	P/N	Description	QTY
1	0850-20-30705	Screen cover	1
2	0850-20-30700 or other	Front housing	1

3	512D-30-90200	SpO2 sensor	1
4	0850-20-30703	Button	1
5	0850-10-30722	LCD module	1
6	0850-30-30719	Main board	1
7	0850-20-30708	Socket fastening slide	1
8	0850-20-30704	SpO2/PC socket	1
9	0850-20-30701	Back housing	1
10	0850-20-30723	Equipment label(English)	1
11		Battery	4
12	0850-20-30702	Battery cover	1
13	0850-20-30710	Electrode spring - B	1
14	0850-20-30709	Electrode spring - A	2
15	M04-051060---	Panhead screws M2x8	6
16	0010-10-12356	Neck strap	1
17	0850-20-30707	Cathode contact spring	1
18	0850-20-30706	Anode contact spring	1

4.2 Batteries Installation and Maintenance

4.2.1 Install Batteries

The Pulse Oximeter is operated by four 1.5V AA batteries. Follow the steps below to install batteries before use:

1. Hold the Pulse Oximeter face-down firmly by one hand.
2. Push the battery cover gently by the other hand along the vertical direction of Pulse Oximeter.
3. Take the battery cover off（as shown in Fig4-1）.
4. Insert the batteries in the slot per the electrode indications (as shown in Fig4-2).
5. Finally push back the battery cover.

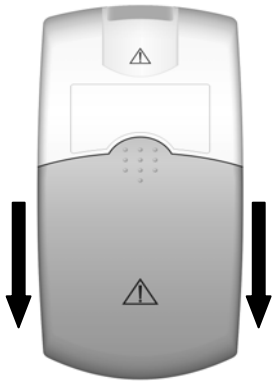

Fig 4-2 Battery assembly 1

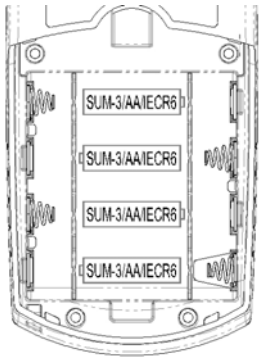

Fig 4-3 Battery Assembly 2

4.2.2Battery Maintenance

1. Use the generic 1.5V AA alkaline battery or rechargeable battery, and do not use carbon battery or poor quality batteries. Remove the battery when nonuse for long time.
2. Replace the battery when the battery charge is insufficient for operation; abnormal power supply may lead to equipment damage or even personal injuries.

Notes：

1. The low battery symbol appears when the battery voltage is lower than 4.0V;
2. Shutdown will be executed automatically when the battery voltage is lower than 3.85V.

4.3 Disposable Spo2 sensor/transdycer

Disposable SpO_2 sensor/transducer	
Adult, 2211-1, ’ENVITE’	0010-10-12333
Pediatric, 2211-2, ’ENVITE’	0010-10-12334
Infant, 2211-5, ’ENVITE’	0010-10-12335
Neonate, 2211-6, ’ENVITE’	0010-10-12336
NELLCOR MAX-A, Adult (>30Kg)	0010-10-12202
NELLCOR MAX-P, Pediatric (10~50Kg)	0010-10-12203
NELLCOR MAX-I, Infant (3~20Kg)	0010-10-12204
NELLCOR MAX-N, Neonate / Adult (<3Kg 或 >40Kg)	0010-10-12205

Chapter 5 Test and Prompt List

5.1 Test Procedure

5.1.1 Connection

Install batteries and connect a simulator with the Pulse Oximeter. Turn on the power. LCD will display startup image and then the Pulse Oximeter enters the normal working mode.

5.1.2 Button Function Test

Press all the buttons one by one to inspect if the expected operation is executed promptly.

5.1.3 SpO2 Measurement Test

ID number display test: turn on the power and the ID number should blink for a few seconds. Then the ID number will change according to the operation of the ID conform button.

SpO2 measurement test: put the sensor on one figure and SpO2 value will appear on the screen shortly. Normal SpO2 value should be larger than 97%.

Pulse rate (PR) measurement test: check the PR value during SpO2 measurement;

Pulse strength bar test: check the pulse strength bar indication during SpO2 measurement under normal conditions as well as weak signal strength conditions.

5.1.4 Communication with PC

Connect the Pulse Oximeter with a PC (RS-232 port) by a cable. The data can be sent to PC.

5.2 Prompt List

Table 5-1 Prompt Information on LCD

Indications	Cause	Solution
Low battery symbol	The battery voltage is below the threshold value	Replace the battery
Memory full symbol	Available data memory locations ＜10	The existing data will be overwritten. Export the data in time.
Memory full symbol blinks	The memory is full	The existing data has been overwritten. Export the data in time.

ID full symbol	ID > 95	ID will be overwritten. Export the data in time.
ID full symbol blinks	ID has been overwritten	ID has been overwritten. Export the data in time.
Standby symbol	Standby mode	None
Communication symbol	Communication mode	None
DELETE ALL?	Delete button pushed	None
ALL DELETED	Delete button pushed again after “DELETE ALL?”	None

Table 5-1 Error indications

Error Message	Cause	Solution
Initiate Error	Failed self-test	Shut down the device (if can’t, remove the batteries) and contact Mindray for service.
Please Release the Button	Button error	Check for jammed button. If problem remains, contact Mindray for service.
Pulse Not Found Searching…	Pulse not found	Check the patient and alert the doctor.

Chapter 6 Maintenance and Cleaning

6.1 Maintenance

6.1.1 Unpacking and Inspection

1. Inspect the Pulse Oximeter for possible damage during shipment;
2. Check all the cables joint part and accessories;
3. Test all the functions applicable to the patients and assure the Pulse Oximeter in right states.

If the equipment shows any signs of malfunction, do not carry out any measurement on the patient and contact with the biomedicine engineer in the hospital or the Mindray service engineer immediately.

6.1.2 Routine Maintenance

A thorough examination shall be carried out every 6~12 months or after each maintenance by qualified personnel, including function and safety test.

Tests which need open the equipment should be done by qualified personnel. Safety and maintenance check can also be done by employee of Mindray. The local agency of Mindray would like to provide the materials related with the maintenance contract.

6.2 Cleaning

Make sure that the power is shut off before cleaning for the purpose of safety.

The equipment should be kept from dust. If the shell or screen needs cleaning, the detergent should be noncorrosive, such as soap or rinsing etc.

Notes：

1. **Do not use strong solvent, such as acetone.**
2. **Most cleanser need dissolving before use. Keep to the cleanser's instructions for use.**
3. **Do not use abrasive materials, such as fine steel wire or silver polishing agent.**
4. **Do not let any liquid ingress into the equipment and do not immerge the**

equipment into any liquid.

5. **Keep the surface of the equipment clean after cleaning.**

Detergents

1. Diluted ammonia.
2. Diluted sodium hypochlorite（bleaching powder for washing）。
3. Diluted formaldehyde 35～37%.
4. Hydrogen peroxide 3%.
5. Ethanol.
6. Isopropano.

6.3 Disinfection & Sterilization

Disinfection:

Disinfection may damage the equipment, so, it is not advised to do unless necessary in the hospital's maintenance plan. Cleaning is recommended before disinfection. Recommended disinfecting agents include：ethylation and aldehyde。

⚠**Caution**⚠

1. **Dilute the solution per manufacturer instructions or use the solution as low as possible.**
2. **Do not let the liquid ingress into the equipment.**
3. **Do not let any part of the equipment immerged into the liquid.**
4. **Do not spill the liquid on the equipment.**
5. **Clean any residual solution immediately from the surface of the equipment with dry cloth.**

Sterilization:

Sterilization may damage the equipment, so, it is not advised to do unless necessary in the hospital's maintenance plan. Cleaning is recommended before sterilization. Refer to the Instructions for use for the sterilization of SpO2 sensor.

Do not use gas（EtO）or formaldehyde to sterilize the equipment.

P/N: 0850-20-30763