

# SERVICE MANUAL



# vital signs MONITOR



# **SOTEIRA S41**

KEMENKES RI AKD 20502320540

# List of contents

Chapter 1 Introduction	1
1.1 Symbol Definition	1
1.2 Warning Information	1
Chapter 2: Overview	6
2.1 Purpose and Scope	6
2.2 Disassembly Procedure	7
2.2 Recommended Service Intervals	7
2.3 Indicators and Display with Embedded Submenus	8
2.4 Buttons 1	2
2.5 Left Panel 1	.4
2.6 Back Panel1	5
Chapter 3: Functional Verification1	.6
3.1 Introduction 1	.6
3.2 Self Test 1	7
3.3 Safety test 1	7
3.3.1 Risk (Leakage) Current Test1	7
3.4 Functional Verification1	.8
3.4.1 Power System 1	.8
3.4.2 System Test 1	9
Chapter 4: Repair Procedures20	0
4.1 Introduction 2	0
4.2 Replacing the Fuse Insert Power	0

4.3 Repla	cing the Battery	21
4.4 Open	ing the Monitor	22
Chapter 5: I	ntroduction to Circuits	26
5.1 Syste	m Module	
5.2 Introd	duction to PCBA Interface	
5.2.1 N	Лain Board	
5.2.2 S	oteira S41 PDK Board	30
5.2.3 D	0M80 Board	
5.2.4 A	C/DC Power Supply Module	39
Chapter 6: 1	Froubleshooting	40
6.1 Introd	duction	40
6.2 Scree	n Messages	40
6.3 Batte	ry Capacity Check	41
6.4 Clean	ing the Monitor Surface	42
6.5 Long	Term Storage	43
6.6 Opera	ator Troubleshooting Chart	43
6.7 Maint	tenance Menu	45
6.7.1 A	access the Maintenance Menu	45
6.7.1 R	eturn to Factory Default Value	46
6.7.2 L	Jsing Demo Mode	47
Chapter 7: S	Specifications	48
7.1 Displa	эу	48
7.2 Indica	ators	48
7.3 Alarm	n Volumes	49
7.4 Butto	ns/User Controls	49

7.5 ECGs	. 49
7.6 SpO2	. 50
7.7 NIBP	. 50
7.8 Respiration Rate (Resp)	. 50
7.9 Temperature (Temp)	. 51
7.10 Default Alarm Limits	. 51
7.11 Power Requirements	. 52
7.12 Size	. 52
7.13 Environment	. 52
7.14 Equipment Classification	. 52

# Chapter 1 Introduction

# 1.1 Symbol Definition

The following symbols appear in the monitor documentation and on the monitor label. This internationally recognized symbol is defined by the International Electrotechnical Commission, IEC 878 and IEC 417A.

Symbol	Definition	
$\Lambda$	Attention, look in the instruction for use	
₩	Type BF Defibrillation	
	Defibrillator resistant type CF equipment	
¥	NIBP Start /Stop Button	
*	Freeze Button	
×	Turn Off Alarms	
Ē	Battery Power Indicator LEDs	
~	AC Power LED	
<b>[</b> *]	Battery Charging LEDs	
$\sim$	Manufacture Date	
IPX1	Drip Proof (Monitor Only)	
X	Shows separate collections for electrical and electronic equipment.	

# 1.2 Warning Information

KEYWORDS	DEFINITION
WARNING	Tells you something can damage the device.
NOTES	Tells you other important information.

#### General Warnings, Cautions, and Notes

**WARNING!** Do not use this device in the presence of flammable anesthetics or other flammable substances in combination with air, an oxygen-enriched environment, or nitrous oxide.

**WARNING!** DANGER OF ELECTRIC SHOCK when cover is removed. Do not remove the cover. Refer service to qualified personnel.

**WARNING!** Do not use this device in the presence of magnetic resonance imaging (MR or MRI) equipment.

**WARNING!** Do not plug the monitor into an outlet that is controlled by a wall switch.

**WARNING!** This device is intended for use by persons trained in health care professionals. Operators should be thoroughly familiar with the information in this manual before using the device.

**WARNING!** Do not autoclave, sterilize with ethylene oxide, or immerse your monitor and other accessories in liquid.

**WARNING!** This device should be used in combination with clinical signs and symptoms. This device is intended only as an adjunct in patient assessment.

**WARNING!** Equipment is protected from defibrillator discharge. The gauges and displays may be temporarily affected during defibrillation, but will recover quickly.

**WARNING!** Vital Signs Monitor suitable for use in patient environments equipment approved to IEC 60950 should be placed outside the patient environment. A patient environment is defined as any volume where intentional or accidental contact can occur between a patient and a system part or between a patient and other persons touching the system part. **WARNING!** When connecting this monitor to any instrument, ensure proper operation before clinical use. Use only equipment that meets the specifications given in this manual. See the instrument's user manual for complete instructions. Accessory equipment connected to the monitor data interface must be certified according to the respective IED standards, namely IEC 60950 for data processing equipment or IEC 60601-1 for electromedical. All equipment combinations must comply with the system requirements of IEC 60601-1-1. Whoever connects additional equipment to the signal input port or signal output port configures a medical system, and therefore, is responsible for ensuring that the system complies with the requirements of the IEC 60601-1-1 system standard.

**WARNING!** Any monitor that has been dropped or damaged should be inspected by qualified service personnel to ensure proper operation before use.

**WARNING!** Use only the original manufacturer's or recommended patient cables. Use of accessories other than those specified may result in increased electro-magnetic (EM) emissions or decreased EM immunity of the device. To avoid potential electrostatic discharge interference, do not use cables with metal or metal-lined connectors.

**WARNING!** Medical electrical equipment, including this device, requires special precautions regarding electro-magnetic compatibility (EMC) and should be installed and serviced according to the EMC information provided in this service manual.

**WARNING!** No sync defibrillator output on monitor. Do not make a connection between the monitor and the defibrillator.

**WARNING!** This monitor will not work effectively in patients who have seizures or tremors.

WARNING! This monitor is not for home use.

**WARNING!** Monitors should not be used adjacent to or stacked with other equipment. If contiguous or stacked use is required, monitors should be observed to verify normal operation in the configuration to be used.

**WARNING!** This monitor is not for apnea detection. The monitor has not been tested or validated for use in the detection of apnea.

**WARNING!** Verify the proper mode of operation before placing the patient. See Selecting a Patient Type in Chapter Setting Up the Monitor.

**WARNING**! Default alarm limits are provided for convenience. Verify that alarm limits are appropriate for the particular patient and condition, and conform to institutional policies.

**WARNING!** Ensure that the monitor's AC rating is correct for the AC voltage in your installation location before using the monitor. The monitor's AC rating is displayed on the rating plate on the rear panel. If the rating is not correct, do not use the monitor.

**WARNING!** Unplug the AC power supply from the wall outlet before removing it from the monitor. Leaving an AC power supply connected to an AC outlet without a monitor connected to it may result in a safety hazard.

**WARNING!** Do not allow moisture to touch the AC power supply plug or a safety hazard may result. Make sure hands are completely dry before handling AC power supplies.

**WARNING!** Do not place the monitor on the patient's bed. Do not place the monitor on the floor.

**WARNING!** Failure to place the monitor away from the patient could allow the patient to turn off, reset, or damage the monitor,

which could result in the patient not being monitored. Make sure the patient cannot reach the monitor from his bed.

**WARNING!** If there is any risk of the AC power supply being disconnected from the monitor while in use, secure the cable to the monitor a few inches from the connection.

**WARNING!** This device is intended for use by trained healthcare professionals. Operators must fully understand the information in this manual before using the device.

**WARNING!** Do not disassemble the unit. Unusable unit. Refer to qualified service personnel.

**WARNING!** It is the operator's responsibility to set the proper limit alarm for each patient.

**WARNING!** If the measurement accuracy is questionable, check the patient's vital signs by alternative methods and then check the monitor for proper functioning.

**WARNING!** Operation of this device may be affected by the presence of powerful mobile and portable communications equipment.

**WARNING!** Operation of these devices may be negatively affected by the presence of computed tomography (CT) equipment.

**WARNING!** Do not allow water or other liquids to spill onto the monitor. Unplug the AC power cord from the monitor before cleaning or disinfecting the monitor.

**WARNING!** This unit contains a lithium coin battery and a rechargeable alkaline battery. This battery is not user replaceable. Refer service to qualified personnel.

**WARNING!** Pressing the front panel buttons with sharp or pointed instruments can permanently damage the keypad. Press the front panel buttons with only your finger.

**WARNING!** Closing the ventilation holes on the back of the monitor panel can prevent air from circulating inside the monitor, which may result in damage to the monitor. Leave an air gap behind the monitor to allow air to circulate through the ventilation holes.

**WARNING!** The chemicals used in some cleaning agents can cause plastic components to brittle. Follow the cleaning instructions in this manual.

**WARNING!** If the device gets wet, remove all moisture and allow sufficient time to dry before operating.

**WARNING!** Follow local government regulations and recycling instructions regarding the disposal and recycling of device components and packaging.

**NOTES!** All materials accessible to users and patients are non-toxic.

**NOTES!** Each input and output connection of the monitor is electrically isolated. Connection of this monitor to other equipment will not increase leakage current.

#### Chapter 2: Overview

#### 2.1 Purpose and Scope

The Maleo S41 Monitor Vital Signs Service Manual is intended as a reference for monitor maintenance and repair. This manual provides troubleshooting information, repair procedures, calibration and performance verification to technically qualified service personnel. A technical overview of the monitor subsystem is given as an introduction to the circuitry and pneumatics of the device.

**NOTES!** Configurations vary for different customers. You may only need to correct some parameters.

#### 2.2 Disassembly Procedure

Use the following guidelines when unpacking the monitor from its shipping carton.

- 1. Before opening the shipping carton of the monitor, inspect it for damage.
- 2. If damage is visible, stop unpacking the carton and contact the shipping company for further instructions. If the carton is intact, unpack the monitor.
- 3. With the monitor out of the carton, check to see if all the items listed on the packing slip (provided with the shipment) are in the shipping carton.
- 4. If any item is missing, check the carton again first, then check with your receiving department.

# 2.2 Recommended Service Intervals

At the intervals listed below, check the Encore monitor for normal operation.

Intervals/Conditions	Do	Place it in This Manual
Every 6 months to 2 years (according to hospital protocol).	Complete risk (leakage) Security Check is currently followed by Functional Verification.	"Functional Verification"
If the battery does not store a charge.	Check battery capacity.	"Problem solving"

The monitor has been dropped or suspected of being damaged or rough handling.	Complete Safety Check followed by Functional Verification.	"Functional Verification"
Suspected malfunction with all or part of parameter monitoring.	Functional Verification of suspected parameters	"Functional Verification"
Monitor has not passed functional verification	The fix is followed by a safety check and functional verification	"Functional Verification"

**WARNING!** If the monitor is opened for repair or calibration, a dielectric strength test must be completed to ensure the integrity of the patient's insulation barrier.

# 2.3 Indicators and Display with Embedded Submenus

This monitor has a high-resolution, high-contrast color LCD screen. It provides continuous real-time display of up to four waveforms. It also shows measured values, chronological data, measurement trends, alarm limits and patient information.



Appearance	Information	
Patient Type	<ul> <li>You must select the patient type (ADULT, CHILD, or NEONATE) before monitoring the patient. When you change the patient type:</li> <li>Alarm limits will be reset to default settings. (if not in LIMIT STATIC mode) The NIBP inflation pressure setting will be reset for adult, pediatric, or neonatal patients.</li> <li>NIBP mode will be reset to MANUAL.</li> </ul>	
Patient Information	The patient's name and bed number will be displayed here	
Status Bar Alerts	Indicates an active alarm event	
Main course	The main menu provides the means to modify monitor settings, such as alarm limits and patient information, and perform monitoring functions. There are several entry points to the monitor menu system including	

	the main Menu, the parameters menu, and the waveform menu	
Waveform Channel	the waveform menu Up to three channels of waveforms can be displayed simultaneously. Each channel can be assigned to a waveform of any enabled parameter, graph, table or blank. The waveform labels provide access to a menu for each waveform where you can adjust various waveform-related settings. For some parameters, such as the ECG, the waveform label displays information about the primary lead and the size of the ECG tracing.	
Waveform	The waveform label shows the name of the	
Labels	waveform.	
Information	Shows date and time, battery symbol and	
Bar	volume icon etc.	
	Paralleter Maine	
Parameters Box	Measured Value 99 99 Measured Value 95 92	
Parameters Box	Measured Value 99 Measured Value 95 99 99 92 Alarm Limits Alarm Limits 99 92 Alarm Limits 99 92 Alarm Limits 99 92 91 92 92 Alarm Limits 93 94 94 95 95 92 95 95 95 95 95 95 95 95 95 95	
Parameters Box Name	Measured Value 99 Measured Value 95 99 99 91 Alarm Limits Alarm Limits 99 92 Alarm Limits 99 92 Alarm Limits 99 92 93 94 94 94 95 92 94 94 95 92 94 95 95 97 97 97 97 97 97 97 97 97 97	

Numerical Measured Value	The numerical value for the selected measurement (such as HR or SpO2) is displayed. Values can be derived or calculated. A hyphen () in place of a measured numeric value indicates that the measure is invalid or unavailable	
Alarm High and Low Limits	The high and low alarm limits for the measured numeric values are displayed. If you don't set alarm limit for newly patient, the default high and low limit will be used	
Units of Measuremen t	The unit of measurement can be changed for pressure. Units of pressure measurement can be displayed as millimeters of mercury (mmHg) or kilopascals (kPa)	

# 2.4 Buttons



No.	Information	Instruction
1	On or Off	Hold down this button for 3 seconds
Ţ		to turn the monitor on or off
		Press this button to activate direct
		non-invasive blood pressure
2	2 NIBP	measurement (NIBP). To cancel an
		ongoing NIBP measurement, press
		the button again.
n	3 Freeze	Press this button to freeze the
3 F		displayed waveform.
4	Silent Alarm	Press alternately to mute the alarm
		volume for 30 seconds, 60 seconds,

		90 seconds, 120 seconds or indefinitely
5	Mode Lock	Use this button to switch between the four main display modes: 1 ECG mode, 3 ECG modes, oxyCRG mode, and large digit mode.
6	Menu Button	Press to enter or exit the main menu.
7	Play Button	The rotary knob is a control dial with a push switch selection. It is located in front of the monitor, in the lower right corner. Rotate the dial to navigate the cursor around the view. Press the knob to select the highlighted option
8	Battery Supply LEDs	The Green Battery Supply LED will illuminate to indicate that the monitor is powered by a battery.
9	AC Power LED	The green AC Power LED will illuminate to indicate that the monitor is connected to an AC power source.
10	Battery Charge LED	The Green Charge LED will illuminate to indicate that the monitor is charging.
11	Silent Alarm LED	The Silent Alarm LED flashes red to indicate that the alarm volume has been muted for 30 seconds, 60 seconds, 90 seconds, 120 seconds, or indefinitely.
12	Working Status LEDs	The LED is green when the monitor is working normally and red when there is an alarm.

# 2.5 Left Panel



No.	Information	Instruction
1	Oximetry Connector (SpO2)	Attach the SpO2 sensor to the monitor. Measured values for blood oxygen saturation (%SpO2) and pulse rate (PR) will be displayed when the sensor is attached to the patient
2	Dual Temperature connectors (top T1 and bottom T2)	If a temperature is set to your monitor, a temperature parameter box will appear on the screen when the patient connector is attached to the monitor. The measured value for temperature (TEMP) will be displayed when the sensor is attached to the patient

3	Non-Invasive	Attach the NIBP cuff to the
	Blood Pressure	monitor. Measured values for
	Connector (NIBP)	non-invasive blood pressure
		(systolic, diastolic and mean) will
		be displayed when the latest NIBP
		measurement is completed
4	ECG connector	Attach the ECG lead to the monitor. The measured value for ECG heart rate (HR) will be displayed when the ECG Lead is placed on the patient

# 2.6 Back Panel



No.	Information	Instruction	
1	Battery	This monitor is equipped with a lithium battery.	
2	Equipotential grounding		

3	AC power connector	Plug the AC power cord into the AC power outlet on the back of the monitor. When the other end is plugged into a grounded, three wired hospital grade receptacle, the AC Power LED will illuminate. The monitor automatically switches between 100V and 240V AC line source voltage. WARNING! Do not plug the monitor into an outlet controlled by a wall switch.
4	USB connector	
5	Interface Network	Connect to central monitor.
6	Air ventilation	The monitor has air vents on the top back of the panel and on the bottom of the monitor.

# **Chapter 3: Functional Verification**

# 3.1 Introduction

Functional verification procedures ensure proper operation of the monitor and its options. This procedure should be performed as follows: module-level repair, calibration, or whenever there is a question about the accuracy or safety of patient function.

**WARNING!** Whenever the monitor is opened for calibration or repair, a risk (leakage) current safety check as well as a dielectric strength (hi-pot) integrity test must be performed as described in this section.

# 3.2 Self Test

Many functions, such as alarms, waveforms and scale sizes, are software operations. During the monitor's power-on self-test, the integrity of all programs is first checked. If the software test is successful, the hardware test starts. If all tests are successful, the monitor is ready for use

# 3.3 Safety test

The following two safety tests, a risk current (leakage) safety check and a dielectric strength (hi-pot) integrity test, should be performed each time the monitor is opened for calibration or repair.

# 3.3.1 Risk (Leakage) Current Test

A risk current (leakage) test should be performed to verify that the patient remains electrically isolated from the monitor's power circuit.

Check the leakage current using a Dynatech/Nevada 431F-1D safety analyzer or equivalent. The source current must not exceed 10 $\mu$ A rms. The sink current, measured between the isolated patient connection (ECG) and the monitor's dc power input connector, shall not exceed 20 $\mu$ A rms. See the analyzer operator's manual for the proper safety check procedures.

Security Test	power	Monitors	Monitors	security
------------------	-------	----------	----------	----------

	Adapter	input dc	Cable	Analyzer
	Plugged into		RA	RA
Current		Connected	LA	LA
		to power	LL	LL
source	analyzei	adapter	С	С
	outlet		RL	RL

		Connects to	RA	RA
Sinking		the ground	LA	LA
SINKING	Not used	ised connector	LL	LL
current		on the	С	С
		analyzer	RL	RL

# 3.4 Functional Verification

Functional verification should be performed only when the monitor is fully assembled. If the monitor has been stored for more than one month without the monitor connected to the AC adapter (for recharging), the battery voltage should be checked. The battery must be replaced if it is unable to charge.

**NOTES!** Before starting the verification procedure, charge the battery for at least 8 hours with the monitor turned off.

# 3.4.1 Power System

The following steps check the integrity of the monitor's power system.

- 1. Turn off the power switch of the AC power adapter.
- 2. Plug the AC power adapter into an AC power outlet and connect it to the monitor's rear panel DC power connector.
- 3. Ensure that the green LED charging indicator on the right side panel of the monitor is off.
- 4. Turn on the power adapter's power switch.
- 5. Check that the green LED on the power adapter is on and the green LED charging indicator on the right side of the monitor is lit.
- 6. Remove the power adapter from the monitor. Check that the monitor's green LED charging indicator on the right is turned off.

# 3.4.2 System Test

The following procedure checks that the buttons operate correctly, the display functions correctly, and the date is displayed correctly.

- 1. Turn on the monitor.
- 2. Make sure no error messages appear and the monitor is on properly.
- Press the Rotary Knob> MEMU>MODE > FREEZE > Alarm Silence key to test the display and verify that there are no missing pixels.
- 4. Using the appropriate table below as a guide, press the indicated buttons in sequence and ensure that the monitor is responding as indicated and the buttons are not sticking.

FREEZE/CANCEL button	Freeze the waveform
EDEEZE/CANCEL button	Maltauguatarma
FREEZE/CANCEL DULLON	IVIEIL WAVEFORMS
ALARNA Silont/RESUME button	Change the silent status of
ALARIVI SILEITI RESOLVE DULLOIT	the alarm
MAIN MENU button	Return to the main menu
NIBP START/STOP button	Start the NIBP pump
NIBP START/STOP button	Stop the NIBP pump

- 5. Press the menu button -> "System" -> "Volume". Press the play button and rotate to change the volume level. Make sure the tone volume changes on and off while turning it off.
- 6. Press menu button -> "System"-> "date" and check if the displayed time and date are correct. If wrong, please use the rotary knob to adjust it.
- 7. Turn off monitors

# **Chapter 4: Repair Procedures**

# 4.1 Introduction

Instructions on how to remove the battery pack are followed by instructions on how to disassemble the monitor, expansion modules, etc.

**NOTES!** In general, the reassembly procedure is the reverse of the disassembly procedure. If there are items that need attention during reassembly, they are described after the disassembly section.

**WARNING!** Whenever the monitor is opened for calibration or repair, a risk (leak) current safety check and hi-pot test must be performed, followed by a complete functional verification.

# 4.2 Replacing the Fuse Insert Power

Fuses protect the Recharger board circuits against overcurrent in the dc input connectors. You do not need to disassemble the monitor to replace this fuse.

Check the fuses to see if the ac power adapter is working properly and there are two of the following conditions:

- The green LED charging indicator on the right side panel of the monitor does not light up.
- Monitor battery is not charged.

To remove the fuse, follow the steps below:

WARNING! Replace the fuse only with one of the same rating and size.

1. Use a flat screwdriver to twist the fuse cover and remove the fuse.



2. Replace fuse with spare one.



#### 4.3 Replacing the Battery

Insert a new battery pack into the monitor when the current battery no longer has sufficient charge.

Dispose of used batteries immediately. Keep away from children. Do not dismantle and do not burn or burn.

**WARNING!** Do not pinch the battery cable when inserting the battery pack into the monitor. Monitor failure or fire may result if the cable is pinched.

You must remove the battery pack before opening the monitor case and replacing components. The following steps describe how to remove the battery pack from the monitor:

1. Using a flat screwdriver, unscrew the screws securing the battery cover as shown below.



2. Disconnect the battery pack cable from the battery pack



3. Remove the battery pack from the monitor.



4. Keep the battery in a safe place when disassembling the monitor.

# 4.4 Opening the Monitor

Follow these steps to open the monitor case and gain access to the three removable monitor boards.

1. Remove the battery ("Replacing the Battery").

2. Using a screwdriver, remove the four screws securing the monitor case.



3. Remove the two front silica gel pads and two support legs.



**WARNING!** Before opening the case more than an inch in the next step, remove the tube from the pressure transducer at the joint. Failure to remove the tube could result in damage to the transducer or the tube.

4. Press the top and bottom edges of the rear chassis to separate the front and rear chassis.



5. Disconnect the battery and speaker connectors to fully expose the front and rear chassis



- 6. Spread the open sheath at an angle of about 80 level.
- **7.** Disconnect the following cables from the front chassis (shown in the image below):
  - Power cable
  - Temperature Cable
  - SpO2 cable
  - ECG cable
  - Parameter Board Cable
  - Pressure Transducer





8. Remove the two screws and remove the main board plug to completely separate the bezel assembly and core assembly.



Chapter 5: Introduction to Circuits

# 5.1 System Module



# 5.2 Introduction to PCBA Interface

# 5.2.1 Main Board

Maleo S41 monitor main board must be equipped with the following items: CPU more than 200MHz, LINUX system, 64MByte memory, 64MByte flash.

It supports LCD display, internet, USB HOST, Audio decoding, RTC, SPI, UART function etc.



N o	Conn ector	Function	Definition	Co mm ent
(1)	J1	JTAG interface	10 PINS,	NC
			Intervals:	
			2.54mm	
(2)	J3	Speaker Interface,	2 PINs,	
0		Connect Speakers	Intervals:	
			2.54mm	
(3)	J4	Host USB	UAB Type A	
0		interface		
(4)	J5	UART interface	3 PINs,	NC
			Intervals:	
			2.54mm	
(5)	J7	Nurse Call	RJ11	NC
0		Interface	Connector	
6	J8	Network Interface	RJ45 connector	
(7)	J9	Connect the PDK	40 PINs,	
		Board	Intervals:	
		J4 module	2.54mm	

J1 connector function definition:

P I N	Function	Information	Comment
1	VDD	+ 3.3V power supply	
2	NTRST	Test the system reset signal	
3	TDI	Test input serial data	
4	TMS	Test Mode Selection	
5	ТСК	Testing the Clock	
6	RTCK	The test clock returns asignal	
7	TDO	Output serial test data	
8	nRESET	Target system reset signal	
9	NC	Not connected	
10	Mr	Ground	

J3 connector function definition:

PIN	Function	Information	Comment
1	SPK+	Speaker output	
2	SPK-	Speaker output	
PIN	Function	Information	Comment
1	V BUS	+5V power supply	
2	D-	Data-	
3	D+	Data +	
4	GND	Ground	

J4 connector function definition:

J5 connector function definition:

PIN	Function	Information	Comment
1	TXD	UART 6 Transmitting Data	
2	GND	Ground	
3	RXD	UART 6 Receive Data	

J7 connector function definition:

PIN	Function	Information	Comment
1	VCC	+ 3.3V power supply	
2	microphone	Enter Microphone Phone	
3	Nurse Call	Nurse call signal	
4	GND	Ground	

J8 connector function definition:

PIN	Function	Information	Comment
1	TX+	Transitive Data+	
2	TX-	Transient Data-	
3	RX+	Receive Data+	
6	RX-	Receive Data-	
4,5,7,8	T/C	Not connected	

J9 connector function definition:

Pin	Function	Information	Comment
1,2	VDD	+5V power supply	
3,4,19,26,33,40	GND	ground	
5	TXD1	UART1 Transmits Data	
6	RXD1	UART1 Receive Data	
7	TXD2	UART2 Transmits Data	
8	RXD2	UART2 Receiving Data	
9	TXD3	UART3 Transmits Data	
10	RXD3	UART3 Receiving Data	

11	TXD5	UART5 Transmit Data	
12	RXD5	UART5 Receiving Data	
13	SPK	audio signal	
14	Nurse _Call	Nurse call signal	
15	LCD_E N	LCD data allows	
16	LCD_V SYNC	Vsync LCD signal output	
17	LCD_H SYNC	Hsync LCD signal output	
18	LCD_D OTCK	LCD sample clock	
20,21,22,23,24, 25	LCD_D ATA_B 0 ~5	Blue LCD data output	
27,28,29,30,31, 32	LCD_D ATA_G 0~5	Green LCD data output	
34,35,36,37,38, 39	LCD_D ATA_R 0 ~5	Red LCD data output	

# 5.2.2 ZENMED+ Soteira S41 PDK Board

The main function of the PDK board is to manage the DC-DC power supply, manage the battery charge, check the keyboard/buttons, etc.





No.	Connect or	Function	Definition	Comment
1	J1	Lithium Ion Battery Interface	3 PINs, Intervals: 3.96mm	
2	J2	DC15V input interface	2 PINs, Intervals: 3.96mm	
3	J3	TFT LCD interface	40PIN, Intervals: 0.5mm	
4	J4	Connect the J9 Motherboard module	40 PINs, Intervals: 2.54mm	
5	J5	Connect the J900 Module DM80	6 PINS, Intervals:	

		Board	2.54mm	
6	JG	Connect the J100 Module DM10 Board	6 PINS, Intervals: 2.54mm	NC
7	J7	Connect the CO2 link module	8PINs, Intervals: 2.54mm	
8	J8	encoder	ALPS EC11E1524 4B2	
9	J9	PIC-ICSP Serial in Programming Circuits	5 PINS, Intervals: 2.0mm	
10	J10	SpO2 Link Interface	6 PINS, Intervals: 2.0mm	

# J1 connector function definition:

Pin	Function	Information	Comment
1	Bat+	Battery +	
2	NC	Not connected	
3	Bat-	-Gnd battery	

J2 connector function definition:

Pin	Function	Information	Comment
1	DC15V	Enter DC 15V	
2	Mr	ground	

# J3 connector function definition:

Pin	Function	Information	Comment
1,2	VLED	+5V Power voltage	
		for the LED Driver	

3	ADJ	Adjust led brightness with PWM Pulse	
4,5,	GLED	Ground for the LED circuit	
6,7	VDD	+3.3V Power supply voltage for digital circuits	
12,16,20, 24,28,32, 36,38	GND	ground	
8	Mode	DE or HV mode control	
9	DE	Enable Data	
10	VS	Input Vsync signal	
11	HS	Hsync signal input	
13	B5	Blue data input (MSB)	
14	B4	Enter blue data	
15	B3	Enter blue data	
17	B2	Enter blue data	
18	B1	Enter blue data	
19	BO	Blue data input (LSB)	
21	G5	Green data input (MSB)	
22	G4	Enter green data	
23	G3	Enter green data	
25	G2	Enter green data	
26	G1	Enter green data	
27	GO	Green data input (LSB)	

29	R5	Input data red (MSB)	
30	R4	Enter red data	
31	R3	Enter red data	
33	R2	Enter red data	
34	R1	Enter red data	
35	RO	Red data input (LSB)	
37	DCLK	Clock example	
39	L/R	Select left or right scanning direction	
40	U/D	Select the up or down scan direction	

J5 connector function definition:

Pin	Function	Information	Comment
1	VCC	+5V power supply	
2	VCC	+6V power supply	
3,	GND	ground	
5			
4	TXD1	UART1 Transmits	
		Data	
6	RXD1	UART1 Receive	
		Data	

J6 connector function definition:

Pin	Function	Information	Comment
1,2	VCC	+5V Power Supply	
3,5	Mr	Ground	
4	TXD3	UART3 Transmits Data	
6	RXD3	UART3 Receiving Data	

J7 connector function definition:

Pin	Function	Information	Comment
1,3	VCC	+5V Power Supply	
2,6,8	Mr	Ground	
4	CO2 TXD	RS232 Transmit Data	
5	CO2RXD3	RS232 Receiving Data	
7	NC	Not connected	

J9 connector function definition:

Pin	Function	Information	Comment
1	VDD	+ 3.3V power supply	
2	GND	Ground	
3	MCLR/VPP	Programming/	
		Inspection	
4	ICPCLK	Enter hours	
5	ICSPDAT	Serial data transmission	

J10 connector function definition (Only used for Maleo S41 SpO2 Oximeter):

Pin	Function	Information	Comment
1	DOUT	Enter data	
2	VDD	+ 3.3V power supply	
3	RD+	Red light	
4	IR+	Infrared light	
5	DGND	ground	
6	Pro_Det	Probe Detection	

#### 5.2.3 DM80 Board



N 0.	Singer	Function	Definition	Com ment
1	J900	Connect the J5 module PDK Board	6 PINS, Intervals: 2.54mm	
2	J1	DM80 JTAG interface	6 PINS, Intervals: 2.0mm	
3	J100	ECG link interface	6 PINS, Intervals: 2.54mm	
4	J302	SPO2 link interface	6 PINS, Intervals: 2.0mm	
5	J500	TEMP link interface	4 PINs, Intervals: 2.0mm	

6	1800	Pump Interface	2 PINS, Intervals:
			2.54mm
(7)	J801	Air valve interface	4 PINs,
			Intervals:
			2.0mm
8	J802	MCU2-ISP	4 PINs,
-			Interv
			als:2.0
			mm

J900 connector function definition:

Pin	Function	Information	Comment
1	VCC	+5V power supply	
2	VCC	+6V power supply	
3,5	GND	ground	
4	TXD1	UART1 Serial Data Input	
6	RXD1	UART1 Serial Data	
		Output	

J1 connector function definition:

Pin	Function	Information	Comment
1	TDI	Test Data serial input	
2	TDO	Test Data serial output	
3	TMS	Test Mode Selection	
4	ТСК	Testing the Clock	
5	DGND	Ground Digital	
6	VDD	+ 3.3V power supply	

J100 connector function definition:

Pin	Function	Information	Comment
1	V	Channel V	

2		LL channel	
3	RL	RL channel	
4	LA	LA Channel	
5	ECG GND	Shields	
6	RA	RA Channel	

J302 connector function definition:

Pin	Function	Information	Comment
1	DOUT	Enter data	
2	VDD	+ 3.3V power supply	
3	RD+	Red light	
4	IR+	Infrared light	
5	DGND	ground	
6	Pro_Det	Probe Detection	

J500 connector function definition:

Pin	Function	Information	Comment
1	T1+	Temperature 1 Channel +	
2	T1-	1 Channel Temperature -	
3	T2+	Temperature 2 Channels +	
4	T2-	2 Channel Temperature -	

J800 connector function definition:

Pin	Function	Information	Comment
1	PUMP+	Air Pump +	
2	PUMP-	Air Pump -	

J801 connector function definition:

Pin	Function	Information	Comment
1	Air relief	Quick Air Release Valve	
	valve 1+	+	

2	Air release valve 1-	Quick Air Release Valve -	
3	Air release valve 2+	Slow Air Release Valve +	
4	Air release valve 2 -	Slow Air Release Valve -	

J802 connector function definition:

Pin	Function	Information	Comment
1	VDD	+ 3.3V power supply	
2	RXD	Enter serial data	
3	thx	Serial Data Output	
4	DGND	ground	

# 5.2.4 AC/DC Power Supply Module



Ν	Conn	Function	Definition	Com
о.	ector			ment
1	CN1	AC Input Interface	3PIN,Intervals	
			: 3.96mm	
2	CN2	DC Output	4 PINs,	
		Interface,	Intervals:	
		Connect PDK	3.96mm	

	Board J2 module	

CN1 connector function definition:

Pin	Function	Information	Comment
1	N	AC N	
2	NC	Not connected	
3	L	AC L	

CN2 connector function definition:

Pin	Function	Information	Comment
1,2	DC output	DC output +15V	
3,4	GND	Ground	

# Chapter 6: Troubleshooting

#### 6.1 Introduction

This section provides information that can assist in resolving monitor problems.

#### 6.2 Screen Messages

Messages may appear on the screen to inform the operator of some conditions that require operator or service attention. Messages indicating that the monitor may need service are listed below.

Screen Message	Size
Full history data	Restore factory default
Full alarm record	settings or change system
Full event	date
No parameter board	Check module
communication	connection and
No Oxi Module communication	integrity
No CO2 Module communication	

Over temperature on sensor	Make sure the sensor is not exposed to extreme heat
Faulty Sensors	Re-insert or reset sensor is required.
In Sleep Mode	The bit is set when the sensor has been positioned in sleep mode.
Zero In Progress	Capnostat zero is currently underway
Sensor Heating	This error condition is normal at startup. This error should disappear when the warm-up is complete
Check Sampling Line	Check that the sampling line is not clogged or kinked.
Zero Required	For cleaning, check the air inlet adapter and clean as needed
CO2 Out of Reach	Do zero
Check the Air Line Adapter	To clean, clean the airway adapter if mucus or moisture is visible.

#### 6.3 Battery Capacity Check

Several variables affect the monitor's running time on battery:

- Active option
- NIBP measurement frequency
- Print frequency and length
- Ambient temperature
- Battery age and condition
- Information displayed.

**WARNING!** The new battery must pass the following tests. The operating time of older batteries will decrease proportionately with age.

Replacement is recommended when the running time becomes insufficient for the monitor's intended application.

- Use the AC power adapter and charge the monitor for at least 8 hours with the monitor turned off.
- 2. Disconnect the cuff and all cables from the monitor.
- 3. Disconnect the power adapter.
- 4. Turn on the monitor.
- 5. Run the monitor for 4 hours.
- 6. Check that the monitor does not turn off automatically.
- Use the AC power adapter and charge the monitor for at least 8 hours with the monitor turned off.

#### 6.4 Cleaning the Monitor Surface

**WARNING!** Do not autoclave, sterilize ethylene oxide, or immerse the monitor in liquid.

**WARNING!** Do not allow water or other liquids to spill onto the monitor. Unplug the AC power cord from the monitor before cleaning or disinfecting.

**WARNING!** If equipment accidentally gets wet, it must be wiped dry externally and allowed to dry thoroughly before use.

**NOTES!** Use only a soft cotton cloth, or a cloth specially designed for cleaning LCD screens, to clean the monitor screen. Do not clean the screen with tissues, paper towels or other paper-based wipes. Paper-based wipes can scratch the screen.

**NOTES!** Do not clean the screen with isopropyl alcohol or glutaraldehyde. This liquid can scratch the screen. Use only water or a mild soap solution to clean the screen. Clean the surface of the monitor with a soft cloth dampened in water or a mild soap solution. If disinfectant is needed, wipe the monitor surface (but

not the screen) with isopropyl alcohol or glutaraldehyde. Then clean the surface with a soft cloth dampened in water.

# 6.5 Long Term Storage

If the monitor is to be stored for an extended period of time, pack the monitor and its accessories in the original packing materials and shipping carton. That

Long term storage facilities must meet the following requirements:

- In
- From -40 to 75 °C (-40 to 167 °F)
- Relative humidity from 10-95% (non-condensing)
- No periodic checks required

Problem	Possible Causes	Corrective action
The AC power LED	The AC power cord	Connect the AC
on the front of the	is not connected to	power cord to the
monitor does not	the monitor, the	monitor and to the
light up.	AC line, or both.	AC line.
	The power supply	Only plug the AC
	cord is not	power cord into an
	connected to a	outlet that is not
	controlled wall	controlled by a
	power source	wall switch.
	AC line fuse blown.	Contact your
		authorized repair
		center.
Battery operating	Damaged battery	Contact your
time is too short	usage	authorized repair
on a fully charged		center.
battery		
The display on the	Broken screen	Contact the service
monitor does not	backlight	department.
light up		

#### 6.6 Operator Troubleshooting Chart

Sensor Off appears on the pleth wave channel	The SpO2 sensor is not positioned correctly on the patient.	Reposition sensors on the patient.
	The SpO2 sensor used is not suitable for the application	Replace the sensor or contact the equipment manufacturer
	Faulty SpO2 sensor	Replace the sensor or contact the equipment manufacturer
The pulse rate is erratic, intermittent, or incorrect.	The SpO2 sensor is not positioned correctly on the patient	Reposition sensors on the patient
	The patient moves a lot	Make sure the patient doesn't move much
	The patient's perfusion performance is poor	Position the sensors precisely
	There is too much ambient light around the sensor	Protect the SpO2 sensor with a towel or cloth
There are no identified peripheral pulses on the bar graph in the SpO2 parameter box.	The SpO2 sensor is not connected to the monitor or to the patient	Connect the sensor to the extension cable and connect the extension cable to the monitor
	The SpO2 sensor is not properly	Reposition sensors on the patient

	positioned on the patient	
	The patient's perfusion performance is poor	Position the sensor correctly
	SpO2 sensor or extension cord is damaged	Replace the sensor or contact the equipment manufacturer
Leads Fails appear on the ECG waveform channel	One or more of the ECG Leads are not connected to the electrodes	Connect the ECG lead to the electrodes
	One of the ECG leads is faulty, resulting in a high impedance	Replace the ECG lead
	The electrode impedance is too high	Remove and reattach the electrodes

# 6.7 Maintenance Menu

# 6.7.1 Access the Maintenance Menu

Press the menu button to bring up the main menu and turn the rotary knob on the monitor to move the cursor to the "Maintenance" option. Then press the play button to enter the submenu.

OPTIONS	INSTRUCTIONS
Machine	Return to factory default and use DEMO mode
Login	These three menus can only be changed using
config	a password and have an impact on "System configure" and calibration of ECG, NIBP and TEMP which can only be accessed by
Calibrate	distributors and manufacturers.

#### 6.7.1 Return to Factory Default Value

You can set your monitor to operate using the default values you choose for alarm limit, volume, LCD brightness, parameter settings.

Maintenance				
Factory Default	Factory Default Setup			
Data Manager	Are you sure to restore the factory settings?			
System Status				
Demo				
Exit				
	V OK X Cancel			

1. Press the menu button to bring up the main menu and turn the rotary knob to move the cursor to the "Maintenance" option.

- 2. Press the spin button to access the "Maintenance" submenu and select the "Machine" option. Turn the knob to highlight the "Factory Defaults" option.
- 3. Press the rotary knob to access the factory default submenu and rotate the knob to "OK" and press if you want to restore factory settings.

# 6.7.2 Using Demo Mode

This demo mode is intended for service operators. Contact your authorized repair center for assistance.

**WARNING!** When demo mode is active, no patient data is collected or analyzed. Never attach the patient to the device and monitor while in demo mode.

The monitor is included in the DEMO mode which will be used for training and sales activities. Installed parameters are simulated when demo mode is turned on. All monitor functions will be simulated in demo mode, including NIBP alarms, trends and history.

Maintenance				
Factory Default	Demo			
Data Manager	Status Disable			
System Status				
Demo				
	Attention			
Exit	Confirm access to Demo Mode?			
	OK Cancel			
17月月月	V OK X Cancel			

To enable demo mode:

- 1. In the maintenance menu, point to DEMO and press the knob to make a selection.
- 2. Turn the rotary knob to turn OFF and press the knob to select.
- 3. Turn the knob to ON and press to select.
- 4. Turn the rotary knob to point to YES and press the knob to select. An attention will appear to remind you when you are ready for demo mode. Turn the rotary knob to point to OK and press to select.

DEMO will be displayed, gray in the middle of the monitor display. To turn off demo mode:

- 1. In the maintenance menu, point to DEMO and press the knob to make a selection.
- 2. Turn the rotary knob to turn ON and press the knob to select.
- 3. Turn the rotary knob to OFF and press to select.
- 4. Press the OK button to turn off demo mode.

The monitor will return to its normal operating state and will collect patient data.

#### **Chapter 7: Specifications**

#### 7.1 Display

7-inch diagonal TFT (Thin Film Transistor) high resolution Active Matrix LCD

Resolution: 800 X 480 pixels

#### 7.2 Indicators

LEDs:	Work Status	LEDs
	AC Power	LED
	Battery Charge	LED
	LED Battery Supply	
	LED Silence Alarm	

#### 7.3 Alarm Volumes

45dBA to 85 dBA at 1 meter (changeable).

#### 7.4 Buttons/User Controls

- On/Off button
- NIBP button
- Freeze button
- Alarm Silence button
- Mode Button
- Menu Button
- Spin Knob

#### 7.5 ECGs

Heart Rate Range: 20-350 bpm Heart Rate Accuracy:  $\pm 2$  bpm or  $\pm 2\%$  (largest) QRS Detection Range: 0.5 to 5 mV Pulse Detection Speed: ±2 mV to ±700 mV amplitude **Detection Duration:** 0.1-2.0ms High:20-350 bpm and OFF Heart Rate Alarm Range: Low:20-350 bpm and OFF Heart Rate Average: Fix 8 second averaging Choice of Leads: I, II, III, V, aVR, aVL, or aVF (5-lead) **Display Gain Settings:** X1/4, X1/2, X1, X2, X4 -5.0 mV to+5.0mV Input Range: Frequency Response: 0.05 Hz to 150 Hz Input Impedance: >5 Mohms difference. ANSI/AAMI EC-13 compliant. I-Leakage: <10uA Patient Electrical Isolation: >4000 VAC Waveform display: 6.25, 12.5, 25 or 50 mm/s Digit Video Update Rate: 1 H7

#### 7.6 SpO2

SpO2 Range: Functional Saturation SpO2 Accuracy: Range Pulse Rate: Pulse Rate Accuracy: SpO2 Alarm Ranges: 0-100%

±2%@70-100% <70% unspecified 30-250 bpm

High: 0-100% and OFF Low: 0-100% and OFF

#### 7.7 NIBP

Blood Pressure	Measureme	ent		
Measurement N	Aethod:	Oscillometric with step down deflation		
Range:		Systolic: 10 to 280 mmH		
		Arterial mean: 20 to 240 mm Hg		
		Diastolic: 10 to 220 mm Hg		
		Pulse: 25 to 300 bpm		
NIBP Accuracy:	The algorithm is based on a human algorithm that meets the requirements of ANSI/AAMI SP10:1992 and 2002 standards for non-invasive blood			
	pressure m	neasurement using the oscillometric		
	method.			
Inflation Pressu	re Setting			
Measurement T	ime:	30 to 50 seconds typical, .120 seconds		
		maximum		
Default Inflation	n Pressure:	165 mmHg-Adult		
		145 mmHg-Pediatric		
		135 mmHg-Neonate		
Calibration:		Factory Calibration		
AUTO Interval T	imes:	2,3,5,10, or 30 minutes, or 1,2 hours		
Alarm Range:		0-300 (in 1mmHg steps), and OFF		
7.8 Respiration	Rate (Resp)			
Range:		0-120 breaths per minute (rpm)		

Accuracy: Resolution: RESP Alarm Range: ±1rpm 1rpm

High: 0-120 rpm and OFF Low: 0-120 rpm and OFF

#### 7.9 Temperature (Temp)

Channels:	Тwo
Range:	25-45°C
Accuracy:	±0.2°C plus the temperature tolerance
Resolution:	0.1° <b>C</b>
TEMP Alarm Range:	

High: 35.5-43.5°C and OFF in 0.1 scale increments Low: 35.5-43.5°C and OFF in 0.1 scale increments

#### 7.10 Default Alarm Limits

Parameters		Alarm Upper Limit Default Value			Alarm Lower Limit Default Value		
(Units)		Matur	Pediat	Neon	Matur	Pedi	Neon
		е	rics	atal	е	atrics	atal
HR(bp	m)	100	110	120	60	70	80
	Sys	140	110	90	95	80	60
(mmH H g) Fo	He	110	110	60	50	50	40
	Fol der	125	125	75	70	70	50
SpO2(%)	)	99	99	99	92	92	92
RR		30	40	50	8	8	8
TEMPC		38.5	38.5	38.5	35.5	35.5	35.5

l(mV)	23	22	20	-23	-22	-20
ll(mV)	20	20	20	-20	-20	-20
III(mV)	20	20	20	-20	-20	-20
aVR(mV)	23	22	20	-23	-22	-20
aVL(mV)	20	20	20	-20	-20	-20
aVF(mV)	20	20	20	-20	-20	-20
V(mV)	20	20	20	-20	-20	-20

#### 7.11 Power Requirements

AC Input: 100 to 240V, 50/60 Hz

# 7.12 Size

300mm (11.81 inch)
180mm (7.09 inch)
129mm (5.08 inch )
2.05kg (4.52 1bs)

#### 7.13 Environment

Temperature:

0 to 50°C (When Operating) -40 to 75°C (Storage) 15 to 95% (When Operating)

Humidity: 10 to 95% (Storage)

#### 7.14 Equipment Classification

Class 1 Protection Type and electric shock)

Internally Powered (Against

Continuous		
Operation Mode	Protection Leve	1
IPX1, Spill Proof	:	
(Against Liquid Ingress)		
Portable		
Mobility	Level Protection Level	Type CF
(Against Electric Shock)		
Safety Requirements		EN60601-1-2002