# Welch Allyn® 1500 Patient Monitor



Service manual



Advancing Frontline Care™

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# Safety

This service manual is intended only for qualified personnel that have been trained by the manufacturer.

# User responsibility

- The numerical and graphical results and any interpretation given must be examined with respect to the overall clinical condition of the patient and the general recorded data quality.
- The indications given by this equipment are not a substitute for regular checking of vital functions.
- This monitor is only to be used by those trained in its operation or repair.
- Ensure that the personnel have read and understood these operating instructions and in particular this "Safety" section.
- Damaged or missing components must be replaced immediately.
- It is the owner's responsibility that the valid regulations for safety and prevention of accidents are observed.

### Intended use

- The Welch Allyn® 1500 Patient Monitor patient monitoring unit is designed for the monitoring of vital parameters such as ECG, SpO<sub>2</sub>, etCO<sub>2</sub>, non invasive blood pressure (NIBP), invasive blood pressure (IBP), temperature and respiration of a patient. Cardiac output and hemodynamic calculations are also possible.
- The device is intended to be used by qualified doctors or trained medical personnel.
- The device is not suitable for transport.
- There is no danger for patients with pacemaker.
- The device is intended for the monitoring of one patient at a time.
- The device is not designed for sterile use nor is it designed for outdoor use.
- Do not use this monitor in areas where there is any danger of explosion or in the presence of flammable gases.
- - The device is classified CF. It is defibrillation protected when the original accessories are used. However, as a safety precaution when possible, remove the electrodes before defibrillation.
- This product is not designed for direct cardiac application.
- The arrhythmia module is not intended for use with neonatal patients.
- The ST-analysis module is not intended for use with neonatal patients.

### Organizational measures

- Before using the monitor, ensure that an introduction regarding the monitor functions and the safety precautions have been provided by a medical product representative.
- Observe the operating instructions and maintenance instructions.
- These operating instructions do not override any statutory or local regulations, or procedures for the prevention of accidents and environmental protection.

# Safety



**WARNING** Mount the monitor securely so that there is no possibility of it falling on the patient or on the floor.



**WARNING** If uncertain about the accuracy of any measurement, first check the patient's vital signs by alternate means, and then make sure the monitor is functioning correctly.



**WARNING** Do not touch the monitor during defibrillation.



**WARNING** To ensure patient safety, none of the ECG electrodes including the neutral electrode, nor the patient or any person with simultaneous patient contact, must come in contact with conductive parts, even when these are grounded.



**WARNING** If you notice any changes that impair safety (including operating behavior) remove the monitor from service and report it to the person responsible for servicing the monitor.



**WARNING** Do not place any liquids on the monitor. If liquid is spilled over the monitor, immediately disconnect the monitor from the mains and dry. The monitor must be serviced before reusing.



**Caution** This manual, and especially these safety notes, must be read and observed.



**Caution** Electrical installation of the room or the building in which the monitor is to be used must comply with regulations specified by the country in which the equipment is to be used



**Caution** Ensure the monitor is always mounted on a Welch Allyn approved bracket or stand. The monitor is unstable when the unit is not secured to an approved Welch Allyn mounting system.

### Safety equipment

Operating the monitor without the correctly rated fuse, or with defective cables, constitutes a danger to patient safety. Therefore:



**Caution** Do not operate the monitor if the ground connection is suspect or if the mains lead is damaged or suspected of being damaged.



**Caution** Damaged cables and connections must immediately be replaced.



Caution Electrical safety devices, such as fuses, must not be modified.



**Caution** Blown fuses must only be replaced with the same type and rating as the original.

### Alarms



**WARNING** Do not silence the audible alarm if patient safety could be compromised.



**WARNING** Always respond immediately to an equipment alert because the patient may not be monitored during certain alarm conditions.



**WARNING** Before each use, verify that the alarm limits are appropriate for the patient being monitored.



**WARNING** Check the audible alarm silence duration before temporarily silencing the audible alarms.

((+))

# Operation with other devices



**Caution** Do not use the monitor in or near an MRI suite.

- Only use accessories and other parts recommended or supplied by Welch Allyn. Use of other than recommended or supplied parts may result in injury, inaccurate information and/or damage to the monitor.
- Accessory equipment connected to the analogue and digital interfaces must be certified according to the respective IEC standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the correct version of the system standard IEC/EN 60601-1-1. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult the technical service department or your local representative.
- Any other equipment used with the patient must use the same common ground as the monitor.
- Precautions must be observed when using high frequency devices. Operating high frequency electro-surgical equipment in the vicinity of the monitor can produce interference in the monitor and cause incorrect measurements. Only use patient cables recommended by Welch Allyn to avoid possible signal interference during ECG acquisition.
- There is no danger when using the ECG monitor simultaneously with electrical stimulation equipment. However, during defibrillation, keep discharge paddles away from the monitor ECG lead wires, electrodes, any other monitor sensors, and other conductive parts in contact with the patient.
- If the patient cable should become defective after defibrillation, a lead-off indication is displayed and an audible alarm is issued.
- Portable communication equipment, HF two-way radios and devices marked with the symbol can affect this monitor (see see "EMC information tables" on page 211).

# Networks and internet

- When the monitor is part of a network, (LAN, HIS, etc.), transmitting over a telephone network or any other transmission /reception medium, or if exposed to the Internet or other networks that are not secure, appropriate security measures must be provided to protect the patient information stored.
- Patient security and security of the network is the sole responsibility of the user.

# Maintenance



**WARNING** Danger of electric shock. Do not open the monitor case. There are no user serviceable parts inside. Servicing may only be performed by a qualified technician authorized by Welch Allyn.



**WARNING** Before cleaning and to isolate the mains power supply, switch the monitor off and disconnect it from the mains by removing the plug.



**Caution** Do not use high temperature sterilization processes (such as autoclaving). Do not use E-beam or gamma radiation sterilization.



**Caution** Do not use solvent or abrasive cleaners on either the monitor or cable assemblies.



**Caution** Do not immerse the monitor or cable assemblies in liquid.

### Symbols

These symbols appear in this manual.

	<b>WARNING</b> Warning statements in this manual identify conditions or practices that could result in personal injury.
4	<b>WARNING</b> Used for electrical dangers, warnings and other notes in regarding operation with electricity.
	<b>Caution</b> Caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property.
ATTENTS ATTENTS Market Mark	<b>Caution</b> Observe precautions for handling electrostatic sensitive monitors.
U	Reference to other guidelines.
7!	Tools / equipment required for the following procedure.

Symbol	Definition	Symbol	Definition
$\bigtriangledown$	Potential equalization ground)	⊣♥⊢	CF symbol. This monitor is classified safe for internal and external use. However, it is only defibrillation protected when used with the original Welch Allyn patient cable!
	The monitor can be recycled.	X	Recycle the monitor and battery separately from other waste. Refer to www.welchallyn.com/weee for collection point and additional information.
<b>(€</b> 0123	Notified body of the CE certification (TÜV P.S.).	$\triangle$	Note accompanying documents.
4000 m max (15.00 ft) (755 hPa) 300 m min (100 ft) (100 hPa)	Altitude limits	80 15	Humidity limits
*	Keep away from sunlight	5	Stacking limit
50°C max (122°F) 0°C min (32°F)	Temperature limits	Ť	Keep away from rain
	This way up	Ţ	Fragile
¢	CO <sub>2</sub> in		CO <sub>2</sub> out
	Temperature		NIBP

The following symbols appear on the monitor, or accessories.

The following symbols appear on the screen.

Symbol	Definition	Symbol	Definition
$\bigotimes$	Alarm off	8 Ĥ	Patient mode symbols; neonate, pediatric, adult
	Acuity connected		Acuity not connected

**Note** Acuity is not available for software versions1.0 or 1.3.

### Additional terms

### Implied authorization

Possession or purchase of this monitor does not convey any express or implied license to use the monitor with replacement parts which would alone, or in combination with this monitor, fall within the scope of one or more patents relating to this monitor.

### Terms of warranty

Your monitor is warranted against defects in material and manufacture for the duration of one year (from date of purchase). Excluded from this guarantee is damage caused by an accident or as a result of improper handling. The warranty entitles free replacement including labor, of the defective part. Any liability for subsequent damage is excluded. The warranty is void if unauthorized or unqualified persons attempt to make repairs.

In case of a defect, send the apparatus to your dealer or an authorized Welch Allyn service center. The manufacturer can only be held responsible for the safety, reliability, and performance of the apparatus if:

- assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by the manufacturer.
- the monitor and approved attached equipment is used in accordance with the manufacturer's instructions.
- **Note** There are no express or implied warranties which extend beyond the warranties hereinabove set forth. Welch Allyn makes no warranty of merchantability or fitness for a particular purpose with respect to the product or parts thereof.
- **Note** This equipment has been tested and found to comply with the limits for a class A digital device, pursuant to both Part 15 of the FCC (Federal Communications Commission) rules and the radio interference regulations of the Canadian Department of Communications. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with this instruction user guide, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

WHEN USED IN CANADA: To prevent radio interference to the licensed service, this device is intended to be operated indoors and away from windows to provide maximum shielding. Equipment (or its transmit antenna) that is installed outdoors is subject to licensing.

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# 2 Introduction

The monitor is designed for adult, pediatric and neonatal use. It has a 15-inch screen for comprehensive vital data monitoring. The monitor can be used with mains power (100 - 240 VAC) or with an internal battery.

## Standard features

- Function buttons and trim knob for easy operation
- 15-inch color screen
- Vital parameters:
  - ECG (3, 5 or 12 lead)
  - Heart rate
  - Respiration
  - Non invasive blood pressure
  - SpO<sub>2</sub> (Masimo<sup>1</sup> or Nellcor)
  - Invasive blood pressure (x2)
  - Temperature (x1)
  - <sup>1</sup> Drug calculations

### Options

- Printer
- Capnography
- <sup>1</sup> etCO<sub>2</sub> and Integrated Pulmonary Index<sup>™</sup> (IPI)
- 12-lead resting ECG with measurements
- 12-lead resting ECG with measurements and interpretation
- Arrhythmia analysis
- ST analysis
- <sup>1</sup> Cardiac output and hemodynamic calculations
- <sup>1</sup> Invasive blood pressure (x4)
- <sup>1</sup> Temperature (x2)
- <sup>2</sup> Acuity connection

**Note** <sup>1</sup> Available for software version 1.3 and later.

 $^{2}$  Not available for software versions 1.0 or 1.3.

# The Welch Allyn® 1500 Patient Monitor

### Front panel



### **Back panel**



\*The nurse call can be used to give an external indication of a parameter alarm.

### **Connection panel**



**Note** The connection panel layout will vary according to the options installed.

# **Function buttons**



#### Print

Printout of three waveforms and all parameters. The waveforms and print settings are defined in the printer menu. Note that an auto printout can also be obtained when a limit is violated. This is also defined in system setup.

#### Alarm silence

Silence / resume an audible alarm, or confirmation of displayed messages. The silence time is defined in the Setup/Administrator menu.

#### NIBP measurement interval

Interval setup for non-invasive blood pressure measurement or switch-off of the interval measurement. Saves patient information.

#### NIBP measurement

Start or stop of the non-invasive blood pressure measurement (.

#### Standby

In standby mode patient monitoring is interrupted and the screen is blank. Monitoring is resumed when any button is pressed.

#### Setup

Display of the Setup menu. The required menu item can be selected by turning the trim knob and pressing (see next page).

#### Trend

Displays trend data .

#### Home

Pressing this button closes opened dialogues and returns to the monitoring screen. Any settings that were changed in the opened dialogue screen are saved. Pressing this button is the same as selecting OK on the opened dialogue screen.

#### **ON/OFF**

Press to switch the monitor on.

- Press and hold for 4 seconds to switch the monitor off. e
  - The LEDs below this button indicate:
  - Left LED mains power is connected to the monitor. .
  - Right LED mains connected to the monitor and internal battery being charged.

#### Trim knob

The trim knob is used for navigation, value selection and value change. Use as follows:

- Turn the trim knob to the left or right to select a field or value. A white frame appears around 1. the field.
- 2. Press the trim knob to open the menu of the selected parameter field or value.
- Turning the trim knob to the left or right to select the desired value. 3.
- 4. Press the trim knob to apply the changed value.



# Setup menu overview

Press 📧 to enter the setup menu and adjust the following settings and options:

**Note** The following is an overview of the setup menu options. Full details are given in the directions for use.

Parameter	Settings/Submenus
Alarm Suspend	Silences all alarms for a set period. The silence time is defined in the Administrator menu (alarms).
Arrhythmia <sup>1</sup>	Arrhythmia limits and alarm levels. Pacer Display and analysis (on/off).
Alarms	Alarm overview. All alarm limits and print on alarm settings.
Speaker Volume	Speaker volume.
HR/PR Tone Volume	Heart beat volume.
Waveform area	Defines the waveforms to be displayed and the size and sweep speed.
Recorder <sup>2</sup>	Defines the data on the printout.
Parameters <sup>3</sup>	Enable/disable any combination of the following: ST measurements, etCO <sub>2</sub> , Masimo SpO2 settings, cardiac output, invasive blood pressure display and temperature display options.
12-lead Resting ECG <sup>4</sup>	View electrode status, and take a resting ECG. After the resting ECG has been taken, the option to obtain a printout is given.
Hemodynamic Calculations <sup>5</sup>	Screen for entry of hemodynamic measurement parameters with automatic hemodynamic calculations based on entered parameters.
Drug Calculations	Screen for entry of drug parameters with dose and titration calculations based on entered parameters.
Patient Information	Enter/edit patient ID and patient information.
Patient Mode	Neonatal: Birth through 28 days. Pediatric: Between 29 days and 12 years. Adult: 13 years and older.
Restore User Defaults	Reset all settings to user defaults (see administrator > system, below).

Parameter	Settings/Submenus
Administrator	Configuration
	Display of monitor ID, network settings, options, etc. This is for information
	only.
	Alarms
	Alarm settings - silence time, suspend time, etc. This requires a password to
	enter.
	System
	Time and date settings and unit preference (cm/in, kg/lb). This screen also gives the option to save the current settings as the user default settings, and the option to display the event log screen. This screen requires a password to enter.
	Communications, Service and Factory
	These menu options are for service and factory personnel and can only be accessed by password only. Details are given in the service handbook.
Close	Exits the setup menu.

1. The full arrhythmia option is only viewable when the full arrhythmia option is installed.

2. The recorder option is only viewable when the printer is installed.

3. The parameter options will vary according to the monitor configuration and licensed options.

4. The 12-lead resting ECG option is only viewable when the resting ECG option is installed.

5. The hemodynamics calculations option is only viewable when the cardiac output option is installed.

## **Display overview**



- Note The waveform display is changed in setup menu.
- **Note** The parameter fields can be changed in the setup menu according to licensed options, parameter selection and patient panel options.

### Information field

Top line

a 	b	c 
B6	: î İ	$\mathbf{X}$
DAVI	D NEA	ΑTΗ
10	:30:4	8

The left box on the top line **(a)** displays the patient's room number (entered in the patient information screen). If the monitor is connected to the Acuity Central Station, the room number is taken from Acuity.

The middle box **(b)** displays the patient mode (Neonatal, Pediatric, or Adult) indicated by the highlighted icon.

The right box (c) indicates the monitor's network connection:

E Connected to Acuity Central Station.

Acuity enabled but no connection.

When the Acuity Central Station option is not enabled, this box remains blank.

**Note** Acuity is not available for software versions 1.0 or 1.3.

#### Middle line

Displays the patient name. If the monitor is connected to Acuity Central Station, the patient name is synchronized with Acuity.

#### Bottom line

Displays the current time. When mains is not connected, a battery symbol is also displayed to the left of the time.



Administrator and service screens

The administrator and service screens provide system information and option settings.

The administrator and service screens are entered from the settings menu:



### Administrator menu

Some sub menus can only be accessed with a password. The passwords are divided into clinical, service and factory passwords. Additionally, a password is needed to enable options. The following table details the passwords needed for the monitor:

Menu option	Password
Setup > Administrator > <b>Configuration</b>	No password (view only)
Setup > Administrator > Communications	53, 51, 54 (Service password)
Setup > Administrator > <b>Alarms</b>	49, 48, 46 (Clinical password)
Setup > Administrator > <b>System</b>	49, 48, 46 (Clinical password)
Setup > Administrator > <b>Service</b>	53, 51, 54 (Service password)
Setup > Administrator > <b>Factory</b>	Menu access is restricted to the manufacturer (Factory Password).

# Administrator settings

Sub menu 1	Parameter	Description
Configuration (no password required)	Serial Number	The serial number of the monitor.
	Ethernet MAC	MAC address
	MAIN	The release and date of the main software. This is the main system software.
	PRESS	Non-invasive blood pressure software
	CF <sup>1</sup>	
	ZAC <sup>1</sup>	
	STAR	Arrhythmia and ST analysis software
	VPB	Main parameter software
	VPBDLL	Main parameter software dll file
	HREM <sup>1</sup>	
	Recorder	Printer software
	SpO <sub>2</sub>	Nellcor software
	NIBP	Non invasive BP software
	C0 <sub>2</sub>	CO <sub>2</sub> module software
Communications <sup>2</sup>	IP Address <sup>3</sup>	
	Subnet <sup>3</sup>	
	Gateway <sup>3</sup>	
	DNS	Domain Name Server
	Use DHCP	Automatically assign RTCP/IP address

Sub menu 1	Parameter	Description		
Alarms	Alarm Silence Time	1 to 2 minutes (1). Time for which an audible alarm is silenced		
	Alarm Suspend Time	1 to 2 minutes ( <b>1</b> ). Time for which all alarms are suspended.		
	Can disable HR/PR alarms	<b>Enabled</b> / Disabled. When this setting is disabled, the Heart rate alarms cannot be disabled.		
	Alarm Delay	<b>On</b> /Off. If the alarm validation is enabled, alarm limits must be exceeded for at least 6 seconds for an alarm to be issued.		
	Second Speaker Time	0 to 3 minutes (2). Time after which a secondary speaker is enabled.		
System	Height units	Inches/centimeters - sets the monitor's measurement units.		
	Weight units	Pounds/Kilograms - sets the monitor's measurement units.		
	Acuity Enabled	Yes/ <b>No</b> . Note that Acuity can only be enabled when Enable Acuity connection in the service setup is set.		
	Set Date and Time	Entry of the year/month/day/hour/minute		
	Save User Defaults	With this function, values changed by the user are saved.		
	Show Event Log	Display of the monitor event log (see "Event log screen" on page 27).		

1. The 'CF", "ZAC", and "HREM" entries are names / acronyms for software components. They are development tools and are posted only to make sure that the correct version of each software component is installed. They cannot be changed and are not used for servicing the monitor.

2. Networking is not available for software versions 1.0 and 1.3.

3. The IP address, Subnet, and Gateway are filled in automatically if DHCP is enabled. If DHCP is not enabled, the values for these fields must be entered manually.

Sub menu 1	Parameter	Description		
Service	Simulated data mode <sup>1</sup>	<b>Off</b> /On. Enabling the simulator.		
	Language	Select <b>English</b> , German, Spanish, Portuguese, French, Italian, Polish		
	Notch Filter (see note below)	<b>50 Hz</b> , 60 Hz, or Off. The notch filter must be set for the country specific mains frequency.		
	Recorder Diagnostics	Activation of a test printout to check the printer.		
	Restore Factory Defaults	Confirm with OK to load the default settings.		
	Start CO2 Calibration	Yes/ <b>No</b>		
	Options: <sup>2, 3</sup>	1. Enable Acuity connection		
		2. Enable full arrhythmia option		
		3. Enable Full arrhythmia option and ST option		
		4. Enable 12-lead resting ECG with measurements		
		5. Enable 12-lead resting ECG with measurements and interpretation		
		6. Enable 2 IBP channels		
		7. Enable 4 IBP channels		
		8. Enable CO and 4 IBP channels		
		9. Enable second temperature		
		10. Enable IPI		
Factory <sup>4</sup>	Serial Number	Enter the serial number into the monitor (shown on the Setup > Administrator > Configuration menu).		
	Show Diagnostic Messages	Yes/ No. This is a development tool.		
	Printer Installed	Yes/ No <sup>1</sup>		
	etCO <sub>2</sub> Installed	Yes/ No <sup>1</sup>		
	SpO <sub>2</sub> hardware	Nellcor / Masimo. <sup>1</sup> Select for the manufacturers module installed.		
	Knob press delay	0 to 2000 ms (300 ms default). A delay in the time between turning the trim knob and pressing (i.e activating the choice), can be programmed. This is to help prevent accidental settings.		
	Re-lock all Options	Yes/ No. This setting disables all options.		

- 1. Restart the monitor after enabling to activate these changes.
- 2. To enable the options in the Setup Service menu, a unique key number must be entered that is generated from a combination of the option and the service ID number of the monitor. The procedure to enable the software options is given later in this section see "Enabling software options" on page 28).
- 3. The options available will depend on the software installed and the hardware configuration of the monitor. Not all options will be available for all configurations.
- 4. The factory settings are usually factory set and need not be accessed in the normal life of the monitor. In particular the serial number should not be changed. If a printer is installed or the SpO2 module changed, the relevant settings can be changed.
- **Note** Notch Filter: The default setting from the factory is 50 Hz. This should be changed if frequency of the mains supply is different.

### Event log screen

The event log screen provides software versions, module status and provides an event log including:

- NIBP status
- Printer status
- Temperature status
- CO2 status
- Hours until CO2 calibration required.
- Module software
- Event log table including switch on time

The event log screen is displayed as follows:

Setup Menu > Administrator > System (password 49, 48, 46) > Event log

The following is typical screen:



**Note** The data in the log event screen are viewed only, and entries in the table cannot be erased.

### **Enabling software options**

**Note** The options available will depend on the software installed and the hardware configuration of the monitor. Not all options will be available for all configurations.

Software options available for the monitor are as follows:

- Acuity
- Full Arrhythmia
- Arrhythmia with ST
- 12-lead Resting ECG with measurements
- 12-lead Resting ECG with measurements and interpretation
- 2 IBP channels
- 4 IBP channels
- Cardiac output and 4 IBP channels
- Second temperature
- Integrated Pulmonary Index (IPI)

Software only options are enabled via a unique license key that is specific for the individual option and individual monitor. Enabling an option requires the following steps:

- 1. Obtain the unique Service ID of the monitor (see "Obtaining the service ID of the monitor" on page 29).
- 2. Provide the Service ID of the monitor and receive the option key.
- 3. Enter the option key at the monitor (see "Enabling an option" on page 31).

### Obtaining the service ID of the monitor

- 1. Power on the monitor by pressing the power button
- 2. Press the trim knob to select **No** when prompted for a new patient.

New Patient	
New Pati	nt?
Yes	No

- 3. Press the setup menu button and the setup menu appears.
- 4. Select the administrator option by using the trim knob to highlight and then press to select.



5. Select the service option from the setup administrator menu by using the trim knob to highlight and then press to select.



- 6. Enter the Service Password by scrolling and selecting each individual Dial with the Trim Knob and inputting the numbers as follows:
  - Dial 1 53
  - Dial 2 51
  - Dial 3 54
- 7. Select OK, the service screen appears:

Simulated Data Mode	On
Language	English
Notch Filter	50 Hz
Recorder Diagnostics	
Restore Factory Defaults	
Start CO2 Calibration	
Check CO Resistors	
- Options	

8. Select Options, the options screen appears:

Setup Options	
1 - Enable Acuity connection	
2 - Enable full arrhythmia option	
3 - Enable full arrhythmia and ST option	
4 - Enable 12-lead resting ECG with measurements	
5 - Enable 12-lead resting ECG with measurements and interpretation	
6 - Enable 2 IBP channels	
7 - Enable 4 IBP channels	
8 - Enable CO and 4 IBP channels	
9 - Enable second temperature	
10 - Enable IPI	
Close Service ID: 414780	

9. The Service ID is located on the lower right corner of the screen. Note the Service ID number. The service ID is used to generate a unique license key for the option on the specific monitor.

### Enabling an option

1. From the service screen (see previous instructions), scroll and highlight the option you wish to enable. The example below shows option 3 being highlighted.

Setup Options	
1 - Enable Acuity connection	
2 - Enable full arrhythmia option	
3 - Enable full arrhythmia and ST option	
4 - Enable 12-lead resting ECG with measurements	
5 - Enable 12-lead resting ECG with measurements and interpretation	
6 - Enable 2 IBP channels	
7 - Enable 4 IBP channels	
8 - Enable CO and 4 IBP channels	
9 - Enable second temperature	
10 - Enable IPI	
Close Service ID: 414780	

2. With the option highlighted press the trim knob to proceed. The Enter Key screen appears.

Enter Key				
Key	_			
	1	2	3	
	4	5	6	
	7	8	9	
	0			
	Clear			
	Backspace			
	ок		Cancel	

3. Input the key obtained from Welch Allyn using the Trim Knob to highlight and select each digit one at a time. The number appears in the key box as entered:





- 4. Double check the key and then use the trim knob to highlight OK and press to select.
- 5. The monitor will confirm when the option is activated by clearing the administrator menu and displaying **Feature enabled** in the message area at the bottom of the screen.



Repeat as required to enable other options.

# 4 Software

# Introduction

### Version check

The software is checked in the Setup menu:



#### Setup > Administrator > Configuration

The software versions are displayed (along with the serial number of the monitor).

The MAIN software is the main monitor software and the VPB software is the parameter software.

### Software that can be updated

Main software

The main software is updated directly via the USB connector on the back of the monitor.

#### Printer software

The printer software is updated directly via the USB connector on the back of the monitor.

#### Parameter software

The parameter software is downloaded via a PC connected to the SVC connector on the side panel. A service tool is needed to update the parameter software via the SVC connector on the side panel. A USB drive with parameter update software is also required to set the monitor to service mode when updating the parameter software.



## Downloading and unpacking the software

The latest software is downloaded from the extranet as follows.

#### http://extranet.schiller.ch

Proceed as follows:

1. Open the extranet site and select Welch Allyn.


2. Select WA 1500 PM.

	medilog	▶ Software	• User Manuals	→ Se
	Monitoring Units			
	Defibrillation Units			
	MRI Monitoring Units			
	Schiller America	11.03.2011	🖹 WA 1500 F	PM - R
	Welch Allyn	11.03.2011	🖹 WA 1500 F	PM - R
	CP300	11.03.2011	🖹 WA 1500 F	PM - R
►	← WA 1500 PM	11.03.2011	🖹 WA 1500 F	PM - S'
	Esaote	11.03.2011	🖹 WA 1500 F	PM - W
	Diagnostik Deutschland	11.03.2011	🖹 WA 1500 F	PM - W
	From Brocksbland	02 02 2011	Euco boy fr	vr maiı

3. Select Software:

Isoftware	• User Manuals	Service Manuals
1		
WA 1500 PM	I	

- 4. Select and download the files:
- **Note** The format, location and titles of the folders on the extranet site is liable to change at any time. If the file cannot be found please contact the SCHILLER monitoring support center for the latest versions.
  - WA 1500PM Main SW 1.x.xxx.zip
  - WA 1500PM NIBP firmware 1.xx.zip
  - WA1500PM PB 9.x.xx.xx.zip
  - WA1500 Parameter UPDATE mode.zip
  - WA 1500 PM printer UPDATE.zip
  - Service tool 2.xx.xx.zip
- 5. After the download, unpack the software and place the main, printer, and parameter update softwares on USB drives (see following).
- **Note** 1. The UPDATE mode software puts the monitor in service mode during parameter update and NIBP test.
  - 2. The Service tool software is for NIBP software update, PB software update and NIBP test.

	Main software 💌
Manufacturer_declaration_SW_update.pdf	(PDF, 120.4 kB)
WA1500PM Main SW 1.0.1.zip	(ZIP, 1.9 MB)
	NIBP firmware 💌
WA1500DM NIBD firmware 1 20 zin (7)	P 19.3 (P)
	1, 10.5 KD)
	PB software 💌
The WA1500PM PB 9.3.00.39.zip (ZIP, 102.5	5 kB)
<b>WA1500PM PB 9.3.00.40.zip</b> (ZIP, 102.5	5 kB)
Parar	meter update mode 🗷
WA1500PM Parameter update mode.zip	(ZIP, 36,1 kB)
<b>_</b>	()
Da	oordor ooftware
ĸe	corder software
WA1500PM Recorder 15.zip (ZIP, 107.3) (ZIP, 107.3)	9 kB)
	Release notes 💌
Release note PB 9.3.00.39.pdf	(PDF, 34.5 kB)
Release note PB 9.3.00.40.pdf	(PDF, 34.5 kB)
Release note WA1500PM Main SW 1.0.1.pdf	(PDF, 34.6 kB)
SW Matrix 04_03_2011.pdf	(PDF, 74.5 kB)
	Service tool 💌
ServiceTool 2 47 03 zin (7/P 51 9 kP)	

#### Unpacking the software

The MAIN software and the printer software must be included on the root directory of a USB drive for correct installation. The parameter UPDATE software must also be placed on the root directory of a USB drive (this is required when updating the parameter software to put the monitor in service mode).

For older versions of archiving software it is possible that the files are not unzipped in the original directories. The file structure on the USB must look as shown below:

#### WA 1500 PM Main UPDATE

^	Name 🔺	Größe	Тур	Geändert am	
	🚞 Startup		Dateiordner	05.11.2010 11:06	
	🔊 ceETM.dll	183 KB	Programmbibliothek	05.10.2010 17:22	
	🔊 ceETMDiag.dll	432 KB	Programmbibliothek	05.10.2010 17:22	
	🔊 cehremlib.dll	617 KB	Programmbibliothek	05.10.2010 17:22	
	船 Flacon.exe	3'818 KB	Anwendung	26.10.2010 16:03	
	STARce.dll	466 KB	Programmbibliothek	05.10.2010 17:22	
	S VPBDLLce.dll	215 KB	Programmbibliothek	05.10.2010 17:22	
	🔊 ZACce.dll	547 KB	Programmbibliothek	05.10.2010 17:22	
~					

When unpacked the root of the USB must be as follows:

#### WA 1500 PM printer UPDATE

When unpacked the root of the USB must be as follows:

🔼 Name 🔺	Größe Typ	Geändert am
🗧 🧰 Startup	Dateiordner	05.11.2010 11:06
🚽 🖻 apop_V9.2.0.15.s	287 KB S-Datei	10.09.2010 10:12
	286 KB 🛛 😔 La	okales Intranet

#### WA 1500 PM Parameter UPDATE

When unpacked the root of the USB must be as follows:

📩 Name 🔺	Größe Typ	Geändert am	
🗮 🚞 Startup	Dateiordner	05.11.2010 11:06	
~			
	0 Byte 🛛 😒 Loka	iles Intranet	

#### Startup Folder

The startup folder content for each of the three software folders (main, printer and parameter), must look as follows:

🔺 Name 🔺	Größe	Тур	Geändert am	
FileLoader.exe	63 KB	Anwendung	04.11.2010 17:00	
FileLoader.inf	1 KB	Setup-Informationen	07.06.2010 13:16	
~				

Note The difference for each startup folder is the .inf file

# MAIN software update

• USB drive with unpacked software (see previous page)

Proceed as follows:

- 1. Open the USB cover and insert the USB drive with the software.
- 2. Start the monitor and the software installs itself. The screen displays the progress of the installation.
- 3. On completion, power off the monitor and remove the USB drive.



## Printer software update

## 11

• USB drive with unpacked software (see previous page)

Proceed as follows:

- 1. Open the USB cover and insert the USB drive with the software.
- 2. Start the monitor and the software installs itself. The screen displays the progress of the installation.
- 3. On completion, power off the monitor, remove the USB drive, and close the USB cover.

# Removing and replacing SVC and other connector blanking covers

- Cover blanking plate removal tools, Part No. 4.410287 (set of two)
  - Self-adhesive blanking covers (smaller), Part No. 717552
    - Self-adhesive blanking covers (larger), Part No. 717511
    - Lime based oil spray for removing uncured glue residue and other rough impurities like oil and grease; solvent-free, pH neutral, 3M 50098 (bought locally).

A self-adhesive blanking cover is attached to the service connector (SVC) and must be removed to update the software (see "Parameter software update" on page 43) and to test the NIBP (see "NIBP test" on page 127).

Depending on your monitor configuration, blanking covers may also be placed over some patient parameter connectors (see below).

**Note** Older versions of the side panel have fixed plastic connector covers that are not removable. The side panel must be replaced to enable these patient connectors.

To facilitate removal of the covers two special removal tools (one large, one small) are available as a set (Part No. 4.410287).



The removal tool (large), is used for the following connectors:

• IBP3

11

• IBP4

Removal tool (small), is used for the following connectors:

- SVC
- CO
- T2

#### Cover removal



**Caution** The burr end of the tool is sharp. Take care when handling.

The procedure is the same for the both sizes of cover. Proceed as follows:

- 1. Select the correct removal size for the blanking cover to be removed (the SVC blanking cover requires the smaller tool).
- 2. Firmly press the cover removal tool onto the blanking cover until the end burrs engage with the cover.
- 3. Twist the tool (either direction) to break the cover adhesive seal and disengage the cover from the casing. Remove and discard the cover.



4. If necessary, clean the connector recess by spraying a cloth with adhesive removal spray (3M 50098 or similar approved solution) and use the cloth to remove any adhesive and clean the recess.



**Caution** Use 3M 50098 cleaning spray or similar approved cleaning solution. Use of non-approved cleaners may damage the monitor.



**Caution** Observe all warnings and cautions on the cleaning solvent container.







#### **Cover replacement**

Two sizes of self adhesive blanking covers are available:

- Part No. 717511 larger size for IBP connectors.
- Part No. 717552 smaller size for SVC connector, Temp (T2) and cardiac output (CO).

Note Blanking covers must be placed over all inactive connectors.



To replace a self adhesive blanking cover, proceed as follows:

- 1. Ensure that the recess is clean with no old adhesive or oil-based cleaner still present. Clean with an alcohol solution if necessary.
- 2. Select the correct size of blanking cover and peel the cover away from the strip.
- 3. Position the cover centrally on the connector recess and secure it by applying finger pressure.



# Parameter software update

- USB drive with unpacked parameter update mode software (see previous instructions).
  - USB service adaptor USB / SVC cable assembly (Part No. 2.320020).
  - PC / laptop with unzipped software (Parameter software and Service tool).
  - SVC cover removal tool (Part No. 4.410287).
- Note The above are also needed when carrying out the NIBP checks.

#### Procedure

- 1. Remove the cover from the SVC connector (see "Cover removal" on page 41).
- 2. Connect the adapter cable between the SVC connector on the side panel and the PC.



- 3. Open the USB cover and insert the USB drive with the software.
- 4. Start the monitor: The monitor goes into service mode and the following is displayed:

Parameter Processor Service Mode is active



5. From the PC, open the Service Tool. The following window appears:

Download	Set up COM	l-port			
	Select Comm	Port			
Cuff Press	O COM1	C COM5			
	O COM2	O COM6			
.eak Rate	О сомз	O COM7			
Defletion	COM4	О сома			
Set COM-port	SW VV Tes Enable SW	st V V+V Test E C T ! ! !			
Set COM-port	SW VV Tes Enable SW D I S C O N N E	st V V +V Test E C T I I I			
Set COM-port	SW VV Tes Enable SW D I S C O N N E PB1000 switch on	st V V+V Test E C T I I I Enter transparent switch on	APLC switch on	Exit	

- 6. Select the correct Com Port **(a)**. The com settings are defined in the system settings of your PC. The com port of the USB Service Adapter depends on your system configuration and can change on every PC.
- 7. Turn on the communication to the monitor by pressing the button **PB-1000 switch on** button **(b)**.
  - Three information lines are displayed when the monitor is connected as follows:



- These values are:
- Boot software version
- Serial number of the monitor
- Parameter box firmware version

- 8. Select the software you want to download:
  - Press the **Download** button (c),
  - Press the **Search** button **(d)** and look for the file for download (this may be on the USB drive or PC).

	11 10 10	" ServiceTool ARGUS Mo	nitoring SCHILLER AG Ver. 2.43	
с —		Download	Download software into connected device	
d		Cuff Brass	Search Filename:	
		Leak Rate	Size: Checksum:	
е		Set CDM-port	try to connect with : 57600 baud	
			PB1000 Enter LCM APLC switch on transparent switch on	<u> </u>

- 9. Press the **Download** button (e). The bar indicates the progress.
- 10. After completion, power off the monitor, remove the USB drive, close the USB cover, remove the cable assembly and position a new blanking cover over the SVC connector (see "Cover replacement" on page 42).
- **Note** The service tool is also used for testing the NIBP parameters. If the NIBP tests are to be carried out after the parameter software has been updated, leave the PC connected to the monitor.

46 Software

# 5 Networking (Acuity central station)

- **Note** Acuity connectivity is a licensable feature. To order this feature contact your Welch Allyn sales representative (see page ii). The network settings are defined by the system administrator.
- **Note** Networking is not available for software versions 1.0 and 1.3.

# Safety

 $\triangle$ 

**WARNING** Connect the monitor to an Acuity system only. Connecting to other networks could damage the monitor or injure the patient. If in doubt about the network jacks or devices, consult your facility's Administrator Engineering Department.



**Caution** Make sure the Acuity network cable is not damaged. The Acuity network cable is the sole link between the monitor and the Acuity Central Station



**Caution** When the monitor is not connected to the network there are no patient alarms or alerts at the Acuity Central Station.



**Caution** If you don't set alarm limits, the Acuity system uses preset settings (for arrhythmia test limits), and the power up default settings for the monitor.



**Caution** Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g., EN 60950 for data processing equipment and EN 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Anyone connecting additional equipment to the signal input or output connectors is configuring a medical system, and is therefore responsible that the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, consult your Administrator Engineering Department.

# Introduction

The Acuity Central Station provides central patient monitoring for monitoring devices connected to the network. The monitor communicates through a hard-wired Acuity connection.

While connected to the network, the monitor sends data to Acuity. This data is continuously forwarded to provide appropriate alarm or alert messages at the central station and other network devices such as a hallway message panel. Acuity also stores the patient information for viewing or report printing.

If the monitor loses communication with Acuity, it continues to monitor the patient and display patient information. While not communicating with Acuity, the monitor continues to generate local patient alarms or alert messages. When connection is restored it automatically reconnects to Acuity and uploads trend information.

# Connect to the Acuity central station

The ethernet connector (RJ45) is positioned on the back of the monitor.





**Caution** Ensure that only a Welch Allyn approved RJ45 cable assembly is used. Use of any other cable assembly may damage the monitor.

## Working with Acuity

Please consult the Acuity directions for use for full operating instructions.

#### Enabling the Acuity connection

- **Note** Acuity can only be enabled when the option is licensed. If the Acuity option is not licensed, this menu item is not available.
- 1. Press the Setup button 🔳.
- Select Administrator > System (password required 49, 48, 46) and set Acuity Enabled (yes).

Setup Systen	n	
Height uni		in
Weight un	its	b
Acuity Ena	abled	Yes
Set Date a	ind Time	
Save User	Defaults	
Show Ever	nt Log	
OK	Cancel	

#### Notes

When the monitor is connected to Acuity, it acts as described in this manual except for the following:

- Alarm limits can be changed at the monitor or at Acuity. When confirmed, the alarm limits are synchronized for both the monitor and Acuity.
- The patient information can be changed at the monitor or at Acuity. When confirmed, the patient information is synchronized for both the monitor and Acuity. When Acuity is enabled but not connected, the patient information menu option is not available.
- The room number is set at Acuity and cannot be changed at the monitor (menu option greyed).
- The arrhythmia menu is not available.
- The etCO<sub>2</sub> unit configuration in the etCO<sub>2</sub> setup menu is not available.
- The monitor sends a 12-lead resting ECG automatically to Acuity when taken.

## Monitor settings

Press the setup menu key

and select Administrator > Communications.

Enter the service password 53, 51, 54

(also see "Administrator and service screens" on page 23).

Setup Communio	ation	S			
		100 100 10 100			
IP Address		192.108.40.100			
Subnet		265.266.255.0			
Gateway					
DNS		64.69.100.68			
Use DHCP		Yes	DHCF	Values:	
				MAC Address	00.00.00.00.00
ок	Cano	cel		DHCP Enabled	0
				IP Address	000.000.000.000
				Subnet	000.000.000.000
				Gateway	000.000.000.000
				DNS	000.000.000.000
				DHCP Server	000.000.000.000
				Lease Obtained	
				Lease Expires	

#### Dynamic host configuration protocol (DHCP)

DHCP is an automatic configuration protocol that allows the monitor to be configured automatically eliminating the need for intervention from the network administrator. It also provides a central database for keeping track of monitors that have been connected to the network. This prevents two units from being configured with the same IP address accidentally.

To set the IP address, Subnet, and Gateway automatically, set the DHCP setting to Yes.

#### Defining the settings manually

If DHCP is not enabled (use DHCP > No), the values for the IP address, Subnet, and Gateway and Domain name server (DNS) must be entered manually. These values must be obtained from the system administrator.

# 6 Module removal and replacement

# Safety



**WARNING** Before carrying out any module replacement procedures, disconnect the monitor from the mains and remove the mains plug.



**WARNING** Switch off the monitor before disassembly and remove the battery in order to ensure that the monitor does not start up accidentally.



**Caution** Follow the procedures for the prevention of accidents and environmental protection according your facility's guidelines.



**Caution** No liquid must enter into the monitor. If that does happen, the monitor may not be used before thorough drying and undergoing a full functional check.



**Caution** Take care not to place any strain on the connecting cables when separating the housing. Ensure that the cable assemblies are not crimped or twisted when the front and rear sections are separated. Take when removing and replacing connectors. Never use force. Never strain the cable assemblies.



**Caution** Observe precautions for handling electrostatic sensitive monitors when opening the monitor. The monitor contains static sensitive CMOS components; observe antistatic precautions:

- When carrying out any maintenance procedures always place the monitor on a grounded antistatic mat.
- Personnel must be grounded when handling any boards or components
- Always use an antistatic bag when transporting boards or components



**Caution** Screw recesses in the casing do not have metal inserts and care must be taken not to overtighten the screws or to cross-thread the screws when replacing. Danger of stripping the thread if a screw is overtightened or cross threaded. Use a torque screwdriver to ensure screws are not overtightened.



**Caution** Danger of abrasion damage. To prevent scratching, always place the monitor on a soft, non-abrasive cloth when carrying out maintenance procedures.



Caution Before re-assembly a full visual inspection must be carried out.



**Caution** After re-assembly the functional and safety tests must be carried out according to the checklist at the end of this manual (see "Yearly test and test after repair" on page 111).

## Tools and equipment

The standard tools required to carry out the removal and replacement procedures are as follows:

11	٠	Set of Phillips torque screw drivers. Size PH1 is suitable for most screw
II		fixtures in the monitor. Printer will require PH0

- Small flat-bladed screwdriver
- Flat nose pliers
- 5/16<sup>th</sup> nut driver
- Extra tools required for side panel components:
  - small soldering iron
  - torque wrench

# Part numbers of replaceable modules

Parts and accessories are detailed at the end of this manual (see "Parts and accessories" on page 187). The drawings sections also details the part numbers of replaceable modules and items (see "Schematics" on page 191).

## **Torque settings**

Screw, connector	Tool size	Torque setting Nm [Ft - Ibs]	
Battery cover	Screwdriver size PH1	0.30 Nm [2.65 in - lbs] (± 10%)	
Main casing	Screwdriver size PH1	1.0 Nm [8.85 in - lbs] (± 10%)	
All print and internal screws (including the side panel)	Screwdriver size PH1 or PH0	0.6 Nm [5.31 in - Ibs] (± 10%)	
NIBP connector (on the side panel)	Wrench No.11	0.5 Nm [4.42 in - lbs] (± 10%)	
CO <sub>2</sub> connector (on the side panel)	Wrench No.8	0.8 Nm [7.08 in - Ibs] (± 10%)	

Torque settings are given on the following table:

**Note** When replacing screws, it is recommended that the screw is first lightly turned counter-clockwise until it 'drops' slightly. This means that the screw is aligned with the thread correctly and helps minimize the danger of cross threading.

**Note** When removing screws, it is recommended that magnetic screwdrivers are used.

## Battery

Note Two types of battery are available for the monitor as follows:

- Lead-acid battery (12V, 2600 mAh),
- Li-Ion battery (10.8V, 7200 mAh)

The lead-acid battery is connected to the monitor with two wires; the Li-lon battery connect directly with the monitor via a battery connector in the battery recess.

- 1. Disconnect the monitor from the mains.
- 2. Unscrew the five phillips screws from the battery cover.



3. Remove the cover. Take the battery out (disconnect the power wires if a lead-acid battery is installed).

## Replacing the battery

#### Li-lon battery

The Li-Ion battery connects directly to battery contacts in the battery recess.

1. Before replacing the battery, ensure that the two connection wires (for lead acid batteries) are secured to the base of the battery recess with non-conduction tape.





Caution Ensure the contacts of the lead wires cannot short circuit.



- 3. Replace the battery cover with the 5 Phillips screws: torque setting 0.30 Nm (± 10%).
- 4. Charge the battery for 6.5 hours.

#### Lead acid battery

1. Connect the new battery to the power leads (ensure correct polarity) and mount the battery in position. Be careful not to crimp the power leads.



- 2. Replace the battery cover with the 5 Phillips screws: torque setting 0.30 Nm (± 10%).
- 3. Charge the battery for 3.5 hours.

#### Battery disposal



**WARNING** Explosion warning. The battery must not be burned or disposed of in domestic trash.

**WARNING** Flammability and chemical danger. Do not open the battery.



**WARNING** Protect the contacts from shorting when disposing of the battery. Apply non-conducting tape to the contacts.



This battery and monitor must be disposed of in a municipally approved collection point or recycling center when no longer used.

If no such collection point or recycling center is available, you can return the monitor and battery to your distributor or the manufacturer for proper disposal.

Refer to www.welchallyn.com/weee for collection points and additional information.

# Replacing the fuses



**WARNING** Blown fuses must only be replaced with the fuse types indicated in the below table.

### Fuse types

Voltage range	Number	Fuse type	WA Part No.	Manufacturer Part No.
100-240 VAC	2	M 1.6A E 250V	4.210004	Schurter Inc, FSM 0034.2518
M= Medium time E= Enhanced bre	lag aking capacity			

## Changing the fuse

- 1. Disconnect the monitor from the mains.
- 2. Release the fuse holder by gently squeezing the side retaining clips and remove the fuse holder.



- 3. Replace both fuses (see above).
- 4. Re-insert the fuse holder until the two side clips snap in place.

# Opening the monitor

- 1. Disconnect the monitor from the mains and remove the mains plug.
- 2. Position the monitor face down on a non-abrasive anti-static mat. Take care to protect the trim knob encoder.
- 3. Remove the battery (see previous section)
- 4. Unscrew the nine housing screws and remove the screws. Note that one of the screws is covered by the calibration label. Break the label with the screwdriver to gain access to the screw beneath.
- **Note** If a magnetic screwdriver has not been used, it may not be easy to remove the screws and it can be necessary to return the monitor face up to let the screws fall out. Be careful not to lose the screws.
- 5. Firmly secure the two parts of the casings together and turn the monitor face up.



- 6. Gently part the two sections of the monitor to gain access to the cable assemblies.
- **Note** Dependent on how the two sections are opened, the keyboard cable or LCD cable may not be long enough to allow the two assemblies to be opened fully. That means the connectors may have to be disconnected, and the holding tape removed, before the two sections are can be fully separated.
- 7. Disconnect the following cables:



- 8. Remove the tape securing the cable assemblies to the back of the LCD.
- 9. The two housings can now be separated.

# Closing the monitor

#### Procedure

- 1. Check that the side panel is in the right position and all cables are connected.
- 2. Position the two housing assemblies so that access can be gained to the LCD and connectors.
- 3. Connect the backlight and LCD cables.
- 4. Position the LCD connecting cable and the LCD backlight cable and secure to the back of the LCD with tape (see previous page).
- 5. Position the LCD connecting cable on the Z-bitsy board EMC shield so that the cable is positioned so that the wires go through the padding on the ECG shield and secure to the shield with tape as shown. Take care that no wires are positioned over the padding.
- 6. Before securing the two sections together, carry out a visual check detailed on the following page.
- 7. Gently lower the top section closer so that the keypad interface cable connector can be secured.
- 8. Ensure that the two sections fit correctly and secure the two parts of the housing together with the nine Phillips screws: **torque setting 1.0 Nm (± 10%).**

#### Checks before re-assembly

#### Visual Inspection

**Note** A full visual inspection must be performed after replacing a component and at every stage of monitor reassembly. A final overall check must be carried out before the monitor is screwed back together.

Check the following:

- All printed circuit boards are securely screwed in position.
- All plugs and sockets are connected and properly aligned and secured.
- All cable assemblies between the individual boards are not crushed or lying on, or close to, a sharp object (e.g. protective shields). Cable assemblies are secured with non-conducting tape.
- Isolation foils and shields are inserted and correctly positioned.
- Check that no loose parts are inside the monitor by tipping the monitor, or turning it upside down.
- Check that all loose cable assemblies are secured with tape (see previous page).

#### **Functional Test**

**Note** Once the visual check has been completed, the monitor can be closed and tested (see "Yearly test and test after repair" on page 111).

# Printer

- **Note** This section gives the procedure to replace a printer. If a monitor (without a printer) is to be upgraded to have a printer, contact Welch Allyn.
- 1. Open the monitor as described previously (see "Opening the monitor" on page 58).
- 2. Remove the printer bay filler panel. Retain the four screws.



- 3. Remove the paper tray from the printer module.
- 4. Position the printer. The printer snaps behind the paper chain guides when correctly positioned.

- 5. Take the four screws from the printer cover and fix the printer module: **torque setting 0.6 Nm (± 10%).**
- 6. Connect the printer cable.



7. Close the monitor (see "Closing the monitor" on page 60) and carry out functional check (see "Yearly test and test after repair" on page 111).

# LCD display and connection cable

- 1. Open the monitor as described (see "Opening the monitor" on page 58).
- 2. Disconnect and dismount the LCD and backlight cable from the display.



3. Unscrew the six Phillips screws and dismount the display. Loosen the screws from the two display retainer rails and mount them on the new display.



- 4. Replace the LCD display and secure with the six screws: torque setting 0.6 Nm (± 10%).
- 5. Connect and fix the cables as shown.
- 6. Close the monitor (see "Closing the monitor" on page 60) and carry out functional check (see "Yearly test and test after repair" on page 111).

# Interface ZM1-4, speaker, trim knob and keypad foil

- 1. Open the monitor as described (see "Opening the monitor" on page 58).
- 2. Unscrew the four Phillips screws and remove the Interface ZM1-4 board.



- 3. Disconnect the trim knob cable and the keyboard cable from the Interface board.
- 4. Disconnect the speaker and replace the interface board.

### Speaker

- 1. Position the speaker ensuring the speaker is central in the housing recess.
- 2. Connect the speaker cable to the Interface board and be sure that the speaker is pinched between the interface board and the front housing.

#### Trim knob encoder

- 1. Pull the blue knob away from the encoder.
- 2. The trim knob encoder is fixed with a serrated lock washer and a screw nut.
- 3. Loosen the screw nut and replace the trim knob encoder.



### Keyboard foil

To change the keyboard foil there is no need to remove the trim knob encoder.

- 1. Pull the trim knob away from the trim knob encoder.
- 2. Using a small flat-bladed screwdriver, pry the old foil away from the monitor. Ensure that the protective film is also detached.
- 3. Remove the cover from the adhesive backing and carefully place the new foil on the monitor. When reassembling the keyboard foil ensure that it is positioned properly so that the trim knob encoder connects when pushed.
- 4. Close the monitor (see "Closing the monitor" on page 60) and carry out functional check (see "Yearly test and test after repair" on page 111).

# Side panel

- 1. Open the monitor as described (see "Opening the monitor" on page 58).
- 2. Disconnect the cables indicated below.



3. With a pair of pliers, remove the circlip holding the CO<sub>2</sub> plug in the side panel and remove the plug.



4. Pull off the black  $CO_2$  exhaust tube.



- 5. Unscrew the NIBP tube. The side panel can now be removed.
- 6. Reassemble in the reverse order. Check all connections for good contact.
- 7. Close the monitor (see "Closing the monitor" on page 60) and carry out functional check (see "Yearly test and test after repair" on page 111).

# Side panel components

#### **IBP** connectors

- Position the board and secure with seven, 25 x 8 screws, torque setting 0.6 Nm (± 10%).
- **Note** Do not place a screw in the second screw thread of the upper connector (IBP1) because when a screw is inserted, this may chaff the ribbon cable and cause short circuits.



- 2. Solder the 10 pins to the board.
- **Note** The monitor can have two IBP connectors or four connectors. The pictures above show a side panel with two. When the side panel has four connectors the procedure is similar.

#### **NIBP** Connector

1. Position the NIBP connector and secure with washer and torque wrench: **torque setting 5 Nm (± 10%).** 


## SpO<sub>2</sub> Connector

1. Position and secure with two, 25 x 8 screws, torque setting 0.6 Nm (± 10%).



**Note** The monitor can have a Nellcor or Masimo module installed. The connectors for the two are different. The pictures above show a side panel with a Nellcor connector. When the side panel has a Masimo connector the procedure is similar.

#### ECG Connector

1. Position and secure with four, 25 x 8 screws, torque setting 0.6 Nm (± 10%).



### SVC service connector

- 1. Place a small amount of blue loctite on the thread and position the connector with the red dot towards the top
- 2. Secure the connector with a torque wrench: torque setting 5 Nm (± 10%).



## $\mathrm{CO}_2$ connector and cover spring (only with the $\mathrm{CO}_2$ option)

1. Position the connector and washer and secure with the hexagon nut and tighten with the torque wrench: torque setting 0.8 Nm (± 10%) (see "SVC service connector" on page 72).



- Note The gas input connector and exhaust connection are attached from the  $\rm CO_2$  module.
- **Note** If the temperature connector module is already installed (see "Temperture and cardiac output" on page 74), it is necessary to remove it to gain access to the spring securing post.
- 2. Position the rubber washer over the spring securing post.





- 3. Position the spring as shown.
- Note The gas input connector and exhaust connection are attached from the  $CO_2$  module see "Side panel" on page 67).

#### Temperature and cardiac output

- **Note** The temperature module comes with two temperature inputs and the cardiac output connector. If the monitor is does not have the T2 option or the CO option, blanking covers must be placed over the connectors on the outside of the side panel (see "Removing and replacing SVC and other connector blanking covers" on page 40).
- 1. Secure with three, 25 x 8 screws, torque setting 0.6 Nm (± 10%).



- 2. Secure the CO connector (see "SVC service connector" on page 72).
- 3. Using standard electrical double-sided tape, secure the cable assembly to the side panel.



# Removing and replacing EMC shields

Remove EMC shields by straightening the securing lugs with the flat pliers.



**Caution** Take care not to dislodge any surface mount components when twisting the lugs.



## **Replacing EMC shields**

Position the shield lugs through the slots and twist the lugs approximately 30° to secure.



**Caution** Take care not to over twist the lugs that could result in breakage.

# Main board ZM2-1

**Note** The layout of the main board ZM2-1 will vary slightly for different series productions. If a Masimo SpO2 module is installed, the series index of the board (Indicated after the ZM2-1 designation), must be G or later.



## Removing the main board ZM2-1

- 1. Open the monitor as described (see "Opening the monitor" on page 58).
- 2. Disconnect the printer cable and the potential equalization (ground) cable.
- 3. Remove the foil on the right side.
- 4. Unscrew the 17 screws from the main board.



- 5. Carefully lift up the main board.
- 6. Disconnect the battery, and the two power cables (if the battery has not already been removed).
- 7. Remove the main board.

## Replacing and Installing a new main board

- 1. Remove the two blanking pieces from the new board.

2. Carefully disconnect the hose and gently turn the NIBP pump.



3. Install the following EMC shield.



4. Return pump in position and reconnect the hose.





5. Install all other EMC shields ((see "Removing and replacing EMC shields" on page 75).

6. Attach the insulation sheet as shown. Make sure that the end is folded over as shown.



7. If the Z-bitzy board is not located on the main board, secure as detailed in this section (see "Z-bitsy board" on page 86.)



8. Install the board and connect the cables in reverse order of disassembly.

9. Position the board and make the connections as shown.



Make sure that the securing pad is in position

- 10. Secure the board with the 17 screws.
- 11. Using standard workshop electrical tape, tape the loose leads to the board



# **NIBP** module

- 1. Open the monitor as described (see "Opening the monitor" on page 58).
- 2. Remove the NIBP cables and tubes and loosen the two screws from the pump assembly.



3. Remove the entire NIBP system.

#### Replacement

- 1. Connect the tubes and the cables as in the picture and secure the pump with two screws.
- 2. Secure the long tube on the EMC shield.
- 3. Mount the tube nut over the tube, push the tube over the micro connector and secure with the tube nut.

# SpO<sub>2</sub> module

- 1. Remove the SpO<sub>2</sub> EMC shield.
- 2. Remove the two screws (four screws when a Masimo module is installed) of the  $SpO_2$  module and unplug it.



**Caution** The  $SpO_2$  module connects with the main board via two connectors. When removing or replacing a  $SpO_2$  module, remove and replace the module as straight as possible in order to prevent any damage to the connectors. Different connectors are used for the Nellcor module and for the Masimo module.

**Note** If the SpO<sub>2</sub> module is changed from the original module manufacturer (Nellcor / Masimo), it must be enabled after reassembly. This can only be performed at an authorized Welch Allyn service provider (see "Converting the SpO<sub>2</sub> module" on page 91).



# CO<sub>2</sub> module

The  $CO_2$  module is mounted on spacers and secured to the main board with four screws. To remove the module proceed as follows

- 1. Before removing the module, make sure that the two gas connectors are removed from the side panel (see "Side panel components" on page 69)
- 2. Unplug the connector to the main board; this can be removed from either the CO2 module or the main board) (a).
- 3. Remove the four screws of the  $CO_2$  module and unplug it **(b)**. Note some of the four securing screws are hidden from view:



**Note** It may be necessary to remove the NIBP hose **(c)** to gain access to the bottom screw.

#### Replacement

- 1. Position the module on the spacers and secure it to the main board with the four screws.
- 2. Using the short connecting cable assembly connect the module to the main board.
- 3. Connect the gas exhaust and connector to the side panel (see "Side panel components" on page 69).

# ECG amplifier

The ECG amplifier is an integral part of the main board and cannot be changed independently.

**Note** After replacing any modules, close the monitor (see "Closing the monitor" on page 60) and carry out functional check (see "Yearly test and test after repair" on page 111).

# Z-bitsy board

The Z-Bitsy board is a single board CPU.

1. From the underside of the main board remove the three EMC shields **(a, b, c)** shown below. Note that the NIBP hose may need to be released (see "Replacing and Installing a new main board" on page 77).



2. Remove the EMC shield and separate the Z-Bitsy board from the main board. Take care when removing not to damage any components or connector pins.



## Replacement

1. Make sure that the SpO<sub>2</sub> isolation foil is in position and not covering the connector pin holes.



Do not cover connector pins

2. Make sure that the SD-Card is in place and correctly seated; plug in and secure the new board.



- 3. Position the 3mm rubber heat sink pad on the underside of the shield and the 5mm rubber heat sink pad on the upper side of the shield as shown. Make sure that the rubber heat sink pads are firmly in place.
- 4. Reinstall the Z-bitsy shield.



- 5. Replace the three EMC shields on the opposite side of the main board.
- 6. Close the monitor (see "Closing the monitor" on page 60) and carry out functional check (see "Yearly test and test after repair" on page 111).

# Power supply

- 1. Open the monitor as described (see "Opening the monitor" on page 58) and remove the main board (see "Main board ZM2-1" on page 76).
- 2. Detach the isolation foil and disconnect the two power wires from the mains plug.



3. Loosen the four screws and remove the power supply.

#### Replacement

- 1. Position the power supply and secure with the four screws.
- 2. Connect the two cables from the mains plug. The blue wire is on the outer side of the board.
- 3. Replace the shield and reassemble.
- 4. Close the monitor (see "Closing the monitor" on page 60) and carry out the functional check (see "Yearly test and test after repair" on page 111).

# Checks before and after monitor re-assembly

## **Visual Check**

The monitor must be given a visual check before the monitor is screwed back together. This is detailed in the Closing the Monitor (see "Closing the monitor" on page 60).

## **Functional Test**

Once the visual check has been completed, the monitor can be closed and the functional tests carried out according to the procedures detailed in the yearly test and test after repair section (see "Yearly test and test after repair" on page 111).

## Completion

On completion of the tests the protocol and checklist must be filled in (see "Test protocol and checklists" on page 167), and the yearly check and calibration label marked and positioned on the back panel (see "On completion of the tests" on page 166).

# Converting the SpO<sub>2</sub> module

The monitor comes with either a Nellcor  $\text{SpO}_2$  measurement module or a Masimo  $\text{SpO}_2$  module as original equipment.

This section provides the procedures necessary to convert the SpO2 module from Nellcor to Masimo, or from Masimo to Nellcor.

# Safety



**WARNING** Read and observe all safety warnings and cautions detailed at the beginning of the removal and replacement section (see "Safety" on page 51).



**WARNING** Before carrying out any module replacement procedures, disconnect the monitor from the mains and remove the mains plug.



**WARNING** Switch off the monitor before disassembly and remove the battery in order to ensure that the monitor does not start up accidentally.

# **General notes**



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**Caution** Take care not to overtighten when replacing screws in the casing. There is a danger of stripping the thread if a screw is overtightened or cross threaded. Use a torque screwdriver to ensure screws are not overtightened. Torque settings are detailed in the removal and replacement section (see "Torque settings" on page 52).

# **Tools Required**

 The standard tools required to carry out the exchange procedure are detailed in the removal and replacement section(see "Tools and equipment" on page 52).

- Flat-bladed tweezers, flat-bladed knife or similar (for adhesive label removal)
- Lime based oil spray for removing uncured glue residue and other rough impurities like oil and grease; solvent-free, pH neutral, 3M 50098 (bought locally).

# Converting from Nellcor to Masimo

**Note** This procedure can only be performed by an authorized Welch Allyn service provider.

## Requirements

To convert a Nellcor equipped module to a Masimo equipped module the following is required:

- The main board ZM2-1 (part number 3.2810) must have an index of G or later.
  - For index G and later, the main board comes with connectors and mounting locations for both Nellcor and Masimo modules).



- **Note** For monitors with main boards index A to F, the main board must be changed if a Masimo module is to be installed.
- A new side panel must be installed.
  - The two manufacturers use different patient sensor connectors and different side panel connector moulding. When the SpO<sub>2</sub> module is changed, the side panel must be changed to accommodate the different SpO<sub>2</sub> connector.

#### Main board and software

Equipment	Requirement
Main Board ZM2-1	Part number 3.2810, Index G or later.
Software:	The monitor software must be software release 1.3 or later.

#### Side panels

Side panel wit	Side panel with Nellcor module conne		Change to sid connector	e panel with Masimo module	
Side panel number	Parameters	Printer	Side panel number	Parameters	Printer
3.930444	2T/4IBP/CO		3.930448	2T/4IBP/CO	
3.930444	2T/4IBP/CO	х	3.930448	2T/4IBP/CO	х
3.930443	2T/4IBP/C0-C02		3.930447	2T/4IBP/CO-CO2	
3.930443	2T/4IBP/C0-C02	х	3.930447	2T/4IBP/CO-CO2	х

**Note** Blanking covers must be positioned on the parameters that are not used see "Removing and replacing SVC and other connector blanking covers" on page 40). Make a note of connectors that had blanking covers on the removed side panel and position blanking covers on the replaced side panel (if not already there).

#### Masimo module

Equipment	Part number
Masimo MX-3 module	104352
Bolt spacers (x4)	4.430353
Screws M3x12 (x4)	4.910008
Masimo Sticker	4.120539
Masimo module fixing kit containing the bolt spacers, screws and Masimo sticker (detailed above).	2.100794
Sensors:	
Masimo SpO <sub>2</sub> cable, LNC-10	713657
Masimo LNCS-DC1 reusable sensor	706831

## Procedure

- 1. Open the unit as detailed in the removal and replacement section (see "Opening the monitor" on page 58).
- 2. Remove the main board (see "Main board ZM2-1" on page 76).



3. On the main board, remove the EMC shield from the SpO<sub>2</sub> module (see "Removing and replacing EMC shields" on page 75).





4. Remove the two screws securing the Nellcor  $SpO_2$  board and remove the board.





 $\begin{array}{c} \fbox{} \hline \label{eq:calibration} \hline \end{tabular} \textbf{Caution} & \end{tabular} \end{tabular} \end{tabular} \textbf{SpO}_2 \mbox{ module connects with the main board via two connectors.} \\ \hline \end{tabular} \end{tabular} \end{tabular} \textbf{SpO}_2 \mbox{ module, remove it as straight as possible in order to prevent any damage to the connectors. Different connectors are used for the Nellcor module and for the Masimo module.} \end{array}$ 



Nellcor module connectors

Masimo module connectors



5. Position the four spacers and secure the Masimo board with four screws.



**Caution** The  $\text{SpO}_2$  module connects with the Z2-1 main board via two connectors. When replacing the module position it as straight as possible in order to prevent any damage to the connectors.



6. Position the EMC shield and secure to the board (see "Removing and replacing EMC shields" on page 75).





- 7. Replace the main board (see "Replacing and Installing a new main board" on page 77).
- 8. Remove the side panel and replace with a side panel with a Masimo connector (see "Side panel" on page 67.



9. Make all connections as detailed in the removal and replacement instructions.



10. Main boards with index G and later have connectors for both Nellcor and Masimo side panels. Connect the cable assembly from the side panel to the Masimo module.

11. Before closing the monitor carry out the visual checks:



- b. Once the visual check has been completed, the monitor can be closed and the hardware enabled (see following steps).
- 12. Switch the monitor on and define the  $SpO_2$  module as Masimo in the factory settings:
  - a. Enter the factory setup: Press 🖪 Setup Menu > Administrator > Factory
  - b. The following screen is displayed:
- **Note** A factory password is required to enter the factory settings.



c. Set the SpO<sub>2</sub> hardware to Masimo.

13. Remove the Nellcor logo on the side of the monitor with flat-bladed tweezers, flatbladed knife or similar tool, carefully pry the Nellcor label off the side panel recess.



**Caution** Take care not to scratch or damage the monitor casing.



14. Clean the label recess by spraying a cloth with adhesive removal spray (3M 50098 or approved equivalent) and use the cloth to remove any adhesive and clean the recess.



**Caution** Use 3M 50098 cleaning spray or similar approved cleaning solution. Use of non-approved cleaners may damage the monitor.



Caution Observe all warnings and cautions on the cleaning solvent container.





- 15. Attach the Masimo logo sticker:
  - a. Clean the recess and local area with an alcohol solution to remove any trace of the cleaning solvent.
  - b. Peel the cover away from the Masimo logo and position the label centrally on the recess and secure it by applying finger pressure.



16. Check the REF patent label on the back of the monitor.



17. If the label does not contain the Masimo patent information (as shown above), remove the label and clean the area as described previously. Position a new label (Art. no. 4.120541) on the monitor (see "Safety, patent and information labels" on page 116).

Functional check

After the Masimo hardware has been enabled perform the functional test according to the procedures detailed in the test and test after repair section (see "Yearly test and test after repair" on page 111).

#### Completion

On completion of the tests, the protocol and checklist must be completed (see "Test protocol and checklists" on page 167), and the yearly check and calibration label marked and positioned on the back panel (see "On completion of the tests" on page 166).

# Converting from Masimo to Nellcor

This procedure can only be performed by an authorized Welch Allyn service Note provider.

## Requirements

To change a Masimo module to a Nellcor module the following is required:

Main board and software

Equipment	Requirement
Main Board ZM2-1	Part number 3.2810 - The Nellcor module can be installed on any index series of the ZM2-1 main board
Software:	The Nellcor module will work with any software release.

#### Side panels

Side panel wit	ide panel with Masimo module connector		Change to side panel with Nellcor module connector		
Side panel number	Parameters	Printer	Side panel number	Parameters	Printer
3.930448	2T/4IBP/CO		3.930444	2T/4IBP/CO	
3.930448	2T/4IBP/CO	х	3.930444	2T/4IBP/CO	Х
3.930447	2T/4IBP/C0-C02		3.930443	2T/4IBP/CO-CO2	
3.930447	2T/4IBP/C0-C02	х	3.930443	2T/4IBP/C0-C02	Х

Blanking covers must be positioned on the parameters that are not used see Note "Removing and replacing SVC and other connector blanking covers" on page 40). Make a note of connectors that had blanking covers on the removed side panel and position blanking covers on the replaced side panel (if not already there).

#### Nellcor module

Equipment	Part number
Nellcor module	712891
Bolt spacers (x2)	4.430347
Screws M3x12 (x2)	4.910008
Nellcor Sticker	4.120538
Nellcor module fixing kit containing the bolt spacers, screws and Nellcor sticker (detailed above).	2.100793
Sensors:	
DS-100A DURASENSOR, reusable sensor	008-0054-01
Nellcor SpO <sub>2</sub> cable, DOC-10	103490

## Procedure

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- 1. Open the unit as detailed in the removal and replacement section see "Opening the monitor" on page 58 and sequence).
- 2. Remove the main board (see "Main board ZM2-1" on page 76).



3. On the main board, remove the EMC shield from the SpO<sub>2</sub> module (see "Removing and replacing EMC shields" on page 75).





4. Remove the four screws securing the Masimo  $SpO_2$  board and remove the board.





**Caution** The SpO2 module connects with the Z2-1 main board via two connectors. When removing the SpO2 module, remove it as straight as possible in order to prevent any damage to the connectors. Different connectors are used for the Nellcor module and for the Masimo module.



Nellcor module connectors

- 5. Position the two spacers and secure the Nellcor board with two screws
- **Note** The Nellcor board is smaller than the Masimo board and the spacers must be placed on the corner screw boss and the inner screw boss on the opposite side.





**Caution** The SpO2 module connects with the main board via two connectors. When replacing the module position it as straight as possible in order to prevent any damage to the connectors.



6. Position the EMC shield and secure (see "Removing and replacing EMC shields" on page 75).





- 7. Replace the Main board (see "Replacing and Installing a new main board" on page 77).
- 8. Remove the side panel and replace with a side panel with a Nellcor connector. Make all connections to the side panel (see "Side panel" on page 67).
- 9. Connect the cable assembly from the side panel to the Nellcor module.



Connector for Nellcor Connector for Masimo (side panel) (side panel)

**Note** Main boards with index G and later provide connectors for both Nellcor and Masimo modules. Main boards with index F and earlier, only have a Nellcor connector.

a.

- 10. Before closing the monitor carry out the visual checks:
  - a. The monitor must be given a visual check before the monitor is screwed back together. This is detailed in Section 6 (see "Closing the monitor" on page 60).
  - b. Once the visual check has been completed, the monitor can be closed and the hardware enabled (see following steps).
- 11. Switch the monitor on and define the SpO2 module as Nellcor in the factory settings:
  - Enter the factory setup: Press the 🔃 Setup Menu > Administrator > Factory
  - b. The following screen is displayed:
- **Note** A factory password is required to enter the factory settings.

Serial Number	PFD1010
Show Diagnostic Messages	No
Recorder Installed	Yes
ETCO2 Installed	Yes
SpO2 Hardware	Masimo
Knob press delay (ms)	300
Re-lock All Options	
OK Cancel	

c. Set the SpO<sub>2</sub> hardware to Nellcor.
12. Remove the Masimo logo on the side of the monitor with flat-bladed tweezers, flatbladed knife or similar tool, carefully pry the Masimo label off the side panel recess.



**Caution** Take care not to scratch or damage the monitor casing.



13. Clean the label recess by spraying a cloth with adhesive removal spray (3M 50098 or approved cleaning solution) and use the cloth to remove any adhesive and clean the recess.



**Caution** Use 3M 50098 cleaning spray or similar approved cleaning solution. Use of non-approved cleaners may damage the monitor.



Caution Observe all warnings and cautions on the cleaning solvent container.





- 14. Attach the Nellcor logo sticker:
  - a. Clean recess and local area with an alcohol solution to remove any trace of the cleaning solution).
  - b. Peel the cover away from the Nellcor logo and position the label centrally on the recess and secure it by applying finger pressure.



### Functional check

After the Nellcor hardware has been enabled perform the functional test according to the procedures detailed in the yearly test and test after repair section (see "Yearly test and test after repair" on page 111).

### Completion

On completion of the tests the protocol and checklist must be completed (see "Test protocol and checklists" on page 167), and the yearly check and calibration label marked and positioned on the back panel (see "On completion of the tests" on page 166).

# General cleaning instructions



WARNING Do not autoclave the monitor or any accessories.



**WARNING** Do not immerse the monitor in liquid when cleaning. Do not immerse accessories in liquid when cleaning unless the accessory manufacturer's cleaning instructions explicitly instruct you to do so.



**WARNING** Fire and electrical shock hazard. Always unplug the monitor from the electrical power outlet before inspecting or cleaning the monitor and accessories. Exposing any of these to liquids, such as cleaning solutions, while they are connected to electrical power could result in electrical shock or fire.

Before cleaning the monitor or any accessories, thoroughly inspect them.

- Look for any signs of damage and any improper mechanical function of buttons or connectors.
- Gently bend and flex cables, inspecting them for damage or extreme wear, exposed wires, or bent connectors.
- Confirm that all connectors engage securely.
- Immediately report any sign of damage or malfunction to your service department.

To clean the monitor or any accessories, follow these steps:

- 1. Wipe the equipment with a cloth slightly moistened (not wet) with one of the approved cleaning solutions listed (see "Cleaning instructions and cleaning solutions" on page 110).
- 2. Clean cable assemblies by gently wiping from the center of the cable. Do not allow the sheathing to be displaced.
- 3. Thoroughly wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, latches, or crevices. If liquid gets into connectors, dry the area with warm air, and then check the equipment to confirm that it operates properly.



**Caution** Use only a cleaning solution recommended by Welch Allyn for this equipment. Use of any other cleaning solutions which have a high acid content or are otherwise inappropriate can cause damage to the equipment, including cracking and deterioration of the plastic case.



**Caution** Always follow the mixing/diluting instructions provided by the manufacturer of the cleaning solution.



**Caution** Never use any of the following solutions or similar products to clean the equipment: ethyl alcohol, ethanol, acetone, hexane, abrasive or scouring powder or material, any cleaning material that damages plastic.

# **Cleaning instructions and cleaning solutions**

Equipment	Cleaning instructions	Approved cleaning solutions
Monitor <sup>1</sup>	Wipe with a nearly dry cloth moistened with cleaning solution. Thoroughly wipe off any excess cleaning solution. Do not let cleaning solution run into connector openings or crevices. <sup>2</sup>	70 % solution isopropyl alcohol; neutral mild detergent solution; all products designed for cleaning plastic.
ECG cable, extension cable	Consult manufacturer's instructions.	Mild detergent solution; also consult manufacturer's instructions.
SpO <sub>2</sub> cable, extension cable	Consult manufacturer's instructions.	Consult manufacturer's instructions.
Other accessories	Consult manufacturer's instructions.	Consult manufacturer's instructions.

 The equipment can be disinfected to comply with OSHA requirements for cleaning and decontaminating spills of blood and other body fluids. (Federal OSHA blood borne pathogens standard: 29 CFR 1910.1030, 12/6/91.)

2. If liquid gets into the connectors, dry the area with warm air and then verify all monitoring functions.

# Cleaning the thermal print head

A residue of ink (from the grid on the paper) can build up on the print head over a period of time. This can cause the print quality to deteriorate. It is recommended that the print head is cleaned during the yearly test.

Extend the paper tray and remove paper. The thermal print head is found under the paper tray. With a lint-free cleaning cloth dampened in alcohol, gently rub the print-head to remove the ink residue. If the print head is badly soiled, the color of the paper grid ink (i.e. red or green) will show on the tissue.

# Yearly test and test after repair



**Caution** Defective monitors must be removed from service and repaired or replaced immediately.

# Introduction

This section describes the visual, functional, safety, and measurement checks that should be carried out yearly, after monitor repair, and at any time the unit has been opened. Any of these checks can also be performed at any time as required.

This guideline is intended for qualified service personnel who have been trained by Welch Allyn.

# **General requirements**

The test procedure is performed in accordance with directive IEC/EN 62353. The tests are as follows:

- Tests before putting into service. A comprehensive test performed by the manufacturer before dispatch.
- At the recommended service interval detailed below and defined as 'recurrent test'.
- After repair.
- At any time after the monitor has been opened or modified.

# Service interval

The monitor must be serviced at regular intervals. The test results must be documented and compared with the values documented. The recurrent test checklist is provided at the end of this manual. The interval is as follows:

Interval	Maintenance	Responsible
Every 12 months	Recurrent test and test after repair according to IEC/EN 62353.	Service staff authorized by Welch Allyn
As required	CO <sub>2</sub> Calibration <sup>1</sup> Replacement of the CO <sub>2</sub> pump and infra red source <sup>2</sup>	Service staff authorized by Welch Allyn

 The need for calibration is based upon physical component changes that occur during use. The module requires its first calibration after 1200 operating hours or one calendar year, whichever comes sooner, and then after each 4000 operating hours or once a year, whichever comes sooner. The message calibration due appears when the hourly limit is reached. It is advisable to calibrate in the one-year maintenance program especially if the monitor is used for intermittent, short term use typical of patient monitors.

2. The CO<sub>2</sub> pump and the IR source must be replaced every 20,000 operating hours. The operating hours of the CO<sub>2</sub> module is given on the event screen (see "CO<sub>2</sub> calibration" on page 154).

# Recurrent test and tests after repair overview

- 1. Visual inspection
- 2. Test of:
  - Protective ground conductor
  - Leakage current
  - Isolation resistance
- 3. Functional test
- 4. Test protocol dated and signed.

We recommend that the tests are carried out in the order described.

The monitor must not be opened during the tests.

# Leakage and potential equalization ground measurement

## Test equipment

**Note** The safety testing of the monitor and the safety limits are carried out according to IEC/EN 62353 (See also table IEC62353 / 5.3.3 e). The equipment used is subject to the instructions according to ISO 9000 in regards to test equipment control.

## Tests that must be carried out

The following tests must be carried out:

- Potential equalization / ground
- Leakage current of the monitor
- Leakage current patient
- Insulation resistance This test need only be carried out if there is any doubt about the insulation of the equipment, e.g. if residual current monitor or ground fault circuit interrupt has tripped several times, or if saline has been spilled over the equipment and therefore creepage distances are in doubt.

Specify and document the equipment and measuring setup details in the test protocol according IEC 62353 and 60601-1.

## **Test Criteria**

The monitor must meet the safety limits specified in IEC/EN 62353.

## Documentation

Note the results or have them printed by the tester. Always include one copy of the results with the test report. The original remains with the monitor and is provided to the customer to file.

# Software

The software version check and the procedure to update the software is detailed earlier (see "Software" on page 33).

Check the Software version per the software matrix and update if required. Record in the checklist at the end of this section.

## Test Criteria

Check the installed and current software versions for the following :

- Main Software
- Parameter Software
- Printer Software
- NIBP firmware

# **Visual inspection**

## Fuses



**WARNING** Disconnect the monitor from the mains before removing the fuses.



**WARNING** Fuses must only be replaced with the fuse types indicated in the below table.

### **Fuse Types**

Voltage range	Number	Fuse type	WA Part No.	Manufacturer Part No.
100-240 VAC	2	M 1.6A E 250V	4.210004	Schurter Inc, FSM 0034.2518
M= Medium time E= Enhanced bre	e lag eaking capacity			

**Note** The fuse type is also written on a label on the back of the unit (see next page).

1. Release and remove the fuse holder as detailed in the replacing fuse section (see "Replacing the fuses" on page 57).



2. Re-insert the fuse holder until the two side clips snap in place.

### Test Criteria

• Both fuses are rated type M, 1.6, E, 250.

## Safety, patent and information labels



### Test Criteria

- Manufacturer label with serial number, CE reference and safety label (1) intact and readable.
- REF label with patent information (2) intact and readable.
- **Note** On some monitors the REF label may look slightly different from that shown. If the label is readable, it need only be changed if the SpO<sub>2</sub> module has been exchanged (see "Converting from Nellcor to Masimo" on page 92).
- **Note** If no label is present, position a new label (Art. no. 4.120541) on the monitor.
- Manufacturer type label with monitor type, address, fuse rating, and power requirements (3) intact and readable.
- SpO2 module manufacturer label (4) intact and readable.
- **Note** Two SpO2 modules are available with the monitor Nellcor or Masimo, make sure that the correct label is attached for the module installed in the monitor.
- **Note** A calibration / next yearly check label must also be placed on the back of the monitor after the yearly checks have been carried out. (see "On completion of the tests" on page 166).

# Physical condition of the monitor

Check the monitor for signs of damage.

Test Criteria

- No cracks or chips in the casing.
- Mains, patient and all other cable assemblies are in good condition with no crushing, chafing or cuts, etc.
- All plugs and sockets are straight and in good condition.
- No soiling which could hamper the safety of the monitor.

# **Functional tests**

**Note** Comprehensive instructions for operating the monitor are provided in the monitor directions for use.

## Power indicator and battery check

### Mains LED

- 1. Connect mains to the monitor.
  - Check that when mains is connected the mains LED is illuminated.



## Battery charge

- 1. Leave the monitor connected to the mains supply for 4.5 hours to fully charge the battery.
- 2. Disconnect the mains supply and allow the monitor to run for an extended period.
  - Check that the battery symbol displays an indication of the capacity as the battery is depleted.



- Full = between 87.5% and 100% capacity.
- 3/4 full = between 62.5% and 87.5% capacity.
- Half full = between 37.5% and 62.5% capacity.
- 1/4 full = between 12.5% and 37.5% capacity
- Empty = between 0% and 12.5% capacity.

3. Check that when the battery capacity is close to depletion the following happens:



- the battery symbol flashes
- an audible alarm occurs
- the visual alarm indicator flashes blue



- 4. Reconnect the mains supply.
  - Check that when mains is reconnected, the mains LED is illuminated and the battery symbol disappears.
- 5. Leave the unit connected to the mains supply for 30 to 60 minutes and then remove the mains supply.
  - Check that when the mains supply is again removed, the battery symbol is displayed. Check that it indicates a battery capacity of 1/4 full or greater, i.e. not empty.



- Full capacity OK
- 3/4 full OK
- Half full OK
- 1/4 full OK
- Empty not OK

### Troubleshooting

If any test fails, possible reasons are as follows:

- Battery needs replacing
- Incorrect battery installed
- Power board needs replacing
- Power monitoring fault replace main board
- Power monitoring fault replace z-bitsy board

• the alarm message Battery low appears

## Speaker and piezo check

This check verifies that the speaker and piezo are functioning.

Procedure

- 1. Power on the monitor.
- 2. Wait a few seconds for the monitor to switch on and for the monitor to be ready.

### Test Criteria

- Immediate single high pitch piezo beep when the on button is pressed.
- After a few seconds the device is ready two tone speaker beep is heard, followed by two shorter, higher pitched piezo beeps.

### Troubleshooting

If any test fails, possible reasons are as follows:

- Speaker/cable speaker assembly, speaker cable assembly
- Speaker Z-bitsy board
- Piezo main board

## Keypad check

Examine the keypad for mechanical wear and check buttons for function.

### Test Criteria

- No excessive mechanical damage or wear.
- All buttons function correctly.

### Troubleshooting

If any test fails, possible reasons are as follows:

- Keypad
- Inter-print board
- Keyboard monitoring fault replace main board
- Keyboard monitoring fault replace z-bitsy board

## LCD screen test

### Procedure

- 1. Power on the monitor.
- 2. During the boot sequence when the splash screen is displayed, visually inspect the screen for spots, or black fields.
- 3. Check that the LCD shade (contrast and brilliance) is even and consistent.
- **Note** The boot sequence provides the best opportunity to see missing pixels. The LCD can also be examined when switched on during normal operation.
- **Note** If any spots, darkened areas, unevenness, etc., are apparent, the LCD must be replaced (a few faulty pixels is normal).

## Test Criteria

- No spots or black fields.
- LCD shade (contrast and brilliance) is even and consistent.

## Troubleshooting

If any test fails, possible reasons are as follows:

- LCD
- Back light replace LCD
- LCD cable
- Back light cable
- Z-bitsy board

## **Printer Checks**

**Note** The printer checks only need to be performed if a printer is installed in the monitor.

Print quality and alignment check

Enter the Service screen (password **53**, **51**, **54** - see "Administrator and service screens" on page 23):



Setup > Administrator > Service > Recorder diagnostics

The text printout gives the time, software version and the current print head temperature.

Check that the printhead temperature is ambient (+20°C dependent on printer use before the test has been carried out).

**Note** The printhead temperature will depend on printer use immediately before the test printout. The more the printer has been used, the higher the temperature.

Check that the parallel lines on the printout are not stepped.

Examine the printout for:

- fading
- alignment
- faulty pixels
- blackness, regularity and good readability on the complete print width.

## Troubleshooting

If any test fails or if individual pixels are missing, the printout fades or is darker in one area then the problem is usually with the thermal print head. If the print quality is not good:

- clean the print head with alcohol (see "Cleaning the thermal print head" on page 110).
- check that new good quality paper is installed in the unit.
- examine the printer for signs of mechanical damage.
- replace the printer.

**Note** It is recommended that the printhead is cleaned during the yearly check.

# Measurement checks

All measurements must be recorded in the test protocol measurement checklist (see "Measurement checklist" on page 172).

## Test equipment

- Some or all of the following measurement equipment will be required to carry out the measurement checks:
- **Note** This list gives the recommended test equipment to carry out the measurement checks detailed on the following pages. Certified equivalent test equipment can be used if desired.

Description	Part Number
5% $\rm CO_2$ Calibration Gas canister with an Oridion $\rm CO_2$ sensor fitting <sup>1</sup>	Scott Medical T46530RFCD
IBP cables / transducer (optional) see the Welch Allyn 1500 patient monitor directions for use for part numbers	
Calibrated test ECG patient simulator with ECG reference waveform defined in EN 60601-2-51, CAL 20160 (e.g. Müller and Senastiani MS410 ECG simulator). (For units with resting ECG only).	Approved standard (obtain directly from the manufacturer)
Manometer, Braun Delta Cal, or equivalent	Approved standard (obtain directly from the manufacturer)
NIBP test volume repair fixture, including: 500ml pressure test cylinder (cuff simulator) Manual hand pump with valve Three way valve assembly Hose	407672
Nellcor SpO <sub>2</sub> Cable, DOC-10	103490
Nellcor SRC-MAX SpO <sub>2</sub> Tester (or equivalent)	Obtain directly from the manufacturer
Masimo SpO <sub>2</sub> Cable	713657
Masimo Rainbow SET tester (Masimo part #2368) - Masimo ${\rm SpO}_2$ Tester (or equivalent)	Obtain directly from the manufacturer
PC with Argus pro service tool installed	(see "Downloading and unpacking the software" on page 34)
SVC,1500PM, ODU Connector tool size 0 (Socket wrench for CO2 connector)	4.950155
Standard RJ45 Ethernet cable (or Standard RJ45 crossover cable (if network connection not available)	Approved standard cable
SVC, 1500PM Nurse Call Tester	2.320012 (or multimeter)
SVC, 1500PM Sticker cover removal tool set	4.410287
SVC, 1500PM, IBP test cable (for use with multi parameter tester, 2.310011)	2.310293
SVC, 1500PM, multi parameter tester for IBP, temperature and cardiac output	2.320011
SVC, 1500PM, USB service adaptor cable (SVC -PC)	2.320020

SVC, 1500PM, connector tool, size 0	4.435253
SVC, 1500PM,Temperature/ cardiac output test cable (for use with multi parameter tester, 2.310011)	4.520694
SVC, 1500PM,Temperature test cable (for use with multi parameter tester, 2.310011)	4.520678
Test ECG patient simulator with respiration (e.g. Fluke MPS450 or HKP ARSI-2).	Approved standard (obtain directly from the manufacturer)
USB drive with unpacked parameter update mode software	(see "Downloading and unpacking the software" on page 34)

1. For testing the  $etCO_2 a 5 \%$  or  $10\% CO_2$  concentration gas bottle can be used. For  $etCO_2$  calibration a 5% CO<sub>2</sub> gas concentration gas bottle must be used.

**Note** Test equipment is subject to the instructions according to ISO 9000 in regards to Test Equipment Control. Measurement equipment and must have a valid calibration certificate.

It is responsibility of the person carrying out these tests to ensure that all test equipment has a valid calibration certificate and is functioning correctly.

## **Environmental conditions**

- Temperature:10 °C to 40 °C (50 °F to 104 °F)
- Relative humidity: 30 to 80%
- Pressure: 700 to 1060 hPa

# NIBP test

## NIBP test setup

Setup as follows:



# Argus pro service tool (for NIBP tests)

The service tool facilitates the download of parameter firmware and enables NIBP checks and tests to be carried out.

Each function contains its own property page. Select a function by pressing the relevant button.

Au R	ServiceTool ARGUS Mo	nitoring SCHILLER AG Ver. 2.47.03	
	Download	Download software into connected device	
	Cuff Press	Search	Info line
	Leak Rate Deflation Set COM-port	Size:         Checksum:           Loadadr:         No blocks:           Download         Progres:	Brief description of the selected property page. —— Client area Contains all control
	NIBP Software	D I S C O N N E C T !!!       PB1000       Enter       switch gn       transparent       switch gn         Exit	elements of the selected property page.
(	Control buttons	l Info window	
C t t	Control buttons to perform he tests and settings for he tests.	Contains information about the process or state of the different settings.	

## Connection and opening the service tool



Details of tools and equipment is detailed at the beginning of this section (see "Test equipment" on page 125).

### Procedure

- 1. Remove the cover from the SVC connector (see "Removing and replacing SVC and other connector blanking covers" on page 40).
- 2. Connect the adapter cable between the SVC connector on the side panel and the PC.
- 3. Open the USB cover and insert the USB drive with the software.
- 4. Switch on the monitor. The monitor goes into service mode and the following is displayed:

#### Parameter Processor Service Mode is active



5. From the PC, open the service tool. The following window appears:

OWNIDGU	out up comport
	Select Comm Port
uff Press	О сом1 О сом5
	O COM2 O COM6
ak Rate	O COM3 O COM7
Tables	● COM4 ○ COM8
BP Software	DISCONNECTIII
	PB1000 Enter. LCM APLC Exit switch on transparent switch on switch on

6. Select the correct Com Port (a). The com settings are in the system settings of the PC, and depends on the system configuration. The unavailable ports cannot be selected.

- 7. Turn on the communication to the monitor by clicking the **PB-1000 switch on (b).** button.
- 8. Switch to the transparent mode. Click the **Enter transparent** button.

	PB-1000 switch off	Enter transparent	LCM switch <u>o</u> n	APLC switch on	<u>E</u> xit
--	-----------------------	----------------------	--------------------------	-------------------	--------------

In the transparent mode the following tests can be carried out:

- Over pressure
- Leak rate
- Deflation
- **Note** Click the **Enter transparent** button as soon as communication with the monitor is established and the button is active.
- **Note** The transparent mode is automatically cancelled by the monitor after 3 minutes. When in transparent mode, the annotation on the transparent button changes to **Leave transparent**. This can be pressed at any time; any test that is running will stop before the transparent mode is exited.

# Service tool troubleshooting and general notes

## Connection

The service tool can communicate at different speeds with the host determined by a hand-shake process. This hand-shake procedure may be repeated at the end of a test resulting in minor delays during connection. This is normal and can be ignored.

## Command time out

It is possible that the confirmation of a command sent by the service tool exceeds its time out and the test will be aborted. If this happens, restart the test.

## Test does not start

If any NIBP test does not start, check that the monitor is in transparent mode.

## Transparent mode

The monitor leaves the transparent mode automatically after three minutes. When this happens no information is transmitted to the service tool. It is possible therefore, that the service tool thinks it is in transparent mode when the monitor is disconnected. When this happens, press the **Leave Transparent** and then the **Enter Transparent** button again.

## Over pressure

Two safety valves are incorporated in the NIBP system: a software activated over pressure valve to release the pressure at 310 mmHg and a hardware over pressure valve that releases the pressure at 320 mmHg. During this test the software overpressure does not need to be tested and is disabled so that the hardware overpressure value can be checked.

To reset NIBP module, click **Leave transparent** mode and then enter the transparent mode again.

Download	Cuff Pressure Test	
 Cuff Press	Peak Tin Cuff mmHg	ner [s] start
Leak Rate	max Cuff mmHg	60
100 C	mmHa	
Deflation		
Deflation Set COM-port	Close Valve	
Deflation Set COM-port NIBP Software	Close Valve	
Deflation Set COM-port NIBP Software	Close Valve	

**Note** The software must be in transparent mode for the following steps.

- 1. Connect a hand pump and a 500ml pressure cylinder to the NIBP Luer lock of the monitor.
- 2. Click the Cuff Press (1) button.
- 3. Click the Close valve (2) button.
- 4. Using the hand pump, increase the pressure quickly to 300 mmHg.
- 5. Increase the pressure slowly. Observe the pressure until the overpressure valve opens. The opening of the over pressure valve is indicated by the strong sound of the relieved air with accompanying fast deflation rate.
- **Note** If the pressure does not increase with the hand pump after clicking the **Close valve (2)** button it indicates that the valve may not have closed properly (because the communication from the service tool has not registered). If this happens leave transparent mode, re-enter transparent mode and start the test again.

### Test criteria

• At 320 ± 10mmHg the valve opens and the pressure decreases to 0 mmHg.

## Measurement accuracy and leak rate

This test is used to measure the leak rate of the NIBP valve. There are different pressures that can be set; this test uses the 200 mmHg pressure setting. The test is automatic and the internal NIBP module pumps until the initial pressure is reached. The state **wait** is shown within the numeric field **Cuff** until the cuff pressure is stable for approximately two seconds. From that point, the counter is started. After 60 seconds the test terminates and the final leak rate is shown in the **Leak Rate** numeric field.



- 1. Click the Leak Rate (1) button.
- 2. Set the Initial Pressure (2) to 200mmHg.
- 3. Click the **Start 200 mmHg (3)** button. When the pressure is reached and is stable for two seconds the timer starts for 60 seconds.
- 4. Note the displayed pressure (4) compared to the pressure displayed on the reference pressure monitor.
- 5. Note the Leak Rate (5) after 60 seconds.

### Test criteria

- The pressure difference between the monitor value and the reference value does not exceed ± 3 mmHg.
- The maximum leakage (leak rate) after 60 seconds is 6 mmHg.

## Deflation curve test

In this test, the linearity of the NIBP valve's deflation curve is analyzed. The test is performed with deflation rates of 5 and 3 mmHg in both adult and neonate modes. When the test is started, the internal NIBP pump inflates until a pressure of 200 mmHg (150 mmHg for neonate) is reached. The pressure curve is shown in real time with the deflation rate (declining part of the pressure curve).

**Note** This test simulates a NIBP measurement taken by the monitor. This means that, because the pulse signal is missing, the test is aborted by the NIBP module and an error message displayed - ignore this error message.

The deflation tests are defined as follows:

- Adult 5 = dp/dt 5 mmHg/s, Pmax 200 mmHg
- Adult 3 = dp/dt 3 mmHg/s, Pmax 200 mmHg
- Neonate 5 = dp/dt 5 mmHg/s, Pmax 150 mmHg
- Neonate 3 = dp/dt 3 mmHg/s, Pmax 150 mmHg

The curve panel shows first the increasing pressure to the Pmax. value and then the declining curve until the test is aborted by the monitor because the pulse is missing. An error message appears.

PCuff: Shows the current pressure in real time during the test.

**dp/dt:** Shows the average deflation rate of the declining part of the curve.



**Note** The two margin lines define the range in which the declining part of the deflation curve must lie. The margin lines represent a deviation of  $\pm$  15 mmHg.

### Procedure

- 1. Click the **Deflation** button (1).
- 2. Set the **Deflation Rate (2)** to **Adult 5**.
- 3. Click the **Start** button (3).



4. Repeat steps (1) to (3) for the three remaining deflation rate settings (adult 3, neonate 5 and neonate 3) and record deflation rates in the checklist.

Test criteria

- The displayed dp/dt value does not exceed  $\pm 1$  mmHg/s of the selected value.
- The curve is linear and does not cross the margin lines.

## Troubleshooting

If any test fails, possible reasons are as follows:

- Leak in the system check all tubes and connectors for leaks.
- NIBP module faulty replace NIBP module.
- NIBP monitoring fault replace main board.

## **Test completion**

On completion of the NIBP tests:

- Record results in the checklist.
- Remove the cable from the SVC connector and apply the connector cover (part No. 716275 or 717552) over the SVC connector. (see "Cover replacement" on page 42).
- Power off the monitor and remove the USB drive.

# ECG test



Details of tools and equipment is detailed at the beginning of this section (see "Test equipment" on page 125).

## Amplifier and parallelism check

•

- 1. Connect the ECG simulator to the ECG cable for the greatest number of leads configured for the monitor (5 or 12 lead).
- 2. Set the simulator to give a normal ECG (NSR) with a heart rate of 60.
- 3. Set the screen display as follows: Waveform settings: (SETUP > Waveforms)
  - Size for all waves is 1mV/cm
  - Wave 1 = Lead I
  - Wave 2 = Lead II
  - Wave 3 = Lead V
  - Wave 4 = Lead III
  - Sweep speed = 25mm/Sec
- 4. If a printer is installed, use the following printer waveform settings: (SETUP > printer)
  - Wave 1 = ECG 1
  - Wave 2 = ECG 2
  - Wave 3 = ECG 3
- 5. If a printer is installed, start the manual printout.
- 6. Go to the HR menu and click the Cal. field five times in quick succession.
- 7. On any of the leads displayed or printed, check the parallelism and amplitude of the calibration pulse.



Test criteria

- On any one lead the difference between consecutive pulses (parallelism) is <0.5 mm.
- On any lead and any pulse, the amplitude is 10 mm  $\pm$  0.25 mm. Check three pulses; all must be within tolerance.

## Sweep speed test

- 1. Set the simulator to give a normal (NSR) ECG with a heart rate of 60.
- 2. Set the screen display as follows: Waveform settings: (SETUP > Waveforms)
  - Size for all waves is 1mV/cm
  - Wave 1 = Lead I
  - Wave 2 = Lead II
  - Wave 3 = Lead V
  - Wave 4 = Lead III
  - Sweep speed = 25mm/Sec
- 3. If a printer is installed, printer waveform settings: (SETUP > printer)
  - Wave 1 = ECG 1
  - Wave 2 = ECG 2
  - Wave 3 = ECG 3
- 4. If a printer is installed, start the manual printout.
- 5. Check the waveform on the screen or printout according to the example below and record value in checklist.



### Test Criteria

- With a heart rate of 60 bpm the distance between the beats is  $25 \text{ mm} \pm 0.5 \text{ mm}$
- The heart rate displayed on the monitor is 60 bpm ± 2 bpm

### Troubleshooting

If any test fails, possible reasons are as follows:

- Faulty printer (if installed) replace printer
- Check parameter software and install latest version
- ECG amplifier faulty replace the main board
- Notch filter incorrectly set change the notch filter to 50 Hz or 60 Hz according to supply
- Monitoring fault replace main board

## Pulse tone test

- 1. With the trim knob select the HR parameter field and push the trim knob to display the settings.
- 2. Set the HR/PR Tone Source to ECG and select HR Tone to On.

### Test Criteria

- The beep sounds synchronously with the QRS pulse.
- If OK, reset the setting to Off.

### Troubleshooting

If this test fails, possible reasons are as follows:

• Faulty speaker

## Alarm test

1. Power off the simulator.

### Test Criteria

- After approximately eight seconds the Alarm "ASY" is shown and an audible alarm given.
- After approximately 35 seconds the piezo sounds.
- Record result in the checklist.

## Troubleshooting

If this test fails, possible reason is as follows:

• Alarm settings

# Respiration

• Details of tools and equipment is detailed at the beginning of this section (see "Test equipment" on page 125).

- 1. Connect ECG/respiration simulator to the ECG cable.
- 2. Set the simulator as follows:
  - Respiration rate = 15
  - Lead = LL
  - Heart rate = 60
  - Amplitude = low
  - Normal (NSR) ECG waveform
- **Note** The above simulator settings are recommended. If using a different manufacturer's simulator that doesn't have the same settings, select a similar respiration rate.
- 3. Set the screen display as follows: Waveform settings: (SETUP > Waveforms)
  - Wave 2 = RESP
- 4. Ensure the respiration is enabled on the monitor (Parameter settings > RESP enabled > Yes)
- 5. Check the respiration per the test criteria.

### Test criteria

- Respiration rate is the same as that set on the simulator ± 1
- Respiration waveform displayed

### Troubleshooting

If this test fails, possible reasons are as follows:

- Incorrect simulator settings check simulator settings
- Respiration signal processing circuit fault replace main board
- ECG cable replace ECG cable
- Inter-print board
- Monitoring fault replace main board

# ECG Reference (for units with 12-lead resting ECG option)

• Details of tools and equipment is detailed at the beginning of this section (see "Test equipment" on page 125).

- **Note** This test is only for units with the resting ECG option enabled. A calibrated test ECG Patient Simulator (e.g Müller & Sebastiani MS410 ECG Simulator) is required.
- Connect the simulator to the unit and select the calibrated ECG reference waveform > CAL 20160.
- **Note** Any reference waveform from a calibrated simulator can be used. The reference waveform specified here and the results table and sample printout given on the following pages are an example only and if another waveform is used, the results must be compared to that specified for the waveform.
- 2. Press the Setup button 🖪.
- 3. Select 12-lead ECG.
- 4. Verify the status for all electrodes are green.

art 12-Lead Resting ECG	
ncel 124 ead Resting ECG	RA On
Mana Research and a state of	LL On
	RL On
nnt 12-cean Heating ECG	V1 On
	V2 On
weep Speed 25 mm/sec	V3 On
	V4 On
	V5 On
	V6 On

- Select Start 12-lead Resting ECG. The message Rest ECG Analysis in Progress is displayed while the resting ECG is being taken. This is followed by Rest ECG -Complete.
- 6. Select Print 12-lead Resting ECG and wait for the printout.
- 7. Check measurement table (given on the printout) against the following table.
- 8. Check the waveform and polarity on the printout against the reference waveform (see "Reference Waveform Printout" on page 143). Note that the reference waveform is representative of the waveform shape only and is not accurately scaled.

### Reference Table (CAL 20160)

Measurement	Value	Tolerance	Minimum	Maximum
RR	1000 (ms)	<u>±</u> 10	990	1010
Ρ	116 (ms)	<u>±</u> 10	106	126
PQ	178 (ms)	<u>±</u> 10	168	188
QRS	60 (ms) <sup>1</sup>	<u>±</u> 6	54	66
QT	356 (ms)	<u>±</u> 12	344	386

1. Because of the sharp fall time on the computer generated waveform (that would not be found biologically), and the signal averaging, sampling and processing of this signal, the QRS value reads slightly higher than the input value from the simulator.

## Test Criteria

- All interval measurements are within the minimum and maximum limits shown in the reference table (CAL 20160) or for the reference waveform used.
- Record result in the checklist.
- The waveform shape and polarity is the same as that shown on the reference waveform printout.

### Troubleshooting

If any test fails, possible reasons are as follows:

- Faulty printer replace printer
- ECG amplifier faulty replace main board
- ECG cable replace cable
- Inter-print board
- Monitoring fault replace main board
## Reference Waveform Printout



# SpO<sub>2</sub> test (Nellcor)

• Details of tools and equipment is detailed at the beginning of this section (see "Test equipment" on page 125).

# Saturation and peripheral pulse test

1. Connect the Nellcor  $SpO_2$  simulator to the monitor.



- 2. Set the screen display to display  $SpO_2$  in waveform settings:
  - SETUP > Waveforms > Wave 3 = SpO<sub>2</sub>
- 3. Set the modulation setting to low and the light level to low.
- 4. Test the following values and record results in the checklist:

Pulse Rate in bpm	SpO <sub>2</sub> in %
60	75
200	75
60	90
200	90

**Note** If using a different manufacturer's tester, test over a similar range of settings and apply the same criteria.

- 5. Set the pulse rate to 60 and the  $SpO_2$  to 75%.
- 6. Change the light level from low (arrow down) to high (arrow up).
- 7. Check that the pulse rate and  $SpO_2$  reading do not change.
- 8. Change the modulation level from low (arrow down) to high (arrow up).
- 9. Check that the pulse rate and SpO<sub>2</sub> reading do not change.

#### Test criteria

- SpO<sub>2</sub> waveform displayed on the screen
- SpO<sub>2</sub> saturation  $\pm$  2 digits
- Peripheral pulse rate ± 3 digits
- Values are still in tolerance when the light level is set to high.
- Values are still in tolerance when the modulation level is set to high.

## Pulse tone test

- 1. Set the pulse rate to 60 and the  $SpO_2$  to 75%.
- 2. With the trim knob select the  ${\rm SpO}_2$  parameter field and push the trim knob to display the settings.
- 3. Set HR/PR Tone Source to SpO2
- 4. Set HR/PR Tone to On.

#### Test Criteria

• The beeper sounds synchronously with the SpO<sub>2</sub> pulse displayed.

#### Troubleshooting

If any test fails, possible reason is as follows:

• SpO<sub>2</sub> module faulty - replace Nellcor module

# SpO<sub>2</sub> test (Masimo)

• Details of tools and equipment is detailed at the beginning of this section (see "Test equipment" on page 125).

# Saturation and peripheral pulse test

1. Connect the Masimo SpO<sub>2</sub> tester to the monitor.



- 2. Set the screen display to display  $SpO_2$  in waveform settings:
  - SETUP > Waveforms > Wave 3 = SpO<sub>2</sub>
- 3. Check that the SpO2 reading is 81 % and the Peripheral pulse rate is 61 bpm.
- **Note** If using a different manufacturer's tester, test over a similar range of settings and apply the same criteria.

## Test criteria

- SpO<sub>2</sub> waveform displayed on the screen
- SpO<sub>2</sub> saturation  $\pm$  3 digits (for the Masimo tester this is 81%  $\pm$  3)
- Peripheral pulse rate  $\pm 1$  digit (for the Masimo tester this is 61 bpm  $\pm 1$ )

## Troubleshooting

If any test fails, possible reason is as follows:

• SpO<sub>2</sub> module faulty - replace Masimo module

# IBP test

11

Details of tools and equipment is detailed at the beginning of this section (see "Test equipment" on page 125).

## Invasive blood pressure test of the monitor

•

- 1. Connect the test box to IBP1 connector of the monitor.
- 2. On the IBP / TEMP tester, set the pressure to 0.



- 3. On the monitor, select the P1 parameter field and push the trim knob to display the settings.
- 4. Select Zero set and check on the display the P1 value 0/0 (0) is displayed. Repeat if necessary to obtain 0/0 (0).
- 5. Select each of the pressures on the IBP / TEMP Tester (30, 50, 100, 200, 300 mmHg), and note the pressure displayed on the monitor.
- 6. Connect the test box to IBP2 and repeat steps 2 to 5.
- 7. If the monitor is equipped with four IBP connectors, repeat steps 2 to 5 for IBP3 and IBP4.
- 8. Record the values displayed on the test protocol checklist.

#### Test criteria

Pressure (mmHg)	Tolerance (mmHg)
0	± 1.0
30	± 1.0
50	± 1.0
100	± 1.0
200	± 2.0
300 (see following)	± 3.0

Max.  $\pm$  1% or 1mmHg (whichever is greater) between displayed and reference values.

**Note** If using a different manufacturer's tester, test over a similar range of pressures and apply the same criteria.

#### 300 mmHg test

The 300 mmHg value is optional and does not need to be carried unless there is a strong suspicion that this upper pressure is not measuring correctly.

The maximum IBP pressure that can be shown on the monitor is 300mmHg and therefore a measurement that is slightly more than 300 mmHg but still in tolerance, cannot be displayed. When 300 mmHg is exceeded, the monitor displays the following message: Px out of range (too high).

If the 300 mmHg is to be checked, proceed as follows:

- 1. Set IBP tester to 30mmHg
- 2. Zero set at 30mmHg
- 3. Set IBP tester to 300mmHg
- 4. Verify IBP value displayed: 270mmHg ±3mmHg
- 5. Reset zero set to 0

## Invasive blood pressure test of the monitor and transducer (optional)

• Details of tools and equipment is detailed at the beginning of this section (see "Test equipment" on page 125).

Using a manometer the complete invasive pressure system (monitor, cable, and IBP transducer) can be checked. This has the advantage that the transducer system of the customer is checked with the monitor itself.



- 1. Connect the manometer and test setup to IBP1as shown.
- 2. Open the valve to ambient.
- 3. On the monitor select the IBP1 parameter field and push the trim knob to display the settings.
- 4. Select **Zero set** and check on the display the P1 value 0/0 (0) is displayed.
- 5. Close the valve for the ambient pressure.
- 6. Using the manual pump increase the pressure in steps of 50mmHg up to 300mmHg. At every step (50, 100, 150, 200, and 250 mmHg). Check the reference value against that displayed on the monitor.
- 7. Repeat for IBP2 (if required).
- 8. Repeat for IBP3 and IBP4 if installed (and required).

#### Test criteria

- Make sure that the maximum deviation between the displayed value and the reference value on the manometer is within the overall system tolerance stated by the manufacturer of the transducer.
- Record the displayed and reference value in the checklist.

## Troubleshooting

If any test fails, possible reasons are as follows:

- Check for leaks in test setup
- IBP module faulty replace main board
- IBP cable or transducer faulty replace accessory

# Temperature test

• Details of tools and equipment is detailed at the beginning of this section (see "Test equipment" on page 125).

1. Connect the IBP / TEMP Tester to the temperature input 1 (T1).



- 2. Set the IBP / TEMP Tester to 16.0° C (60.8° F)
- 3. Note the displayed values and set values and record in the checklist.
- 4. Repeat for temperatures 25.3° C (77.5° F), 34.7° C (94.5° F),36.7° C (98.1° F), 39.3° C (102.7° F),44.7° C (112.5° F).
- 5. Repeat for temperature input 2 (T2) if installed.

#### Test criteria

Make sure the monitor displays the reference temperatures  $\pm 0.1^{\circ}$  (for both  $^{\circ}C$  or  $^{\circ}F$ )

**Note** If using a different manufacturer's tester, test over a similar range of temperatures and apply the same criteria.

#### Troubleshooting

If any test fails, possible reasons are as follows:

- Temperature cable fault replace cable
- Temperature module faulty replace temperature card
- Temperature signal processing faulty replace main board

# etCO<sub>2</sub> test

• Details of tools and equipment is detailed at the beginning of this section (see "Test equipment" on page 125).

**Note** For testing the etCO2 module, a gas bottle with a 5% or 10% concentration CO2 may be used. For calibration, only a gas bottle with a 5% concentration of CO2 can be used.

## etCO<sub>2</sub> test with gas

- 1. Power monitor and activate  $etCO_2$  (Setup > Parameter >  $ETCO_2$  enabled).
- 2. Wait a minimum of 5 minutes before proceeding to allow the  $CO_2$  module to stabilize.
- 3. Set the  $etCO_2$  scale on the monitor to 0 to 80 mmHg.
- 4. Obtain repair bench ambient pressure in mmHg.
- 5. Note the **exact** percentage volume of CO<sub>2</sub> stated on the test gas container and use in the following calculation.
- 6. Calculate the normalized pressure of the 5% or 10%  $CO_2$  test reference gas at current ambient pressure and record in checklist:
  - CO<sub>2</sub> ref. (mmHg) = [CO<sub>2</sub> ref. (%)] × [amb. press. (mmHg)] × 0.0097
  - Example for 5% CO<sub>2</sub> reference mix and ambient pressure of 770 mmHg:
    - CO<sub>2</sub> ref. (mmHg) = 5% × 770 mmHg × 0.0097
    - $CO_2$  ref. (mmHg) = 37.3 mmHg
- 7. Connect the test gas sample line to the CO<sub>2</sub> input of the monitor.
- 8. Simulate breathing by turning the gas on and off every 5 seconds for a minimum of 15 seconds.
- 9. Verify the etCO<sub>2</sub> numeric value meets the following criteria for the chosen gas mix and record result in the checklist.

### Test Criteria

- Normalized 5%, CO2 reference pressure (obtained from the calculated value),  $\pm$  2 mmHg.
- Normalized 10% CO2 reference pressure (obtained from the calculated value), ± 5 mmHg.

## Troubleshooting

If any test fails, possible reasons are as follows:

- Warm up time insufficient allow a minimum warm-up time of five minutes
- Leak in test setup check hoses and fittings
- Test gas incorrect value verify CO<sub>2</sub> concentration in the gas bottle
- CO<sub>2</sub> module faulty replace the module
- Inter-print board
- Processing fault replace main board

# $CO_2$ calibration

1

 Details of tools and equipment is detailed at the beginning of this section (see "Test equipment" on page 125).

**Note**  $etCO_2$  calibration must be performed with a 5%  $CO_2$  concentration gas.

## When to calibrate

The module requires its first calibration after 1200 operating hours or one calendar year, whichever comes sooner, and then after each 4000 operating hours or once a year, whichever comes sooner. The pump and the IR source need to be changed after 20,000 operating hours.

The message **Calibration due** appears when the hourly limit is reached. It is advisable to calibrate in the one-year maintenance program especially if the monitor is used for intermittent, short term use typical of patient monitors. The number of running hours until calibration is due is in the event log screen in the system menu:



Setup Menu > Administrator > System (password 49, 48, 46) > Event log



The CO2 Hours until calibration (service) due gives the number or hours until a calibration is due. When the hours until cal/service due is 0 when a CO2 probe is connected, an alert message is displayed: **CO2 calibration due** or **CO2 service due**.

**Note** The number in parenthesis after the calibration hours is the number of hours until the  $CO_2$  pump and IR source must be replaced. This service require replacement of the  $CO_2$  module.

# CO<sub>2</sub> calibration procedure

- 1. Suspend all alarms in the setup menu.
- 2. Connect the gas canister (5%  $CO_2$  Calibration Gas canister with an Oridion  $CO_2$  sensor fitting) to the  $CO_2$  sampling input.
- 3. Enter the Service menu:



Setup Service		
Simulated Data Mode	On	
Language	English	
Notch Filter	50 Hz	
Recorder Diagnostics		
Restore Factory Defaults		
Start CO2 Calibration		
Check CO Resistors		
Options		
OK Cancel		

- 4. Turn the gas on and apply the gas to the monitor during the entire calibration process.
- 5. Select the Start CO2 Calibration option to start the calibration process.
- 6. During calibration the message **CO2 calibrating** is displayed in the message area.
- 7. The process will take approximately 50 seconds to complete.

## **Calibration successful**

When calibration is successful the message **CO2 calibration ok** is displayed. The timer in the event log screen is reset.

## Calibration unsuccessful

If CO2 unable to cal appears during the calibration process check the following:

- Calibration gas ensure correct gas is used (5% CO<sub>2</sub>).
- Ensure that there is sufficient gas in canister.
- Check all connections for leaks.

Attempt to calibrate again. If still not possible it indicates other technical problems. Check or replace the  $CO_2$  Module.

# Cardiac output test

• Details of tools and equipment is detailed at the beginning of this section (see "Test equipment" on page 125).

1. Connect the IBP / Temp /CO test box to the CO connector on the side panel.



2. Enter the Service menu:





3. Select the Check CO Resistors option and check the resistance displayed:

Setup Service		
Simulated Data Mode	On	
Language	English	
Notch Filter	50 Hz	
Recorder Diagnostics		
Restore Factory Defaults		
Start CO2 Calibration		
Check CO Resistors		
Options		
		IT SENSOR: 14080
		BT SENSOR: 13840
		IT REFERENCE: 39010
		BT REFERENCE: 13500

#### Test criteria

- The IT reference resistance is 39,000  $\Omega$   $\pm$  400  $\Omega$
- The BT reference resistance is 13,500  $\Omega$  <u>+</u> 160  $\Omega$

**Note** The IT sensor and BT sensor values can be ignored.

**Note** If using a different manufacturer's tester, test over a similar range of CO and apply the same criteria.

## Troubleshooting

If any test fails, possible reasons are as follows:

- Temperature cable fault replace cable
- Temperature module faulty replace temperature card
- CO module faulty replace CO module
- CO signal processing faulty replace main board

# Nurse call test

• Details of tools and equipment is detailed at the beginning of this section (see "Test equipment" on page 125).

- 1. Connect the tester to the Nurse call input of the monitor.
- 2. Generate an alarm.
- 3. Press and hold the silver button.

## Test criteria

- The green lamp is illuminated and changes red when the alarm is generated.
- The output can also be tested with a multi-meter. A short circuit is generated (maximum 2 Ohms) on the nurse call jack when the alarm is active.







# Ethernet port connectivity test

• Details of tools and equipment is detailed at the beginning of this section (see "Test equipment" on page 125).

This test checks that the ethernet connection on the monitor is functioning.

- **Note** This test is only carried out if the Acuity option is licensed. If the Acuity option is not licensed, this test does not need to be carried out.
- **Note** This test checks that the ethernet network connection is functioning. If a network (with DHCP services) is not available, use the alternative test to check the ethernet port (see "Alternative Ethernet port test (when network not available)" on page 163).

## Procedure

1. Using a standard Ethernet RJ45 cable assembly, connect the ethernet connector on the back panel to a 10/100 Ethernet switch port on a network providing DHCP services.



2. Enable the Acuity connection:

Note This menu item is not available if the Acuity option is not licensed.

- a. Press the Setup button 🕕.
- b. Select Administrator > System (password required 49, 48, 46) and set Acuity Enabled (yes).

Setup System					
Height units	in				
Weight units	lb				
Acuity Enabled	Yes				
Set Date and Time					
Save User Defaults					
Show Event Log					
OK Cancel					

- c. Select OK to exit Setup screen.
- 3. Enable DHCP on the monitor:
  - a. Press the Setup button 📧 .
  - b. Select Administrator > Communications (password required 53, 51, 54) and select Use DHCP (Yes).



- 4. Select OK to exit setup communications screen.
- 5. Power off the monitor.
- 6. Power up the monitor and wait 60 seconds before proceeding.

- 7. View the communications screen:
  - a. Press the Setup button 🔳.
  - b. Select Administrator > Communications (password required 53, 51, 54).

P Address			
Subnet	255.255.255.0		
Gateway	192.168.40.1		
ONS	64.69.100.68		
Jse DHCP	Yes	DHCP Values:	
		MAC Address	00.50.C2.7B.F3.8D
ок	Cancel	DHCP Enabled	1 1 1
		IP Address	172.20.6.146
		Subnet	255.255.255.0
		Gateway	172.20.6.1
		DNS	
		DHCP Server	172.30.0.125
		Lease Obtained	2011.06.20 16:47:53

- 8. Make a note of the monitor IP address for use later in this procedure. In this example the IP address is 172.20.6.146.
- **Note** The IP address is assigned to the monitor. The IP address is not fixed and will vary by network.
- 9. Ping the monitor:
  - a. From the start menu of a computer on the network computer enter the run menu option (Start > Run ) and on the command screen enter CMD:



b. The command screen is shown. Enter ping xxx.xxx.xx (the IP address of the monitor.



c. Check that the bytes sent are returned.



Test criteria

- The monitor responds to the ping and on the PC the bytes are shown as received. Ping request does not time out.
- Lost bytes on ping = 0.

#### Troubleshooting

If this test fails no bytes are returned and the following screen is displayed.



Possible reasons are as follows:

- Settings in the PC check PC network settings.
- Incorrect cable connection check cable.
- Main board fault change main board.
- Z-bitsy board fault change the Z-bitsy board.

# Alternative Ethernet port test (when network not available)

 Details of tools and equipment is detailed at the beginning of this section (see "Test equipment" on page 125).

This test checks that the ethernet connection is functioning.

**Note** This test only needs to be carried out when the Acuity option is licensed and a network is not available at the time of test. When a network is available the standard test detailed previously (see "Ethernet port connectivity test" on page 159), can be carried out.

## Procedure

- 1. Connect the ethernet connector on the back panel to a PC using a standard RJ45 crossover cable assembly and enable the Acuity connection (see "Ethernet port connectivity test" on page 159).
- 2. Note the IP address of the monitor, or define any IP setting:
  - a. Press the Setup button 🔳.
  - b. Select Administrator > System > Communications (password required 53, 51, 54).

Setup Communicati	ons	
IP Address	192.168.100.2	
Subnet	255.255.255.0	
Gateway	192.168.40.1	
DNS	64.69.100.68	
Use DHCP	No	
OK (	Cancel	

**Note** The IP setting shown here is an example only. The IP setting will differ for all monitors. Any IP setting can be used i.e., the current monitor setting displayed can be used or any other IP setting can be defined.

- 3. From the computer setup a local network and enter the network details of the monitor:
- **Note** The following procedure is a guideline only and will differ for different operating systems and configurations.
  - a. Open the Start menu > Settings> Network connections.



b. Network connections are shown:



c. Highlight a network and right click to display the properties.



d. Select TCP IP protocol and click the properties button.



e. Define the IP address and gateway of the monitor.

Internet Protoco	il (TCP/IP) Prope	rties	? ×		
General					
You can get IP this capability. the appropriate	settings assigned au Otherwise, you need IP settings.	itomatically if your network suppor to ask your network administrator	ts for		
◯ <u>O</u> btain ar	IP address automat	ically			
Use the f	ollowing IP address:				
<u>I</u> P address:		192.168.100.2			
S <u>u</u> bnet mas	c	255 . 255 . 255 . 0			
<u>D</u> efault gate	way:				
C Obtain DNS server address automatically					
_ ⊂ Us <u>e</u> the f	allowing DNS server	addresses:			
Preferred DN	IS server:	· · · ·			
<u>A</u> lternate DN	S server:				
		A			

- f. Exit the network screens.
- 4. Ping the monitor (see "Ping the monitor:" on page 161)

#### Test criteria

- The monitor responds to the ping and on the PC the bytes are shown as received. Ping request does not time out.
- Lost bytes on ping = 0.

#### Troubleshooting

• see "Troubleshooting" on page 162.

# On completion of the tests

On completion of the tests:

- The test protocol and checklists must be filled in and filed (see next page).
- The calibration / yearly test label must be marked to indicate the month and year when the next test must take place (12 months from test completion), and the label positioned over the left middle casing securing screw indent.



**Note** The calibration label type is not critical but it must contain month and year.

# **10** Test protocol and checklists

# Test protocol

Test Organization:	Check before first use (refer		(میراد	
Name of the tester:			nuc)	
Manitan Carial na a	Recurrent test			
Monitor Senai no.:	Test after repair			
Safety measurement according IEC / EN62353		N/A	Pass	Fail
Measurement:	measured value <sup>1</sup>			
Protective around	Ω			
Fauipment leakage current	mA			
Patient leakage current	mA			
Isolation resistance (optional)	ΜΩ			
Visual inspection according to checklist				
Functional and general checks according to check	list.			
Measurement Check according to checklist				
Overall comments:				
No safety or functional problem detected.				
No direct risk, but it is advised that the following	are carried out, checked or note	d (see r	emarks	below).
The monitor must be placed out of service (see r	remarks below).			
Remarks:				

Validated by: ..... Date

1. Safety measurement limits depend on which measurement is performed; please refer to IEC62353.

# Software

Reference	Updated	Not updated	Remarks
Software page 114			
Main Software			Software revision installed on monitor:
			Current software revision:
			NA 🔲 (latest rev. already installed)
Parameter Software			Software revision installed on monitor:
			Current software revision:
			NA 🔲 (latest rev. already installed)
Printer Software	NA (printer not in- stalled)		Software revision installed on monitor:
			Current software revision:
			NA 🔲 (latest rev. already installed)
NIBP firmware			Software revision installed on monitor:
			Current software revision:
			NA 🔲 (latest rev. already installed)

# Visual checklist

Reference	pass	fail	Remarks
Visual inspection page 115			
Fuses page 115			
• Both fuses are rated type M, 1.6, E, 250.			
Safety, patent and information labels page 116			
<ul> <li>Manufacturer label with serial number, CE reference and safety label (1) intact and readable.</li> </ul>			
<ul> <li>REF label with patent information</li> <li>(2) intact and readable.</li> </ul>			
• Manufacturer type label with monitor type, address, fuse rating, and power requirements (3) intact and readable.			
<ul> <li>SpO2 module manufacturer label</li> <li>(4) intact and readable.</li> </ul>			Nellcor SpO <sub>2</sub> module and label
			Masimo $\text{SpO}_2$ module and label
Physical condition of the monitor page 118			
• No cracks or chips in the casing.			
<ul> <li>Mains, patient and all other cable assemblies are in good condition with no crushing, chafing or cuts, etc.</li> </ul>			
• All plugs and sockets are straight and in good condition.			
<ul> <li>No soiling which could hamper the safety of the monitor.</li> </ul>			

# Functional and general checklist

	Reference	pass	fail	Remarks
Po	wer indicator and battery check page			
119				
•	Check that when mains is connected the mains LED is			
	illuminated.			
٠	Check that the battery symbol			
	displays an indication of the			
	depleted.			
٠	Check that when the battery			
	capacity is close to depletion the following happens:			
•	an audible alarm occurs			
•	the visual alarm indicator flashes blue			
•	the alarm message Battery low appears.			
٠	the battery symbol flashes			
•	Check that when mains is reconnected, the mains LED is			
	illuminated and the battery			
	symbol disappears.			
٠	Check that when the mains			
	supply is again removed, the			
	Check that it indicates a battery			
	capacity of 1/4 full or greater, i.e.			
	not empty.			
Sp	eaker and piezo check page 121			
•	Immediate single high pitch piezo			
	pressed.			
•	After a few seconds the device is			
	ready - two tone speaker beep is			
	heard, followed by two shorter,			
Ko	nigner pitched piezo beeps.			
KG.				
•	or wear.			
•	All buttons function correctly.			

	Reference	pass	fail	Remarks
LCE	) screen test page 122			
٠	No spots or black fields.			
•	LCD shade (contrast and brilliance) is even and consistent.			
Pri	nter Checks page 123			
•	Check that the printhead temperature is ambient (+20° C dependent on printer use before the test has been carried out).			No printer installed.
٠	Check that the parallel lines on the printout are not stepped.			
٠	Examine the printout for:			
	• fading			
	• alignment			
	faulty pixels			
	<ul> <li>blackness, regularity and good readability on the complete print width.</li> </ul>			

# Measurement checklist

Reference	Value	Pass	Fail	Remarks
NIBP test page 127				
Over pressure page 132				
• At 320 ± 10mmHg the valve opens and the pressure decreases to 0 mmHg.	service tool val- ue:			
	mmHg			
Measurement accuracy and leak rate page 133				
<ul> <li>Accuracy: At the 200 mmHg setting:The pressure difference between the monitor value and the reference value does not exceed ± 3 mmHg</li> </ul>	monitor value:			
ig.	meter value:			
	mmHg			
	difference:			
	mmHg			
• Leak rate: At the 200 mmHg setting: The maximum leakage (leak rate) after 60 seconds is 6 mmHg.	displayed leak- age value after one minute:			
	mmHg			

	Reference	Value	Pass	Fail	Remarks
De	flation curve test page 134				Check in each case that the curve is linear and does not cross the margin lines.
•	Adult 5: dp / dt value: 5 mmHg/s (± 1 mmHg/sec).	dp/dt disp val- ue:			
		mmHg/s			
•	Adult 3: dp / dt value: 3mmHg/s (± 1 mmHg/ sec).	dp/dt disp val- ue:			
		mmHg/s			
•	Neonate 5: dp / dt value: 5 mmHg/s (± 1 mmHg/sec).	dp/dt disp val- ue:			
		mmHg/s			
•	Neonate 3: dp / dt value: 3mmHg/s (± 1 mmHg/ sec).	dp/dt disp val- ue:			
		mmHg/s			
•	The curve is linear and does not cross the margin lines.				
Tes	st completion page 136				
•	SVC connector cover applied over the SVC connector.	Yes 🗆			

Reference	Value	Pass	Fail	Remarks
ECG test page 137				
Amplifier and parallelism check				
page 137				
Parallelism check: < 0.5     mm between pulses				
<ul> <li>Height measurement: 10 mm <u>+</u> 0.25 mm</li> </ul>				
Sweep speed test page 138				
• With a heart rate of 60 bpm the distance between the beats is 25 mm ± 0.5 mm				
<ul> <li>The heart rate displayed on the monitor is 60 bpm ± 2 bpm</li> </ul>	meas.			
	bpm			
Pulse tone test page 139				
<ul> <li>The beep sounds synchronously with the QRS pulse.</li> </ul>				
Alarm test page 139				
• After approximately eight seconds the Alarm "ASY" is shown and an audible alarm given.				
After approximately 35     seconds the piezo     sounds.				
Respiration page 140				
<ul> <li>Respiration rate is the same as that set on the simulator ± 1</li> </ul>				
Respiration waveform     displayed				

Reference	Value	Pass	Fail	Remarks
ECG Reference (for units with 12-lead resting ECG option) page 141	Not taken 🗆			
All interval measurements are within the minimum and maximum limits	meas.			
table (CAL 20160) or for the reference waveform used.	RR ms			Type of simulator:
	P ms			Waveform Used:
	PQ ms			
	QRS ms			
	QT ms			
• The waveform shape and polarity is the same as that shown on the reference waveform printout.	NA (If a CAL 20160 waveform not used)			

Reference	Value	Pass	Fail	Remarks
SpO2 test (Nellcor) page 144				
<ul> <li>SpO2 waveform displayed on the screen</li> </ul>	NA Masimo module installed			
<ul> <li>75%, 60 bpm setting:</li> <li>SpO2 saturation ± 2 digits</li> <li>Peripheral pulse rate ± 3 digits.</li> </ul>	Sat %			
	PR bpm			
<ul> <li>75%, 200 bpm setting:</li> <li>SpO2 saturation ± 2 digits</li> <li>Peripheral pulse rate ± 3 digits.</li> </ul>	Sat %			
	PB hnm			
<ul> <li>90%, 60 bpm setting:</li> <li>SpO2 saturation ± 2 digits</li> <li>Peripheral pulse rate ± 3 digits.</li> </ul>	Sat%			
	PR bpm			
<ul> <li>90%, 200 bpm setting:</li> <li>SpO2 saturation ± 2 digits</li> <li>Peripheral pulse rate ± 3 digits.</li> </ul>	Sat %			
	PR bpm			
• Values are still in tolerance when the light level is set to high.				
<ul> <li>Values are still in tolerance when the modulation level is set to high.</li> </ul>				

Reference	Value	Pass	Fail	Remarks
Pulse tone test page 145				
<ul> <li>The beeper sounds synchronously with the SpO<sub>2</sub> pulse displayed.</li> </ul>				
SpO2 test (Masimo) page 146				
SpO2 waveform displayed				
on the screen	Nellcor module installed			
<ul> <li>SpO2 saturation ± 3 digits (for the Masimo tester this is 81% + 3)</li> </ul>				
	Sat %			
<ul> <li>Peripheral pulse rate ± 1 digit (for the Masimo tester this is 61 bpm + 1)</li> </ul>				
	PR bpm			

Reference		Value	Pass	Fail	Remarks
IBP	' test page 147				
Invasive blood pressure test of the monitor page 147 (P1 and P2)					
•	0 mmHg setting (± 1 mmHg)				
		P1mmHg			
		P2mmHg			
٠	30 mmHg setting (± 1 mmHg)				
		P1mmHg			
		P2mmHg			
•	50 mmHg setting (± 1 mmHg)				
		P1mmHg			
		P2mmHg			
•	100 mmHg setting (± 1 mmHg)				
		P1mmHg			
		P2mmHg			
•	200 mmHg setting (± 2 mmHg)				
		P1mmHg			
		P2mmHg			
•	300 mmHg setting (optional check - 270 mmHg displayed) (+ 3				Re-zeroed after this test if taken 🗆
	mmHg)	P1mmHg			Test not taken re-zeroing not required 🗆
		P2mmHg			
Reference	Value	Pass	Fail	Remarks	
---	------------------------------	------	------	--	
IBP test page 147					
Invasive blood pressure test of the monitor page 147 (P3 and P4)	NA D P3 and P4 not installed				
• 0 mmHg setting (± 1 mmHg)	P3 mmHa				
	1 0				
	P4mmHg				
<ul> <li>30 mmHg setting (± 1 mmHg)</li> </ul>					
	P3mmHg				
	P4mmHg				
<ul> <li>50 mmHg setting (± 1 mmHg)</li> </ul>					
	P3mmHg				
	P4mmHg				
• 100 mmHg setting (± 1 mmHg)					
	P3mmHg				
	P4mmHg				
• 200 mmHg setting (± 2 mmHg)					
	P3mmHg				
	P4mmHg				
<ul> <li>300 mmHg setting (optional check - 270 mmHg displayed) (± 3</li> </ul>	D2 mml/s			Re-zeroed after this test if taken 🗆	
mmHg)	rзттнд			Test not taken re-zeroing not required 🗆	
	P4mmHg				

Reference	Value	Pass	Fail	Remarks
Invasive blood pressure test of the monitor and transducer (optional) page 149	Not taken 🗖			
• Make sure that the maximum deviation between the displayed value and the reference value on the manometer is within the overall system tolerance stated by the manufacturer of the transducer.	disp meas. mmHg ref. value.			
	mmHg			

Reference	Value	Pass	Fail	Remarks
Temperature test page 151				
• $16.0^{\circ}$ C (60.8° F) setting: ± 0.1° (for both °C and °F)	disp meas.			
	T1			
	°C or °F			
	disp meas.			NA 🔲 only T1 installed
	T2			
	°C or °F			
• $25.3^{\circ}$ C (77.5° F) setting: ± $0.1^{\circ}$ (for both $^{\circ}$ C and $^{\circ}$ F)	disp meas.			
	T1			
	°C or °F			
	disp meas.			NA 🗆 only T1 installed
	T2			
	°C or °F			
<ul> <li>34.7° C (94.5° F) setting: ± 0.1° (for both °C and °F)</li> </ul>	disp meas.			
	T1			
	°C or °F			
	disp meas.			NA 🔲 only T1 installed
	T2			
	<sup>o</sup> C or <sup>o</sup> F			
• $36.7^{\circ}$ C (98.1° F) setting: ± 0.1° (for both °C and °F)	disp meas.			
	T1			
	°C or °F			
	disp meas.			NA 🔲 only T1 installed
	T2			
	°C or °F			

	Reference	Value	Pass	Fail	Remarks
•	$39.3^{\circ}$ C (102.7° F), setting: ± 0.1° (for both $^{\circ}$ C and $^{\circ}$ F)	disp meas.			
		T1			
		°C or °F			
		disp meas.			NA 🔲 only T1 installed
		T2			
		°C or °F			
•	44.7° C (112.5° F) setting $\pm$ 0.1° (for both °C and °F)	disp meas.			
		T1			
		°C or °F			
		disp meas.			NA 🗆 only T1 installed
		T2			
		°C or °F			

	Reference	Value	Pass	Fail	Remarks
etC	O2 test page 152				
•	With 5% reference gas concentration:	NA 🗆 gas mix CO <sub>2</sub> :			
	<ul> <li>Normalized 5%, CO2 reference pressure (obtained from the calculated value), ± 2 mmHg.</li> </ul>	%			
		calculated			
		value:			
		mmHg			
		measured			
		value:			
		mmHg			
٠	With 10% reference gas				
	<ul> <li>Normalized 10% CO2 reference pressure (obtained from the calculated value), ± 5</li> </ul>	gas mix CO <sub>2</sub> :			
		%			
	mmHg.	calculated			
		value:			
		mmHg			
		measured			
		value:			
		mmHg			

	Reference	Value	Pass	Fail	Remarks
CO	2 calibration page 154				
•	Calibration carried out				Enter date when calibration was carried out:
					Date
					Event screen (see page 154) numbers of hours left re- maining when calibration performed:
					Hours
•	Calibration not carried out				
					Date
					Event screen - numbers of hours left remaining:
					Hours
•	Module retuned to Oridion for pump and IR source replacement				Enter date when module was replaced:
					Date
					Event screen - numbers of hours left remaining when pump and IR source replaced:
					Hours
•	Pump and IR source do not need replacement.				Event screen - numbers of hours left remaining:
					Hours

	Reference	Value	Pass	Fail	Remarks
Ca	rdiac output test page 156				
•	The IT reference resistance is 39,000 $\Omega$ + 400 $\Omega$	meas. value			Cardiac output not installed
		 Ohms			
•	The BT reference resistance is 13,500 Ω + 160 Ω	meas. value			Cardiac output not installed
		Ohms			
Nu	rse call test page 158				
•	LED changes red when an alarm is generated				
•	Short circuit when an alarm is generated. Enter resistance <u>&lt;</u> 2 Ohms:	NA 🗆 meas. value			
		 Ohms			
Etr	iernet port connectivity test ie 159				
•	The monitor responds to the ping and on the PC the bytes are shown as received. Ping request does not time out.	NA  (Network not available - al- ternative Ether- net port test			Acuity not licensed
٠	Lost bytes on ping = $0$ .	carried out)			
Alt (wh pag	ernative Ethernet port test en network not available) je 163				
•	The monitor responds to the ping and on the PC the bytes are shown as received. Ping request does not time out. Lost bytes on ping = 0.	NA (Network avail- able -Ethernet port connectivi- ty test carried out)			Acuity not licensed

	Reference	Value	Pass	Fail	Remarks
On completion of the tests page 166					
•	The calibration / yearly test label marked to indicate when the next yearly test must take place, and the label positioned on the back panel.	Yes 🗆			Enter month and year set on the label: Month
					Year

# Parts and accessories



**WARNING** Use only accessories supplied or recommended by Welch Allyn. Use accessories according to your facility's standards and manufacturer's recommendations. Always refer to the manufacturer's directions for use. To order accessories, contact your local Welch Allyn representative (see page ii).

# Parts

The following parts are available for the monitor:

Part number	Description
2.100787	SVC,1500PM,SCREWS SET
2.100788	SVC,1500PM,ORIDIAN ETCO2 EXHAUST SET
2.100789	SVC,1500PM,NIBP TUBING KIT ASSEMBLED
2.100793	SVC,1500PM, NELLCOR MODULE INSTALLATION KIT (SPACERS, SCREWS AND NELLCOR STICKER
2.100794	SVC,1500PM, MASIMO MODULE INSTALLATION KIT (SPACERS, SCREWS AND MASIMO STICKER
3.2751	SVC,1500PM & LCX,ZM1-4 INTER PRINT BOARD
3.2810	SVC,1500PM,ZM2-1 MAIN BOARD
3.2811	SVC,1500PM,POWER SUPPLY
3.2812	SVC,1500PM,ZM2-40 TEMP-CARD OUT BRD
3.2813	SVC,1500PM,ZM2-41 CO2-UPDATE CONNECT BRD
3.2814	SVC,1500PM,ZM2-42 ECG CONNECTOR BOARD
3.2815	SVC,1500PM,ZM2-43 IBP CONNECTOR BOARD
3.2816	SVC,1500PM,ZM2-44 SPO2 NELL ADAPTER
3.2817	SVC,1500PM,ZM2-52 USB-BAT PRINT BOARD
3.2824	SVC,1500PM,ZM2-401 TEMP ADAPTER
3.2832	SVC,1500PM,ZM2-45 SPO2 MASIMO ADAPTER
3.900466	SVC,1500PM,NIBP BLEED VALVE
3.930433	SVC,1500PM,PRINTER MODULE COMPLETE
3.930440	SVC,1500PM,NIBP MODULE COMPLETE
3.930441	SVC,1500PM,SIDEPANEL NELL 1TEMP 2IBP
3.930442	SVC,1500PM,SIDEPANEL NELL 1TEMP 2IBP CO2
3.930443	SVC,1500PM,SIDEPANEL NELL 2TEMP 4IBP CO CO2
3.930444	SVC,1500PM,SIDEPANEL NELL 2TEMP 4IBP
3.930447	SVC,1500PM,SIDEPANEL MASIMO 2TEMP 4IBP CO CO2
3.930448	SVC,1500PM,SIDEPANEL MASIMO 2TEMP 4IBP CO
3.930449	SVC,1500PM,SD-CARD PROGRAMMED

Part number	Description
4.120426	SVC,1500PM,CALIBRATION STICKER
4.120538	SVC,1500PM,"NELLCOR OXIMAX" STICKER
4.120539	SVC,1500PM,"MASIMO SPO2" STICKER
4.120541	SVC,1500PM, REF PATENT LABEL
4.150251	SVC,1500PM,Z-BITSY BOARD
4.210004	SVC,1500PM,FUSE 1.6AM
4.210062	SVC,1500PM,FUSE BOX FOR MAINS CONNECTOR
4.220072	SVC,1500PM & LCX,ENCODER
4.240034	SVC,1500PM RUBBER HEAT SINK PAD (5 mm) FOR EMR SHIELD Z-BITSY
4.240035	SVC,1500PM RUBBER HEAT SINK PAD (3 mm) FOR EMR SHIELD Z-BITSY
4.260033	SVC,1500PM,GROUND CONNECTOR
4.270016	SVC,1500PM,MAINS CONNECTOR
4.310483	SVC,1500PM,FRONT HOUSING
4.310484	SVC,1500PM,REAR HOUSING
4.330044	SVC,1500PM,NIBP PUMP ONLY
4.340022	SVC,1500PM & LCX,LOUDSPEAKER
4.410278	SVC,1500PM,NIBP TUBE FIXING
4.415655	SVC,1500PM,LCD FIXING RAIL
4.415733	SVC,1500PM,BATTERY COVER
4.415734	SVC,1500PM,ORIDIAN SPRING
4.415737	SVC,1500PM,PRINTER BAY FILLER PANEL
4.416185	SVC,1500PM,EMR SHIELD UP
4.416186	SVC,1500PM,EMR SHIELD ECG
4.416187	SVC,1500PM,EMR SHIELD DC
4.416188	SVC,1500PM,EMR SHIELD TEMP/CO
4.416189	SVC,1500PM,EMR SHIELD SP02
4.416190	SVC,1500PM,EMR SHIELD IBP
4.416191	SVC,1500PM,EMR SHIELD NIBP
4.416192	SVC,1500PM,EMR SHIELD Z-BITSY
4.430342	SVC,1500PM,TRIMKNOB
4.435328	SVC,1500PM,USB COVER
4.435329	SVC,1500PM,ORIDIAN PLUG COVER
4.450422	SVC,1500PM,KEY FOIL
4.450424	SVC,1500PM,ISOLATION FOIL SP02
4.450425	SVC,1500PM,ISOLATION FOIL ECG
4.450426	SVC,1500PM,ISOLATION FOIL POWER SUPPLY
4.450427	SVC,1500PM,ISOLATION FOIL NIBP
4.520659	SVC,1500PM & LCX,LCD CABLE

Part number	Description
4.520709	SVC,1500PM,DC POWER CABLE
4.520724	SVC,1500PM,ORIDIAN CONNECTION CABLE
4.520725	SVC,1500PM,AG-UPDATE CONNECT CABLE
4.520726	SVC,1500PM,BACKLIGHT CONNECT CABLE
4.520732	SVC,1500PM,GROUND CABLE INTERNAL
4.600101	SVC,1500PM,15 INCH LCD WITH BACKLIGHT
103461	BATTERY,LEAD ACID, WA1500PATM
103462	BATTERY,LITHIUM ION, WA1500PATM
103464	CO2 MODULE, ORIDION, MINIMEDCO2
104352	MASIMO,MX-3,PULSE OX MODULE
712891	NELLCOR,NELL-1,PULSE OX MODULE
716235	LABEL, BLANK, SVC ACCESS COVER, WA1500PATM

# Test equipment

The test equipment required to carry out the functional tests is detailed in the test section (see "Test equipment" on page 125)

### Accessories

For a list of approved accessories available for the monitor, see the Welch Allyn 1500 patient monitor directions for use.

# **12** Schematics









# Side panel



### Interconnections





EMC



# Isolation



200 Schematics

**13** Technical data

# System data

Manufacturer	SCHILLER AG for Welch Allyn
Monitor name	Welch Allyn <sup>®</sup> 1500 Patient Monitor
Dimensions	396 x 284 x 81 mm (15.6 x 11.2 x 3.2 inches)
Weight	5.0 kg (11 lbs) (with lead acid battery)
	4.5 kg (9.9 lbs) (with Li-Ion battery)
Mode of operation	Continuous
Power supply	Internal Charger
Voltage	100 – 240 V, 50 – 60 Hz
Power consumption	max 70 VA
Typical battery operating time	With the battery fully charged, 25°C, display on, NIBP measurement every 15 minutes, and with all parameters ECG/RESP/NIBP/Temp/SpO <sub>2</sub> /IBP(x2)/CO <sub>2</sub> :
	Lead Acid: approximately 1 hour
	Li-Ion: approximately 2 hours
Fuses	2 x M 1.6A E 250V
Environmental conditions for operating	
Temperature	10 °C to 40 °C (50 °F to 104 °F) at relative humidity of 30 to 80 % (non- condensing)
Atmospheric pressure	700 to 1060 hPa
Environmental conditions for transport and storage	
Temperature	-10 °C to 50 °C (14 °F to 122 °F) at relative humidity of 10 to 95 % (non- condensing)
Atmospheric pressure	572 to 1060 hPa
Monitor display	Color TFT LCD
Resolution	1024 x 768 pixels
Dimensions	30.7 x 23 cm (12 x 9 ins),15 in diagonal
Speed	6.25/12.5/25 mm/s

Printer	High-resolution thermal printer
Resolution	8 dots/mm (amplitude-axis), 40 dots/mm (time-axis) at 25 mm/s
Paper	Thermoreactive, Z-folded Width: 80 mm Length 20 m (approx.)
Print speed	25 mm/s
Printout length	10 second ECG recording on 4 pages
Recording tracks	3-channel display, with optimal width of 72 mm, automatic baseline adjustment
Printout	Curves, trend and saved values
Battery	
Battery type	Lead acid battery, 12 V
Capacity	2600 mAh
Recharging time	80% capacity: 2.8 hours 100% capacity: 3.5 hours (monitor switched off)
Battery life	up to 1000 cycles
0	r
Battery type	Lithium-Ion battery, 10.8V
Capacity	7200 mAh
Recharging time	80% capacity: 2.5 hours 100% capacity: 6.5 hours (monitor switched off)
Battery life	min. 500 cycles
Connections	ECG
	SpO <sub>2</sub>
	NIBP
	etCO <sub>2</sub>
	CO
	Temperature (x1) or (x2)
	Invasive blood pressure (x2) or (x4)
Interfaces	Ethernet via RJ45
	Nurse call: Alarm delay at the signal output component <0.5 s Plug type: 1/8 in (3.5 mm) mini-phone jack stereo connector Tip: Normally closed Ring: Normally open Maximum switch current: 1A Maximum switch voltage: 30 V AC/DC Isolation: 1,000 Vrms for 1 min
	USB 1.1
Demo Mode	Simulated patient information including waveforms for training and education

rend	
Entries	All recorded parameters are saved
	Up to 1728 trend records can be saved (updated every minute)
	NIBP trends entered after each reading
Format	The values displayed in tabular numeric format in intervals of 1, 5, 15, 60, and 240 minutes
	Page up/down trend view
larms	
Alarm limits	The upper and lower limits can be selected for all parameters.
Mode	All parameters: Adult/Pediatric/Neonate patient mode-specific limits
	Factory default or programmable settings for all patient modes
Alarm indicators	Red, yellow, blue numeric
	Red, yellow, blue LED indicator
	Alarm(s) off indicator
	Alarm status message
	Audible alarm tone: high/med/low
Alarm suspend	Suspend time user programmable: 1, 1.5 and 2 minutes
Technical alarm	Alert: blue

# Safety standards

Safety standard	IEC 60601-1/A2: 1995: Delta -consideration related to IEC60601-1:2005 incl. corrections 1:2006 and 2:2007:General requirements for basic safety and essential performance. Protection Class I Type CF.
	IEC 60601-1-4/A1: 1999: General requirements for collateral standard: programmable electrical medical systems.
	IEC 62366: 2007: Application of usability engineering to medical devices.
	IEC 60601-2-27: 2005: Particular requirements for the safety of electrocardiographic monitoring equipment.
	IEC 60601-2-30: 1999:Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment.
	IEC 60601-2-34: 2000:Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment
	IEC 60601-2-49: 2001:Particular requirements for the safety of multifunction patient monitoring equipment.
	ISO 9919. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.
	ISO 21647. Particular requirements for the basic safety and essential performance of respiratory gas monitors.
Protection class	Protection against electric shocks, Class I according to IEC/EN 60601-1 (with internal power).
Protection	This monitor is not designed for outdoor use (IPX0).
EMC	IEC/EN 60601-1-2: 2007: (class A).
Additional requirements	EN 1060-1 and EN 1060-3 (noninvasive blood pressure recorders part 1). EN12470-4 (Performance of electrical thermometers for continuous measurement).
Conformity	CE according to directive 93/42/EEC class IIb.

# Measured values

#### ECG

Patient cable	3-lead, 5-lead, 12-lead cable
	Automatic 3, 5 and 12 lead detection
	Lead fault detection
	AAMI 6 pin and 12 pin connectors
Leads	Simultaneous, synchronous recording of up to nine active electrodes giving 12 leads
Filters	
Mains	50 Hz / 60 Hz / off
Bandwidth	0.05 Hz / 0.5 Hz , 35 Hz / 150 Hz
Input impedance	≥ 2.58 MΩ
Heart rate range	15 to 300 beats/min
QRS tone	On / Off
Protection	ESU and defibrillator protected
Lead display	Selectable leads Selection of 1 to 5 simultaneous leads
Display update interval	1 second
Lead fail sense current	< 0.5 μΑ
Tall T-wave rejection	max. amplitude of the T-wave according to IEC 60601-2-27 chapter 50.102.17: 4 mV
HR averaging method	The average of the last 16 beats is used, when RR interval corresponds to a HR of $<$ 48 bpm.
	The average of the last 4 beats is used, when RR interval corresponds to a HR of ${\geq}48$ bpm.
HR accuracy	± 5 % or ± 5 bpm (whichever is greater)
HR meter response time	Change from 80 to 120 bpm: 11s
	Change from 80 to 40 bpm: 11s
Response to Irregular rhythm	A1: 80/min A2: 60/min A3: 120/min A4: 90/min (according to IEC specification 60601-2-27, 6.8.2.bb)
Time to Alarm for tachycardia	B1 and B2: 3 s (according to IEC specification 60601-2-27, 6.8.2.bb)
Sensitivity	According to ANSI/AAMI EC13 / IEC60601-2-27

ECG amplifier	
Sampling frequency	1000 Hz
Pacemaker detection	$\pm$ 2 to $\pm$ 700 mV / 0.1 to 2 ms
Pacemaker rejection	$\pm$ 2 to $\pm$ 700 mV / 0.1 to 2 ms Note: Pacemaker signals can differ from one pacemaker to the next. Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias, mainly with pacemakers generating high amplitudes ( > 20 mV) or those generating overshoot. Pacemaker patients should be kept under close or constant observation.
Protection	Fully isolated, defibrillation protected >5 kV
Line frequency filter	50 or 60 Hz sinusoidal interferences filtered by means of adaptive digital filtering.

### Respiration

Respiration rate range	0 to 200 breaths / min (pediatric: 0 to 120 breaths per minute)
Connector	Shared with ECG
Signal	28 kHz square wave ± 2.5 V
Patient current	max. 80 μA
Dynamic impedance range	1 k to1.5 k $\Omega$ , variation of 0.1 to 3 $\Omega$
Sampling Rate	250 Hz
Respiration rate accuracy	± 1 digit
RR display update interval	Max. 2 s

### Temperature

Channels	One or two channels
Sensor	YSI 401, rectal, skin or ear
Amplifier	Fully isolated, defibrillation protected >5kV
Sampling Frequency	125 Hz
Measurement interval	1x per second
Measurement range	15 °C to 45 °C (59 °F to 113°F)
Resolution	0.1 °C (0.1 °F)
Accuracy	± 0.1° C (± 0.1° F)

#### NIBP

Measurement	Quick action start / stop button
	Automotio or monucl
Measuring intervals	3 to 60 minutes
modeling meritate	
Manager in a seath a d	Op sille metric
weasuring method	Uschlometric
Measurement range	15 to 270mmHa
Weddarennentrange	10 to 27 offining
D (I	
Deflation rate	3 to 9 mmHg / second
	-
Cuff	Adult Pediatric and Neonate
oun	
Pulse rate measurement	25 to 300 bpm
rando	-
lange	
Protection	Uverpressure protection
	• •

#### IBP

Channels	Two channels or four channels
Measurement range	-30 to 300 mmHg
Accuracy	1 mmHg or ± 1% (whichever is greater)
Sampling Frequency	500 Hz
Amplifier	Fully isolated, defibrillation protected >5kV
Calibration	Manual or automatic
Pulse rate measurement range	25 to 250 bpm

### SpO<sub>2</sub>

#### Nellcor Module

Sensors	Nellcor ® OxiMax ® sensors
Amplifier	Fully isolated, defibrillation protected >5kV
Sampling Frequency	62.5 Hz
Display update interval	1 second
Measurement range	
SpO <sub>2</sub>	1 to 100 %
PR	20 to 250 /min
Accuracy (Probe 70%, to 100 %, 28°C to 42°C)	
SpO <sub>2</sub>	Adult / pediatric ± 2 digits Neonate ± 3 digits
PR (no motion)	20 to 250 /min ± 3 digits
Calibration range	70 to 100 % (calibration is fixed, no calibration required)
PR Calculation	Averaged over 4 / 8 / 16 beats

#### Masimo Module

Amplifier	Fully isolated, Fully isolated, defibrillation protected >5kV
Sampling frequency	62.5 Hz
Display update interval	1 second
Signal IQ waveform	A waveform that indicates pulse detection confidence. Values range from 0 to 127 where 0 is low confidence and 127 is high confidence
Perfusion Index numeric	A numeric provided that indicates perfusion. Perfusion is measured in % and ranges from 0.000 to 20.000.
Saturation range:	1 to 100%
Averaging Time	2/4/8/10/12/14/16/18
Sensitivity	Normal / Max / APOD
Fast SAT	A mode that enables rapid tracking of arterial oxygen saturation changes by minimizing the averaging.

#### Capnography

Module	Mini Medi CO <sub>2</sub>
Measuring method	Non dispersive Infrared Spectroscopy
CO <sub>2</sub> units	mmHg or kPa
$CO_2$ , et $CO_2$ , fi $CO_2$ , range	0 to 99 mmHg (CO <sub>2</sub> [mmHg] / Environment pressure) x 100 = CO <sub>2</sub> [%])
Curve Resolution	0.1 mmHg
etCO <sub>2</sub> , inCO <sub>2</sub> Resolution	1 mmHg
CO <sub>2</sub> Accuracy	0 to 38 mmHg: ± 2 mmHg
	39 to 99 mmHg: $\pm$ 5 % of reading and 0.08 % for every 1 mmHg above 38 mmHg
Respiration Rate range	0 to 150 Resp/min
Respiration Rate Accuracy	0 to 70: ± 1 Resp/min
	71 to 120: ± 2 Resp/min
	121 to 150: ± 3 Resp/min
Flow rate	50 ml/min, (42.5 $\leq$ flow $\leq$ 65)flow measured by volume
Waveform sampling	20 samples/s
Initialization Time	40 s (typical)
System Response Time	5.6 s (typical combined response time)
Calibration Interval	Initially calibrate after 1,200 operating hours, then once a year or after 4,000 operating hours, whichever comes first. The initial calibration should not occur before 720 hours of use. If the initial calibration is done before 720 hours of use, the module will reset to require its next calibration after 1200 hours, instead of after 4000 hours.

Note The capnography component of this product is covered by one or more of the following US patents: 6,428,483; 6,997,880; 5,300,859; 6,437,316; 7,488,229; 7,726,954 and their foreign equivalents. Additional patent applications pending.

### Cardiac output

Module	Schiller
Amplifier	Fully isolated, defibrillation protected >5kV
Measuring method	Thermodilution
Sampling frequency	250 Hz
Measuring method	Thermodilution
Parameters:	Cardiac output Injectate temperature Catheter temperature
Measuring range	Cardiac output: 0 to 20 l/min Injectate temperature: 0° to 40°C / 32° to 104°F Catheter temperature: 33° to 40°C / 91.4° to 104°F
Resolution	Cardiac output: 0.01 l/min Injectate temperature: 0.01°C / 0.018°F Catheter temperature: 0.002°C / 0.018°F
Accuracy	Cardiac output: ± 5% at 0°C / 32°F (injectate temperature)
Measurement	Start is detected by temperature difference >0.05°C at distal thermistor

### Drug calculator

Calculations	Setting of a dose, rate, amount, and volume for which any 3 set will cause the 4th to be calculated. Concentration mg/ml Dose and rate
	Titration table (dose and rate)

## **EMC** information tables

The monitor meets the Collateral Standards of Electromagnetic compatibility – Requirements and tests IEC/EN 60601-1-2: The limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical radio frequency equipment.

Medical electrical equipment is subject to the requirements of electromagnetic compatibility (EMC). The monitor must be installed and operated with reference to the electromagnetic environment specified in the following tables 201, 202, 204 and 206.

Emission	Test Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	This monitor uses RF energy only for its internal function. Therefore its RF emission are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The monitor is suitable for use in all establishments, including those
Harmonic emissions IEC 61000-3-2	Class A	directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Voltage fluctuations/Flicker emissions IEC 6100-3-3	Complies	

Immunity Test	IEC 606101 Test level	Compliance Level	Electromagnetic environment guidance
ESD EN 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/ h should be at least 30%.
EFT IEC 61000-4-4	± 2 kV Power supply lines ± 1 kV I/O lines	± 2 kV Power supply lines ± 1 kV I/O lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	< 5 % U <sub>T</sub> (> 95 % dip in Uτ) for 0,5 cycle 40 % U <sub>T</sub> (60 % dip in Uτ) for 5 cycles 70 % U <sub>T</sub> (30 % dip in Uτ) for 25 cycles < 5 % U <sub>T</sub> (> 95 % dip in Uτ) for 5 s	< 5 % U <sub>T</sub> (> 95 % dip in Uτ) for 0,5 cycle 40 % U <sub>T</sub> (60 % dip in Uτ) for 5 cycles 70 % U <sub>T</sub> (30 % dip in Uτ) for 25 cycles < 5 % U <sub>T</sub> (> 95 % dip in Uτ) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. The monitor shutoff during the >95% for 5 second disturbance. If the user of the monitor requires continued operation during power mains interruptions, it is recommended that the monitor be powered from an interruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

#### Immunity Table 202

NOTE  $U_T$  is the AC mains voltage prior to application of the test level.

Emissions equipment and sys	stems that are NOT	life-supporting table 204
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Immunity Test	IEC 606101 Test Level	Compliance Level	Electromagnetic environment guidance	
Conducted RF EN 61000-4-6 Radiated RF EN 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	[V <sub>1</sub> ] = 3 Vrms [E <sub>1</sub> ] = 3 V/m	Portable and mobile communications equipment should be used no closer to any part of this monitor, including cable, than the recommended separation distance (d) calculated from the equation applicable to the frequency of the transmitter.	
			Recommended separation distance:	
			d = $\frac{3.5}{V_1} \times \sqrt{P}$ for 150 Khz to 80 MHz	
			d = $\frac{3.5}{E_1} \times \sqrt{P}$ for 80 MHz to 800 MHz	
			d = $\frac{7}{E_1} \times \sqrt{P}$ for 800MHz to 2.5 GHz	
			where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site <sup>a</sup> survey, should be less than the compliance <sup>b</sup> levels (V <sub>1</sub> and $E_1$ ).	
			Interference may occur in the vicinity of equipment marked with following Symbol	
			(((-)))	
			"non ionizing radiation"	

- Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.

 Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than  $[V_1]$  V/m.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast ant TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocation the monitor.

# Recommended separations distance between portable and mobile RF communications equipment and the monitor Table 206

The user of the monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitter) and this monitor as recommended below, according to the maximum output power of the communication equipment

Max Power Output	Separation distance according frequency of the transmitter [ m ]			
[Watts]	150 kHz to 80 MHz	800 MHz to 2.5 GHz		
	$d = \frac{3.5}{V_1} \times \sqrt{P}$	$d = \frac{3.5}{E_1} \times \sqrt{P}$	$d = \frac{7}{V_1} \times \sqrt{P}$	
0.01	0.12	0.12	0.23	
0.1	0.37	0.37	0.73	
1	1.17	1.17	2.3	
10	3.7	3.7	7.3	
100	11.7	11.7	23	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.

Note 1To calculate the recommended separation distance of transmitters in the frequency range at 80 MHz to 2,5 GHz an
additional factor of 10/3 was used, to limit the possibility for the patient area that unintentional brought in mobile or portable
communication equipment cab cause any disturbance.

 Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
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