

SECULIFE SP BASE Digital Pulse Oximetry Simulator

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Contents

1 Safety Precautions	1
2 Applications	3
 2.1 Intended Use / Use for Intended Purpose 2.2 Use for Other than Intended Purpose 2.3 Liability and Guarantee 2.4 Opening the Instrument / Repairs 	
3 Documentation	4
3.1 Identifiers	
4 First Steps	5
5 The Instrument	6
 5.1 Scope of Delivery 5.2 Instrument Overview 5.3 Technical Data 5.4 Applied Standards 5.5 Combined Products 	
6 Menu and Functions	10
6.1 User Interface6.2 Manual Mode6.3 Preset Mode6.4 Setup Menu	
7 Installation	16
7.1 Unpacking the Instrument7.2 Power Supply	
8 Operation	17
 8.1 Switching on/off 8.2 Connecting the Instrument to a DUT 8.3 Adjusting Simulation Environment 8.4 Changing Setup Configuration 8.5 Displaying Instrument Information 8.6 Updating Firmware 	
9 Maintenance	23

9.1	Cleaning	
9.2	Maintenance	
9.3	Troubleshooting	
9.4	Repair	
10Re	eturns and Environmentally Sound Disposal	25
11 Se	ervice and Support	26
11.1	Product Support	
11.2	Repair and Replacement Parts Service Calibration Center * and Rental Instrument Service	
400		

1 Safety Precautions

Observe this documentation, in particular all included safety information, in order to protect yourself and others from injury, and to prevent damage to the instrument.

General

- Carefully and completely read and adhere to these operating instructions. The document can be found at http://www.gossenmetrawatt.com. Retain this document for future reference.
- Use only the specified accessories (included in delivery or listed as optional) with the instrument.
- Carefully and completely read and adhere to the product documentation of the optional accessories. Retain these documents for future reference.
- Observe and comply with all safety regulations which are applicable for your work environment.

Handling

- The instrument may only be used as long as it's in good working order.
- Inspect the instrument before use. Pay particular attention to damage, broken insulation or kinked cables.
- Damaged components must be replaced immediately.
- Accessories and cables may only be used as long as they're fully intact.
- Inspect all cables and accessories before use. Pay particular attention to damage, broken insulation or kinked cables.
- If the instrument or an accessory doesn't function flawlessly, remove it from operation and secure it against inadvertent use.
- If the instrument or accessory is damaged during use, e.g. through falling, remove it from operation and secure it against inadvertent use.

Operating Conditions

- Do not use the instrument after long periods of storage under unfavorable conditions (e.g. humidity, dust or extreme temperature).
- Do not use the instrument after extraordinary stressing due to transport.
- The instrument must not be exposed to direct sunlight.
- Only use the instrument and the accessories in compliance with the specified technical data and under the specified conditions (ambient conditions, IP protection class, measuring category, etc.).
- Do not use the instrument in potentially explosive atmospheres.
- The instrument and the included accessories may only be used for the tests/ measurements described in the instrument's documentation.

Electricity

- Do not use the instrument if the battery compartment cover has been removed. Otherwise you risk touching dangerous voltages.
- Inspect the batteries before use. Pay particular attention to leaking and damage.

2 Applications

Please read this important information!

2.1 Intended Use / Use for Intended Purpose

SECULIFE SP BASE is a digital pulse oximetry simulator. It is intended as a testing instrument for patient monitors. It produces pulses of infrared and red light to simulate various combinations of oxygen saturations, heart rates, and perfusion indices. At the same time it reads the signals from a connected patient monitor.

SECULIFE SP BASE is also designed to function as an accessory for the patient simulator SECULIFE PS300. SECULIFE SP BASE adds the simulation of SpO_2 to the patient simulator's range of parameters.

This instrument must not be used as a medical device. That means, the instrument is intended for testing only and must never be used in diagnostics, treatment or any other capacity where it would come in contact with a patient.

Safety of the operator, as well as that of the instrument, is only assured when it's used for its intended purpose.

2.2 Use for Other than Intended Purpose

Using the instrument for any purposes other than those described in the condensed operating instructions or these instrument operating instructions is contrary to use for intended purpose.

2.3 Liability and Guarantee

Gossen Metrawatt GmbH assumes no liability for property damage, personal injury or consequential damage resulting from improper or incorrect use of the product, in particular due to failure to observe the product documentation. Furthermore, all guarantee claims are rendered null and void in such cases.

2.4 Opening the Instrument / Repairs

The instrument may only be opened by authorized, trained personnel in order to ensure flawless, safe operation and to assure that the guarantee isn't rendered null and void. Even original replacement parts may only be installed by authorized, trained personnel.

Unauthorized modifications to the instrument are prohibited.

If it can be ascertained that the instrument has been opened by unauthorized personnel, no guarantee claims can be honored by the manufacturer with regard to personal safety, measuring accuracy, compliance with applicable safety measures or any consequential damages.

Nor does Gossen Metrawatt GmbH assume any liability for data loss.

3 Documentation

3.1 Identifiers

The following identifiers are used in this documentation:

Identifier	Meaning Safety information that must be complied with	
Attention! Warning		
Note! Important	Important information which must be taken into consider- ation and complied with.	
✓ Prerequisite	A condition etc. which must be fulfilled before a given ac- tion can be taken.	
1. Procedural step	Steps of a procedure which must be completed in the specified order.	
-→ Result	Result of a procedural step.	
EnumerationEnumeration	Bullet lists	
Figure 1: Caption	Description of the content of a figure.	
Tabelle 1:	Description of the content of a table.	
Footnote	Comment	

4 First Steps

Read and adhere to the product documentation. In particular observe all safety information in the documentation, on the product and on the packaging.

- ⇒ "Safety Precautions"
 ■1
- ➡ "Applications" ■3
- ➡ "Documentation" ■4

Familiarize yourself with the product.

- 🗢 "The Instrument" 🗎6
- ⇒ "Menu and Functions" 10
- ➡ "Installation" ■16
- ➡ "Operation" ■17

5 The Instrument

5.1 Scope of Delivery

Please check for completeness.

- 1 SECULIFE SP BASE, product no. M696B
- 1 USB plug-in power supply unit incl. international adapters US/Japan, Euro, GB, China/AUS/NZL
- 1 Cable micro-USB to USB-A
- 1 Cable micro-USB to PS2
- 2 LR6 AA batteries
- 1 Carrying case
- 1 Information CD
- 1 Factory calibration certificate

5.2 Instrument Overview



Figure 2: Front Panel

5.2.1 Symbols on the Instrument and the included Accessories:



Warning concerning a point of danger (attention, observe documentation!)



European conformity marking



The device may not be disposed of with household trash ⇒ "Returns and Environmentally Sound Disposal" <a>25.

5.3 Technical Data

Power	Battery	LR6 AA alkaline battery Voltage: 1.5 V Capacity: 2900 mAh Battery life: 10 h (full backlight)	
Supply	USB plug-in power supply unit	Input: 100 240 V AC, 50/60 Hz, 0.18 A	
		Output: 5 V DC, 1 A	
	Operating temperature:	+15 +40 °C	
Ambient	Storage temperature:	−20 +60 °C	
Conditions	Relative humidity:	max. 80 %, no condensation allowed	
	Elevation:	Not specified	
Electro-	Interference emission:	EN 61325-1:2013 class A	
magnetic Compatibil- ity (EMC)	Interference immunity:	EN 61325-1:2013	
	Protection:	Not specified (IPX0)	
Mechanical	Housing (W \times H \times D):	Approx. 6.35 x 9.53 x 2.54 cm (without finger)	
Design	Weight:	Approx. 170 g (with batteries)	
	Display:	Color touchscreen, 6 cm	
Interfaces		Micro USB	
	SpO ₂	80, 85, 90, 95, 98, 99 %	
	SpO ₂ Accuracy	2 %	
Simulation Parameters	Heart Rate	30, 40, 60, 80, 100, 120, 140, 150, 245 BPM	
	Rate Accuracy	1 %	
	Perfusion index	0.2 %, 2.0 %, 10 %	
Simulation Modes	Manual mode 5 factory presets		
Supported manufac- turer Type	Nellcor, Masimo, Nonin, Philips/HP, BCI	Nihon Kohden, Mindray, GE-Ohmeda,	

5.4 Applied Standards

The instrument has been manufactured and tested in accordance with the following safety regulations:

2014/30/EU	Electromagnetic compatibility (EMC)
2014/35/EU	Low voltage (LVD)
IEC 61 010-1 EN 61 010-1 VDE 0411-1	Safety requirements for electrical equipment for measure- ment, control and laboratory use – General requirements
DIN EN 61 326-1 VDE 0843-20-1	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements
EN 60 529 VDE 0470 Teil 1	Test instruments and test procedures Degrees of protection provided by enclosures (IP code)
EN 61000-3-2	Electromagnetic compatibility (EMC). Part 3-2: Limits. Limits for harmonic current emissions (equipment input current =16 A per phase)
EN 61000-3-3	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Lim- itation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current = 16 A per phase and not subject to conditional con- nection

5.5 Combined Products

Product	Item no.
SECULIFE PS300	M695N

6 Menu and Functions

The instrument is operated via touchscreen.

- Touch a button to open a menu.
- Touch a button repeatedly to advance through a list of options.
- Slide your finger up or down to scroll a scrollable list.

6.1 User Interface

6.1.1 On-screen Indicators

Indicator	Description
	Battery life indicator – Green: Battery level ok – Red: Battery level below 20 %
RED	Input light intensity meters

6.1.2 On-screen lcons and Buttons

Icon/Button	Description
MANUAL MODE Preset Mode	Mode selection
98 140 %Sp02 BPM Nellcor 10 % Perfusion % Perfusion	Selection area
98 %Sp02	Selection field %Sp02
140	Selection field BPM
10 % Perfusion	Selection field %Perfusion
Nellcor	Selection field Monitor

Icon/Button	Description
Setup	Enter setup menu
	Scroll through a list of options
Back	Back to previous menu level
+	Increase a value
-	Decrease a value
Exit	Exit without saving
Save	Save new settings
	Control bar
	Function on/off

6.2 Manual Mode

In manual mode, the user can select individual combinations of $\mbox{SpO}_2\%$, heart rate, and perfusion index.

	MANUAL MODE	
	98	140
-	%SpO2	BPM
	Nellcor	10 % Perfusion
REL	iED 📻 👘	Setup

Figure 1: Manual mode

Selectable parameters in manual mode

Parameters	Options
SpO ₂	80 % 85 % 90 % 95 % 98 % 99 %
Monitors	Nellcor Nonin Nihon Kohden Masimo Mindray GE-Ohmeda Philips/HP BCI

Options
30 BPM
40 BPM
60 BPM
80 BPM
100 BPM
120 BPM
140 BPM
150 BPM
245 BPM
0.2 %
2 %
10 %

6.3 Preset Mode

In preset mode, the user can advance through 5 preset combinations of SpO $_2$ %, heart rate, and perfusion index. These combinations are factory set and not customizable by the user.



Figure 2: Preset mode

Preset combinations

SpO ₂	Heart Rate [BPM]	Perfusion Index
85 %	80	High (2 % perfusion)
95 %	40	High (2 % perfusion)
98 %	80	High (2 % perfusion)

SpO ₂	Heart Rate [BPM]	Perfusion Index
98 %	140	High (2 % perfusion)
99 %	80	Low (0.2 % perfusion)

6.4 Setup Menu

The setup menu is a scrollable list of user configurable options. The setup screen can be accessed at any time by pressing **Setup**.

Figure 3: Setup menu

Configuration options

Parameter	Description	Range
Display Brightness	Adjusts the brightness of the screen	5 %–100 % in 5 % increments
Sounds	Adjusts the volume of all system sounds	0 %–100 % in 5 % increments
Auto Off Timer	Adjusts the timeout that will turn the instru- ment off after a period of inactivity (only appli- cable when the instru- ment is running on bat- tery power)	5–100 minutes in 5 minute in- crements Turning this setting off will dis- able the auto off feature.

Parameter	Description	Range
Auto Dim Timer	Adjust the timeout that will turn the display brightness down to 15 % after a period of inactivity	5–100 minutes in 5 minute in- crements Turning this setting off will dis- able the auto dim feature.
Custom User Offset	Adjusts the derived R- curve value for SpO ₂ setting to a user's pref- erence	+/- 100 adjustment increments
Instrument Information	Displays the current version of the software and any other applicable information	
Update Firmware	Erases the firmware from the instrument in order for the user to update to a newer version of the firmware	

Installation 7

7.1 Unpacking the Instrument

- 1. Carefully remove instrument and accessories from the packaging.
- 2. Check delivery for completeness and possible damage.
- In case of detected damages, hidden defects and short deliveries, document type and scope and contact the manufacturer or supplier immediately.
- 4. Keep packing material for further transport.

Power Supply 7.2

The instrument can be powered by battery, via AC adapter or via a connected monitor.

7.2.1 Establishing Power Supply via AC Adapter

- 1. Connect the USB cable to the Micro USB plug of the instrument.
- 2. Connect the other side of the USB cable to the USB-A plug of the AC adapter.
- 3. Connect the AC adapter to the mains socket.

7.2.2 Establishing Power Supply via connected Monitor

- 1. Connect the sync cable to the Micro USB plug of the instrument.
- 2. Connect the other side of the sync cable to the auxiliary port of a compatible monitor.

7.2.3 Establishing Power Supply by Batteries

- 1. Press the two arrows on the battery compartment lid on the back of the instrument.
- 2. Slide the battery compartment lid down.
- 3. Insert two AA batteries into the battery tray. Ensure the correct polarity.
- 4. Place the battery compartment lid onto the battery tray.
- 5. Push the battery compartment lid gently upwards until it audibly clicks into place.



Decrease screen brightness and audio volume to preserve battery life.

8 **Operation**



Attention!

All connections to patients must be removed before connecting the DUT to the SECULIFE SP BASE. A serious hazard may occur if the patient is connected when testing with the instrument.

8.1 Switching on/off

8.1.1 Switching on the Instrument

- 1. Press the key on/off.
- → The splash screen appears for a few seconds, then the main screen is displayed. The instrument is ready for operation.

8.1.2 Switching off the Instrument

- 1. Press the key on/off.
- \mapsto The instrument is switched off.

8.2 Connecting the Instrument to a DUT

8.2.1 Applying Finger Cuff

- 1. Attach the finger cuff to the top of the instrument placing the cuff LEDs on bottom and the cuff sensor on top.
- → The the sensor's light pulses enter the back of the finger portion of the instrument.



Figure 4: Correct position of finger cuff

8.2.2 Connecting the Instrument to a SECULIFE PS300 Patient Simulator (Sync Mode)

The instrument can be connected directly to a SECULIFE PS300 patient simulator equipped with an SpO₂ pulse output. In this configuration the instrument can synchronize its pulsating output heart rate with the settings of the patient simulator. SECULIFE SP BASE adds the simulation of SpO₂ to the patient simulator's range of parameters.

- \checkmark The connected monitor is enabled.
- \checkmark The SpO₂ output of the connected patient simulator is activated.
- 1. Connect the sync cable to the instrument.
- 2. Connect the other side of the sync cable to the auxiliary port of the patient monitor.
- → The instrument synchronizes its pulsating output heart rate with the settings of the patient monitor.

For more information, refer to the operating instructions of SECULIFE PS300.



Figure 5: Connection in Sync Mode

8.3 Adjusting Simulation Environment

8.3.1 Selecting Monitor

Use this option to select the manufacturer of the patient monitor to be tested.

- ✓ Manual mode is selected.
- 1. Repeatedly touch the selection field **Monitor** in the selection area until the desired monitor is displayed.
- → The desired monitor is set.

The instrument has a built-in memory to save the current selected manufacturer of the patient monitoring system when the instrument is turned off. When switching the instrument on again, the latest settings are recalled automatically.

8.3.2 Selecting individual Parameters

✓ Manual Mode is selected.

- 1. Repeatedly touch the selection field **%Sp0**₂, **BPM** or **%Perfusion** in the selection area until the desired value is displayed.
- \mapsto The desired value is set.

8.3.3 Selecting preset Parameters

- 1. Touch the mode selection button to change to **PRESET MODE**. A list of preset combinations of SpO₂ %, heart rate, and perfusion index is displayed.
- 2. Touch the upper scroll button to select the desired preset combination. The selected combination is highlighted.
- 3. Touch the lower scroll button to select the desired monitor.
- 4. Touch the mode selection button to turn back to MANUAL MODE.
- \mapsto The selected combination is set.

8.4 Changing Setup Configuration

8.4.1 Changing Display Brightness

- 1. Touch Setup.
- 2. Select Display Brightness.
- 3. Slide the control bar with your finger to adjust the display brightness in a range between 5 % to 100 % in 5 % increments.
- 4. Touch **Back** to save the new settings.

8.4.2 Adjusting the Volume of System Sounds

- 1. Touch Setup.
- 2. Select Sounds.
- 3. Slide the control bar with your finger to adjust the volume of all system sounds in a range between 5 % to 100 % in 5 % increments.
- 4. Set the function switch to off to turn the sound off.
- 5. Set the function switch to **on** to turn the sound on again.
- 6. Touch **Back** to save the new settings.

8.4.3 Setting Auto Off Timer

Adjusts the timeout that will turn the instrument off after a period of inactivity.

- ✓ The instrument is running on battery power.
- 1. Touch Setup.
- 2. Select Auto Off Timer.
- 3. Slide the control bar with your finger to adjust the timeout in a range between 5 to 100 minutes in 5 minute increments.
- 4. Set the function switch to **off** to disable the timeout.
- 5. Set the function switch to **on** to enable the timeout again.

8.4.4 Setting Auto Dim Timer

Adjusts the timeout that will turn the display brightness down to 15 % after a period of inactivity.

- 1. Touch Setup.
- 2. Select Auto Dim Timer.
- 3. Slide the control bar with your finger to adjust the timeout in a range between 5 to 100 minutes in 5 minute increments.
- 4. Set the function switch to off to disable the timeout.
- 5. Set the function switch to on to enable the timeout again.

8.4.5 Selecting Custom User Offsets



Attention!

These adjustments must be used with caution as they will allow the user to adjust the output results to invalid values.

These adjustments should only be used to aid in the simplification of testing and with documented controls.



Figure 6: Offset menu

- \checkmark The desired monitor is selected.
- 1. Touch Setup.
- 2. Select OFFSET MENU.
- 3. Touch the scroll button and select the SpO₂-setting you want to adjust.
- 4. Touch + to increase the factory-programmed R-curve.

- 5. Touch to decrease the factory-programmed R-curve.
- ➡ The current adjustment value is displayed. (The current adjustment value does not have a direct correlation to the displayed SpO₂ value on the DUT.)
- 6. Touch Exit to return to the main screen without changes.
- 7. Touch Save to save the new settings.
- → The operating screen displays the SpO₂ setting in red letters on the main screen and with a red highlighted bar on the preset screen.

Note!

There are no absolute standards for pulse oximetry, and each manufacturer has defined its own proprietary R-curve. For this reason, some oximeter readings may be outside of an acceptable range.

8.5 Displaying Instrument Information

- 1. Touch Setup.
- 2. Select Instrument Information.
- ➡ The current version of the software and any other applicable information is displayed.

8.6 Updating Firmware

Erases the firmware from the instrument in order to update to a newer version of the firmware.

- 1. Touch Setup.
- 2. Select Update Firmware.
- A warning message is displayed: "Warning! Pressing OK will erase current program. New program must be loaded by the user."
- 3. Touch OK to confirm.
- → The current firmware is erased from the instrument.
- 4. Touch **Back** to return to the setup menu without changes.

9 Maintenance

9.1 Cleaning

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Attention!

Do not immerse.

Clean the instrument by wiping it gently with a damp, lint-free cloth. A mild detergent can be used if desired.

9.2 Maintenance

To ensure the accuracy of the instrument, the instrument must be calibrated at least once every 12 months. Calibration must be performed by the indicated Calibration Center in order to maintain the lifetime warranty.

⇒ "Repair and Replacement Parts Service Calibration Center * and Rental Instrument Service"

9.3 Troubleshooting

In the following we list common problems that may occur during operation and suggest remedies for the elimination of simple faults. If the recommended procedures do not succeed, please contact our Service Center.

Problem	Remedy
The display remains dark after switch-	Power supply by battery:
ing on.	 Check if batteries are inserted.
	 Check if the batteries are inserted correctly (polarity).
	Power supply via AC adapter:
	 Check if the USB cable is firmly connected to the instrument and to the AC adapter.
	Power supply via connected monitor:
	 Check if the sync cable is firmly connected to the instrument and to the connected patient monitor.

9.4 Repair

The instrument is intended to be serviced only by authorized service personnel. Service procedures should only be performed by qualified technical personnel.

⇒ "Repair and Replacement Parts Service Calibration Center * and Rental Instrument Service" <a>[]26

10 Returns and Environmentally Sound Disposal

This instrument is subject to directive 2012/19/EC on Waste Electrical and Electronic Equipment (WEEE) and its German national equivalent implemented as the Waste Electrical and Electronic Equipment Act (ElektroG) on the marketing, return and environmentally sound disposal of electrical and electronic equipment. The instrument is a category 9 product (monitoring and control instrument) in accordance with ElektroG (German Waste Electrical and Electronic Equipment Act).



The symbol at the left indicates that this device and its electronic accessories must be disposed of in accordance with applicable legal regulations, and not together with household waste. In order to dispose of the device, bring it to a designated collection point or contact our product support department (\Rightarrow "Product Support" **1**26).

This instrument is also subject to directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators and its German national equivalent implemented as the Battery Act (BattG) on the marketing, return and environmentally sound disposal of batteries and accumulators.



The symbol at the left indicates that batteries and rechargeable batteries must be disposed of in accordance with applicable legal regulations. Batteries and rechargeable batteries may not be disposed of with household waste. In order to dispose of the batteries or rechargeable batteries, remove them from the instrument and bring them to a designated collection point.

Separate disposal and recycling conserves resources and protects our health and the environment.

Current and further information is available on our website at http://www.gossenmetrawatt.com under the search terms "WEEE" and "environmental protection".

11 Service and Support

11.1 Product Support

If required please contact:

Gossen Metrawatt GmbHProduct Support HotlinePhone+49-911-8602-0Fax+49 911 8602-709Emailsupport@gossenmetrawatt.com

11.2 Repair and Replacement Parts Service Calibration Center * and Rental Instrument Service

If required please contact:

GMC-I Service GmbH			
Service-Center			
Beuthener Straße 41			
90471 Nürnberg • Germany			
Phone	+49 911 817718-0		
Fax	+49 911 817718-253		
Email	service@gossenmetrawatt.com		
Web	www.gmci-service.com		

This address is only valid in Germany.

Please contact our representatives or subsidiaries for service in other countries.

Competent Partner

Gossen Metrawatt GmbH is certified in accordance with DIN EN ISO 9001.

Our **DAkkS calibration laboratory** is accredited by the Deutsche Akkreditierungsstelle GmbH (national accreditation body for the Federal Republic of Germany) under registration number D-K-15080-01-01 in accordance with DIN EN ISO/IEC 17025.

Accredited quantities: direct voltage, direct current value, direct current resistance, alternating voltage, alternating current value, AC active power, AC apparent power, DC power, capacitance, frequency and temperature.

We offer a complete range of expertise in the field of metrology: from test reports and factory calibration certificates right on up to DAkkS calibration certificates.

An on-site DAkkS calibration station is an integral part of our service department. If errors are discovered during calibration, our specialized personnel are capable of completing repairs using original replacement parts.

As a full service calibration laboratory, we can calibrate instruments from other manufacturers as well.

Our spectrum of offerings is rounded out with free test equipment management.

12 CE Declaration

The instrument fulfills all requirements of applicable EU directives and national regulations. We confirm this with the CE mark. The CE Declaration of Conformity is available upon request.

A factory calibration certificate or test report is included with the instrument.

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