HUNTLEIGH

Anwendungshinweise

Kullanım Talimatları

Brugsvejledning

Instrucciones de uso

χρήσης

使用方法

Mode d’emploi

Gebruiksaanwijzing

Bruksanvisning

INSTRUCTIONS FOR USE

Bruksanvisning

limatları

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Οδηγίες χρήσης

Anwendungshinweise

smartsigns® MiniPulse

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1. Quality, Reliability & Safety

This section contains important safety information related to the use of the Smartsigns® MiniPulse pulse oximeter. Other important safety information appears throughout the manual.

Before using this equipment, please study this manual carefully and familiarise yourself with the controls, displays and operating techniques.

All modifications and repairs must be carried out by a qualified service engineer, agent or hospital technician authorised by Huntleigh Healthcare.

	Atttention, consult accompanying documents / Instructions for Use
Warning	The Smartsigns® MiniPulse pulse oximeter should only be operated by qualified personnel.
Warning	Do not use the Smartsigns® MiniPulse pulse oximeter in the presence of flammable anesthetics.
Warning	Apart from the batteries, there are no user-serviceable parts inside the instrument.
Warning	To ensure accurate performance and prevent device failure, do not expose the Smartsigns® MiniPulse pulse oximeter to extreme moisture.
Caution	The Smartsigns® MiniPulse pulse oximeter is intended only as an adjunct to patient assessment. It must be used in conjunction with all clinical signs and symptoms
Warning	Pulse oximetry readings and pulse signals can be affected by certain ambient, environmental and certain patient conditions.
Warning	Do not use the Smartsigns® MiniPulse during magnetic resonance imaging (MRI) scanning
Caution	Do not autoclave, or use ethylene oxide sterilization process on any part or accessory of the system. Do not immerse the system in any liquid.
Caution	Electromagnetic Compatibility (EMC). This product complies with the requirements of applicable EMC Standards. The use of accessories not specified by the manufacturer may result in increased emissions by, or decreased immunity of, the equipment, affecting its performance.

2. Introduction

2.1 Unpacking

Carefully remove the Smartsigns® MiniPulse and its accessories from the shipping carton. Save the packing materials in case the device must be shipped or stored.

2.2 Preliminary Checks

Huntleigh Healthcare takes every precaution to ensure that their products reach you in perfect condition. We recommend that a thorough visual inspection is made prior to installation.

Should any damage be evident or any part missing, please ensure that Huntleigh Healthcare, Diagnostic Products Division are informed at once.

Each system is supplied with the following accessories:

Item	MP1	MP1R
1 x Smartsigns® MiniPulse 1 pulse oximeter	•	
1 x Smartsigns® MiniPulse 1R pulse oximeter		•
1 x SpO_2 Sensor	•	•
4 x AA high capacity alkaline batteries	•	
4 x Rechargeable AA NiMH batteries		•
1 x Desk stand with integrated charger		•
1 x Charger wall cube		•
1 x Instructions for Use	•	•

2.3 Recommended Clinical Applications

The Smartsigns® MiniPulse handheld pulse oximeter is intended for non-invasive continuous or spot check monitoring of functional arterial oxygen saturation (SpO_2%), and pulse rate.

2.3.1 Intended Use

The Smartsigns® MiniPulse pulse oximeter is intended for use by healthcare professionals for monitoring adult and paediatric patients in hospitals and hospital-type facilities. A range of sensors are available for use with the MP1/ MP1R. These are listed in section 2.4 along with details of each application site. Under low perfusion or patient motion conditions, the displayed pulse rate and SpO_2 may become erratic or intermittent. In these circumstances, reposition the sensor and ensure the patient remains still.

2.3.2 Indications for Use

The specific medical indications for the use of this device are:

- This device is a prescription device.
- This device is reusable and is intended for spot or continuous measurement.
- This device is intended to display oxygen saturation, heart rate and pulse strength or pulsatile signal.
- This device is intended to indicate an alarm if the measured saturation or heart rate are outside user-set alarm limits.

Warning	**The Smartsigns® MiniPulse pulse oximeter is designed for attended monitoring only and must be used under the direct observation of a qualified health care provider.**
Warning	**The MP1R must not be charged when connected to a patient.** **The MP1R cannot be used while being charged.**
Warning	**Any doubt concerning the accuracy of any measurement, an alternative method should be used.**
Warning	**In extreme situations, tissue damage can be caused by incorrect application or duration of use of the SpO_2 probe. Regularly inspect the probe site.**

Caution	**Ambient light, movement, low patient perfusion, electromagnetic interference, artefacts, dysfunctional haemoglobin, and certain dyes, may interfere with the pulse oximeter's function.**
Caution	**Do not autoclave, or use ethylene oxide sterilization process on any part or accessory of the system.** **Do not immerse the system in any liquid.**

2.3.3 Contra Indications

Inaccurate measurements may be caused by:

- Excessive patient movement
- Venous pulsations
- Intravascular dyes, such as indocyanine green or methylene blue
- Significant levels of dysfunctional haemoglobin
- Defibrillation

2.4 Recommended Sensors

Description	Application Site	Part No.
Adult Sensor	Finger	ACC-VSM-171M
3178 Pediatric Sensor	Finger	ACC-VSM-170
3043 Universal Y Sensor	Finger/Toe - Adult/Paediatric Hand/Foot - Infant	ACC-VSM-169
3025 Infant Wrap Sensor	Toe	ACC-VSM-167

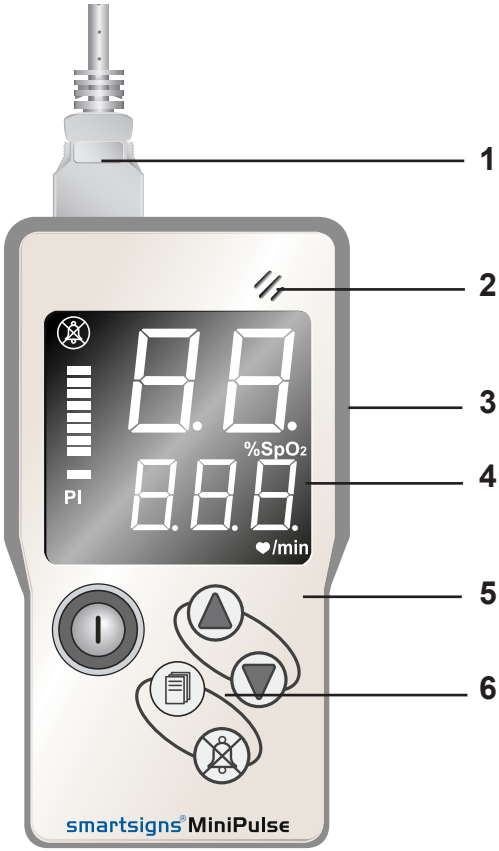
2.5 Accessories

Item	Part No.
Pole Clamp	ACC47
Carry Case	ACC-VSM-172
Desk stand (MP1)	ACC-VSM-173
Desk stand with integrated charger (MP1R)	ACC-VSM-174

3. Controls, Indicators, Symbols & Displays

3.1 Front panel

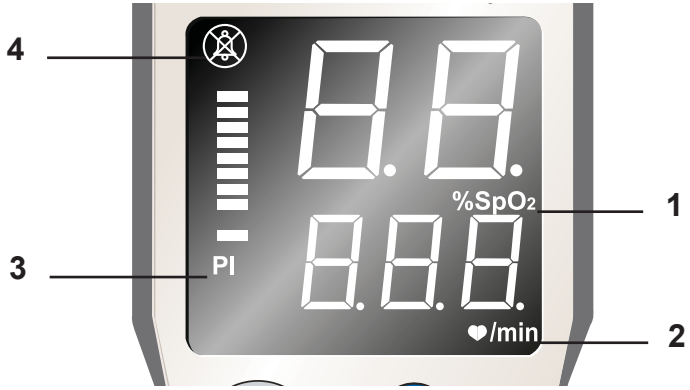
Item	Description
1	Sensor connection
2	Loudspeaker
3	Protective grip
4	Display
5	Front Panel
6	Keypad



3.2 Keypad

Button	Description	Button	Description
	Power - ON / OFF Key		Up Key
	MENU – Alarm limits and Pulse tone setting		Down Key
	Alarm suspend - turns the alarms ON or OFF. Press and hold for 2 seconds to permanently disable the alarms; the system will sound a confirmation tone.		

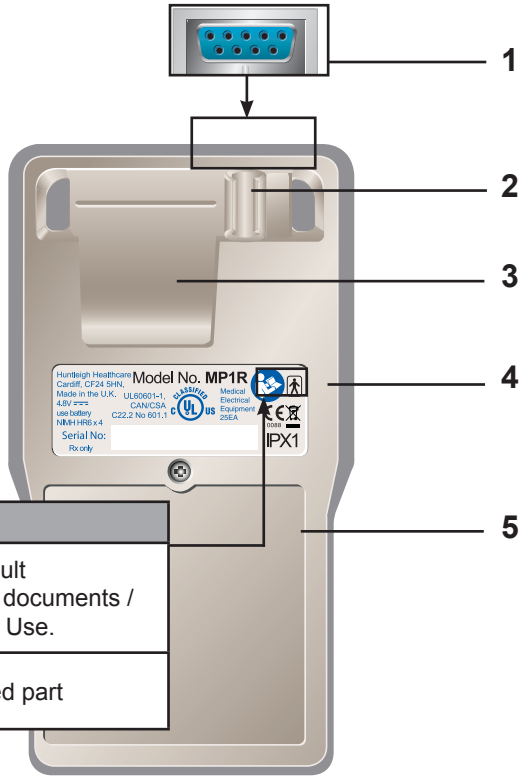
3.3 Displays and Audible Alarms



Item	Description	
1	**%SpO$_2$**	• Patient's saturation • 'Flashing' alarm threshold exceeded
2	**♥/min**	• Patient's pulse rate • 'Flashing' alarm threshold exceeded
3	Pulse Strength	• 8-segment bar graph pulse indicator (PI) and pulse strength
4	Alarm suspend	• Illuminated - Alarm OFF

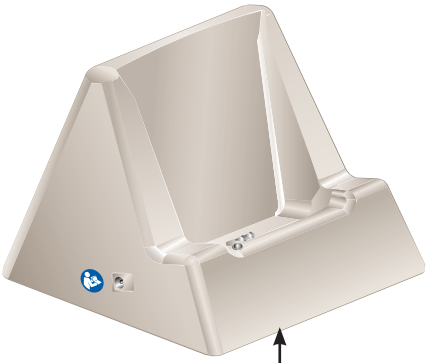
3.4 Rear panel

Item	Description
1	Probe socket
2	Probe storage
3	Belt Clip
4	Rear panel
5	Battery cover

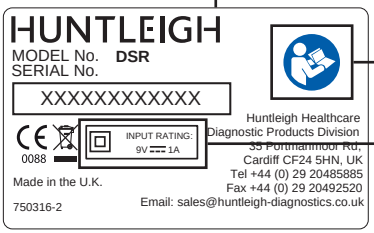


Symbol	Description
	Attention, consult accompanying documents / Instructions for Use.
	Type BF applied part

3.5 DeskStand / Charger



Symbol	Description
	Only use the PSU provided with the product.
	Class II Electrical Equipment



3.5.1 Connecting to Power Supply

Connect the power supply to the desk stand and connect to mains supply.

3.5.2 Battery charging LED status

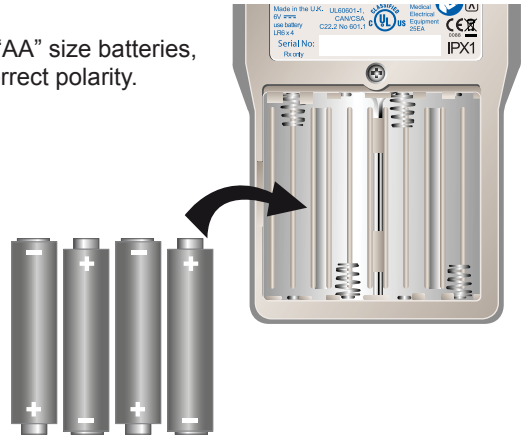
- **Red** **Battery conditioning**
- **Amber** **Charging**
- **Green** **Charged**

4. Set-Up

4.1 Battery Installation - MP1

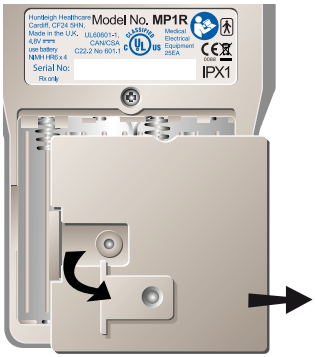
1. Slide the battery compartment latch across to remove the battery cover.

2. Install four “AA” size batteries, ensuring correct polarity.



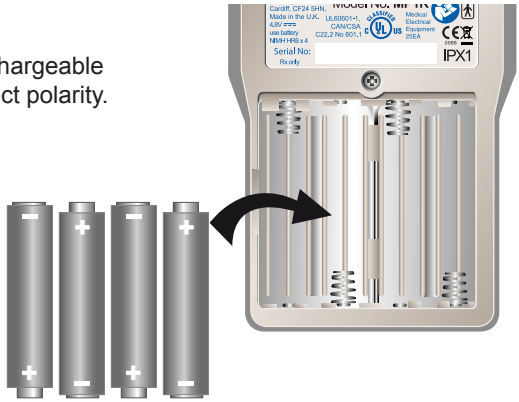
3. Replace the Battery cover before use.

4.2 Battery Installation - MP1R



1. Remove the securing screw and the battery cover.

2. Install four “AA” size rechargeable batteries, ensuring correct polarity.



3. Replace the Battery cover before use.

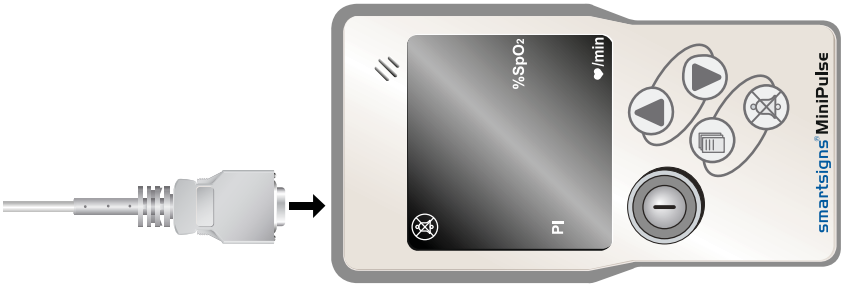
Caution: Use only the prescribed batteries with the system.

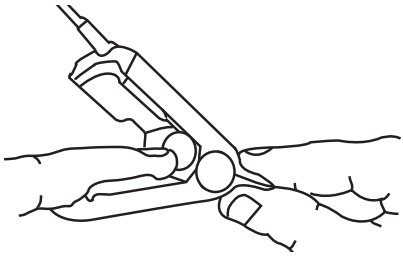
Note: Do not mix alkaline “AA” batteries with rechargeable batteries. When replacing batteries, replace with four fresh batteries. Do not mix new and used batteries.

4.3 Probe Installation and Use

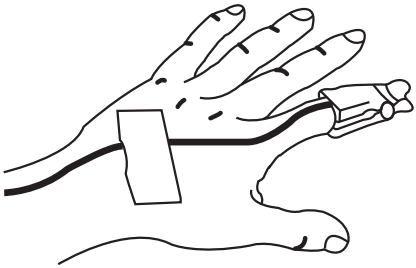
Warning	**Before use, carefully read the probe manufacturers directions for use, including all warnings, cautions, and instructions.**
Warning	**Do not use a damaged probe. Do not use a probe with exposed optical components.**
Warning	**Use *only* BCI sensors for SpO_2 measurements (see section 2.4). Other sensors may cause damage.**
Warning	**Incorrectly applied sensors may give inaccurate readings.**

1. Connect the probe to the pulse oximeter.





2. Insert the patient's finger into the tip of the oximeter probe



3. Ensure the cable extends along the top of the patient's hand.

5. Operation

5.1 Switching the Unit ON

Warning	Do not lift the unit by the probe cable.

Press the ON/OFF button  .

During power up, the system will perform a self test, illuminate the displays for 2 seconds and enter the measurement mode.

5.2 System Operation

With the system connected to a patient, the oximeter will search for a pulse.

After a short period the system will display the patient's saturation level and pulse rate. The pulse indicator will be synchronised with the audible pulse tone (If enabled).

The frequency of the pulse tone is closely related with saturation level; lower tones indicate lower saturation levels.

After 2 mins, the display will reduce to a level which is equivalent to 50% output intensity; press any key to re-establish the normal display intensity setting.

The display will automatically brighten in the event of an alarm condition.

If there is no finger connected to the sensor, the %SpO_2 and Pulse Rate (**♥/min)** will display:

If no probe is connected to the system, the unit will turn off automatically after 3 minutes.

Warning	**Reposition the probe at least once every 4 hours to allow the patient's skin to respire.**

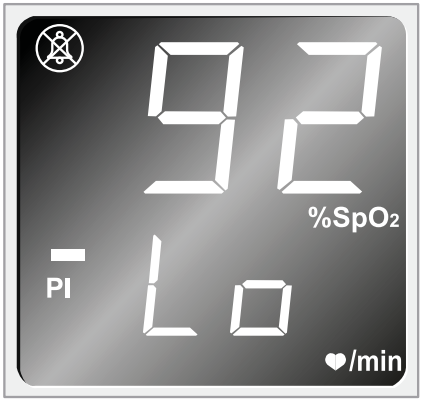
5.3 Setting the Alarms

The default setting for the alarms are:-

- SpO_2 Low 92%
- SpO_2 High 99%
- HR Low 50BPM
- HR High 150BPM

Press the MENU button to enter the Alarm Setup mode.

The display will change to :



Press the UP or DOWN button to adjust the SpO_2 low setting.

Press the MENU button to select the SpO_2 high setting.
Press the UP or DOWN button to adjust the SpO_2 High setting.

Press the MENU button to select the HR Low setting.
Press UP or DOWN button to adjust the setting.

Press he MENU button to select the HR High setting.
Press the UP or DOWN button to adjust the setting.

Press the MENU button to save the settings.

5.4 Setting the pulse tone

Press the MENU button five times to display the Pulse Tone set-up option.
Press the UP or DOWN key to set the pulse tone

Setting	Display
• OFF	PB OFF
• ON	PB ON

Press the MENU button to save the settings.

5.5 Pulse Strength

Press and hold the UP button to display the Pulse Strength. The bar graph will illuminate according to the strength of the pulse signal.

Good Quality

Poor Quality

5.6 Switching the Unit OFF

Press the ON/OFF button  to switch the unit OFF.

6. Care of Your Equipment

It is recommended that the unit and accessories are inspected and tested on a regular basis.

If any part of the system appears to be damaged, the system should be returned to your service centre for repair.

6.1 Storage

Remove the batteries from the unit before long-term storage.

6.2 Cleaning and Disinfecting

Warning	**Turn the Pulse Oximeter OFF before cleaning.**

6.2.1 Care of the Sensor

Clean the probe after each use.

Clean the surface of the sensor and cable with a soft gauze pad by saturating it with a solution of 70% isopropyl alcohol. If low level disinfection is required, use a 1:10 bleach solution.

6.2.2 Care of the Unit

If cleaning is required, wipe the Pulse Oximeter's surfaces with a soft cloth moistened with a non-abrasive cleaner.

Do not allow any liquid to enter any of the system.

7. Specifications

Electrical

Power requirements	
MP1	4 x AA high capacity alkaline batteries
MP1R	4 x AA rechargeable NiMH ≥ 2500mAH cells
Battery Life MP1	60 hours typical
Battery Life MP1R	60 hours typical before recharge is required
Charger MP1R only	
Type	Desk top stand with wall mount power supply
Charge time	6.5 Hours to full charge Built in protection for under / over charge
Wall cube	Input voltage 100 – 240 VAC 60Hz Output 9V ⎓ @ 6VA

General

Dimensions	75 x 140 x 25mm (excluding desk stand, sensor and wall cube)
Weight	300gm (excluding desk stand, sensor and wall cube)
Display indicators	• SpO_2 • Pulse rate • Pulse strength • Alarm status • Charge status (desk stand only)
Alarms	Audible and visual alarms for high and low saturation and pulse rate Synchronized saturation tone

Environmental

Operating temperature	5°C to 40°C
Storage temperature	-40°C to +70°C
Humidity	5% to 95% non condensing
Pressure	600mbar – 1080mbar

SpO_2 /Pulse Rate

%Saturation	
Range	0 – 99% Functional SpO_2 (1% increments)
Accuracy	Adults +/-2% @ 70 – 99% SpO_2 < 70% undefined
Averaging	8 beats
Pulse Rate	
Range	30 – 254 BPM (1 BPM increments)
Accuracy	Better than +/-2 BPM or +/-2%
Averaging	8 seconds
Bargraph	0 – 8 segments providing pulsatile signal or pulse strength
Calibration	Factory calibrated over range 70% to 100%

Compliance

Equipment classification	CLASSIFIED c UL us Medical Electrical Equipment 25EA IEC60601-1, WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY, IN ACCORDANCE WITH UL60601-1, CAN/CSA C22.2 No 601.1 and ISO 9919.
EMC compliance	EN55011 Group 1 Class B, EN60601-1-2, EN61000-3-2, EN61000-3-3
Degree of protection	Type BF
Degree of protection against ingress of water	IPX1

8. Trouble Shooting

Problem	Possible Cause	Corrective Action
Unit will not switch on	Depleted batteries	Replace batteries (MP1) Recharge batteries (MP1R)
Unit switches on but switches off after a short time when not connected to a patient.	Auto off set	Contact Service Dept. (see section 11).
Display goes DIM after a few minutes	Ad (Auto dim) set	Contact Service Dept. (see section 11).
No Fin displayed when connected to a patient.	Faulty sensor	Replace sensor
No Prb displayed when sensor connected	Faulty sensor	Replace sensor
Pulse rate erratic, intermittent or incorrect.	Sensor incorrectly positioned. Poor patient perfusion. Patient motion.	Reposition sensor on patient. Patient must be still for unit to function properly.
Charge lamp does not illuminate when unit placed on charger	Charger wall cube not connected to mains power or to the charger cradle. Open circuit/ faulty batteries. Dirty charger/ MP1R contacts. Faulty charger	Check power and connection. Check/ replace batteries. Clean contacts. Test by shorting charger contacts with metal object charge lamp should go RED.
Charge lamp illuminates and stays RED continuously.	Faulty batteries	Replace batteries
Batteries charge normally but unit runs only for a short time	Faulty batteries	Replace batteries
No bleep from MP1R when placed in charger cradle.	Batteries have insufficient charge. No power to charger Dirty charger contacts	Recharge batteries Connect power to charger. Clean contacts.
MP1/MP1R displays “Err”	Internal system error	Return to supplier for service

9. Maintenance

Huntleigh Healthcare recommends that preventative maintenance checks are carried out at least annually.
Maintenance must only be carried out by qualified personnel.

10. Warranty

The system (hand held device) is guaranteed for a period of 60 months from the date of purchase.
The warranty does not cover the following:

- Damage to the device resulting from misuse.
- Damage to the device resulting from connection of 'non approved' sensors.
- Changes performed by users without the prior written authorisation of the company.

Huntleigh Healthcare Diagnostic Products Division standard terms and conditions apply to all sales. A copy is available on request. These contain full details of warranty terms and do not limit the statutory rights of the consumer.

11. Service

If for any reason the unit has to be returned, please:

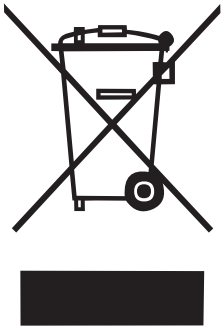
- Clean the product following the instructions in this manual.
- Pack it in suitable packing.
- Attach a decontamination certificate (or other statement declaring that the product has been cleaned) to the outside of the package.
- Mark the package 'Service Department '

Huntleigh Healthcare reserve the right to return product that does not contain a decontamination certificate.

Return the product to:

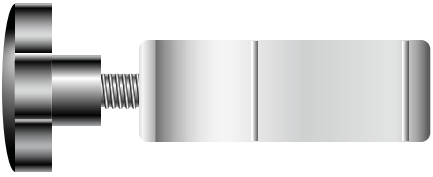
ArjoHuntleigh
50N Gary Avenue
Roselle, Illinois 60172
USA.
T: 800-323-1245 X57928

12. End of Life Disposal



This symbol signifies that this product, including its accessories and consumables is subject to the WEEE (Waste Electrical and Electronic Equipment) regulations and should be disposed of responsibly in accordance with local procedures.

13. I.V. Pole Fixing



Pole Clamp

1. **Slide the pole clamp underneath the belt clip on unit and fix securely to the I.V pole (see Figure 1 below).**

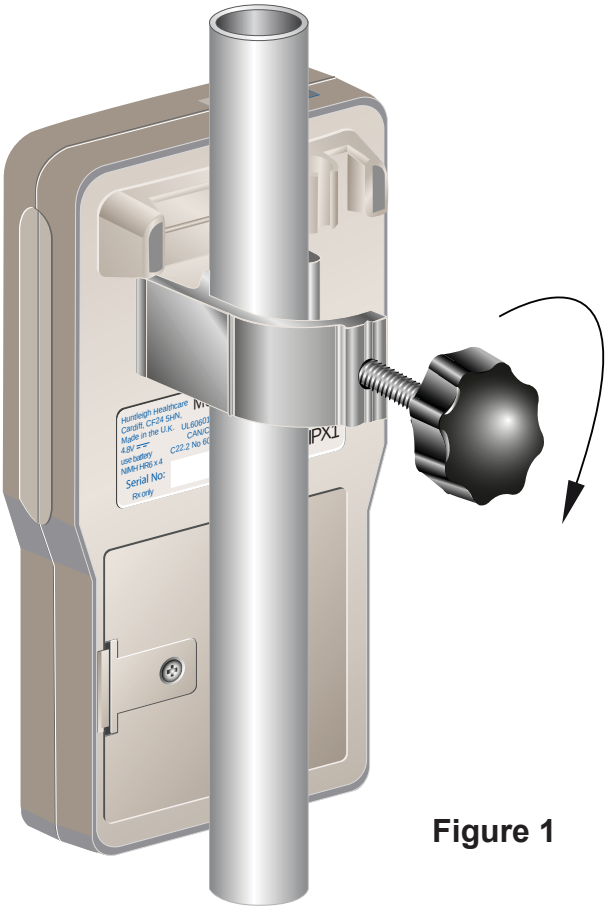


Figure 1

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The Smartsigns® Minipulse is in conformity with the Medical Devices Directive 93/42/EEC as amended by 2007/47/EC and has been subject to the conformity assurance procedures laid down by the Council Directive

Manufactured in the UK by Huntleigh Healthcare Ltd.
As part of the ongoing development programme the company reserves the right to modify specifications and materials without notice.

As a proud member of the Arjo family, we have been committed to supporting healthcare professionals in improving outcomes and enhancing patient wellbeing since 1979. We do this through our proven solutions for Vascular Assessment & Treatment and Fetal & Patient Monitoring. With innovation and customer satisfaction as our guiding principles, we strive for clinical excellence and improved performance, for life.

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