

HALO[®]
MEDICAL DEVICES



Digital Goniometer

Quick-start Guide

HALO Digital Goniometer

Quick-start Guide

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www.halommedicaldevices.com

techsupport@halommedicaldevices.com

Important Safety Instructions

Laser safety and user responsibility

The lasers used in the HALO Digital Goniometer are a low level Class 1 laser. The device has a laser warning on the outer packaging and case.

Looking or staring into the laser should be avoided. If the patient or user does not have a normal blink reflex, then safety glasses must be worn when using the HALO.

HALO Medical Devices accepts no responsibility if the laser has been used incorrectly, if the beam is stared into or the device misused, or if this safety warning has not been adhered to. If you do not know what a normal blink reflex is you should seek advice from your doctor. By using the HALO the user takes full responsibility for determining if it is safe to use on patients and around themselves based on the Class 1 laser guidelines.



WARNING: failure to adhere to these guidelines may result in injury to the user or patient.



Congratulations on your purchase
of the next generation
HALO Digital Goniometer.

Welcome to precision therapy!

HALO is the next generation goniometer. It gives clinics, hospitals and universities reproducible and reliable measures when assessing joint range every single time. Designed to be used by qualified and student health-care professionals in elite sports, physiotherapy, occupational therapy, podiatry and veterinary medicine throughout the world, HALO is the leading technology in hand-held joint ranging today.

How to get help



Please read all of this Guide before using the product.

If you are having problems, contact your agent or sales outlet or email HALO Medical Devices direct on the email below.

See the 'SUPPORT' section of the HALO Medical Devices website for tutorials and video demonstrations.

Get the latest user manual at the HALO Medical Devices website.

Website: www.halomedicaldevices.com

Email: techsupport@halomedicaldevices.com

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Unpacking the HALO Digital Goniometer

1 Remove clear film



2 Charge 

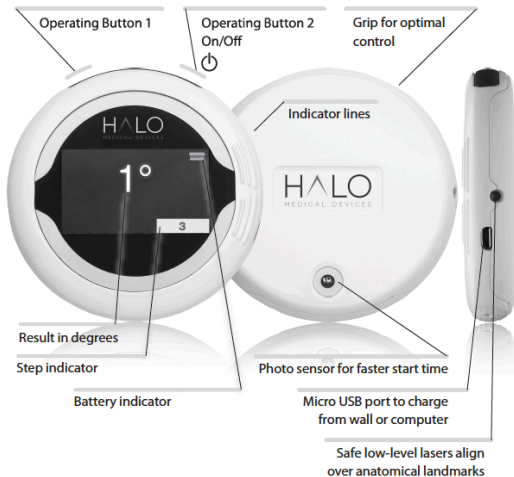
Fully charge your new device. See, *Charging the HALO*.



3 Use

The HALO Digital Goniometer is factory calibrated for your location and is now ready to use. See, *Getting started with your HALO*.

Getting started with your HALO



Where things are

Button 1 is used to take a measurement (in MEASURE MODE). It is also used to navigate the menus.

Button 2 turns the device ON and OFF, takes a measurement (in MEASURE MODE) and is used to navigate the menus.

Operating buttons 1 and 2 are activated by a **rocker mechanism** (like a see-saw) with a pivot in the middle. Do not press in the middle.



Indicator lines are used in automatic mode to show where the zero reference point is.

The **LCD display** shows readings in degrees.

A **battery level indicator** in the top right corner of the display shows the battery status.

Each **step** in the measurement process is shown by a white bar with a number on it.

When activated, a **photo sensor** on the back of the HALO conserves battery life by putting the device into STANDBY MODE when it is laid on flat surface. Pick the HALO up to start it immediately.

Plug the USB cable (supplied) into the **Micro USB port** to charge the battery using the mains to USB power adaptor (supplied) or your computer.

Safe, low-level laser beams align over anatomical landmarks, acting like the arms of a mechanical goniometer.

What you can do with the HALO Digital Goniometer



HALO The Digital Goniometer uses advanced technology to quickly and accurately capture joint angles using a compact, pocket-sized device.



Laser beams on HALO take the place of the plastic arms of a manual goniometer. Using the HALO Digital Goniometer, parallel light beams are projected across the entire limb, intersecting with landmarks on the body from which you take your measurements. You measure from one landmark to another and HALO automatically calculates the angle between them.

First establish the origin of the angle (first position), then rotate the HALO Digital Goniometer to establish the second position. The HALO will calculate the angular difference between position one and position two and display the result in degrees on its large LCD screen.

Advanced motion detectors allow measurements in 3 planes.

There is also a Speed mode, typically used for athletic and elite sports screenings, when multiple, repetitive measurements (such as shoulder range of motion) are required. See, *Speed mode*

How does HALO differ from a manual goniometer?

Compared to a manual goniometer, there are some differences.



1. **Hold the HALO over the limb** to be measured, not over the joint axis. By allowing HALO's laser arms to intersect with the middle of the joint, you achieve greater precision.
2. **Use just one hand.** You can support your patient or record your results with your free hand.
3. **Hold the HALO just above the skin** to achieve zero infection risk. You do not have to press the digital goniometer directly on the skin.
4. **Follow three quick steps** to get any standard joint measurement. Once you master this easy 3-step concept it can be applied to any moving joint.
5. **No interpretation needed.** The result is displayed on a large LCD screen. As you rotate the HALO Digital Goniometer, the numbers remain vertical so that you can easily read your results.

Turning the HALO on and off

To turn the HALO on:

Press and hold Button 2 until the HALO logo appears (about two seconds), then release the button.

A number of degrees will appear on the LCD display.

ON 
↓ 2 SECS
ONLY

STARTUP

READY

The device is now in MEASURE MODE.



To turn the HALO off:

Press and hold Button 2 until the HALO logo appears (about four seconds) then release the button.

The display will go blank.

It is recommended that the device be put into STANDBY MODE to conserve the battery.

See, *Extending Battery Life*.

STANDBY/OFF 
↓ 4 SECS



Before you use the lasers



HALO is designed so that the lasers are only activated when ready to measure (MEASURE MODE). The lasers project towards the limb, to prevent spillover of the beam.

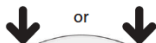
Activating the lasers

! Only activate the lasers when the device is close to the limb to be measured.

Once the HALO is over the limb to be measured, click any operating button to activate the lasers.



LASERS ON



See, *Laser safety and user responsibility* at the start of this booklet and *How to take measurements with HALO*.

Charging your HALO



The device arrives from the factory partially charged (approximately 60% of full charge). While you can use the device immediately, it is recommended that you fully charge your new device.

Using the Mains to USB power adaptor supplied, plug one end of the USB charging cable into the micro USB port on the HALO Digital Goniometer and the other end into the USB power adaptor.



Plug the power adaptor into a mains (240V) wall socket. The device will be fully charged in less than two hours.

Alternatively, you can plug the HALO Digital Goniometer into a USB port on your computer to charge it.



In normal operation, a small on-screen battery-level indicator shows the battery status. When you are charging the battery, a full-screen icon appears briefly to show that charging is taking place.



When does HALO need charging?

When the small on-screen battery-level indicator changes to a plug icon, you have about 5% battery life left and it is time to recharge your device.

In typical use, the HALO Digital Goniometer should operate for a working week.*

*Based on 12–15 patients per day for between 1 and 2 minutes per patient.

NEEDS
CHARGING



How to take measurements with HALO

HALO uses a new concept to standardise joint measurement. Using digital technologies, HALO delivers a new level of accuracy and standardisation to joint range measurements.

If your HALO is not on, turn it on by pressing and holding Button 2 for two seconds. Then follow *The 3-Step overview* process to take a measurement.

Holding the HALO

The HALO Digital Goniometer is designed to be used one-handed, leaving your other hand free to support the patient's limb. With the display facing you, curve your hand around the HALO with your fingers resting on Buttons 1 or 2, whichever is most comfortable.



Only activate the lasers when the device is close to the limb to be measured.

The 3-Step overview

1 Activate the lasers

Once the HALO is over the limb to be measured, click any operating button to activate the lasers. The lasers are used to line up the bony landmarks as you normally would with a manual goniometer.



2 Zero HALO

Once HALO's lasers are aligned over a bony landmark, click any operating button to zero the HALO.

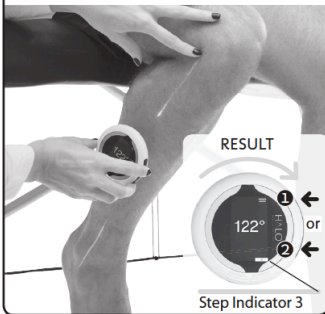


This creates the reference point from which your angle is measured.



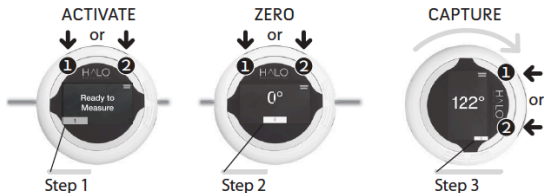
3 Capture

Move the HALO through the joint range you want measured and click any button to capture the angle. The result stays on the screen until you press an operating button and store the angle.



Taking measurements—more detail

There are three steps in taking a measurement. The steps are indicated by the white bars along the base of the display. The Step Indicators change position, moving from left to right across the display and are numbered to show Step 1, Step 2 and Step 3.



In MEASURE MODE, both Button 1 and Button 2 have the same function. Either button can be used to take a measurement.

i You cannot go back a step. If you make a mistake, move forward through Steps 2 and 3 and return to Step 1.

Once the HALO is over the limb to be measured, you will first activate the lasers, establish the origin of the angle (first position), then rotate the HALO Digital Goniometer to establish the second position.

The device will calculate the angular difference between position one and position two and display the result in degrees.

Measurement methods

HALO can be used in two ways to obtain a measurement.

Method 1: For example, measuring knee flexion

First, hold the HALO over the middle of the limb **above the joint** you are measuring (proximal segment). After setting the zero point (Step 2), move the HALO over the middle of the limb **below the joint** you are measuring (distal segment). Complete Step 3 to display your result.



Method 2: For example, measuring ankle dorsi flexion or plantar flexion

Hold the HALO over the middle of the limb below the joint you are measuring (distal segment) and zero the HALO (Step 2). Move the HALO **with the limb** to where the patient's joint range ends. Complete Step 3 to display your result.



This is the normal (default) operating mode.

First measurement

With the HALO on, position the HALO over the limb to be measured. Press either Button 1 or Button 2. The lasers are activated. You are now in MEASURE MODE.

1. With the device in MEASURE MODE, press either Button 1 or Button 2 to begin a measurement. The Step Indicator (white bar) is in the left-hand position and indicates Step 1.
2. To mark the origin of the measurement angle (zero degrees), align the laser on the part of the body representing the origin point, wait until the readout steadies and press a button once. The Step Indicator moves to the middle position and shows Step 2.
3. Rotate the HALO Digital Goniometer to the second position (using the lasers for alignment), wait until the readout is steady and press any button again. The Step Indicator moves to the right-hand position and indicates Step 3.



The resulting measured angle is displayed on the screen in degrees. Your result will continue to be displayed until you either press any button into begin a new measurement, the device goes to standby (1 minute) or you turn it off.

Record your results.

Taking another measurement

1. With the HALO Digital Goniometer still in MEASURE MODE, press any button to begin a new measurement. The Step Indicator returns to 1.
2. Begin your measurement by marking the origin of the measurement angle (zero degrees), then when the readout is steady, press a button once. The Step Indicator moves to 2.
3. Turn the HALO Digital Goniometer to the second position and press any button again. The Step Indicator moves to 3. Your result is displayed on the screen.

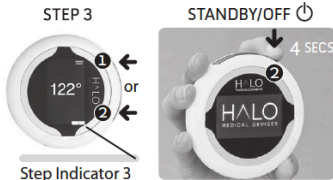
Repeat these steps to take further measurements, recording your results at the end of each measurement.



Remember to deactivate the lasers before removing the device from the patient.

The lasers are turned off automatically at the end of Step 2 of a measurement cycle.

If, for any reason, the lasers are still on, advance to measurement Step 3, or put the device into STANDBY MODE by pressing and holding Button 2 until the HALO logo appears and the display goes blank.



Speed mode

Speed mode is a short-cut method used when multiple, repetitive measurements (such as shoulder range of motion) are required. In Speed mode, measurement is a two-step process.

To change to Speed mode, see *Mode* in *Using the menus*.

With the HALO on, position the HALO over the limb to be measured. Rotate the HALO until the indicator lines on the case are pointing upwards, marking the origin of the measurement angle (zero degrees), then:

1. The Step Indicator (now in the centre of the display) shows 1.
2. Turn the HALO Digital Goniometer to the second position and press any button again. The Step Indicator moves to 2. Your result is displayed on the screen.

Memory Mode

The device stores up to 5 last recorded readings.

Enter Memory Mode

Press and hold Button 1 for 2 seconds, the stored measurements are displayed along with the MEM symbol.

MEM 1	122°
MEM 2	130°
MEM 3	136°
MEM 4	141°
MEM 5	146°

Memory mode



It is accessible via Measurement Mode Step 1 and Step 3.

Exit Memory Mode

Press either button 1 or 2 to exit.

The device will go to Step1 of Measurement Mode .

Caring for your HALO

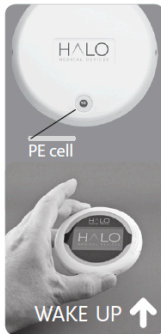
The HALO Digital Goniometer should be operated as described in this Guide and within the parameters of the product specifications. See, *Specifications*. The HALO Digital Goniometer has a durable, impact-resistant case, but, as with any precision measuring device, please handle it with care.

Extending battery life

The photo-electric (PE) cell on the back of the HALO Digital Goniometer (disabled by default) senses when the device is face-up and resting on a flat surface, such as a desk. In this position, no light reaches the sensor on the back and the device is put into STANDBY MODE to conserve the battery.

When the device is picked up, light falls on the sensor, starting the device immediately.

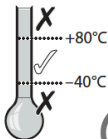
This function can be activated from the Menu. See *PE Cell in Using the menus*.





Cleaning

To clean the device and screen, use a dry cloth. The microfibre wipes used to clean spectacles are also suitable. Do not use water, alcohol or cleaning solvents.



Storage

Store the device in clean, dry place. Do not store in areas where the temperature exceeds 80 degrees C, or falls below -40 degrees C.

Do not immerse the device in water or other liquids, or get it wet.

Do not open the case. Any attempt to tamper with the internal workings of the device will void your warranty.



Using connectors and ports

Important information about connectors, adapters and Buttons:

The USB and Mains to USB power adaptor connectors should not be used with unreasonable force.



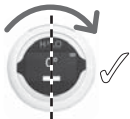
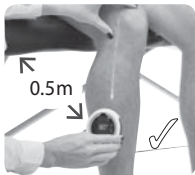
Never force a connector or apply excessive force to a button. If the connector and port do not fit easily then they are not a match. Check the connection port is unobstructed and that the port and connector match.

Contact techsupport@halomedicaldevices.com for further assistance.



Using HALO in medical environments

The HALO Digital Goniometer should not be used in areas where large magnetic devices such as MRI machines are located. The use of such devices may also be restricted in some Intensive Care units. Check with your Hospital or Medical engineering department to ensure the HALO can be used in your area.



For best accuracy, keep the HALO at least 0.5 metres away from large metal objects, such as a plinth, when taking measurements. Rotate the device as close to the axis of rotation as possible.

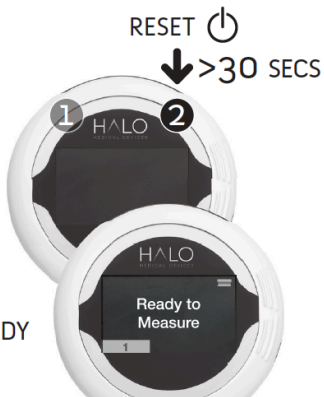
Resetting the HALO

On rare occasions, the device may need to be reset. If the device does not appear to be operating normally, hold Button 2 down for 30 seconds.

The HALO welcome logo will appear followed by the screen displaying "Ready to Measure".

The Unit should now return to MEASURE MODE.

READY



If you are still having problems, contact your agent or sales outlet.

See the *Learn HALO* section of the HALO Medical Devices website for tutorials and video demonstrations, or call the HALO Help Line.

Using the menus

There are 5 menu items.

Enter the menu

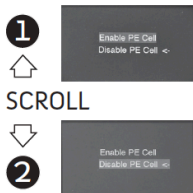
To display the menu, Press Button 1 and Button 2 together.

Exit the menu

To exit from the menu, hold down Button 1 for four seconds. This returns you to MEASURE MODE.

Scrolling

Scroll down with Button 2, up with Button 1. An arrow shows the currently active option. A blue highlight shows your selection.



Choosing a menu item

Options

When the main menu list is displayed, the following options appear:

- **Memory** – shows up to 5 last recorded readings.
- **PE Cell** – allows you to activate or deactivate STANDBY MODE.
- **Mode** – allows you to choose between Normal and Speed modes.
- **Diagnostics** – allows you to test the LCD display and show technical troubleshooting information.
- **About** – shows information about the software version of your device.

Navigation

Navigate to the option of your choice using the buttons to move up or down.

To choose a menu item, press Button 1 and 2 together. To return to the main menu list, press Buttons 1 and 2 at the same time.





See, the website at: www.halomedicaldevices.com for more information on the menus and when to use each menu item.

Memory Mode

The device allows you to store up to 5 last recorded reading. The last stored reading is displayed along with the MEM symbol.



MEM 1	122°
MEM 2	130°
MEM 3	136°
MEM 4	141°
MEM 5	146°

Clear the memory

To clear the memory, power off the device.



See, the website at: www.halomedicaldevices.com for more information on the menus and when to use each menu item.

PE Cell (photo sensor)

When enabled, a photo sensor on the back of the HALO conserves battery life by putting the device into STANDBY MODE when it is laid on flat surface. The HALO comes from the factory with the PE Cell disabled.



There are two options in this list:

- **Enable** PE Cell
- **Disable** PE Cell

To move between options, scroll down with Button 2, up with Button 1.

Select an option by pressing both buttons together.

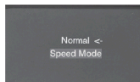
To return to the main menu list, press Buttons 1 and 2 together.

Exit the menu

To exit from the menu, hold down Button 1 for four seconds. This returns you to MEASURE MODE.

Mode

Choose between Normal and Speed modes.



Normal mode

Normal mode is the default operating mode of the HALO Digital Goniometer, taking you through three steps using all three planes (horizontal, frontal and coronal) to take measurements.

Speed mode

Speed mode reduces the number of measurement steps.

To move between options, scroll down with Button 2, up with Button 1.

Select an option by pressing both buttons together.

To exit this option and return to the main menu list, press Buttons 1 and 2 together.

Diagnostics

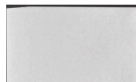
There are three options in this list:

- LCD
- Magnetometer
- Sensor



LCD

The LCD setting is used to check that all pixels in the display screen are functioning. Choose this option to test the LCD display.



Magnetometer

Magnetometer calibration procedure can be found on the HALO Medical Devices website.



Sensor

The Sensor setting is used to establish that the internal magnetometer, accelerometer and gyrometer functions are operating correctly. A stream of diagnostic data is displayed. This information can be interpreted with the aid of a HALO Medical Devices Help Line assistant or the HALO Medical Devices website.

To move between options, scroll down with Button 2, up with Button 1.

Select an option by pressing both buttons together.

To return to the main menu list, press Buttons 1 and 2 together.

Exit the menu

To exit from the menu, hold down Button 1 for four seconds. This returns you to MEASURE MODE.

About

Here a single screen shows information about the software version of your device.

To move between options, scroll down with Button 2, up with Button 1.

Select an option by pressing both buttons together.

To return to the main menu list, press Buttons 1 and 2 together.

Exit the menu

To exit from the menu, hold down Button 1 for four seconds. This returns you to MEASURE MODE.

General information

Support and troubleshooting

For support and troubleshooting information, see the HALO Medical Devices website at: www.halomedicaldevices.com, or email the HALO Medical Devices Team at techsupport@halomedicaldevices.com

Does the battery need replacing or maintenance?

The HALO Digital Goniometer comes fitted with a Lithium Ion Polymer rechargeable battery that cannot be replaced. The on-screen battery-level indicator shows the battery status.

Normal charge-discharge cycles are all that is required for the product's life. No special discharge or deep-cycling measures are necessary.

Do not attempt to replace the battery in your device. If your HALO Digital Goniometer is within the warranty period, return the device to HALO Medical Devices. Instructions on this process can be found at www.halomedicaldevices.com under Returns Policy.

Are the lasers safe?

In normal use, the laser beams are directed at limbs. As with any strong light source, do not shine the light source directly into the eyes and do not stare into or at the laser beam for extended periods.

The HALO Digital Goniometer employs TGA* and FDA† approved Low-level, Class 1 lasers to assist with measurement. In a medical context, this means that no special precautions are necessary providing users and patients have a normal blink reflex‡. Users and patients are advised to wear safety glasses if they do not have a normal blink reflex. See, Laser safety and user responsibility.

* Therapeutic Goods Administration of Australia

† US Food and Drug Administration

‡ A normal blink reflex is usually described as: when exposed to light, your eyes blink automatically and regularly.

Disposal of the device

If your device is five or more years old and is not working at full capacity it should be discarded responsibly.

To discard the device, locate a mobile phone disposal unit and drop the device into the unit. For further information on disposal guidelines, email techsupport@halomedicaldevices.com

Specifications

Dimensions (h x w x d):	88 mm x 88 mm x 17 mm
Weight:	85 g
LCD:	2.4-inch (diagonal) backlit display with 50mm x 28mm viewing area, providing 184x320 pixels in full colour. LCD is TFT type.
Battery:	Lithium Ion Polymer rechargeable battery (3.7V, 1050 mAh)
Charging:	Via Micro USB port or Supplied power adaptor (Input:100-240 V AC, Output:5 V DC, 50/60 Hz, 1A)
Operating temperature range:	-10°C to +40°C
Relative Humidity:	10% ~ 90% RH
Atmospheric Pressure:	80kPA ~ 110kPA
Compatibility:	PC, Mac (no data is transferred)
Compliance:	Designed to comply with IEC 60601-1 and CE mark of European Conformity. Complies with part 15B of the FCC rules.

Characteristics of emitting radiation

Laser:	Low-level, Class 1, safe beam laser
Max output of laser radiation:	0.39 mW
Pulse duration:	continuous
Emitted wavelength(s):	635 nm(typical)
Standard compliance:	IEC 60825-1:2007

Storage and transport environment condition

Storage Temperature:	-40°C ~ +80°C
Relative Humidity:	10% ~ 90% RH
Atmospheric Pressure:	80kPA ~ 110kPA

Important safety instruction



Class 1 laser : It is safe under all conditions of normal use



Read instruction: Refer to the user guide before using the equipment



WEEE: Waste Electrical and Electronic Equipment



Type B: Equipment providing a particular degree of protection against electric shock

- No Modification of this equipment is allowed. It may cause electric shock or equipment damaged.
- When charging , NO parts of the device can be serviced or maintained. This will prevent from electric shock.
- The operator must not touch USB port or the adaptor terminal while simultaneously touching the patient. When input ESD signal, the device should be reset before measurement.
- The wall outlet and power plug must be readily accessible at all time so that it is not difficult to plug/unplug the adaptor.
- This equipment is battery operated device. It can be charged from the supplied micro USB cable and AC adaptor. That are compatible with the requirements of IEC 60601-1 standard. Using different parts from other manufacturer may cause electric shock or equipment damaged.
- This equipment is stand-alone device. No need to connect with any parts or accessories while taking measurement. If not, it can be deteriorated the function of equipment.
- All the instructions in this user manual should be read, understand and followed.
- The MANUFACTURER will make available on request circuit diagram, components part list, descriptions, calibration instructions, or other information as repairable by service personnel.

Warranty

The Product has a 12-month warranty from the date of purchase. Please retain your proof of purchase to claim the warranty. Without a purchase order number or proof of purchase your warranty is not valid. The warranty includes shipping costs for the return of a device under warranty. See, www.halomedicaldevices.com for the returns procedure.

What is covered under your warranty

If the hardware or software is at fault or fails within 12 months of purchase, your HALO Digital Goniometer will be replaced with a new device.

The warranty does not cover

Damage to the outer case, damage to the hardware or software when the device has been exposed to any liquid, being dropped from a height greater than 1.5 metres, or any form of misuse.

This warranty is void if the device is opened by the user, dropped from a height greater than 1.5 metres, put through a washing machine, or exposed to any liquid.

It is at the discretion of HALO Medical Devices to determine if the device is covered by the warranty once the device is returned to the manufacturer.

Should the device be deemed out of warranty or faulty due to any of the above causes, the customer will pay any costs involved in shipping the device back to the manufacturer.

Copyright

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References

References for this guide include:

- ISO 15223-1-2012
- FDA Labelling guide
- TGA Labelling and Package Guide

These guidelines have been created in consultation with the company Regulatory Consultant and the Manufacturer.

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