OSSTELL
A W&H COMPANY

US only

Osstell Beacon

INSTRUCTIONS FOR USE

US

osstell.com

Welcome

Congratulations on the purchase of your new Osstell® Beacon. Before you start using your Osstell Beacon, please read through the entire instructions for use.

Table of content

1) Introduction

Qualifications of the user

This medical device is intended to be used by qualified dentists, doctors, surgeons, or specialist staff appointed by the responsible clinician.

Responsibilities of the user

Read through the entire instructions for use before using this device.

Observe the Warnings and Precautions.

Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority!

Responsibility of the manufacturer

The manufacturer can only accept responsibility for the safety, reliability and performance of the medical device when compliance with the following instructions is ensured:

- The medical device must be used in accordance with these instructions for use.
- Modifications or repairs may only be undertaken by Osstell.
- Unauthorized opening of the unit invalidates all claims under warranty and any other claims.

In addition to unauthorized disassembly, modification or repair of the unit and non-compliance with these instructions for use, improper use will void the warranty and release Osstell from all other claims.

2) Warnings and Precautions

Warnings:

⚠ Read all instructions before operating the Osstell Beacon.

⚠ The instrument emits an alternating magnetic field that potentially could interfere with cardiac pacemakers! Keep the instrument away from implanted electronic devices. Do not place the instrument on the patient's body.

⚠ A transparent, barrier sleeve must be used to cover the Osstell Beacon when used on patients. See section 11 for recommended sleeves and section 15 for information on recommended cleaning and disinfection procedure before attaching a new sleeve.

⚠ Only use the acceptable cleaning and disinfectant fluids listed in section 15 when cleaning and disinfecting the instrument. Using not acceptable cleaning and disinfectant fluids, could damage the device enclosure.

⚠ Do not autoclave the instrument.

⚠ The SmartPeg Mount must be sterilized before use.

⚠ The instrument will flash red-yellow-green during start-up as a functional test of the color indication. If any or all colors are not shown, the instrument must not be used. Contact the local sales representative or distributor for further instructions.

⚠ Always perform a measurement in two directions, Buccal-Lingual and Mesial-Distal, as guided by the instrument. This is important to detect the lowest implant stability.

⚠ The SmartPegs are disposable and should only be used for one or multiple measurements at one treatment session, for a single patient only (to avoid cross-contamination). Repeated re-use may result in false readings due to wear and tear of the soft aluminum SmartPeg threads. Do not use if the product sterile barrier system or its packaging is compromised.

⚠ Do not expose the instrument to extreme high temp, e.g. leaving it in the car dashboard on a warm sunny day.

⚠ The Osstell Beacon is not protected from ingress of fluids, e.g. water, at the USB connector (IP20 classified).

⚠ Mains-operated power supplies or USB cable used for charging, shall not be reachable by the patient.

⚠ Always charge the instrument, using the supplied Osstell USB-cable, directly connected to a 5 Volt USB type A port.
Splitter cables must never be used as these can lead to permanent damage to the device.

Precautions:

⚠ To avoid interference with other equipment, the instrument should not be held close to electronic devices.

⚠ Do not use the instrument in the presence of explosive or flammable materials.

⚠ See section 4, 5 and 10 for information about approved and compatible accessories.

3) Intended Use

Osstell Beacon is intended for use as a Dental Implant Stability Analyzer.

4) Indication for use

Osstell Beacon is indicated for use in measuring the stability of implants in the oral cavity and maxillofacial region.

Conditions

Surgically placed implants or abutments for which there is space to attach a compatible SmartPeg.

Reasons for use

The Osstell Beacon can add important information to the evaluation of implant stability and can be used as part of an overall treatment evaluation program. The final implant treatment decisions are the responsibility of the clinician.

Contraindications

Osstell Beacon is contraindicated for implant systems to which the SmartPeg could not be attached for mechanical incompatibility reasons. See section 10 for more information about SmartPegs. Osstell Beacon is contraindicated when used together with Pegs not approved by Osstell. Osstell Beacon is contraindicated where it is not possible to attach the SmartPeg due to lack of space, or where it impinges on other artificial or anatomical structures.

5) Description

The Osstell Beacon is a handheld instrument that involves the use of the non-invasive technique, Resonance Frequency Analysis. The system involves the use of a SmartPeg attached to the dental implant or abutment by means of an integrated screw. The SmartPeg is excited by a magnetic pulse from the instrument tip.

The resonance frequency, which is the measure of implant stability, is calculated from the response signal. Results are displayed on the instrument as the Implant Stability Quotient (ISQ). The ISQ is scaled from 1 to 100. It is a measurement of the stability of the implant and is derived from the resonance frequency value obtained from the SmartPeg. The higher the number, the greater the stability. The instrument software can be updated by using the Osstell USB cable, type A-C.

Your Osstell Beacon system includes the following items:

① Osstell Beacon Instrument
② Osstell USB cable, type A-C
③ Osstell SmartPeg Mount
④ Osstell TestPeg
⑤ Osstell Key
⑥ Osstell Beacon Instructions for Use
Osstell Beacon Quick Guide

Applied Parts: Osstell Beacon instrument tip and thin part of body.

6) Safety Symbols

	Caution
	Follow instructions for use
	Consult instructions for use
	See section 2) Warnings and Precautions
	Type BF applied part
	Manufacturer
	Country and date of manufacture
SN	Serial number
	Do not dispose of with domestic waste. Li-ion battery.
CE 0297	CE mark with identification number of the notified body.
	This electronic product is approved by Federal Communications Commission (FCC) FCC ID: QOQBLE113 IC: 5123A-BGTBLE113
	Non-ionizing electromagnetic radiation
	Not Sterilizable
	Sterilizable up to 135 degrees Celsius
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
IP20	Protected against solid foreign objects of 12.5 mm Ø and greater. No protection against water.
	Use by date
LOT	Lot/batch code
STERILE R	Sterilized using irradiation
Rx only	For US market only: Prescription use only. U.S. Federal Law restricts this device to sale by or on the order of a licensed practitioner
REF	Catalog Number
	Do not reuse
	Regulatory Compliance Mark (RCM) indicates compliance with the Australian and New Zealand electrical safety, EMC, EME and telecommunications requirements.
MD	Medical device

	Data Matrix code for product information including UDI (Unique Device Identification)
	Do not use if package is damaged and consult instructions for use
	Keep dry
	Keep away from sunlight
	Single sterile barrier system with protective packaging outside
	Single sterile barrier system
	This product contains a module (model BLE113) with Anatel approval code 01237-16-03402
	INMETRO – Marking from the Brazilian National Institute of Metrology, Standards and Industrial Quality
	IEx – This marking indicates that the product complies with Brazilian standards

7) Before You Start

The Osstell Beacon is delivered from factory in a “transport” mode, where the built-in motion sensor is deactivated.

To de-activate the transport mode and start charging, connect the small USB connector of the Osstell USB cable, type A-C, to wide end of the instrument. Connect the large USB connector to a standard USB type A port of a PC, laptop or charger.

The Osstell Beacon will start-up and enter charging mode. Charge the Osstell Beacon for at least 3 hours or until the Osstell Beacon indicates full charge. Remove the Osstell USB cable, type A-C.

Note! It is not possible to perform an ISQ measurement during charging.

8) Operation of the Osstell Beacon Instrument

The Osstell Beacon is activated by a built-in motion sensor. As soon as the motion sensor detects movement, the Osstell Beacon will start-up, flash red-yellow-green and shortly show battery status in the lower display and then be ready for measurement in the BL (Buccal – Lingual) direction, which is indicated in the upper display.

The Osstell Beacon will start to measure, indicated by an audible sound, when near an Osstell Smartpeg or Testpeg due to a built-in magnetic detector that senses the magnet on the top of the Osstell Smartpeg/ TestPeg. Measured data will be shown in the upper display combined with a colored light indication below the instrument tip.

The red, yellow and green color indications are to be used only as visual aid in what range the measured ISQ values are, where red is the lower range, yellow is the middle range and green is the higher range of the ISQ scale. After 60 seconds of no motion, the Osstell Beacon will turn off automatically.

9) TestPeg

The Osstell TestPeg may be used for testing and learning how to use the system. Place the Osstell TestPeg on the table or hold it in your hand. Activate the Osstell Beacon by moving it and hold the instrument tip approximately 2-4 mm away from the top of the Osstell TestPeg. The Osstell Beacon should start to measure and present an ISQ value of 55 +/- 2 ISQ.

10) SmartPeg™

The SmartPeg is available with different connection geometries to fit all major implant products on the market. You can find all available SmartPegs on **osstell.com/smartpegguide.**

The SmartPegs are disposable and should only be used for one or multiple measurement at one treatment session, for a single patient only (to avoid cross-contamination). Repeated re-use may result in false readings due to wear and tear of the soft aluminium SmartPeg threads.

11) How to Measure

Prior to use on a patient, place a barrier sleeve over the Osstell Beacon. The barrier sleeve helps prevent cross-contamination and helps keep dental composite material from adhering to the surface of the instrument tip and body, and discoloration and degradations from cleaning solutions.

Note:

- Barrier sleeves are single patient use only.
- Discard used barrier sleeves in standard waste after each patient.
- Do not leave barrier sleeves on the instrument for extended periods.
- See below for recommended barrier sleeves.
  TIDIshield, Art no: 21021, Art no: 20987. **www.tidiproducts.com**
  PremiumPlus: 123, Small short 123, Small
  Please also see additional recommended barrier sleeves on:
  osstell.com/support-osstell-beacon-us
- The Osstell Beacon instrument must be cleaned and disinfected with appropriate cleaning and disinfectant fluids after each patient. See section 15) Cleaning and Maintenance for acceptable agents.

A first measurement should be taken at implant placement to get a baseline for future measurements throughout the healing process. Before the final restoration, another measurement is taken which makes it possible to observe the stability development of the implant.

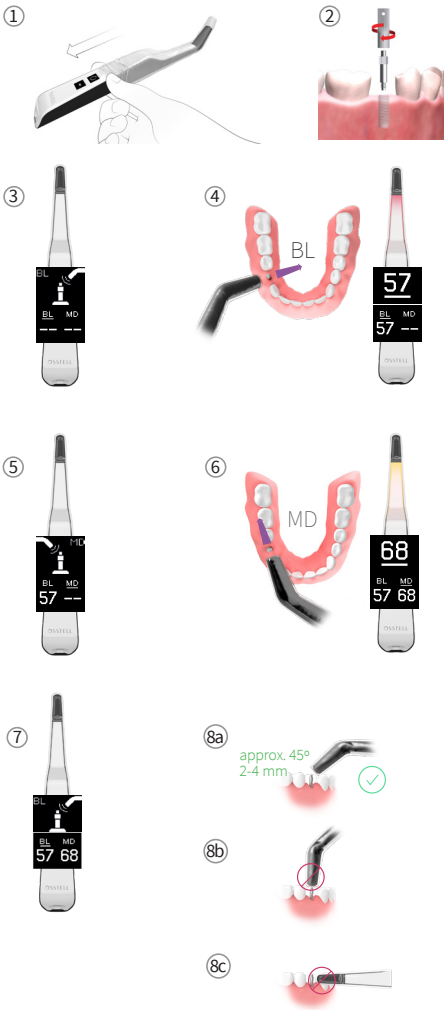
It is recommended to measure in both Buccal-Lingual and Mesial-Distal direction to find the lowest stability. Therefore, the Osstell Beacon prompts the user to measure in both these directions.

We recommend you studying the more detailed information (videos and quick guides) available on **osstell.com/support-osstell-beacon-us**, to utilize the full functionality of your Osstell Beacon.

1. Activate the Osstell Beacon by picking it up. The instrument will start-up and after showing the battery status, the instrument will be ready for measurement in the BL (Buccal – Lingual) direction, which is prompted in the upper display as well as optimal angle of the instrument tip towards the Smartpeg.
2. Place a barrier sleeve over the Osstell Beacon instrument. **See fig 1**.
3. Place the SmartPeg into the SmartPeg Mount. The SmartPeg is magnetic, and the SmartPeg Mount will hold the SmartPeg. **See fig 2**. Attach the SmartPeg to the implant or abutment by screwing the SmartPeg Mount using finger force of approximately 4-6 Ncm. Do not over-tighten, to avoid damaging the SmartPeg threads.
4. Bring the instrument inside the mouth and hold the instrument tip close (2-4 mm) to the top of the SmartPeg without touching it. Hold the tip at approx. 45º angle towards the SmartPeg top as indicated in the upper display and shown in **fig 3** and **fig 8a**. Do not measure in the ways indicated in **fig 8b or fig 8c**.
   An audible sound indicates when measurement has started, and measured data will be shown in the upper display combined with a colored light indication below the instrument tip. **See fig 4**. Bring the instrument out of the mouth to clearly read the ISQ value and the colored indication.

The measured ISQ values will be displayed in the upper display for a couple of seconds and then switch to indicate ready for measurement in Mesial-Distal direction. **See fig 5**.
Note! Do not bring the instrument back in the mouth until the display has switch to the next direction.

5. Repeat step 4 to measure in the Mesial-Distal direction, **see fig. 6**, and then the sequence starts over and the Osstell Beacon is ready for measurement in the BL (Buccal- Lingual) direction again. **See fig 7.**
6. When measurements in both directions are performed, remove the SmartPeg by using the SmartPeg Mount.
7. The instrument is automatically turned off after 60 seconds of no motion.



12) How to Measure on an Abutment

When a measurement is made on an abutment or on an implant with a "built-in" abutment, the ISQ value will be lower compared to a measurement made on the implant. This is due to the difference in height above bone level. To find out the ISQ difference to the measurement performed at implant level, a measurement should be taken on the implant before the abutment is attached and then a second measurement on the abutment.

13) Interpret the Result

Implant Stability

An implant can have different stability in different directions. The stability of the implant is dependent of the surrounding bone configuration. There is often a direction where the stability is lowest, and a direction where the stability is highest and these two directions are most often perpendicular to each other.

To find the lowest stability (lowest ISQ value) it is recommended to measure from two different directions. The lowest stability is in most cases found in the Buccal-Lingual direction. The highest stability is in most cases found in the Mesial-Distal direction.

The ISQ Value

Assuming there is access to the implant, ISQ measurements should be performed at implant placement and before the implant is loaded or the abutment is connected. After each measurement, the ISQ values are used as the baseline for the next measurement performed. A change in the ISQ value reflects a change in implant stability. In general, an increase in ISQ values from one measurement time to the next indicates a progression towards higher implant stability while a decrease in ISQ values indicates a loss in stability and, possibly, implant failure. A stable ISQ value would indicate no change in stability. ISQ values have not been correlated with other methodes of mobility measurements.

Note! The final implant treatment decisions are the responsibility of the clinician.

14) Data Connection to OsstellConnect

OsstellConnect (**osstellconnect.com**) is an online service for data transfer, storage, display and overview of your data. You can have your Osstell Beacon connected to OsstellConnect by the Osstell Key.

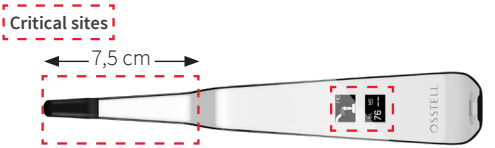
Before you can start using data connection to OsstellConnect you have to register your Osstell Beacon. The serial number can be found on the back of the instrument. For registration assistance and features of data connection to OsstellConnect, please visit:
osstell.com/support-osstell-beacon-us & osstell.com/osstellconnect

15) Cleaning and Maintenance

After each use, follow the below cleaning and desinfection procedures.

Note! Do not autoclave the Osstell Beacon instrument.

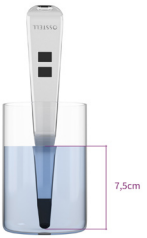
Routinely check the surface of the instrument tip and overall surface for possible cracks and residuals.



Steps	General Cleaning Instruction
1	Remove and dispose of used barrier sleeve.
2	Soak cloth in Medizime LF enzymatic cleaner. Paying particular attention to critical sites, wipe down the housing of the device for at least one (1) minute.
3	Visually inspect Osstell Beacon for contamination and visible debris. If contamination or visible debris is present, remove it with a soft bristle brush, cotton swab, or soaked cloth depending on location of the soil.
4	Soak cloth with distilled water. Pay particular attention to critical sites. Wipe down device for at least one (1) minute.
5	Inspect device again and repeat steps 2 and 3 if soil persist.
6	Wipe down device with soft cloth dampened with 70% IPA to help remove moisture.
7	Allow device to air dry completely before next use (minimum three (3) minutes).

Steps	General Disinfection Procedure
1	According to manufacturer's instructions, the minimum exposure time for the CIDEX® OPA disinfectant is twelve (12) minutes. Disinfectant application should be performed by placing the device in a cup with the tip faced down, see figure below. Fill the cup with CIDEX® OPA to a level which will allow immersion to 7.5 cm (3 inches), which is the level where the instrument neck bends, see figure below. Leave the device immersed for a minimum exposure time of twelve (12) minutes. Upon completion of the exposure time, lift the device from the cup with the tip still faced down and use a clean cloth to manually wipe the device.
2	To remove any residual disinfectant, fill a new cup with distilled water to a level which will allow immersion to 7.5 cm (3 inches) and leave the device immersed for a minimum of one (1) minute.
3	Repeat the one (1) minute distilled water immersion two (2) additional times using fresh water for a total of three (3) rinses.
4	Following removal of the device from water immersion, thoroughly ensure disinfectant residue removal by wiping down the device with a soft cloth dampened with 70% IPA.
5	Repeat the 70% IPA wipe procedure two (2) additional times, for a total of three (3) alcohol wipes.
6	Allow devices to air dry out of exposure to direct sunlight.

Osstell has validated the High Level Disinfection for up to 5000 processing cycles without damage to the Beacon.



Acceptable Cleaning fluids:

Low foaming, neutral pH, enzymatic detergents like:
Medizime LF
Enzol

Acceptable disinfectant fluids:

CIDEX® OPA Solution

Do not use:

Acidic or phenolic based cleaners/disinfectants.
Strong alkali detergent of any type, including hand soaps and dish soaps
Bleach based cleaners
Hydrogen Peroxide based cleaners
Abrasive cleaners
Acetone of hydrocarbon based cleaners
MEK (Methyl Ethyl Ketone)
Birex
Gluteraldehyde
Quaternary Ammonium Chloride salt-based cleaners

The instrument does not require regular maintenance. In the event of an instrument malfunction, contact the local sales representative or distributor for further instructions.

SmartPegs: Delivered sterile. The SmartPegs are disposable and should only be used for one or multiple measurements at one treatment session, for a single patient only (to avoid cross-contamination).

TestPeg: Is not used intra-orally, does not require sterilization.

The Smartpeg Mount should be cleaned and sterilized before each use according to the instructions below.

SmartPeg Mount: Must be autoclaved according to the recommended sterilization method, validated to sterility assurance levels (SAL), according to ISO 17665-1 and ISO 17664. The SmartPeg Mount should be placed in a FDA cleared autoclave bag such as:
PeelVue – Ref# 31610, size 3.5 x 5.25 or equivalent bag.

Sterilization Method:	Exposure temperature	Exposure time
Pre-vacuum	132 °C (270 °F)	4 min
Pre-vacuum	134 °C (273 °F)	3 min
Gravity	134 °C (273 °F)	10 min

Warnings: do not exceed 135 °C (275 °F). Drying time: 30 minutes

Carefully inspect the Smartpeg Mount for damage or wear. Hand wash the Smartpeg Mount using a neutral instrument detergent. Rinse and dry; carefully inspect the Smartpeg Mount for damage and wear. Do not wash in dishwasher.

Store sterile goods dust-free and dry.

16) Technical information

Technical description

Osstell Beacon is CE-marked according to MDR 2017/745 in Europe (Class Im, internally powered, type BF applied parts. Not AP or APG equipment, not protected against ingress of water).

Osstell Beacon is in accordance with applicable parts of IEC 60601-1/ANSI/AAMI ES 60601-1.

The symbols used, follow the European standard EN 60601-1 and ISO 15223 as far as possible.

Notes on electromagnetic compatibility (EMC)

Medical electrical equipment is subjected to particular precautions with regards to EMC and must be put into operation in accordance with the EMC notes included below:

Osstell guarantees the compliance of the device with the EMC requirements only when used with original accessories and spare parts. The use of other accessories / other spare parts can lead to an increased emission of electromagnetic interference or to a reduced resistance against electromagnetic interference.

You can find the current EMC manufacturer's declaration on our website at **osstell.com/Osstell-Beacon** scroll down to **Which product is right for you?** there you will see a button to download **EMC DECLARATION**.

Alternatively, you can obtain it directly from your local sales representative or distributor.

The Osstell Beacon contains a Bluetooth module.

FCC ID: QOQBLE113, IC: 5123A-BGTBLE113

Bluetooth communication

The Osstell Beacon contains a built in Bluetooth 4.0 low energy module for communication with a PC/Laptop via the Osstell Key. The Osstell Key should be within a radius of 6m in an open area from the Osstell Beacon to be able to connect. The data is transmitted encrypted using AES-128.

When the Osstell Key is connecting to the Osstell Beacon, the Beacon will animate a connection symbol ( ) in the upper display. When the connection is successfully established the animation will stop and the symbol shown in full. For more information about using the Osstell Beacon with Bluetooth connection, please visit: **osstell.com/osstell-beacon**.

Battery Charging

The instrument contains a rechargeable lithium-ion battery.

The instrument should be charged using the Osstell USB cable, type A-C, connected to a standard USB 2.0 or 3.0 type A port. Battery status and charging is indicated in the lower display with a battery symbol having 4 levels: 100% (fully charged), 75%, 50% and less than 25%. When the level is less than 10 %, the Osstell Beacon will change the battery symbol to alert that it is time to charge the instrument.

Note! The instrument, when connected to a charger, is a Medical Electrical system. The charger shall conform to relevant EN/IEC safety standards, e.g. IEC 60950-1, IEC 62368-1 or IEC 60335-2-29, in order to comply with safety regulations.

Note! It is not possible to perform an ISQ measurement during charging.

Transport mode

Transport mode can be used when, e.g. travel to different places outside the clinic and thereby frequently move the Osstell Beacon, which will wake up the instrument more frequent than regular use and thereby draining the battery faster.

The transport mode is activated by connecting the Osstell USB cable, type A-C, (when connected to an USB port) and removing it within 5 seconds as illustrated by a count-down sequence in the lower display. The two displays will turn dark and the instrument will no longer wake up by motion.

If the Osstell USB cable, type A-C, is not removed within these 5 seconds, the instrument will enter charging mode.

To deactivate transport mode, connect the cable again, as is described section 7.

Accuracy

The Osstell Beacon instrument has an ISQ accuracy/resolution of +/- 1 ISQ. When the SmartPeg is attached to an implant, the ISQ value can vary up to 2 ISQ depending on SmartPeg attachment torque.

Power, weight & size:

Lithium-ion battery:	3.7 VDC
Charging:	Use only Osstell USB cable (USB type C / USB type A) connected to standard USB 2.0 or 3.0 (type A) port (Max 5,2 VDC).
Instrument size:	210 x 35 x 25 mm
Package size:	272 x 140,2 x 74,60 mm
Instrument weight:	0,07 kg
Gross weight:	0,75 kg

Environmental conditions during transport:

Temperature:	-40 ºC to +70 ºC
Relative humidity:	10% to 95%
Pressure:	500 hPa to 1060 hPa

Environmental conditions during use:

Temperature:	+10 ºC to +35 ºC
Relative humidity:	30% to 75%
Pressure:	700 hPa to 1060 hPa
IP class:	IP20

17) Troubleshooting

No measurement or unexpected value

Re-Used SmartPeg.

The SmartPegs are disposable and should only be used for one or multiple measurement at one treatment session, for a single patient only. Repeated re-use may result in false readings due to wear and tear of the soft aluminium SmartPeg threads.

Wrong SmartPeg type selected for the Implant.

See SmartPeg reference list, osstell.com/smartpegguide

Bone or soft tissue in between SmartPeg and Implant.

Make sure to clean the Implant prosthetic connection before attaching the SmartPeg.

Electromagnetic interference.

Remove the source of electromagnetic interference.

Instrument tip is held too far away from the SmartPeg.

Normally it is sufficient to hold the instrument tip 2-4 mm away from the SmartPeg, but in some cases as close as 1 mm is necessary.

Instrument does not sense the SmartPeg, hence no measurement.

Bring the instrument out of the mouth and then in the mouth again. Try to measure with approx. 45º angle towards the SmartPeg top as indicated in the upper display.

Unit is not charging when USB cable is connected

Wrong USB cable used.

Only use Osstell USB cable, type A-C, connected to a standard USB 2.0 or 3.0 (type A) port (Max 5,2 VDC).

Instrument does not start
Uncharged battery. Charge the Osstell Beacon. ***Instrument in transport mode.*** See section 7 for instruction on how to de-activate transport mode.

Instrument starts up with 
Self-tests failed Contact the local sales representative or distributor for further instructions.

The instrument does not show red-yellow-green color during start-up
The instrument will flash red-yellow-green during start-up as a functional test of the color indication. If any or all colors are not shown, the instrument must not be used. Contact the local sales representative or distributor for further instructions.

Difficult to measure in an exact recommended direction
No space, e.g. due to adjacent teeth. Try to measure at a slightly different direction.

Difficulties attaching the SmartPeg
Wrong SmartPeg Ensure that the SmartPeg is compatible with the implant system. See osstell.com/smartpegguide

18) Service and Support

In the event of an instrument malfunction contact the local sales representative or distributor for further instructions.

19) Waste and Disposal

The Osstell Beacon instrument should be recycled as electrical equipment. SmartPegs should be recycled as metal. Whenever possible, the battery should be disposed in a discharged state to avoid heat generation through inadvertent short-circuiting.

Follow your local and country-specific laws, directives, standards and guidelines for disposal.

- Waste electrical equipment
- Accessories and spare parts
- Packaging

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