OSSTELL
A W&H COMPANY

# Osstell Beacon

## INSTRUCTIONS FOR USE

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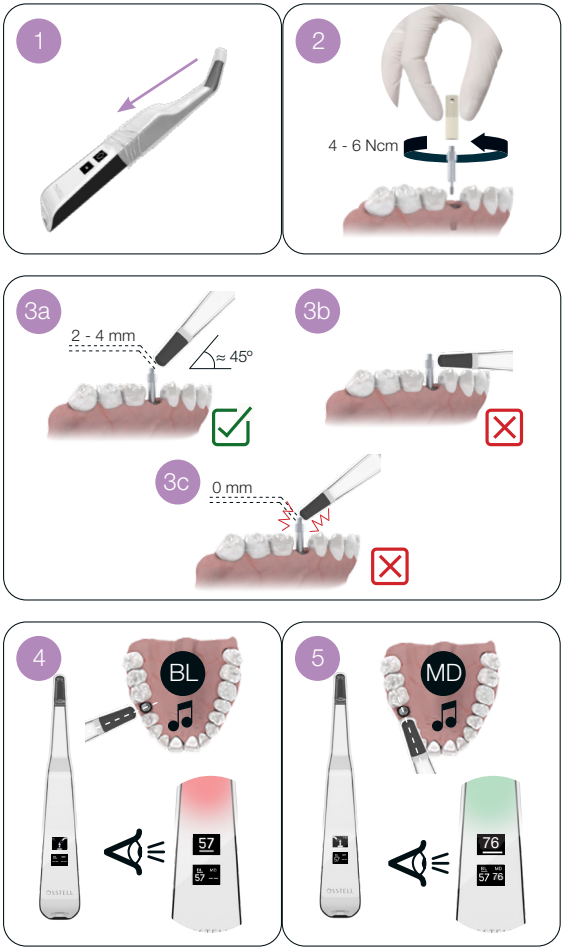
# Osstell Beacon




## Welcome

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

# 1) Introduction

## Qualifications of the user

This medical device is intended to be used by dental implant treatment professionals.

## 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 the manufacturer.
- Unauthorized opening of the instrument invalidates all claims under warranty and any other claims.

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

# 2) Warnings and precautions

## Warnings

⚠ Read all instructions before operating the instrument.

⚠ 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 instrument when used on patients. See section 11 for recommended sleeves and section 15 for information on recommended cleaning and maintenance.

⚠ Only use the acceptable agents listed in section 15 when cleaning and maintaining the instrument. Other agents may permanently damage the instrument enclosure.

⚠ Do not autoclave the instrument.

⚠ The SmartPeg Mount and reusable SmartPegs 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.

⚠ SmartPegs delivered in sterile condition are intended for single use only. They should be used for one or multiple measurements during a single treatment session for a single patient. Repeated reuse may result in false readings due to wear and tear. Do not use if the product sterile barrier system or its packaging is compromised.

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

⚠ The instrument 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 USB cable. Charge this instrument ONLY using a standard USB power source rated at 5 V MAX.

Do NOT use:

- USB Power Delivery (USB-PD) chargers
- Quick Charge or other high-voltage adapters
- Split or dual-output cables

Using anything other than a 5 V USB source may damage the instrument and void the warranty.

## 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

The instrument is intended for use as a Dental Implant Stability Analyzer.

# 4) Indication for use

The instrument 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 instrument 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 dental healthcare professional.





## Contraindications

The instrument 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. The instrument is contraindicated when used together with Pegs not approved by the manufacturer. The instrument 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

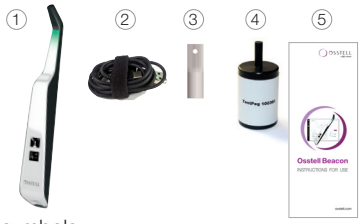
The instrument is a handheld instrument that uses Resonance Frequency Analysis to analyze the stability of dental implants.
An accessory, the SmartPeg is attached to the dental implant or abutment by means of an integrated screw. The SmartPeg is activated by a magnetic pulse from the instrument tip (which shall not make physical contact with the SmartPeg).

The resonance frequency is identified from the response signal. Results are displayed on the instrument as the Implant Stability Quotient (ISQ). The ISQ scale ranges from 1 to 99. A higher number indicates greater stability.

## Your system includes the following items

① Instrument ② USB cable, type A-C ③ SmartPeg Mount
④ TestPeg ⑤ Instructions for Use

Applied Parts: 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 |
| CC YYYY-MM-DD | Country and date of manufacture |
| SN | Serial number |
| Li-ion | Do not dispose of with domestic waste. Li-ion battery. |
| CE | CE mark |
| CE 0297 | CE mark with identification number of the notified body. Only concerns SmartPegs delivered in sterile condition. |
| | Non-ionizing electromagnetic radiation |
| 135°C | Not Sterilizable |
| 135°C | Sterilizable up to 135 °C |
| | 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 |
| MD | Medical device |
| UDI | Unique device identifier + Data Matrix code for product information including UDI (Unique Device Identification) |
| | QR Code, Link to website where IFU and/or Reprocessing guidelines can be retrieved |
| NON STERILE | Non-Sterile |
| | 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 |
| | Regulatory Compliance Mark (RCM) indicates compliance with the Australian and New Zealand electrical safety, EMC, EME and telecommunications requirements. |
| FC | This electronic product is approved by Federal Communications Commission (FCC) – USA FCC ID: QOQ-GM220P and Innovation, Science and Economic Development (ISED) - Canada IC:5123A-GM220P |

## 7) Before you start

The instrument 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 USB cable, to the wide end of the instrument. Connect the large USB connector preferably to a standard USB type A port of a computer. Any other type of charger should be 5V MAX, with only one USB port, no USB PD (high power delivery), no split cables.

The instrument will start-up and enter charging mode. Charge the instrument for at least 1 hour or until the instrument indicates full charge. Remove the USB cable.

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

## 8) Operation of the instrument

The instrument is activated by a built-in motion sensor. As soon as the motion sensor detects movement, the instrument 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 instrument will start to measure, indicated by an audible sound, when near a SmartPeg or TestPeg due to a built-in magnetic detector that senses the magnet on the top of the 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 lower range, yellow is the middle range and green is the higher range of the ISQ scale. After 60 seconds of no motion, the instrument will turn off automatically.

## 9) TestPeg

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





## 10) SmartPeg

The SmartPeg is available with different geometries to fit all major implant products on the market. Some SmartPeg types are available both as single-use and reusable. The reusable SmartPegs are not available on all markets. You can find all available SmartPegs on **osstell.com/smartpegguide.**

## 11) How to measure

Prior to use on a patient, place a barrier sleeve over the instrument. The barrier sleeve helps prevent cross-contamination and helps keep debris and other contaminants 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.
  Omnia: Non sterile cover, Art No 30.Z0600.00,
  Sterile cover Art No 22.Z0600.00. **omniaspa.eu**
  TIDIshield, Art no: 21021, Art no: 20987. **tidiproducts.com**
  PremiumPlus: 123, Small short 123, Small

  Please also see additional recommended barrier sleeves on: **osstell.com/support-osstell-beacon**
- The instrument must be cleaned with appropriate agents 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 instrument prompts the user to measure in both these directions.

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

1. Activate the instrument 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 instrument. **See fig 1, page 1.**
3. Place the appropriate SmartPeg for the implant into the SmartPeg Mount. The SmartPeg is magnetic, and the SmartPeg Mount will hold the SmartPeg. **See fig 2, page 1.** 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. 45° angle towards the SmartPeg top as indicated in the upper display and shown in **fig 4, page 1** and **fig 3a**. Do not measure in the ways indicated in **fig 3b or fig 3c**.
   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, page 1.**
   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, page 1.**
   **Note!** Do not bring the instrument back in the mouth until the display has switched to the next direction.
5. Repeat step 4 to measure in the Mesial-Distal direction, **see fig. 5, page 1**, and then the sequence starts over and the instrument is ready for measurement in the BL (Buccal- Lingual) direction again. **See fig 6, page 1.**
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 measuring on abutment level, the ISQ values will not be equal to when measuring on implant level. They will in most cases be lower. This is due to that the total length of abutment plus the SmartPeg will be a bit different (longer) depending on abutment height used.

To obtain a correct ISQ measurement at the abutment level, follow these steps:

1. Perform an implant level measurement before installing the abutment.
2. Perform an abutment level measurement on the same session using a SmartPeg compatible with the abutment.
3. Note the difference between the implant level and abutment level measurements. This difference, or offset, will remain constant throughout the healing period.
4. During subsequent follow up measurements, use the offset to calculate the implant ISQ.

You can find all available SmartPegs for abutment level measurements on **osstell.com/smartpegguide**.

## 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.

ISQ values have not been correlated with other methods of mobility measurements.
**Note!** The final implant treatment decisions are the responsibility of the dental healthcare professional.

# 14) Cleaning and maintenance

## 14.1 Instrument

Before and after each use, moisten a gauze or soft cloth with a recommended (see list below) surface cleaner and wipe the whole instrument.

### Note! Do not autoclave the instrument.

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

### Recommended cleaners

- Isopropyl alcohol 70%
- BePro Disinfectant Wipes, REF 19500102, **wh.com** (can be ordered from W&H Sterilization)
- *Low foaming, neutral pH, enzymatic detergents like:
  - Medizime LF
  - Enzol

### Do not use

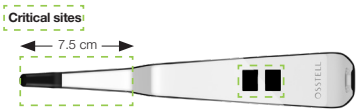
- Acidic or phenolic based cleaners/disinfectants
- Strong alkali detergent of any type, including hand soaps and dish soaps
- Bleach based cleaners
- Hydrogen Peroxide based cleaners
- Abrasive cleaners
- Acetone or other hydrocarbon based cleaners
- MEK (Methyl Ethyl Ketone)
- Birex
- Gluteraldehyde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

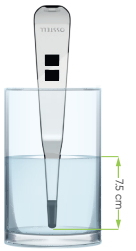
The instrument does not require regular maintenance. In the event of an instrument malfunction, contact the local sales representative or distributor for further instructions.

### Cleaning and disinfection after use

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

**Note!** Do not autoclave the instrument.




| 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 noted in the figure above, wipe down the housing of the instrument for at least one (1) minute. |
| 3 | Visually inspect the instrument 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 the instrument for at least one (1) minute. |
| 5 | Inspect the instrument again and repeat steps 2 and 3 if soil persist. |
| 6 | Wipe down the instrument with soft cloth dampened with 70% IPA to help remove moisture. |
| 7 | Allow the instrument 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 instrument in a cup with the tip faced down, see figure above.<br>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.<br>Leave the instrument immersed for a minimum exposure time of twelve (12) minutes.<br>Upon completion of the exposure time, lift the instrument from the cup with the tip still faced down and use a clean cloth to manually wipe the instrument. |
| 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 instrument 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 instrument from water immersion, thoroughly ensure disinfectant residue removal by wiping down the instrument 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 the instrument to air dry out of exposure to direct sunlight. |

The manufacturer has validated the High Level Disinfection for up to 5000 processing cycles without damage to the instrument.

### Acceptable cleaning fluids

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

### Acceptable disinfectant fluids

- CIDEX® OPA Solution

## 14.2 Single-use SmartPeg

Single-use SmartPegs are delivered sterile and should not be reused or reprocessed.

## 14.3 Reusable SmartPeg and SmartPeg Mount

Prior to the first clinical use, and after each use the reusable products must be cleaned, disinfected and sterilized according to the instructions below:

**POINT OF USE-INITIAL TREATMENT**

After use products should as far as possible be kept moist or immersed in sterile water during the clinical procedure to avoid drying.
After the clinical procedure the product should be disinfected by either immersion in a bath or wiping with a disinfectant wipe.

**Note that the disinfectant used during initial treatment is only for personal protection and cannot replace the disinfectant step after cleaning.**

**CLEANING/DISINFECTION**

**Manual cleaning/disinfection**

- Clean the products under running tap water (< 35°C / < 95°F).
  Rinse and brush off all surfaces (1 minute minimum) until no visible contaminants / soil remain.
- Manual Disinfection after manual cleaning in immersion bath with suitable disinfectant solutions. It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the disinfectant.

Manual cleaning was validated with running tap water for 1 minute.
Manual disinfection was validated using disinfectant CaviCide (Kerr Dental), exposure time: 3 minutes

**CLEANING/DISINFECTION**

**Automated cleaning/disinfection**
Suitable washer disinfectors as well as cleaning and neutralization agents are to be used for automated cleaning. The instructions from the manufacturer of the washer disinfector must be followed. Cleaning and neutralization agents are to be dosed and used in accordance with the manufacturer's instructions.
A cleaning program with thermal disinfection (A0 ≥ 3000) is recommended. Either demineralized water or water which satisfies this level of purity is recommended for the disinfection.

- Step 1 Pre-cleaning cold tap water (< 40 °C) for 1 minute
- Step 2 Cleaning 0.5% cleaner 55°C for 5 minutes
- Step 3 Rinsing with tap water for 1 minute
- Step 4 Thermal disinfection with demineralised water >90°C for 5 minutes

Automated cleaning/disinfection was validated in a washer-disinfector type Miele Professional PG8581 using the cleaning agent neodisher® MediClean forte (0.5%, from Dr. Weigert) in the Vario TD program.

**INSPECTION AFTER CLEANING**

Before sterilization, all products must be inspected with the naked eye for visible soil, impairments and/or corrosion.
Particular attention should be paid to design features such as, threads and mating surfaces.
If remaining soil/contamination is detected, re-perform the cleaning process.
Check all markings on products for visibility and readability by inspection with the naked eye.
Defective products must be discarded.

**STERILIZATION**

Sterilization is to be performed corresponding to the following instruction:

**Preparation for sterilization:**
Place components in an approved sterilization pouch (for the US market: FDA-cleared) for use with the recommended sterilization parameters. Packaging must comply with the requirements according to EN ISO 11607, ANSI/AAMI ST79 and AAMI TIR12.
Every sterilization package must have a sterilization indicator and sterilization date.

**Parameters**
(acc. to ISO 17665, EN 13060, EN 285 and AAMI TIR12)

| Method | Cycle | Temperature | Exposure time | Dry time |
|---|---|---|---|---|
| Steam | Dynamic air removal (prevacuum) | 134°C | 3 min | 20 min |
| Steam | Dynamic air removal (prevacuum) | 132°C (270°F)<br>135°C (275°F) | 4 min<br>3 min | 20 min |
| Steam | Gravity | 134° C (273° F) | 10 min | 30 min |

Validation was performed with the products wrapped in Steriking® See-Through Heat Sealable Rolls sterilisation packing acc. to EN ISO 11607 using a steriliser type Tuttnauer 3870 HSG for the dynamic air removal steam sterilisation process with 3 pre-vacuum pulses.

**STORAGE**

Store the sterilized components in dry and dust-free environment at room temperature.

## 15) Lifetime

**The instrument** can be expected to have a lifetime of 5 years under normal use. It should not be left uncharged for more than 1 year.

**The single-use SmartPeg** is intended for use in one patient at one occasion only.

**The reusable SmartPeg** can be expected to function after being reprocessed up to 20 times as long as the integrity and performance of the product are maintained.

**The SmartPeg Mount** can be reused as long as the integrity and performance of the product are maintained. The SmartPeg Mount must be inspected before each use for visible signs of damage, deformation, wear or corrosion. Devices showing any signs of visible damage or loss of functional compatibility (for example fit with mating products, lifting function etc.) shall be discarded.

## 16) Technical information

### Technical description

The instrument is CE-marked according to MDR 2017/745 in Europe (Class I). It is an internally powered, type BF applied part. Not an AP/APG equipment. Not protected from ingress of fluids, e.g. water, at the USB connector (IP20 classified).

The instrument 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:

The manufacturer 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 until you see a button to download EMC DECLARATION.

Alternatively, you can obtain it directly from your local sales representative or distributor.
The instrument contains a RF low energy module. FCC ID: QOQ-GM220P, IC:5123A-GM220P

### Battery charging

The instrument contains a rechargeable lithium-ion battery.

The instrument should be charged using the USB cable directly connected to a standard USB 2.0 or 3.0, 5 Volt USB 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 instrument will change the battery symbol to alert that it is time to charge the instrument.

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

### Transport mode

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

The transport mode is activated by connecting the USB cable, (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 USB cable is not removed within these 5 seconds, the instrument will enter charging mode.

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

### Accuracy

The instrument has an ISQ accuracy/resolution of ISQ +/- 1. 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 USB cable , type A-C, 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 x 75 mm |
| **Instrument weight** | 0.07 kg |
| **Gross weight** | 0.85 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 and storage

| | |
|---|---|
| **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

**Reuse of single-use SmartPeg**
SmartPegs delivered in sterile condition are intended for single use only. They should be used for one or multiple measurements during a single treatment session for a single patient. Repeated reuse may result in false readings due to wear and tear.

**Wrong SmartPeg type selected for the implant or abutment**
SmartPeg types for implants and abutments are listed in different sections, in the SmartPeg reference list on **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.

### Instrument is not charging when USB cable is connected

**Wrong USB cable and/or wrong charger used**
Always charge the instrument using the supplied USB-cable.

Charge the instrument ONLY using a standard USB power source rated at 5 V MAX.

Do NOT use:

- USB Power Delivery (USB-PD) chargers
- Quick Charge or other high-voltage adapters
- Split or dual-output cables

Using anything other than a 5 V USB source may damage the instrument and void the warranty.

### Instrument does not start

**Uncharged battery**
Charge the instrument.

**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 angle.

### Difficulties attaching the SmartPeg

**Wrong SmartPeg**
Ensure that the SmartPeg is compatible with the implant or abutment 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.

**Serious incidents**

If any serious incident occurs in relation to the product, the user and/or patient should report to the manufacturer and the competent authority of the state in which the user and/or patient is established.

## 19) Waste and disposal

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

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

Li-ion

- Waste electrical equipment
- Accessories and spare parts
- Packaging

www.osstell.com/support-osstell-beacon

**Osstell AB**
Stampgatan 14, 411 01 Göteborg, Sweden
Phone: +46 31 340 82 50
info@osstell.com | www.osstell.com

CE 0297

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