Osseointegration Assessment Device

Osseo 100+

OPERATION MANUAL

CE Made in Sweden

Components

Fig 1

Fig 2

Fig 3

Fig 4

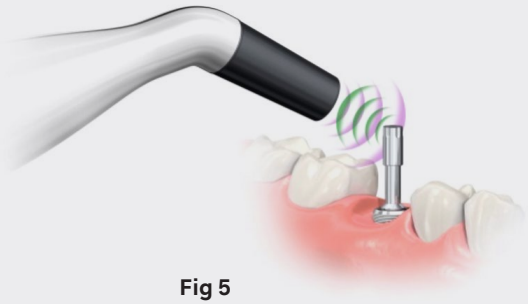

Fig 5

Fig 6

1. Indications for Use

Osseo 100+ is indicated for measuring the stability of dental implant.

The intended patient population is patients having dental implants.

The indication is patients undergoing dental implant procedures.

Osseo 100+ is contraindicated for implant systems to which the MulTipeg could not be attached for mechanical incompatibility reasons.

The direct clinical benefit is that the clinician can get an objective value (an ISQ-value) of the implant stability.

2. Intended users

Professional health care users and professional health care facility environments only.
Please read the instruction for use before the first usage.

3. Figures and System components

Fig 1 Osseo 100+ Instrument
Included in package

Fig 2 MulTipeg Driver
Included in package

Fig 3 Example MulTipeg
Not included, sold separately

Fig 4 Mains adapter and plugs
Included in package

Fig 5 Measurement position
Shows how the instrument tip is held towards the MulTipeg during a measurement

Fig 6 ISQ Tester
Not included, sold separately

Only original parts should be used.

Power supply: Use only the supplied mains adapter and plugs.

No user modification of this equipment is allowed.

Batteries should be collected separately.

4. Specifications

- Power input: 5VDC, 1 VA
- Charger input: 100-240 VAC, 5VA
- Instrument weight: 78g
- Dimensions instrument: 202mm x 29mm x 25mm
- Charger safety class: EN 60601-1 Class II
- Instrument safety class: EN 60601-1 ME Class II
- EMC: EN 60601-1-2, class B
- The instrument is intended for continuous use
- The instrument contains NiMH batteries
  - Battery type: AAA, rechargeable
  - Voltage: 1.2 V
  - Current: 900 mAh
- Bluetooth specification:
  - Frequency band: 2.4GHz ISM band (2.402–2.480GHz)
  - Transmitting power: Class2 2.5mW[dBm]
  - Modulation: GFSK
  - Channnels: 40 channels with 2 MHz spacing
  - Compatibility: EN 300 328, EN 300 489-1, EN301 489-17, EN 62479:2010Connection only possible to pairable instruments listed in chapter 19.
  - No specific security aspects (other than those listed in 14.3) applies to the Bluetooth connection.

5. Operating environment

Ambient temperature: 16° to 40°C (60°–104°F)
Relative humidity: 10%–80% Rh
Atmospheric pressure: 500 hPa- 1060 hPa (0.5–1.0 atm).

6. Transport and storage

Ambient temperature: -20° to 40°C (-4°–104°F).
Relative humidity: 10%–85% Rh.
Atmospheric pressure: 500 hPa–1060 hPa (0.5–1.0 atm).

7. Symbols

 Warning	 Catalogue number	 Keep dry	 Caution: Federal law restricts this device to sale by or on the order of a physician or dentist.
 Follow instructions for use	 Lot/Batch code	 Temperature limits	Waste from electronic equipment must be handled according to local regulations
 Magnetic field warning	 Serial number	 Manufacturer	 Type BF Applied part
 Autoclavable up to 134°C	 Atmospheric pressure limit	 Manufacturing date	 Regulatory Compliance Mark (RCM) - Compliance with requirements of Electric Safety and EMC standards.
 Delivered Non-sterile	 Bluetooth technology	 CE mark	 Certification marks – demonstrate compliance to the requirements of widely accepted product safety standards.
 Unique device identifier	 Medical device	 Humidity limit	 Federal Communications Commission (FCC) approved equipment.

8. Characteristics

Osseo 100+ is an instrument for measuring the stability (ISQ) of dental implants. The instrument measures the resonance frequency of a MulTipeg and presents it as an ISQ value. The ISQ value, 1-99, reflects the stability of the implant – the higher the value, the more stable the implant. The instrument measures the ISQ-value with a precision of +/- 1 ISQ unit. When mounted onto an implant, the MulTipeg resonance frequency can vary up to 2 ISQ units depending on the tightening torque.

By connecting Osseo 100+ to a pairable instrument (defined in section 19), the ISQ value and battery status is transferred. For more information, see the pairable instrument manual and "14. Usage" below.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

9. MulTipeg

The MulTipeg is made from titanium and has an integrated grip for the MulTipeg driver on top. Inspect the MulTipeg for damage before use. Damaged MulTipegs should not be used due to the risk of erroneous measurements.

There are different MulTipegs available made to fit different implant systems and types. Please refer to the updated list from the supplier.

Measurements should only be performed using the correct MulTipegs. Using the wrong MulTipeg could cause erroneous measurements or damages to the MulTipeg or implant.

The instrument emits short magnetic pulses with pulse duration of 1 ms and strength of +/- 20 gauss, 10 mm from the instrument tip. Precautions might be necessary when using the instrument close to cardiac pacemakers or other equipment sensitive to magnetic fields.

10. Technical function

For bringing the MulTipeg into vibration, short magnetic pulses are sent from the instrument tip. The magnetic pulses interact with the magnet inside the MulTipeg and cause the MulTipeg to vibrate. A pickup in the instrument picks up the alternating magnetic field from the vibrating magnet, calculates the frequency and from that, the ISQ value.

11. ISQ-value

The stability of the implant is presented as an "ISQ value". The higher the value, the more stable the implant. The ISQ is described in numerous clinical studies. A list of studies can be ordered from the supplier.

12. Implant stability

An implant can have different stabilities in different directions. Make sure to measure from different directions around the top of the MulTipeg.

It is highly recommended to measure the ISQ value at implant placement to have a baseline for future measurements. When the ISQ is measured at a later stage, a change in the ISQ value will reflect a change in the implant stability. This way, the ISQ progression will support the decision on when to load the implant.

Note: The stability value is an additional parameter for deciding when to load the implant. The final treatment decision is the responsibility of the clinician.

13. Batteries & charging

The instrument contains 2 NiMH battery cells that must be charged before use. A full charge takes approximately 3 hours at 20°C or 68°F. Warmer room temperature will increase the charging time. From fully charged, the instrument can measure continuously for 60 minutes before it needs to be recharged. The yellow LED is lit when the battery needs recharging. The yellow LED flashes when the battery reaches a critical level. When the battery reaches a critical level, the instrument shuts off automatically. When the batteries are charging, the blue LED is lit.

When the batteries are fully charged, the light goes off. The charger should not be plugged in while measuring due to the risk of power line interference making it difficult to measure.

14. Usage

14.1 Instrument on/off

To turn the instrument on, press the operating key. A short beep should be heard and then all display segments are lit up for a short while. Check that all display segments are lit. If any error code (EX, where "X" is the error number) is shown during start up, please refer to the section "Troubleshooting".

To turn off, press the operating key. The instrument will power down automatically after 30 seconds of inactivity.

14.2 Measurement Osseo 100+

A MulTipeg (fig 3) is mounted onto the implant by using the MulTipeg driver (fig 2). Use hand-tightening with 6-8 Ncm of tightening torque. Turn on the instrument and hold the tip close to the top of the MulTipeg (fig 5). When a signal is received, a beep is heard and then the ISQ-value is shown on the display for a short while before the instrument starts to measure again.

If electromagnetic noise is present, the instrument cannot measure. The electromagnetic noise warning is audible as well as visible on the display. Try to remove the source of the noise. The source could be any electric equipment close to the instrument. When an ISQ value is displayed, it is simultaneously sent via Bluetooth to the paired instrument if a Bluetooth connection has been made (as specified in section 14.3.1).

Always use a thread, such as dental floss, to secure the MulTipeg driver when working intra-orally.

14.3 ISQ Bluetooth transfer

Connection to other equipment can result in unidentified risks to patients, operators or others. Identification, analysis, evaluation and control of these risks are the responsibilities of the user. Changes to this or the paired device can introduce new risks that require additional analysis.

14.3.1 Bluetooth pairing

To establish Bluetooth data transfer, the instrument has to be paired with a pairable instrument. The pairing only needs to be done once. See section 19 for a listing of pairable instruments.

To pair, turn on the instrument and press and hold the key for at least 3 seconds until the instrument enters pairing mode, "PA" is shown on the display and the beeper sounds while pairing. To abort pairing attempts, press the key again. When pairing is completed, a beep is heard and measurements starts. After 2 minutes of pairing attempts without succesful pairing, the instrument will return to measurement mode.

14.3.2 Sending ISQ value
If the Osseo 100+ is paired, the displayed ISQ and battery status is automatically sent to the paired device.

15. Cleaning and maintenance

Before use, the parts should be cleaned and disinfected.

15.1 Instrument
The instrument can be cleaned with wipes soaked with detergent solution for one minute and then wiped for one minute with water-soaked lint free wipes.

Specified detergent: Neodisher Mediclean forte.

For use in environments requiring sterility, the instrument should be covered with a sterile cover.

Disinfection
Use a cloth soaked with 70 % isopropyl alcohol to wipe the instrument for one minute, and then let the instrument dry for two minutes before use.

Do not autoclave the instrument.

The instrument must be used with a cover in all uses. (Only US)
The instrument must be cleaned with a disinfectant between patients.

15.2 MulTipeg and MulTipeg Driver
Inspect the MulTipeg and MulTipeg Driver for damage before use. Dispose of the MulTipeg if there are visible damages such as severe miscoloring or damage. Dispose of the Driver if the connection part (to the MulTipeg) is visibly worn.

- **Cleaning**
  Immerse in 1% Alconox solution in tap water (20-30°C) for 5 minutes. Brush with an interdental brush for 1 minute, in the solution. Rinse in running tap water (25–35°C) for 10 seconds. Dry with a lint-free towel.
- **Sterilization**
  Sterilization should be made in a pre-vacuum steam sterilizer (autoclave) according to ISO 17665-1. Clean the products and put them in an FDA-cleared (USA) autoclave bag before sterilization. The following sterilization process shall be used:
  • At least 3 minutes at 134 (-1/+4)°C or 273 (-1.6/+7.4)°F
  • 30 minutes of drying time

Follow the instruction for the autoclave that is used.

Do not clean the MulTipeg by ultrasound.
Could cause damage.

16. Lifetime
The batteries are expected to last >500 charge cycles before a noticeable capacity change. This corresponds to a lifetime of 5 years. The internal batteries can be fully charged more than 500 times. The instrument should not be left uncharged for more than 1 year.

The MulTipeg Driver is guaranteed for at least 100 autoclave cycles, and a MulTipeg is guaranteed for at least 20 autoclave cycles, before they are degraded in any way.

17. Troubleshooting
The instrument can be tested by using the ISQ tester (fig. 6). Turn on the instrument and hold the tip close to the top of the pin. When a signal is received, a beep is heard and then the ISQ-value is shown on the display.

17.1 Possible errors
- **Difficult to achieve a measurement:**
  In some cases it is more difficult for the instrument to bring the MulTipeg into vibration. If so, try to hold the instrument tip closer to the tip of the MulTipeg. Check also that no soft tissue is touching the MulTipeg which might stop its vibration.
- **Noise warning (audible and visible on the display):**
  An electric device close to the instrument is causing the warning. Try to remove the source.
- **The instrument suddenly turns off:**
  The instrument turns off automatically after 30 seconds of inactivity. It also turns off if the battery level is too low, and due to any of the error codes described below.
- **Not all segments are lit up when instrument is started:**
  The instrument is damaged and has to be sent for repair or exchange.

17.2 Error codes
If malfunctioning, these error codes are shown on the display before it turns off:

E1: Hardware error. Malfunctioning electronics

E2: Noise error. Shown if constant electromagnetic noise is present

E3: Pulse power error. Malfunctioning magnetic pulse generation

Use of accessories and spare parts other than those specified or provided by the manufacturer of this equipment could result in increased emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

18. Accessories & Spare Parts

Model	MulTipeg Driver	Sterile Cover	Mains adapter Model No. UE05WCP-052080SPC Or UES06WNCP-052080SPA
REF	55003	55105	55093 55263

Model	EU plug	UK plug	AU plug	US plug	ISQ tester
REF	55094 55264	55095 55265	55096 55266	55097 55267	55217

MulTipeg: Please refer to the updated list from the supplier.

19. Pairable instruments

Product	Model
NSK Surgic Pro2 (Control unit)	NE335

20. Service
In case of a malfunctioning instrument, contact the manufacturer or distributor.

Osseo 100+ is covered by a two-year warranty.

21. Serious incidents

Any serious incident that has occurred in relation to the device should be reported to Integration Diagnostics Sweden AB, and the competent authority of your state.

22. EMC Information

The instrument fulfils the requirements according to EN 60601-1-2 regarding emission and immunity.
If sensitive electronic equipment is affected by the instrument, try to increase the distance to such equipment.
The charger should not be connected during measurements.

Guidance and manufacturer's declaration – Electromagnetic Emissions		
Osseo 100+ is intended for use in the electromagnetic environment specified below.		
Emissions tests	**Compliance**	**Electromagnetic environment – guidance**
RF emissions C1SPR11	Group 1	Osseo 100+ uses RF energy only for its internal function.
RF emissions C1SPR11	Class B	Osseo 100+ Rechargeable battery operated device.
Harmonic emissions IEC61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC61000-3-3	Not applicable	

Guidance and manufacturer's declaration – Electromagnetic Immunity Test Levels		
Osseo 100+ is intended for use in the electromagnetic environment specified below.		
Immunity test	**EMC standard or test method**	**Professional healthcare facility environment**
Electrostatic discharge (ESD)	IEC61000-4-2	± 8kV contact ± 2 kV ± 4 kV ± 8 kV ± 15 kV air
Radiated RF EM fields	IEC61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz
Proximity fields form RF wireless communications equipment	IEC61000-4-3	30 cm minimum separation distance from radio transmitter
Rated power frequency magnetic fields	IEC61000-4-8	30 A/m 50 Hz or 60 Hz
Electrical fast transient/burst	IEC 61000-4-4	± 2kV 100 kHz repetition frequency
Surges Line-to-line, Surges Line-to-ground	IEC 61000-4-5	± 0.5, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields	IEC61000-4-6	3V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips, Voltage interruptions and Electrical transient condition along supply lines	IEC 61000-4-11	5% UT, 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle And 70 % UT; 25/30 cycles (50/60Hz) Single phase: at 0° 0 % UT; 250/300 cycle (50/60 Hz)

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