



Osseointegration Monitoring Device

Osseo 100+

English

OPERATION MANUAL

Please read this OPERATION MANUAL carefully before use and file for future reference



MADE IN SWEDEN

55185 Rev. 3, March 2020





Fig 1



Fig 2



Fig 3



Fig 4



Fig 5

ENGLISH

1. Indications for Use

Osseo 100+ is indicated for use in measuring the stability of implants in the oral cavity and craniofacial region.

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 Osseo100+ 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


4. Specifications

- Power input: 5VDC, 1 VA
- Charger input: 100-240 VAC, 5VA
- Instrument weight: 78g
- 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.
- Bluetooth specification:
 - Frequency band: 2.4GHz ISM band (2.402-2.480GHz)
 - Transmitting power: Class2 2.5mW[dBm]
 - Modulation: GFSK
 - Channels: 40 channels with 2 MHz spacing
 - Compatibility: EN 300 328, EN 300 489-1, EN301 489-17, EN 62479:2010
 - Connection 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.

 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

5. Operating environment





















Ambient temperature: 16° to 40° C (60°-104° F)

Relative humidity: 10% to 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		Keep dry
	Follow instructions for use		Temperature limit
	Magnetic field warning		Manufacturer
	Autoclavable up to 134° C		Manufacturing year
	Delivered Non-sterile		CE mark
	Catalog number		Caution: Federal law restricts this device to sale by or on the order of a physician or dentist.
	Lot/Batch code		Waste from electronic equipment must be handled according to local regulations
	Serial number		Type BF Applied part The instrument and MulTipeg
	Bluetooth technology		Federal Communications Commission (FCC) approved equipment. FCC ID: 2AEMXY7011A00000, IC 20194-Y7011A00000
	Atmospheric pressure limit		Humidity limit

8. Characteristics

Osseo 100+ is an instrument for measuring the stability (ISQ) of dental and craniofacial implants. The instrument measures the resonance frequency of a measurement pin "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 Osseo100+ to a pairable instrument (defined in chapter 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 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 measurement pin into vibration, short magnetic pulses are sent from the instrument tip. The magnetic pulses interact with the magnet inside the measurement pin and cause the pin to vibrate. A pickup in the instrument picks up the alternating magnetic field from the vibrating magnet, calculate the frequency and from that, the ISQ value.

11. Implant stability

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

12. 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.

13. Batteries & charging

The instrument contains 2 NiMH battery cells that have to be charged before use. A full charge takes approximately 3 hours. 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. 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.

The software version is then shown briefly before the instrument starts to measure. 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 and hold the operating key until the instrument turns off. The instrument will power down automatically after 1 minute of inactivity.

14.2 Measurement

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 pin (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.

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. See chapter 19 for a listing of pairable instruments. The pairing only needs to be done once.

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 successful pairing, the instrument will return to measurement mode.

14.3.2 Sending ISQ value

If the Osseo100+ 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 Recommended disinfectants

The following disinfectants are recommended for the instrument, the Multipeg and the Multipeg Driver:

- Schülke & Mayr: Mikrozid AF Liquid
- Dürr: FD 322
- Metrex: CaviCide

Follow the instructions for use for the disinfectant that is used.



Do not autoclave the instrument

15.2 Autoclave sterilization (MultiPeg & MultiPeg Driver)

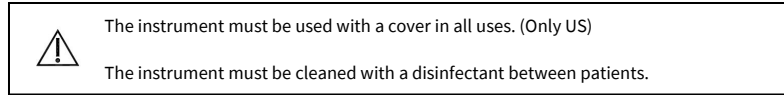
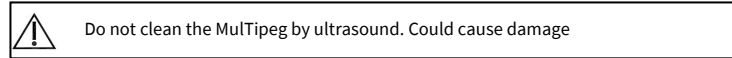
Sterilization should be made in a pre-vacuum steam sterilizer (autoclave) according to ISO 17665-1.

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

Follow the instruction for the autoclave that is used.



15.3 Cleaning

• Instrument

The instrument is cleaned with a wet cloth. Any of the above disinfectants can be used. For use in environments requiring sterility, the instrument should be covered with a sterile cover. Recommended covers (US) are Probe Covers, for instance #DYNJE5900 by Medline or part #10040 by Medical Resources.

• MultiPeg Driver and MultiPegs

The MultiPeg Driver and the MultiPeg should be cleaned with water with or without detergent, using a light brush. Any of the above disinfectant fluids can be used. For use in environments requiring sterility, the MultiPeg Driver and MultiPeg should be autoclaved before use according to the above instructions.

16. Lifetime

The lifetime of the instrument is determined by the number of charging cycles. The internal batteries can be fully charged more than 500 times before they need to be replaced. 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

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 peg. Check also that no soft-tissue is touching the peg 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 1 minute 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.

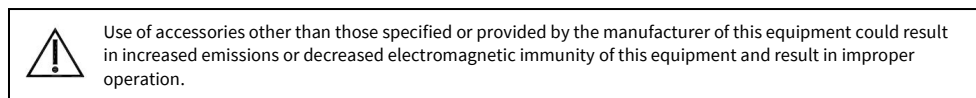
17.2 Error codes

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



18. Accessories & Spare Parts

Model	MultiPeg Driver	Sterile Cover	Mains adapter	EU plug	UK plug	AU plug	US plug
REF	55003	55105	55093 incl 1.5 m cable Fuhua Electronic Co., Ltd UE05WCP-052080SPC	55094	55095	55096	55097

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, the device should be sent to the manufacturer or distributor for repair or exchange. Osseo 100+ is covered by a two-year warranty.

21. 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	Osseo100+ 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		
Osseo100+ 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 from 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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Specifications are subject to change without notice.