English (US)

penguin II

Instructions for use

Monitor
Osseointegration

Components

Fig 1

Fig 2

Fig 3

Fig 4

Fig 5

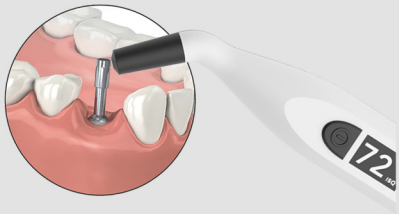

Fig 6

Fig 7

Fig 8

1.1 Indications for Use

Penguin II is indicated for use in measuring the stability of dental implants in the oral cavity and the maxillofacial region.

1.2 Intended Users

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

1.3 Figures and System components

Fig 1 Penguin II Instrument	Included in package
Fig 2 Charging station	Included in package
Fig 3 MulTipeg Driver	Included in package
Fig 4 Example MulTipeg	Not included, sold separately
Fig 5 Mains adapter & plugs	Included in package
Fig 6 Measurement position	Shows how the instrument tip is held towards the MulTipeg during a measurement
Fig 7 ISQ Tester	Included in package
Fig 8 USB with IFU	Included in package

⚠ Only original parts should be used

2. Specifications

- Power input: 5VDC, 2.3W
- Charger input: 100-240 VAC, 50-60Hz, 5VA
- Instrument weight: 89g
- Charger station weight: 285g
- Charger safety class: EN 60601-1 Class II
- Instrument safety class: EN 60601-1 ME Class II
- EMC: EN 60601-1-2, class B
- Intended for continuous use
- Contains NiMH batteries
- Bluetooth specification:
  - Frequency band: 2.4GHz ISM band (2.402-2.480GHz)
  - Transmitting power: Class2 1mW [0 dBm]
  - Modulation: GFSK
  - Channels: 40 channels with 2 MHz spacing
  - Compatibility: EN 300 328, EN 300 489-1, EN301 489-17, EN 62479:2010
  - No specific security aspects (other than those listed in 14.3) applies to the Bluetooth connection

⚠ Power supply: Use only the supplied mains adapter & plugs

⚠ No user modification of this equipment is allowed except for battery change

Batteries should be collected separately

3. 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).

4. Transport & 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).

English (US)

5. Symbols


Warning


Follow instructions for use


Magnetic field warning

Autoclavable up to 134° C

Delivered Non-sterile

Catalog number

Lot/Batch code

Serial number


Bluetooth technology


Atmospheric pressure limit


Electronic instructions for use


Keep dry

Temperature limit


Manufacturer

Manufacturing year

CE mark

Caution: Federal law restricts this device to sale by or on the order of a physician or dentist.


Waste from electronic equipment must be handled according to local regulations


Type BF Applied part


Federal Communications Commission (FCC) approved equipment. FCC ID: A8TBM71S2, IC:12246A-BM71S2


Humidity limit

Certification marks – demonstrate compliance to the requirements of widely accepted product safety standards.

6. Characteristics

Penguin II (fig 1) is an instrument for measuring the stability (ISQ,Implant Stability Quotient) 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. The Bluetooth functionality enables the instrument to connect to another Bluetooth device. For more information, see the pairable unit manual and section "Usage" below.

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

7. 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 (1 ms, +/- 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

8. Technical function

To stimulate 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. The instrument picks up the alternating magnetic field from the vibrating magnet, calculates the frequency and from that, the ISQ value.

9. Implant stability

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

10. 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.

11. Batteries & charging

The instrument contains 2 NiMH battery cells that must be charged before use. A full charge takes approximately 3 The instrument contains 2 NiMH battery cells that must be charged before use. A full charge takes approximately 3 hours. From fully charged, the instrument can measure continuously for up to 2 hours before it needs to be recharged. The battery status is visible in the display. When the battery reaches a critical level, the instrument turns off automatically. When the charging station (fig 2) is connected to the mains adapter (fig 5), it is indicated through a blue LED light on the top of the charging station. When the instrument is correctly placed in the charging station and the batteries are charging, a LED is indicating charging with a flashing green light. When the batteries are fully charged, the light will change to a fixed green light. The instrument should not be docked in the charging station while measuring.

⚠ Make sure to place the instrument correctly in the charging station

11.1 Change of batteries

When the batteries have reached their lifetime they have to be exchanged. Instructions how to change the batteries are provided with the battery pack.

⚠ Only batteries supplied by the manufacturer should be used

12. Usage

12.1 Instrument on/off

To turn the instrument on, press the operating key. Before the measurements starts a short beep will be heard and the software version will be displayed.
If any error code (EX, where "X" is the error number) is shown during start up, please refer to section "Troubleshooting".
To turn off, press the operating key. The instrument will shut down automatically after 30 seconds of inactivity.

12.2 Measurement

A MulTipeg (fig 4) is mounted onto the implant by using the MulTipeg driver (fig 3). Use hand-tightening approximately 6-8 Ncm of tightening torque. Turn on the instrument and hold the tip close to the top of the pin (fig 6). When a signal is received, a beep is heard and the ISQ-value is shown on the display.
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.

12.3 ISQ Bluetooth transfer

The ISQ number is automatically sent through a serial Bluetooth link, and can be received by any device with the The ISQ number is automatically sent through a serial Bluetooth link and can be received by a device with the capability to receive serial Bluetooth data such as an Iphone with app "SmartData" from Microchip.
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.

To establish Bluetooth data transfer, the instrument has to be connected to another Bluetooth device. To connect, find "Penguin II" in the other device and connect.

English (US)

13. Reprocessing

⚠ The instrument must always be used with an FDA cleared sterile dental sleeve (REF 55105).

13.1 Instrument

13.1.1 Cleaning & Disinfection

Use a cloth and water to clean the instrument. To disinfect, wipe the instrument for 1 minute with a cloth soaked in 70% Isopropyl alcohol and leave it for another 2 minutes to let the alcohol vanish.

⚠ Do not autoclave the instrument

13.2 MulTipeg & MulTipeg Driver

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

13.2.1 Cleaning

Immerse the device in 1% Alconox solution in tap water for 5 minutes
Brush with an interdental brush for 1 minute, in the solution
Rinse in tap water for 10 seconds
Dry with a lint-free towel

⚠ Do not sonicate the MulTipeg. Could cause damage

13.2.2 Sterilization

Sterilization should be made in a pre-vacuum steam sterilizer (autoclave) according to ISO 17665-1. Clean the MulTipeg and MulTipeg Driver and put them into an FDA-cleared autoclave bag before sterilization.

The following sterilization process shall be used:

- 3 minutes at 270°F (132°C).
- 30 minutes drying time.

14. 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 100 autoclave cycles, and a MulTipeg is guaranteed for 20 autoclave cycles, before they are degraded in any way.

Troubleshooting & testing

The instrument can be tested by using the ISQ tester (fig. 7). 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.

15.1 Possible errors

- **Difficult to achieve a measurement:**
  In some cases, it is more difficult for the instrument to make the MulTipeg vibrate. If so, try to hold the instrument tip closer to the top of the MulTipeg. Check also that no soft-tissue is touching the peg which could affect the 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 may also turn off if the battery level is too low or due to any of the error codes described below.

15.2 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 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

16. Accessories & Spare Parts

Model	MulTipeg Driver	Sterile Cover	Power adapter Model No. UES06WNCP-052080SPA 05WC052080SPC	EU plug	UK plug	AU plug	US plug	Battery lid	Battery lid screws	Battery pack	ISQ tester
REF	55003	55105	55263	55264	55265	55266	55267	55242	55244	55243	55217

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

17. Repair

In case of a malfunctioning instrument, contact the manufacturer or distributor. Penguin II is covered by a two-year warranty.

18. 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.

Penguin II is intended for use in the electromagnetic environment specified below.		
Emissions tests	**Compliance**	**Electromagnetic environment - guidance**
RF emissions C1SPR11	Group 1	Penguin II uses RF energy for its internal function and for Bluetooth
RF emissions C1SPR11	Class B	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

Penguin II is intended for use in the electromagnetic environment specified below.		
Immunity test	**EMC standard or test method**	**Test levels, 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	80 MHz - 2.7 GHz: 10 V/m 2.7 GHz – 6 GHz: 3V/m 80 % AM at 1 kHz
Proximity fields form RF wireless communications equipment	IEC61000-4-3	3 m 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 5kHz / 100 kHz repetition frequency
Surges Line-to-line, Surges Line-to-ground	IEC 61000-4-5	± 0.5, ± 1 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	0% UT, 0.5 cycle: At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle: At 0°, 180°, 70 % UT; 25 cycles. At 0° 0 % UT; 250 cycles. At 0°

Integration Diagnostics Sweden AB
Furstenbergsgatan 4
416 64 Gothenburg, Sweden
www.penguininstruments.com

CE 0402