English UK

penguin GO

Instructions for use

Assess
Osseointegration

CE Made in Sweden

Components

Fig 1

Fig 2

Fig 3

Fig 4

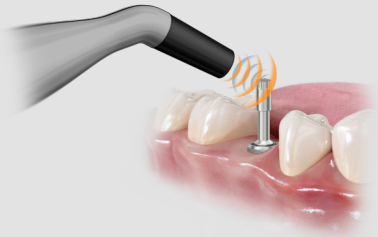

Fig 5

Fig 6

1.1 Indications for Use

Penguin GO is indicated for measuring the stability of dental implants. Indication for use is patients undergoing dental implant procedures and the intended patient population is patients having dental implants.

Contraindication for use of Penguin GO is implant systems to which the MulTipeg could not be attached for mechanical incompatibility reasons.

The direct clinical benefit of using Penguin GO is measuring and obtaining an objective value (ISQ-value) indicating the implant stability.

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

1.2. Intended users

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

1.3. Figures and System components

Fig 1 Penguin GO Instrument
Included in package

Fig 2 MulTipeg Driver
Not included, sold separately

Fig 3 Example MulTipeg
Not included, sold separately

Fig 4 ISQ Tester
Not included, sold separately

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

Fig 6 Battery location. Shows how the bottom has been unscrewed for battery insertion.
Battery not included.

Only original parts should be used.

2. Specifications

- Packaging Specifications
  - Size: 108x85x50 mm
  - Volume: 904 800 mm3
  - Weight: 174g
  - Material: PU (surface) + 6 mm, 75 degree EVA (Body + Knitted fabric lining), Inside: Sandwich pocket in top lid + CNC EVA foam in bottom
- Instrument Specifications
  - Power input: 1.5 VDC, 0.8 W
  - Instrument weight: 75 g
  - Dimensions: 175 mm x 36 mm x 24 mm
  - Instrument safety class: EN 60601-1 ME
  - Applied parts according to IEC 80601-2-60: Instrument tip and instrument up to 80 mm from the tip, MulTipeg and MulTipeg Driver
  - EMC: EN 60601-1-2, class B
  - Ingress protection: IP20
  - Intended for continuous use
  - Requires 1 standard 1.5 V Alcaline AA-battery

No user modification of this equipment is allowed.

3. Operating environment

Ambient temperature: 16° to 40 °C (60°–104 °F).
Relative humidity: 10 % – 80 % Rh.
Atmospheric pressure: 700 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).

5. Symbols

 Warning	 Lot/ Batch code	 Keep dry	 Waste from electronic equipment must be handled according to local regulations
 Follow instructions for use	 Serial number	 Temperature limit	 Type BF Applied part
 Magnetic field warning	 Unique device identifier	 Manufacturer	 Catalog number
 Autoclavable up to 134 °C	 Atmospheric pressure limit	 Manufacturing date	 Humidity limit
 Delivered Non-sterile	 Electronic instructions for use	 CE mark	 Medical device
 INMETRO Compulsory Conformity Identification Seal			

6. Characteristics

Penguin GO (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.

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

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. 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.

10. 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 reco mmended 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.

11. Batteries & charging

The instrument runs on one standard AA-battery (1,5Volt). The status of the battery is indicated on the instrument display. If the battery is too low, the instrument turns off automatically. If stored more than 2 weeks the battery shall be removed.

11.1 Change of batteries

When the battery has reached its lifetime, it can be exchanged (fig 6).

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 10 seconds of inactivity.

12.2 Measurement

A MulTipeg (fig 3) is mounted onto the implant by using the MulTipeg driver (fig 2). Use hand-tightening approximately 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 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.

Portable RF co mmunication equipment, incl antennas, can affect the equipment. When in use, distance to other equipment should be no closer than 30 cm (12 inches), including cables specified by the manufacturer

Always use a thread, (such as dental-floss if sterility is not needed, or surgical thread where sterile conditions are necesarry), to secure the MulTipeg Driver when working intra-orally.

13. Cleaning and maintenance

Before use, the parts should be cleaned and disinfected.

13.1 Instrument

Cleaning

Use a wipe dampened with a detergent solution and clean the instrument for one minute.

Take a lint-free wipe dampened with water and wipe off the detergent solution for one minute.

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

Disinfection

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

The instrument must be disinfected between patients using the reco mmended disinfectants. Do not autoclave the instrument.

Note: Do not try to remove the tip of the instrument.

13.2 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

I mmerse 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. This could cause damage to the MulTipeg.

14. Lifetime

The lifetime of the instrument is set to 5 years.

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.

15. Troubleshooting & testing

The instrument can be tested by using the ISQ tester (fig. 4). 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 a set ISQ-value in the range shown on the label is shown of 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 MulTipeg which could affect the vibration. When the device is measuring, the measurement symbol is shown on the display.

- **Noise warning**
  (audible and visible on the display):
  An electric device close to the instrument is causing the warning symbol to appear.
  Try to remove the source.

- **The instrument suddenly turns off:**
  The instrument turns off automatically after 10 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 i mmunity of this equipment and result in improper operation

16. Accessories & Spare Parts

Model	MulTipeg Driver	ISQ tester
REF	55003	55217

MulTipeg: Please refer to the updated list from the supplier: https://www.penguininstruments.com/multipegs

For other accessories:

https://www.penguininstruments.com/accessories

17. Service

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

18. 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.

19. Waste and disposal

The instrument should be recycled as electrical equipment. MulTipeg 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

20. EMC Information

The instrument fulfils the requirements according to EN 60601-1-2 regarding emission and i mmunity. 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 GO is intended for use in the electromagnetic environment specified below.		
Emissions tests	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR11	Group 1	Penguin GO uses RF energy for its internal function
RF emissions CISPR11	Class B	Battery-operated device
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC61000-3-3	Not applicable	

Guidance and manufacturer's declaration – Electromagnetic I mmunity Test Levels		
Penguin GO is intended for use in the electromagnetic environment specified below.		
I mmunity test	**EMC standard or test method**	**Test levels, professional healthcare facility environment**
Electrostatic discharge (ESD)	IEC 61000-4-2	± 8kV contact ± 2 kV ± 4 kV ± 8 kV ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	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 co mmunications equipment	IEC 61000-4-3	3 m minimum separation distance from radio transmitter
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Electrical fast transient/burst	IEC 61000-4-4	± 2kV 5 kHz / 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	IEC 61000-4-6	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°

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