

English UK



# Penguin<sup>RFA</sup>

## Instructions for use

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Assess

Osseointegration

CE Made in Sweden



Fig 1



Fig 2



Fig 3

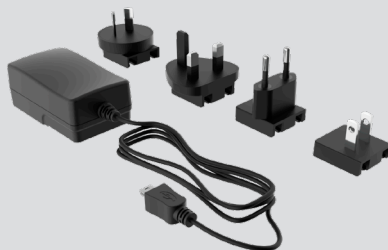


Fig 4

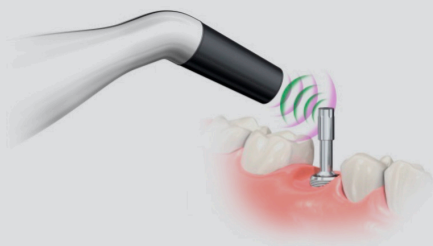


Fig 5



Fig 6

## 1. Indications for Use

Penguin RFA 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 RFA is implant systems to which the MultiTipeg could not be attached for mechanical incompatibility reasons.

The direct clinical benefit of using Penguin RFA is measuring and obtaining an objective value (ISQ-value) indicating 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** Penguin RFA Instrument  
Included in package

**Fig 2** MultiTipeg Driver  
Included in package

**Fig 3** Example MultiTipeg  
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 MultiTipeg 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: 5 VDC, 1 VA
- Charger input: 100 – 240 VAC, 5 VA
- Instrument weight: 82 g
- Dimensions instrument: 201 mm x 26 mm x 31 mm
- 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
- Contains NiMH batteries:
  - Battery type: AAA, rechargeable
  - Voltage: 1.2 V
  - Current: 900 mA
- Applied parts according to IEC 80601-2-60: Instrument tip and instrument up to 80 mm from the tip, MultiTipeg and MultiTipeg Driver.

## 5. Operating environment

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

Relative humidity: 10 % – 80 % Rh.

Atmospheric pressure: 500 hPa – 1,060 hPa (0.5 atm – 1 atm).






















## 6. Transport & storage

Ambient temperature: -20° to 40 °C (-4° – 104 °F).

Relative humidity: 10 % – 85 % Rh.

Atmospheric pressure: 500 hPa – 1,060 hPa (0.5 – 1.0 atm).

## 7. Symbols

 <p>Warning</p>	 <p>Catalog number</p>	 <p>Unique device identifier</p>	 <p>CE mark</p>
 <p>Follow instructions for use</p>	 <p>Lot/ Batch code</p>	 <p>Keep dry</p>	 <p>Caution: Federal law restricts this device to sale by or on the order of a physician or dentist.</p>
 <p>Magnetic field warning</p>	 <p>Serial number</p>	 <p>Temperature limit</p>	 <p>Waste from electronic equipment must be handled according to local regulations</p>
 <p>Autoclavable up to 134°C</p>	 <p>Atmospheric pressure limit</p>	 <p>Manufacturer</p>	 <p>Type BF Applied part</p>
 <p>Delivered Non-sterile</p>	 <p>Electronic instructions for use</p>	 <p>Manufacturing date</p>	 <p>Humidity limit</p>
 <p>Medical device</p>			

## 8. Characteristics

Penguin RFA is an instrument for measuring the stability (ISQ) of dental implants. The instrument measures the resonance frequency of a MultiTipeg 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  $\pm 1$  ISQ unit. When mounted onto an implant, the MultiTipeg 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 because it could result in improper operation.

## 9. MultiTipeg

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

There are different MultiTiegs 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 MultiTiegs. Using the wrong MultiTipeg could cause erroneous measurements or damages to the MultiTipeg or implant.



The instrument emits short magnetic pulses with pulse duration of 1 ms and strength of  $\pm 20$  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 MultiTipeg into vibration, short magnetic pulses are sent from the instrument tip. The magnetic pulses interact with the magnet inside the MultiTipeg and cause the MultiTipeg 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 MultiTipeg.

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.

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 30 seconds of inactivity.

### 14.2 Measurement Penguin RFA

A MultiTipeg (fig 3) is mounted onto the implant by using the MultiTipeg 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 MultiTipeg (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.



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

## 15. Cleaning and maintenance



Before use, the parts should be cleaned and disinfected.

### 15.1 Instrument

#### Cleaning

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



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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.

<b>Guidance and manufacturer's declaration – Electromagnetic Emissions</b>		
Penguin RFA is intended for use in the electromagnetic environment specified below.		
<b>Emissions tests</b>	<b>Compliance</b>	<b>Electromagnetic environment – guidance</b>
RF emissions CISPR11	Group 1	Penguin RFA uses RF energy only for its internal function.
RF emissions CISPR11	Class B	Penguin RFA Rechargeable battery operated device.
Harmonic emissions IEC61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC61000-3-3	Not applicable	

<b>Guidance and manufacturer's declaration – Electromagnetic Immunity Test Levels</b>		
Penguin RFA is intended for use in the electromagnetic environment specified below.		
<b>Immunity test</b>	<b>EMC standard or test method</b>	<b>Test levels, professional healthcare facility environment</b>
Electrostatic discharge (ESD)	IEC61000-4-2	± 8 kV 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	3 V 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)

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.

Manufacturer

**Integration Diagnostics Sweden AB** 

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[www.penguininstruments.com](http://www.penguininstruments.com)

Specifications are subject to change without notice.



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