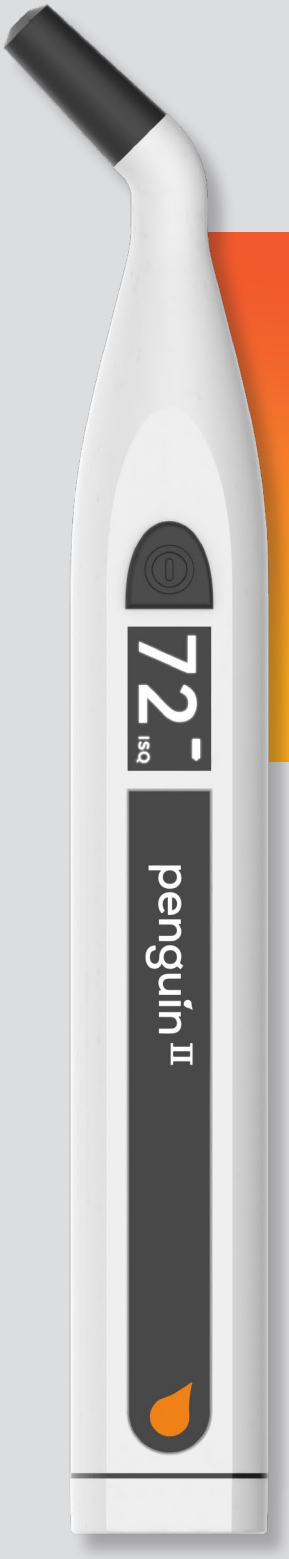
English



penguin II

Instructions for use

Assess
Osseointegration

Components

Fig 1

Fig 2

Fig 3

Fig 4

Fig 5

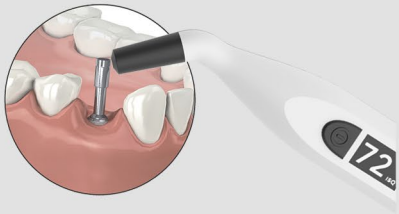


Fig 6

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. Indication for use is patients undergoing dental implant procedures and the intended patient population is patients having dental implants.

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

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

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
- Dimensions: 202 x 26.5 x 25.6 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
- Intended for continuous use
- 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 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

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

5. Symbols

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

11. 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 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 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 can be exchanged. Contact your distributor for support.

⚠ 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 MulTipeg (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.

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

12.3 ISQ Bluetooth transfer

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.

13. Cleaning and maintenance

⚠ Before use, the parts should be cleaned and disinfected

13.1 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.

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

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
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. This could cause damage to the MulTipeg.

14. Lifetime

The batteries are expected to last >500 charge cycles before a noticeable change in capacity. This corresponds to a lifetime of 5 years. 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, to avoid change in capacity.
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. 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 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 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	Mains adapter Model No. UE05WCP-052080SPC Or UES06WNCP-052080SPA	EU plug	UK plug	AU plug	US plug	Battery replacement kit	ISQ tester	Charging station
REF	55003	55105	55093 55263	55094 55264	55095 55265	55096 55266	55097 55267	55291	55217	55225

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

17. Service

In case of a malfunctioning instrument, contact the manufacturer or distributor. Penguin II 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. 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°

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.

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