Shatkin F.I.R.S.T.®

penguin MDI

Instructions for use

Monitor Osseointegration

English

Components

Fig 1

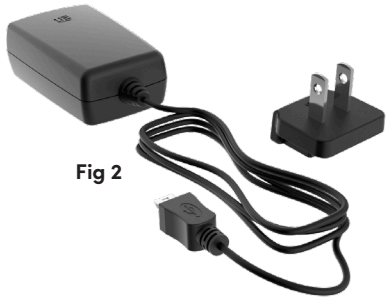

Fig 2

Fig 3

Fig 4

Fig 5

Fig 6

Fig 7

1. Indications for Use

Penguin MDI is indicated for measuring the stability of Mini Dental Implants (MDI) in the oral cavity or maxillofacial 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	Penguin MDI Instrument	– Included in package
Fig 2	Mains adapter and plug	– Included in package
Fig 3	MDI MulTipeg	– Included in package
Fig 4	MulTipeg Driver	– Included in package
Fig 5	Locking Screwdriver	– Included in package
Fig 6	MulTipeg attachment	– Shows how to connect the MulTipeg to a Mini Dental Implant
Fig 7	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: 100g
- 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

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, non-condensing

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 limits
	Magnetic field warning		Manufacturer
	Autoclavable up to 134° C		Manufacturing year
	Delivered Non-sterile		Humidity limit
	Catalogue 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
	Atmospheric pressure limit		

8. Characteristics

Penguin MDI is an instrument for measuring the Mini Dental Implant Stability Coefficient (MSC).
The instrument measures the resonance frequency of a MulTipeg and presents it as an MSC value; 1-99. The MSC value reflects the stability of the implant – the higher the value, the more stable the implant.

The instrument measures the MSC-value with a precision of +/- 1 MSC unit. When mounted onto an implant, the MulTipeg resonance frequency can vary up to 2 MSC units depending on the tightening torque.

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

9. MDI MulTipeg

The MDI MulTipeg is made from titanium and has an integrated grip for the MulTipeg driver on top, and a locking screw for attaching it to the implant. Inspect the MulTipeg for damage before use. Damaged MulTipegs should not be used due to the risk of erroneous measurements.

Measurements should only be performed using an MDI MulTipeg. Using the wrong MulTipeg will cause erroneous measurements or might cause 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 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. A pickup in the instrument picks up the alternating magnetic field from the vibrating magnet, calculates the frequency and from that, the MSC value.

11. Implant stability

An implant can have different stabilities in different directions. The measurement should be made in the direction of the MulTipeg locking screw, so try to mount the MulTipeg in the same rotational direction each time the implant is measured.

12. MSC-value

The stability of the implant is presented as an MSC value; 1–99.

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. When the battery reaches a critical level, the instrument shuts off automatically. When the batteries are charging, the blue LED is lit. When the charging is ready, 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.

Make sure the correct instrument is used: see fig. 1. No other instrument is allowed together with the MDI MulTipeg. Use Penguin MDI with MDI MulTipegs Only.

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 with Penguin MDI

Always secure with floss or wires to secure the Drivers when working intra-orally.

14.2.1 Mounting MulTipeg

- Loosen the locking screw but do not try to remove it from the MulTipeg body.
- Use the MulTipeg Driver (Fig.4) to hold and place the MulTipeg on top of the implant. The MulTipeg will magnetically stick to the Driver.
- Tighten the locking screw with the Locking Screwdriver (Fig.5) with approximately 4–5 Ncm of tightening torque.
- Remove the Drivers from the MulTipeg.

Excess tightening torque can damage the screw.

14.2.2 Measuring

- Turn on the instrument and hold the tip close to the top of the MulTipeg, in the direction of the locking screw (Fig. 7). Beeps are heard when signals are received. The MSC-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.

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

15. Reprocessing

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.

Do not autoclave the instrument.

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.

15.2 MDI MulTipeg, MulTipeg Driver, Locking Screwdriver

Inspect the MDI MulTipeg and Drivers for damage before use. Dispose of the MulTipeg if there are visible damages such as severe miscoloring or if the locking screw is missing or damaged. Dispose of the Drivers if the connection part (to the MulTipeg) is visibly worn.

Cleaning of MDI MulTipeg

Loosen the MulTipeg locking screw slightly, but do not try to remove it from the MulTipeg body. Immerse the devices in 1% Alconox solution in tap water (20–30°C) for 5 minutes. Brush with a soft brush for 1 minute in the solution, use an interdental brush to reach into the lumen at the top and at the screw on the side. Place the device in a beaker with new Alconox solution (1% in tap water 30° C) and place in an ultrasonic bath, sonicate for 5 min. Inspect the instrument carefully and repeat the brushing step if any residual soil remains. Rinse in tap water (25-35°C) for 10 seconds. Dry with a lint-free towel.

Cleaning of MulTipeg Driver and Locking Screwdriver

Immerse the device in 1% Alconox solution in tap water (20-30°C) for 5 minutes. Brush the device 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 of MDI MulTipeg, MulTipeg Driver and Locking Screwdriver

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

The following sterilization process shall be used:
- 3 minutes at 270°F (132°C).
- 30 minutes drying time.

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 Drivers are guaranteed for at least 100 autoclave cycles, and a MulTipeg is guaranteed for 20 autoclave cycles. After 20 autoclave cycles, the MulTipeg should be replaced.

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 MulTipeg. Check also that no soft tissue is touching the MulTipeg 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 30 seconds 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

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.

18. Accessories & Spare Parts

Model	MulTipeg Driver	Locking Screw Driver	Sterile Cover	Mains adapter Model No. UE05WCP-052080SPC	US plug	MDI MulTipeg
REF	55003	55283	55105	55093	55097	55282

19. Repair

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

20. 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 MDI is intended for use in the electromagnetic environment specified below.		
Emissions tests	**Compliance**	**Electromagnetic environment – guidance**
RF emissions C1SPR11	Group 1	Penguin MDI uses RF energy only for its internal function.
RF emissions C1SPR11	Class B	Penguin MDI 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 MDI 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 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	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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