







Figure 1



Figure 2



Figure 3

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Figure 3. SmartPeg and SmartPeg Mount

Description

MEGA ISQ is a portable, handheld instrument that involves the use of the non-invasive technique, Resonance Frequency Analysis, for measuring dental implant stability. The system includes the use of a SmartPeg[™] attached to the dental implant. The SmartPeg is excited by a magnetic pulse from the handheld instrument Probe. The resonance frequency, which is the measure of implant stability, is calculated from the response signals. Numerical digits are displayed on the instrument as the Implant Stability Quotient (ISQ), which is scaled from 1 to 100. The higher the number, the greater the stability. SmartPegs are available for a range of different implants. SmartPegs are for single patient use and delivered sterile.

Indications for Use

MEGA ISQ is indicated for use in measuring the stability of implants in the oral cavity and maxillofacial region. MEGA ISQ can add important information to the evaluation of implant stability and can be used as part of an overall treatment evaluation program. The final implant treatment decisions are the responsibility of the clinician.

Precautions

MEGA ISQ should not be used in the presence of explosive or combustible materials. The instrument Probe emits magnetic pulses with peak strength of 20 Gauss, 9 mm from the Probe tip. To avoid interfering with other equipment, the Probe should not be held in close proximity to electronic devices. To maintain a high level of safety, the power supply designed specifically for the MEGA ISQ must be used when charging the instrument batteries. Additional power supplies must be ordered directly from your local distributor/supplier.

Caution: When switched on, the Probe emits an alternating magnetic field that could potentially interfere with cardiac pacemakers.

Technical Description

MEGA ISQ is CE-marked according to MDD in Europe. MEGA ISQ is designed according to, and fulfilling the standards EN 60601-1, 3rd edition (Class II Type BF applied part, Internally powered equipment, Not AP or APG Equipment, Not protected against ingress of water), EN 60601-1-2, ISO 17665-1, ISO 17664 and ANSI/AAMI ST79:2010.

Specifications

Power, Weight & Size

Power supply:	Type FW 7660M/05, Rated power 8 VA
Instrument size:	130 x 80 x 37 mm
Docking station size:	155 mm in diameter and 85 mm in height
Instrument weight:	0.18 kg
Docking Station Weight:	0.25 kg
Package size:	280 x 240 x 63 mm
Gross weight:	1.0 kg

Environmental Conditions During Transport

Temperature:	-40 °C to +70°C
Relative humidity:	10% to 95%
Pressure:	500 hPa to 1060 hPa

Environmental Conditions During Use:

Temperature:	+10 °C to +40 °C
Relative humidity:	30% to 75%
Pressure.	700 hPa to 1060 hPa
IP-class:	IP20

Accuracy

ISQ accuracy is within +/- 0,5 ISQ units for a single SmartPeg. Including variations in the attachment torque and individual variations between different SmartPegs, the accuracy is +/-2 ISQ units.

Symbols



Caution



Class II Equipment

¥	

Type BF equipment



No protection against water



Manufacturer



Separate collection



Sterilizable up to 135°C (275°F)



Do not re-use

MEGA ISQ Preparation and Set-up

Batteries

The internal battery is rechargeable and should be charged for at least 3 hours, before its first use.

TestPeg

The TestPeg included in the MEGA ISQ package may be used for testing and learning how to use the system. The TestPeg is to be used as follows: Place the TestPeg on a table or hold it by hand. Turn on the instrument and hold the Probe (See Figure 2) close to the top of the TestPeg without touching it. The instrument will emit an audible sound and displays the ISQ value. Aim the Probe tip at the red mark on the TestPeg.

Note: Do not unscrew the TestPeg from the black plastic cylinder!

MEGA ISQ Operation

Operation

To turn the instrument on, press the on/off key (See Figure 1). To turn it off, press and hold the on/off key. The instrument will power down automatically after 6 minutes of inactivity.

The instrument is used with the Probe connected to the instrument via its cable (figure 1). The Probe with its cable can be autoclaved, see section Cleaning and Maintenance.

Note: To remove, pull gently holding around the connector.

Connecting SmartPeg

Before using a SmartPeg, check that the sterile package is not damaged nor expired. If so, the SmartPeg has to be disposed. SmartPeg should be handled carefully, as damages to the SmartPeg may affect the measurement result. Connect the SmartPeg Mount to a SmartPeg (Figure 3). The SmartPeg is magnetic, and the Mount will hold the SmartPeg as it is carried to the implant. Screw the SmartPeg into the implant, and make sure that it engages the threads smoothly. Use approximately 4-6 Ncm of torque. To avoid destroying the SmartPeg threads, do not over-tighten.

The SmartPeg is available with different connection geometries in order to fit all major implant products on the market.

Note: The SmartPeg is for single use only. To avoid dropping the SmartPeg Mount, always use a thread to secure it.

Performing a Measurement

Attach a SmartPeg to the implant. Hold the Probe close to the top of the SmartPeg without touching it (Figure 2). When the instrument senses the SmartPeg and the measurement is recorded, it will emit an audible sound. If two such sounds are heard in a row, they will be followed by a beeping sound and the display will present the ISQ value. If there is much electromagnetic interference noise present, the instrument might not be able to record a measurement. Instead it will emit a warning signal. If this is the case, remove the source of the electromagnetic interference.

Note: Start by measuring in the mesio-distal direction (along the jaw-line). Then try to measure a value in the bucco-lingual direction (perpendicular to the jaw-line). If it is not possible to get a reading in exactly the bucco-lingual direction, measure in a slightly different rotational angle.

Interpreting the Result

The ISQ

Stability Measurements using the MEGA ISQ may be performed at any time after the implant is placed, assuming there is access to the implant. In most cases, measurements are performed at implant placement and before the implant is loaded, or before the abutment is connected. The stability is measured at these time points to determine any change in stability. After each measurement, the ISQ values should be recorded and used as the baseline for the next measurement performed. A change in the ISQ value reflects a change in implant stability.

In general, an increase in ISQ values from one measurement time to the next indicates a progression towards higher stability and lower ISQ values indicate a loss in stability and perhaps, implant failure. A stable ISQ value would indicate no change in stability. ISQ values have not been correlated with other methods of implant mobility measurement.

Implant Stability

An implant has different stability levels in different directions. The total stability consists of the implant stability in relation to the surrounding bone, and the stability of the bone itself. There is always a direction where the stability is the lowest and a direction where the stability is the highest. These two directions are perpendicular to each other.

The SmartPeg measures the stability in those two directions and therefore two different ISQ-values can be achieved on the same implant. Sometimes, the two ISQ values will be very close to each other, or even the same.

Batteries and Charging

The MEGA ISQ instrument must be charged using only the MEGA AC/DC adapter, connected to the docking station. The charger should be used in dry, indoor locations. The instrument contains a Lithium battery. If the battery is completely discharged, the recharge process requires approximately three hours, depending on the room temperature. (Charging the battery in warm environments may require a longer charging duration.)

The power supply operates with mains voltage from 100 to 240 VAC, 50-60 Hz. Thus it can be used in most countries in the world using the appropriate mains adapter. Battery charging is indicated by a flashing blue LED on the instrument display. When the battery voltage is low, the instrument will emit an audible signal together with the symbol "LB" - Low Battery on the instrument display. If the battery level falls under the critical value, the symbol "CB" - Critical Battery is shown and the instrument will turn itself off.

Cleaning and Maintenance

If needed, the instrument may be wiped off with a cloth and water or isopropyl alcohol solution. The instrument does not require regular maintenance. In the event of an instrument malfunction, the MEGA ISQ and accessories should be sent to the seller for repair.

The Probe with its cable and the SmartPeg Mount shall be autoclaved according to the recommended sterilization method which is validated to sterility assurance levels (SAL), according to ISO 17665-1 and ISO 17664. Other sterilization cycles may also be suitable, though the individuals or hospitals are advised to validate other methods before use. The Probe and the SmartPeg Mount should be placed in suitable packaging for the sterilization process.

Method:	Gravity displacement steam
Exposure temperature:	135°C (275°F)
Exposure time:	10 minutes
Drying time:	30 minutes
Symbol:	$\begin{array}{ c c c c }\hline 135^{\circ}C\\\hline \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ $
Warnings:	Do not exceed 137°C (278°F) Remove from autoclave directly after finished cycle Allow to cool down before use, handle carefully when hot Do not use dishwasher / ultrasonic cleaner for cleaning Do not pour liquids directly into any of the connectors

MEGA ISQ is recycled as electrical equipment. The SmartPeg is disposable and should be disposed of after use.

Service

The instrument and accessories must be sent to the seller for repair. Any questions concerning this product should be referred to MEGA'GEN:

MEGA'GEN

MEGA'GEN TOWER 607, Seolleung-ro, Gagnam-gu Seoul, South Korea Tel: +82-2-3014-7812 E-mail: sales@imegagen.com Web: www.imegagen.com

Accessories & Spare Parts

Spare parts and/or accessories should be ordered directly from the seller or from your local distributor.