

The Trust User Manual

Implant Stability Measuring Device

Made In Korea

GENOSS
For Patients & Doctors

Manufacturer

D-Factory, 56, Changnyong-daero 256beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, Republic of Korea www.genoss.com

Dentium
For Dentists By Dentists

Seller

#821, Kangnam Ace Tower, 174-10, Jagok-ro, Gangnam-gu, Seoul, Republic of Korea
Tel. 82-2-555-3750 / www.dentium.co.kr

MS-P2828/RFU-DC2103(Rew.0,2105)

User Manual

The Trust

Implant Stability Measuring Device

Dentium Co., Ltd.



Table of Contents

1	Product Introduction	04
2	Parts	05
3	Specifications	07
4	How to Use	08
5	Display	15
6	Precautions	17
7	Maintenance/Repair	18
8	Symbols	19
9	Electromagnetic Compatibility for TT-1.0	20
10	Warranty	27

Thank you for purchasing 'The Trust' (dental implant stability measuring device).

This user manual informs users of how to use, handle, and manage the device and provides general information for safe use.

Therefore, users are advised to read through the user manual to ensure proper operation of the device before using it.
Please keep the user manual near the device so it can be referred to anytime.

The user manual is subject to change without prior notice due to product upgrades or changes in specifications.

The Trust

Implant Stability Measuring Device

Product Introduction

1. Product Description

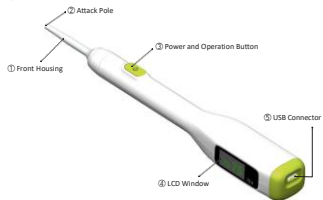
ISV (Implant Stability Value) is a measure that indicates the stability and osseointegration of an implant. The measure ranges from 1 to 99 and a high value means high stability. Via mechanical strike, this medical device measures the fixed (Integration) strength between bones and a dental implant during transplantation and osseointegration.

2. Purpose of Use

This device strikes the surface of an implant healing abutment with its attack pole mechanically and measures the contact time, displaying numbers on the LCD window that indicate the stability between the implant fixture and the alveolar bone numerically. The number is proportionate to stability, which means a higher number denotes higher stability.

2 Parts

Main



Accessories



⑥ USB C-Type Cable



⑦ Front Housing x 2



⑧ Attack Pole x 1

2.1 Main Body

No.	Name	Description
①	Front Housing	When the device strikes the surface of the implant healing abutment with the attack pole, it guides the pole.
②	Attack Pole	Strikes the implant healing abutment to measure the stability of a dental implant.
③	Power and Operation Button	Hold down the power/operation button to turn on the device. When the device powers on, press the power/operation button briefly to operate the device. When holding down the power/operation button again, the device powers off.
④	LCD Window	Displays the value of the measured stability of a dental implant (ISV) and the charging status of the battery.
⑤	USB Connector	Used to charge the battery; the USB C cable is connected to the USB connector.
⑥	USB C-Type Cable	A cable with which to charge the battery of the main body.

3 Specifications

Product Name		The Trust
Model Name		TT-1.0
Main Body	Weight(g)	80g
	Size(mm)	220x25x27.5mm
Measurement Tolerance		Measured Value ± 3
Measuring Angle		0°~90°
Measuring Count		7 Times
Measuring Duration		Less Than 3 Seconds
Strike Intensity		Less Than 3N
Timer		Turns off automatically when the device is not used for more than 2 minutes.
Rated Voltage		DC 3.7V / 0.5A
Charging Cable		USB C-Type
Storage Conditions		Temperature: 0°~40°C / Humidity: 30°~85%

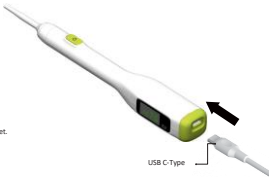
4 How to Use

4.1 Charging the Battery

- ① Connect one end (C-type plug) of the USB C cable to the USB connector at the back of the main body and the other end (A-type plug) to the USB charger.
- ② It takes about an hour to charge the battery from full discharge to full charge.
- ③ Rated Voltage : DC 3.7V, 0.5A

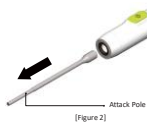
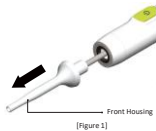
Precautions

- Please charge the device at least an hour after first use.
- When the battery is fully charged, remove the USB charger from the power outlet.
- Do not use the device while the battery is being charged.



4.2 How a User Sterilizes the Device

- ① Disassembly: separate the front housing and the attack pole from the main body (they are attached by magnetic force) in the direction of the arrow. [Figure 1. Figure 2]
- ② Assembly: put together in reverse order of disassembly.



Precautions

- To sterilize the device, detach the front housing and attack pole from the main body of the device.
- Users can sterilize the front housing and the attack pole in a sterilizer (121 °C for 15 minutes).

4.3 Preparation Before Use

- ① Hold the device horizontally.
- ② When it powers on, press the power/operation button and measure the void strikes (strikes in the air).
- ③ The measured value should be 00.
- ④ If the value on the LCD window shows a figure other than 00, please contact the manufacturer and make a request for repair.

4.4 How To Operate

Status	How To Operate
Power On	While the device is off, press the power/operation button briefly.
Measure	While the device is on, press the power/operation button briefly to start the device.
Power Off	While the device is on, hold down the power/operation button.
	If you do not use the device for 2 minutes while it is on, it powers off automatically.

4.5 How To Measure Stability

Measuring ISVs with the direction in which a dental implant is implanted being perpendicular (90°) to the main body of the device (90°) renders accurate values.

① In this manual, implant stability value is referred to as ISV.

② This device does not work while the battery is being charged. When the battery of the device is fully charged, please remove the USB charging cable from the device.

③ To prevent cross infection of the front housing and the attack pole, sterilize them.

④ Press the power/operation button long and the LED window turns on. Then release the button. Now, the device is ready for operation (standby status).



Precautions

- Allow the front housing to make contact with (the surface of) the healing abutment gently and measure the strikes.
- Measuring the strikes when the front housing is not in contact with the healing abutment does not produce an accurate ISV.



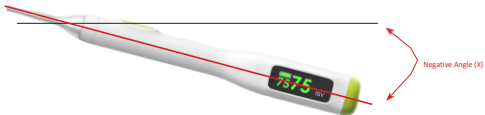
- ⑤ When a user presses the power/operation button briefly, the device buzzes (making a 'beeping' sound) and the attack pole starts to strike the healing abutment, measuring the stability. The first ISV is shown on the right side of the LCD window. The second ISV is shown on the right side of the LCD window. The first ISV appears below the battery indication (on the left side of the LCD window) in a smaller font.
- ⑥ When the device stops measuring, check the ISVs displayed on the LCD window.
- ⑦ ISVs are notated in different colors depending on the ranges as below: red for 1~59, yellow for 60~64, and green for 65~69.

Ranges of Measured Stability (ISV)	1~59	60~64	65~69
Color by Range	Red	Yellow	Green

⑧ If a user operates the device when it is not horizontal (that is, its back end is at a negative angle, it does not work but only makes a buzzing sound).

Use the device only when its end back is at $0^{\circ}\sim 90^{\circ}$ degrees (at 0° , it is horizontal).

When the device is horizontal, it is at 0°



⑨ This device powers off automatically if not used for 2 minutes to save battery power. In addition, a user can power off the device by force by holding down the power/operation button.

When the power shuts off, connect the USB charging cable to the device to charge the battery. When the device is being charged, the LCD window shows the battery charging symbol.



4.6 Checking Results

- ① The reference value for the healing abutment is H3.5mm. If different, calibrate it as specified in the table below.
② If H is higher than the reference by 0.5mm, increase ISV by +1. If it is lower by 0.5mm, decrease ISV by -1.

Height of Healing Abutment	2mm	3.5mm	5mm	7mm
ISV Calibration	-3	0	+3	+7

- ③ The reference value for dual abutment is G/H1.0mm. If different, calibrate it as specified in the table below.
④ If H is higher than the reference by 0.5mm, increase ISV by +1. If it is lower by 0.5mm, decrease ISV by -1.

Height of Dual Abutment	1mm	1.5mm	2.5mm	3.5mm	4.5mm	5.5mm
ISV Calibration	0	+1	+3	+5	+7	+9



Caution: do not push the healing abutment too hard with the front housing.

4.7 Storage and Management After Use

- ① After use, sterilize the front housing and the attack pole.
② Wipe the main body with a dry cloth gently to keep it clean.
③ Store the device in a safe place where it can avoid direct sunlight or water.

5 Display

1. Status and How To Operate

Status	How To Operate	Display and Sound	
		LCD Window	Sound
Power On	While the device is off, press the power/operation button.		Once
Power Off	While the device is on, hold down the power/operation button.	LCD Off	Once
Measurement	When the device is on, press the power/operation button briefly and then the ISV appears on the LCD window. The previously measured ISV is displayed on the right side (below the battery symbol) on the LCD window.		Once

Status	How To Operate	Display and Sound	
		LCD Window	Sound
Charging Starts	When the charging cable is connected to the main body of the device, the battery charge symbol appears on the LCD window.	 	Once
Failure	If a user presses the power/operation button when the main body is at a negative angle (below 0°), the device does not strike.		3 Times
Full Charge	When the battery is fully charged and the charging cable is removed from the main body, the LCD window turns off.	LCD Off	None
Charging Error	When the battery is not charged, a warning sound goes off and a warning image appears on the LCD window.		At Regular Intervals

6 Precautions

1. Precautions When Using the Device

- ① Be thoroughly familiar with the user manual before using the device.
- ② Do not subject the device to impact or disassemble or alter it arbitrarily.
- ③ Do not use the device for purposes other than measuring the stability of a dental implant.
- ④ Use the device only in a dental environment.
- ⑤ For the device to be used, a patient should be seated and under the supervision of a dentist.
- ⑥ Do not use the device in a hot or humid environment.
- ⑦ Do not let water contact the main body of the device. Otherwise, there could be a risk of electric shock and fire.
- ⑧ Do not place the device near a device or equipment using electromagnetic waves or radiation.

2. Don't's

- ① If you are not an expert, do not use the device.
- ② Don't try to maintain or repair the device in a way not specified in the user manual.
- ③ Don't try to maintain or repair the device in a way not specified in the user manual.
- ④ Do not use the device in high ambient temperatures (e.g., near a heater, fan).
- ⑤ Maintenance is prohibited while the device is being operated. While doing maintenance work, please power off the device.
- ⑥ Do not disassemble or alter the device without the permission of the manufacturer.

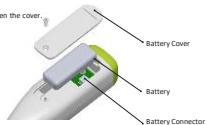
6.3 Warnings

- ① Be fully familiar with the user manual and the precautions before using the device.
- ② If suspecting that the device has been subject to an impact, contact the seller or the manufacturer for inspection. Do not impact the device or disassemble or alter it arbitrarily.
- ③ If the device is not sterile when first delivered, the user needs to sterilize it prior to use.
- ④ Used a certified charger to ensure safety.

7 Maintenance/Repair

Please replace batteries as follows.

- ① Turn the screw of the battery cover counterclockwise with a screwdriver to loosen the cover.
- ② Remove the battery cover.
- ③ Remove the used battery, socket, and the connector connected to the main board.
- ④ Connect the connector of the new battery to the socket of the main board.
- ⑤ Put the battery cover back on and turn the screw of the battery cover clockwise with a screwdriver to tighten the cover.



When disposing of used batteries, please put them in a designated collection bin.

8 Symbols

No.	Symbols	Description	No.	Symbols	Description
1		Manufacturer	5		User manual
2		Do not use the device if packaging is damaged.	6		B-type mounting unit
3		Temperature limit	7		Waste flow handling status
4		Caution	8		Controller

9 Electromagnetic Compatibility for TT-1.0

Guidance and Manufacturer's Declaration – Electromagnetic Compatibility

Guidance and manufacturer's declaration – electromagnetic emissions

TT-1.0 is intended for use in electromagnetic environments specified below. Users of the TT-1.0 should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Class 1	The TT-1.0 uses RF energy only for its internal functioning. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emissions CISPR 11	Group B	The TT-1.0 is suitable for use in all establishments other than domestic environments, but may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded. Warning: This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigating measures such as re-orienting or relocating the TT-1.0 or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The TT-1.0 is intended for use in electromagnetic environments specified below. Users of the TT-1.0 should ensure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) EN 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be made of wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical fast transient/burst EN 61000-4-4	2 kV (for power supply lines) ±1 kV (for input/output lines)	±2 kV (for power supply lines) ±1 kV (for input/output lines)	N/A
Surge EN 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	N/A
Voltage dips, short interruptions, and voltage variations in power supply input lines EN 61000-4-11	0% U _r (100% dip in U _r) for 0.5/1 cycles 70% U _r (30% dip in U _r) for 25/30 cycles 0% U _r (100% dip in U _r) for 250/300 cycles	0% U _r (100% dip in U _r) for 0.5/1 cycles 70% U _r (30% dip in U _r) for 25/30 cycles 0% U _r (100% dip in U _r) for 250/300 cycles	N/A
Power frequency (50/60 Hz) Magnetic field EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the main voltage (AC) prior to application of the test level. a For example, 10/12 means 10 cycles at 50 Hz or 12

cycles at 60 Hz.

Recommended separation distances between portable and mobile communication equipment and Derma LD Scalp Care

The TT-1.0 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Users of the TT-1.0 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TT-1.0 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter (m)				
	IEC 60601-1-2:2007			IEC 60601-1-2:2014	
0.01	150 kHz to 80 MHz d = 1.2Vp	80 MHz to 800 MHz d = 1.2Vp	800 MHz to 2.5 GHz d = 2.3Vp	150 kHz to 80 MHz d = 1.2Vp	80 MHz to 2.7 GHz d = 2.0Vp
	0.12	0.12	0.23	0.12	0.20
0.1	0.38	0.38	0.73	0.38	0.63
1	1.2	1.2	2.3	1.2	2.0
10	3.8	3.8	7.3	3.8	6.3
100	1.2	12	23	12	20

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

*NOTE 1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

*NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Guidance and manufacturer's declaration - electromagnetic immunity

The TT-1.0 is intended for use in electromagnetic environments specified below.
Users of the TT-1.0 should ensure that it is used in such an environment.

Immunity test	Electromagnetic	Compliance	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz – 80 MHz Outside ISM Bands amateur radio bands Bandsd 6 Vrms 150 kHz – 80 MHz In ISM bands amateur radio bands Bandsd	3 Vrms 6 V/m	Portable and mobile RF communications equipment should not be used closer to any part of the ultrasound system, including cables, than the recommended separation distance. This is calculated using the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = 1.2\sqrt{P}$ IEC 60601-1-2:2007 $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 80 MHz to 2.5 GHz IEC 60601-1-2:2014 $d = 2.0\sqrt{P}$ 80 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.7 GHz		



* NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

* NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio, and TV broadcasts cannot be predicted theoretically with accuracy.
- b. To assess an electromagnetic environment containing fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the TT-1.0 is used exceeds the applicable RF compliance level above, the TT-1.0 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the TT-1.0.
If the frequency range exceeds 150 kHz – 80 MHz, the electric field strength should be not higher than 3 V/m.
- c. The ISM (Industrial, Scientific, and Medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz
- d. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

This product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the product. Otherwise, performance degradation of this equipment could occur.

Guidance and manufacturer's declaration - electromagnetic immunity

The TT-10 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the TT-10. Otherwise, degradation of the performance of this equipment could result.

Immunity test	Band a	Service a	Modulation	IEC60601 test level	Compliance level
Proximity fields from RF wireless Communications IEC61000-4-3	380 - 390 MHz	TETRA 400	Pulse modulation 18Hz	27 V/m	27 V/m
	430 - 470 MHz	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	28 V/m	28V/m
	704 - 787 MHz	LTE Band13, 17	Pulse modulation 217 Hz	9 V/m	9 V/m
	800 - 960 MHz	GSM800:900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation 18 Hz	28 V/m	28V/m

Immunity test	Band a	Service a	Modulation	IEC60601 test level	Compliance level
Proximity fields from RF wireless Communications IEC61000-4-3	1700 - 1990 MHz	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,2,4,25 UMTS	Pulse modulation 217 Hz	28 V/m	28V/m
	2400 - 2570 MHz	Bluetooth WLAN 802.11b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	28 V/m	28V/m
	5100 - 5800 MHz	WLAN 802.11a/n	Pulse modulation 217 Hz	9 V/m	9 V/m

*NOTE : If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1m.

A 1m test distance is permitted by IEC 61000-4-3.

a. For some services, only the uplink frequencies are included.

b. The carrier shall be modulated using a 50% duty cycle square wave signal.

c. As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used, because while it does not represent actual modulation, this would indicate the worst case scenario.

10 Warranty

GENOSS Co. guarantees that the Trust is free of defects in its functions and materials for one year from the date of purchase under conditions of normal use and service.

Note that correct use precedes the product warranty. Inferior parts in GENOSS's products may be repaired or exchanged free of charge during the warranty period. However, in the event that GENOSS considers the product warranty not to apply, a customer may be requested to pay for parts, delivery fees, or/and personnel expenses.

When purchasing the product, please fill in the following form and submit it to the relevant individual. When requesting maintenance/repair, users need to submit a letter of warranty to the manufacturer.

Cases in which (free) warranty is not applied.

- ① A product flaw or damage caused by an accident due to user recklessness, misuse, abnormal use, improper storage, etc.
- ② A product flaw or damage caused by an external factor such as use of the product in high ambient temperatures (e.g., near a heater, fan, refractoryware).
- ③ A product flaw or damage caused by a test, operation, maintenance/repair, installation, or modification not authorized by GENOSS.
- ④ A product flaw or damage caused by negligence re. the warnings specified in the user manual.

Warranty (Registration of Genuine Product)			
Product Name	The Trust	Customer Information	
Date of Purchase		Customer Name	
Date of Manufacture		Contact No.	
Serial No.		Address	
Warranty Period			

The Trust

Implant Stability Measuring Device