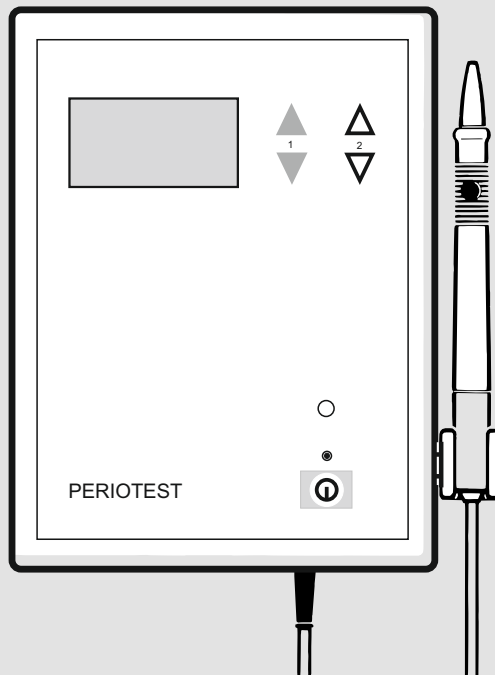


PERIOTEST® classic

Operating Instructions
English



Medizintechnik Gulden e.K.

Operating Instructions

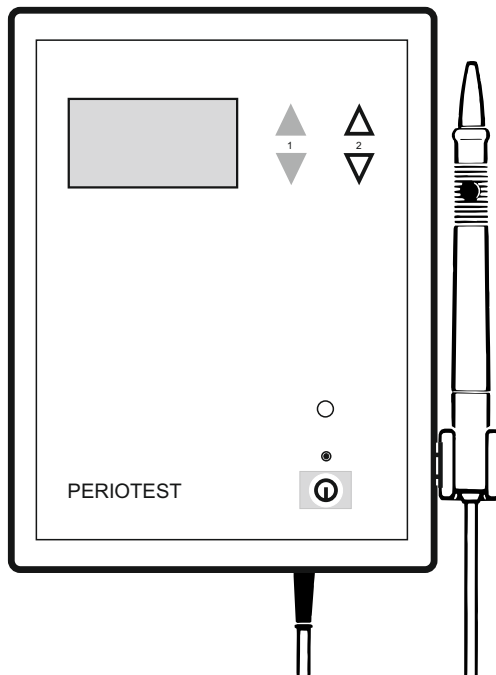
Electrical measuring instrument for dentistry and dental implantology

PERIOTEST[®] classic

Electrical measuring instrument for dentistry and dental implantology

Operating Instructions English

English



About this document

Dear Customer,

Thank you for purchasing the Medizintechnik Gulden Periotest classic.

The technical documentation supplied is part of the product and always must be kept within easy reach. Please read these Operating Instructions carefully and familiarize yourself with the Periotest classic.

If you encounter unsolvable problems after thoroughly studying the Operating Instructions, please contact your dental depot or the manufacturer.

Symbols used in the Operating Instructions

To prevent any personal injury or material damage, please observe the warning and safety information provided in the present operating instructions. All such information is highlighted as follows:

NOTE

Additional information, explanation or supplement.

CAUTION

The information provided under this keyword directly concerns the functioning of the product and / or warns against possible operating errors.

WARNING

The warning symbol warns against possible hazards for the product or the user.

**Symbols used in these
Operating Instructions as well
as on the product and the
package**

VAC (volts alternating current): Alternating current in volts.

VDC (volts direct current): Direct current (DC) in volts.



Serial number of the unit



Electrical protection class: II (double insulation, complies with the requirements of IEC 60601-1.



Part applied to patient: Type BF.



Manufacture date: Date written as year-month.



Name and address of the manufacturer.



Disposal: This product must not be disposed with household garbage.



Order number / item number

Storage and transport conditions



Temperature: The product must not be stored and transported at temperatures ranging outside of -20 °C and +50 °C (-4 °F and +122 °F).



Air pressure: Permissible atmospheric pressure: 500 to 1060 hPa.



Humidity: Permissible relative humidity: 20 to 90 %.



Observe information in accompanying documents.



Fragile; handle with care.



Protect from moisture.



This product bears the CE mark in accordance with the provisions of Council Directive 93/42/EEC of June 14, 1993 concerning medical devices.

Item number and Version of
Operating Instructions

REF 8919521
Version 2015-10-01

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1 Warning and safety information

1.1 General safety information

Retention of documentation

It is very important to make sure that this manual is stored together with the unit so that it will also be available at any time in the future. In case the unit is sold or the right to use is transferred to a different owner, make sure that the manual always remains located near the unit. This is necessary to ensure that the new owner can use the unit properly and has all required information.

Read carefully before starting!

These instructions serve to promote safety. Be sure to read them carefully before installing and using the unit.



This symbol appears on the rating plate to remind the user to observe the manual.

Medical electrical devices may be used with reference to the risk of electrical shock, fire or mechanical hazards, according to IEC 60601-1 only.

Intended use

The Periotest classic is an electrical measuring instrument for dentistry and dental implantology. It may be used only by qualified dental personnel.

Modification of the device

The device must not be modified without the permission of the manufacturer.

Disclaimer

The manufacturer assumes no liability whatsoever in cases involving:

- work or repairs performed by any personnel not authorized by the manufacturer or importer
- an application which does not correspond to the ones described in this manual
- the use of non-OEM components or any components not described in the section entitled **Scope of supply**.

Electromagnetic compatibility	<p>To prevent potential risks from electromagnetic interference, no medical devices or other electronic devices may be operated in the immediate vicinity of the Periotest M (see Chapter 12 for recommended working clearances between Periotest M and portable and mobile RF communication devices). The device meets the currently applicable guidelines for electromagnetic compatibility (IEC 60601-1-2). This unit does not cause any harmful interference. However, it can receive interference from other devices, such as wireless transmitters, mobile communication devices, and other household appliances, including interference that may lead to undesirable functions. Special EMC precautions are required for the installation and operation of the Periotest M. These Operating Instructions contain the corresponding EMC information.</p>
Operating environment	<p>Never use this unit in the presence of flammable anesthetics or anesthetic agents mixed with air, oxygen or nitrogen.</p>
Inspection and maintenance	<p>No preventive inspections or maintenance are required.</p>
Connected devices	<p>The Periotest classic may be used only with the supplied handpiece. The usage of a different handpiece may lead to wrong readings.</p>
Sterilization	<p>Maximum sterilization temperature for the handpiece (without handpiece cable): 134 °C (273 °F).</p>
Handpiece cable	<p>Excessive bending or kinking of the handpiece cable should be avoided to prevent damage.</p>

Power supply

The Periotest classic is powered by a storage battery. The supplied power supply unit is used only to charge the battery, but not to operate the Periotest classic. The power supply unit must be disconnected from the mains supply before switching on the Periotest classic.

Battery compartment

The Periotest classic may be used only with closed battery compartment (see bottom of the unit).

Side effects

Until now, no side effects (e.g. necrosis) have been determined in connection with clinical use of the Periotest classic.

Return shipment for repair

Parts returned for repair must always be disinfected prior to shipment to ensure that no innocent bystander is infected when unpacking and transporting them.

Disposal

It generally applies that any disposal of this product must comply with the relevant national regulations. Please observe the regulations applicable in your country. Within the European Economic Community, Council Directive 2002/96/EU (WEEE) requires environmentally sound recycling / disposal of electrical and electronic devices. Your product is marked with the adjacent symbol. Disposal of your product with domestic refuse is not compatible with the objectives of environmentally sound recycling / disposal. The black bar underneath the „garbage can“ symbol means that it was put into circulation after August 13, 2005 (see EN 50419:2005). Please note that this product is subject to Council Directive 2002/96/EU (WEEE) and the applicable national law of your country and must be recycled or disposed in an environmentally sound manner. Please contact your dental depot if final disposal of your product is required.



2 Technical information

2.1 Technical description

The Periotest classic is an electrical measuring instrument for use in dental practices. It is designed for the following range of applications:

- Assessment of the osseointegration of dental implants
- Diagnosis and assessment of periodontopathies. The Periotest classic measures the damping characteristics of the periodontium and, indirectly, tooth mobility, which it outputs in the form of a Periotest value.
- Assessment of the occlusal load
- Control of the treatment's progress.

The instrument's scale ranges from -8 to +50. The unit of measure is „Periotest values“. Periotest values correspond to the contact time of the probe with the measured object (tooth, implant). A short contact time corresponds to a low Periotest value, while a long contact time corresponds to a high Periotest value.

The Periotest classic is the result of a cooperation between experienced dental technicians and many years of experience in high-end electronics. It represents the state of the art in dental research technology.

Contraindications

The Periotest classic should not be applied in the following cases:

- All types of acute apical periodontitis
- Acute trauma (dislocation, root fracture, alveolar process fracture).

2.2 Technical data

Manufacturer	Medizintechnik Gulden e.K.
Model	Periotest classic type 3218
Dimensions	approx. 193 x 172 x 43 mm
Material	
Housing	ABS (Flammability V0)
Front foil	Polyester
Handpiece sleeve	Brass, nickel and chrome plated
Tapping head	Stainless steel
Weight incl. battery	approx. 870 g
Noise level	< 65 dBA
Mains voltage	100 - 240 VAC
Voltage fluctuations	+/- 10 % max
Frequency	50 - 60 Hz
Power consumption from connected power supply unit during battery charging	900 mA
Battery	NiMH 12 VDC 1500 mAh
Protection class	II
Degree of protection against electrical shock	Applied part type BF
Safety class	Never use this unit in the presence of flammable anesthetics or gases
Operating mode	Intermittent operation: ON 4 sec. / OFF until next measurement
Operating conditions	Temperature: +18 °C / +30 °C (50 / 86 °F) Relative humidity: < 85 % Air pressure: 700 - 1100 hPa
Protection against harmful ingress of water	Normal
Periotest classic housing	IP20
Energy transfer from the tapping head to the measured object (tooth, implant)	max. 0,00018 Joule
Weight of the tapping head	approx. 9 g
Range of the Periotest value scale	-8 to +50
Unit of measure	Periotest values
Accuracy of measure	Scale range -8 to +19 : +/- 1 Periotest value Scale range +20 to +50: +/- 2 Periotest values
Display resolution	1 Periotest value
Transport and storage conditions	Temperature: -20 °C / +50 °C (-4 / +122 °F) Relative humidity: < 90 % Air pressure: 500 - 1060 hPa

2.2 (continued): Technical data

Data power supply unit:

Charging device for NiMH batteries (NiMH charger for 4-10 cells)

Type: FW7219

Input: 100-240 VAC

Output: 4.8 - 12 VDC / 0.8 A

Housing protection class: IP40

Item number / order number: 5959683

2.3 Service life of Periotest classic instruments

When used as intended, the non-moving parts of Periotest classic instruments have a typical service life of 5 years. Moving parts of Periotest classic instruments have a typical service life of 3 years. However, no warranty claim can be inferred here, as wear may occur earlier or later than indicated above depending on use, frequency of sterilization and frequency of maintenance.

If your Periotest classic (the unit as a whole, or in parts) or the accessories shall not be used any more, do not dispose the product or the parts with household garbage. They can be posing a risk to the environment. Please return these parts to the manufacturer. Alternatively, there may be local recycling or collection points.

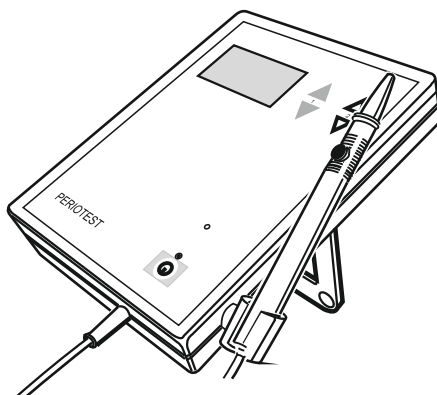
3 Scope of supply

- Periotest classic with handpiece cable and handpiece REF 8916538
- NiMH battery (inserted) REF 5959677
- Battery charger (Technical data see section 2.2) REF 5959683
- Test sleeve REF 5950027
- Cleaning brush REF 5245758
- Operating instructions REF 8919521

4 Installing the Periotest classic

Remove the Periotest classic and its accessories from the box and lay everything on a table. Before installing the Periotest classic, inspect everything for damage. Any damage which may have occurred during transport must be reported to the dealer within 24 hours after receipt of the goods. Check the contents of the box for completeness as described in section 3 (Scope of supply).

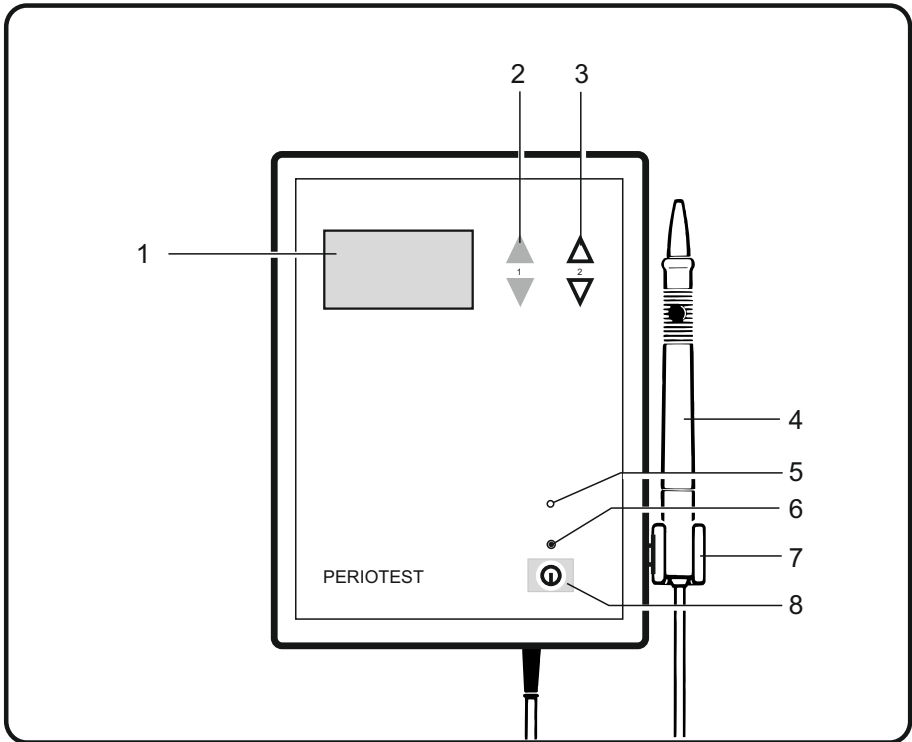
A fold-out lifter is located on the bottom of the Periotest classic. It can be used to tilt the unit to give the user a better view of the display.



CAUTION

- This product is intended only for use by trained dental personnel.
- Do not install the Periotest classic near direct or indirect sources of heat.
- Prior to initial use, all components of the Periotest classic must be disinfected (see section 9).
- The packaging of the unit or its accessories must not be used for sterilization.
- While the battery is charging, make sure that the charger's plugs can be easily reached to enable quick and easy disconnection from the Periotest classic.

5 Controls and functional elements



1 - Display

2 - Type keys

3 -System keys

4 - Handpiece

5 - Loudspeaker

6 - Indicator LED (green) for operation

7 - Handpiece holder

8 - Power ON/OFF switch

6 Operation

6.1 Putting the unit into operation

The Periotest classic is intended solely to be driven by battery (12 VDC). It is not designed for mains operation (100 - 240 VAC).

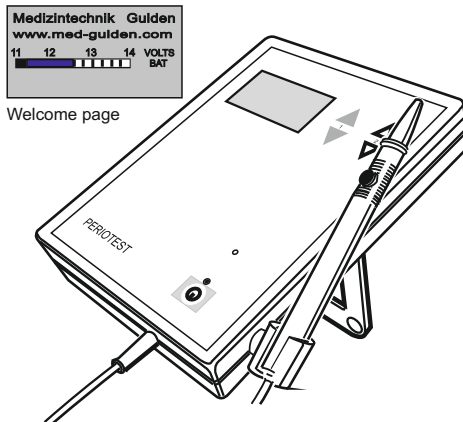
WARNING

The Periotest classic must not be connected with the mains supply during operation!

The Periotest classic is disconnected from the mains supply by pulling the battery charger out of the wall socket.

To switch on the unit, press the ON/OFF switch. The name of the manufacturer, the manufacturer's website and the battery charging level will appear briefly on the display. If the remaining battery voltage is less than 12 VDC, you may charge the battery to ensure the availability of the unit.

After approx. 3 seconds the unit is ready to take measurements.



6.2 Language selection, volume and contrast control

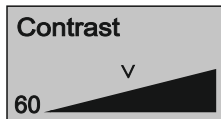
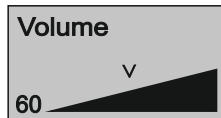
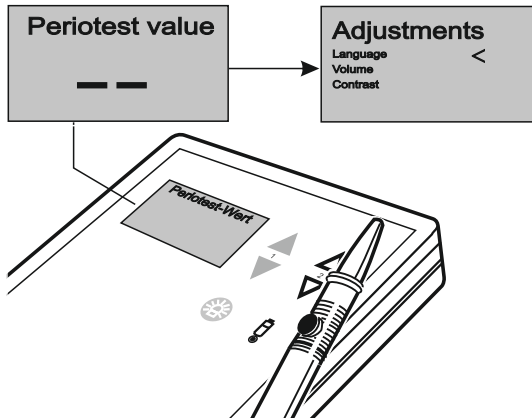
The following setting options can be selected with the „System“ keys:

- Language for display and voice output of the readings
- Volume of control tones and voice output
- Display contrast

Enter the settings by pressing the „System key“ downwards.

With the „Type key“ upwards you can increase the volume or contrast or select a language in the forward direction. With the „Type key“ downwards you can decrease the volume or contrast or select a language in the reverse direction.

Save the settings by pressing the „System key“ upwards.

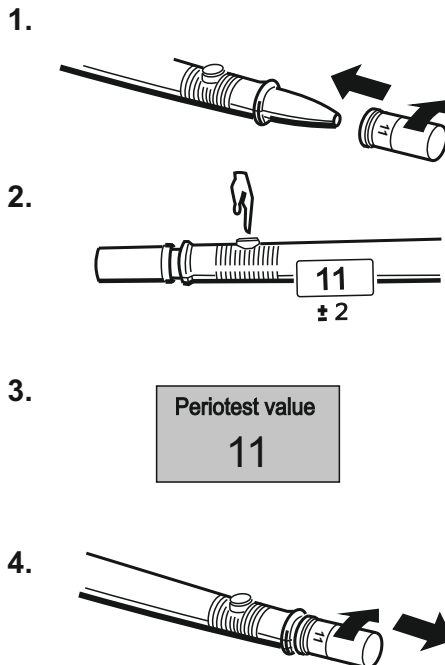


6.3 Functional test

With the functional test as described hereinafter you verify the correct function and readings of the Periotest classic. Please carry out the functional test every time before you take any measurement at a patient. The functional test is done by measuring the supplied test sleeve.

Switch on the unit and wait until the unit is ready to take measurements (approx. 3 seconds). Take the handpiece out of the handpiece holder and fit the test sleeve onto the tip of the handpiece. Hold the handpiece **horizontally** and start the measuring process by pressing briefly the switch of the handpiece.

After the measuring cycle (approx. 4 seconds - 16 impulses) the reading is indicated on the display, and you hear the corresponding voice output. The reading should match the value indicated on the test sleeve. A deviation of ± 2 Periotest values is acceptable. In case of a higher deviation, or in case no reading at all is indicated, the Periotest classic does not measure properly. Please observe the instructions in section 9.1 (Care and cleaning). Above all, the handpiece must be clean and dry, enabling the tapping head to move easily. If cleaning of the handpiece does not solve the problem, please contact your dealer.



7 Conducting measurements with the Periotest classic

7.1 Sitting position of the patient

Most favourable is an upright sitting position of the patient with a corresponding vertical position of the teeth / implants. But it is also possible to conduct measurements on patients in a lying position.

The teeth of the maxilla and the mandible must not have contact to each other. However, the patient should open his mouth only a little bit and not too wide to enable an easy access to the molar area.

7.2 Point of application at the tooth / implant

To measure natural teeth, the handpiece must be positioned from vestibularly (buccally, labially) in direction of lingually / palatinally. The tapping head should hit the center of the lateral surface of the tooth.

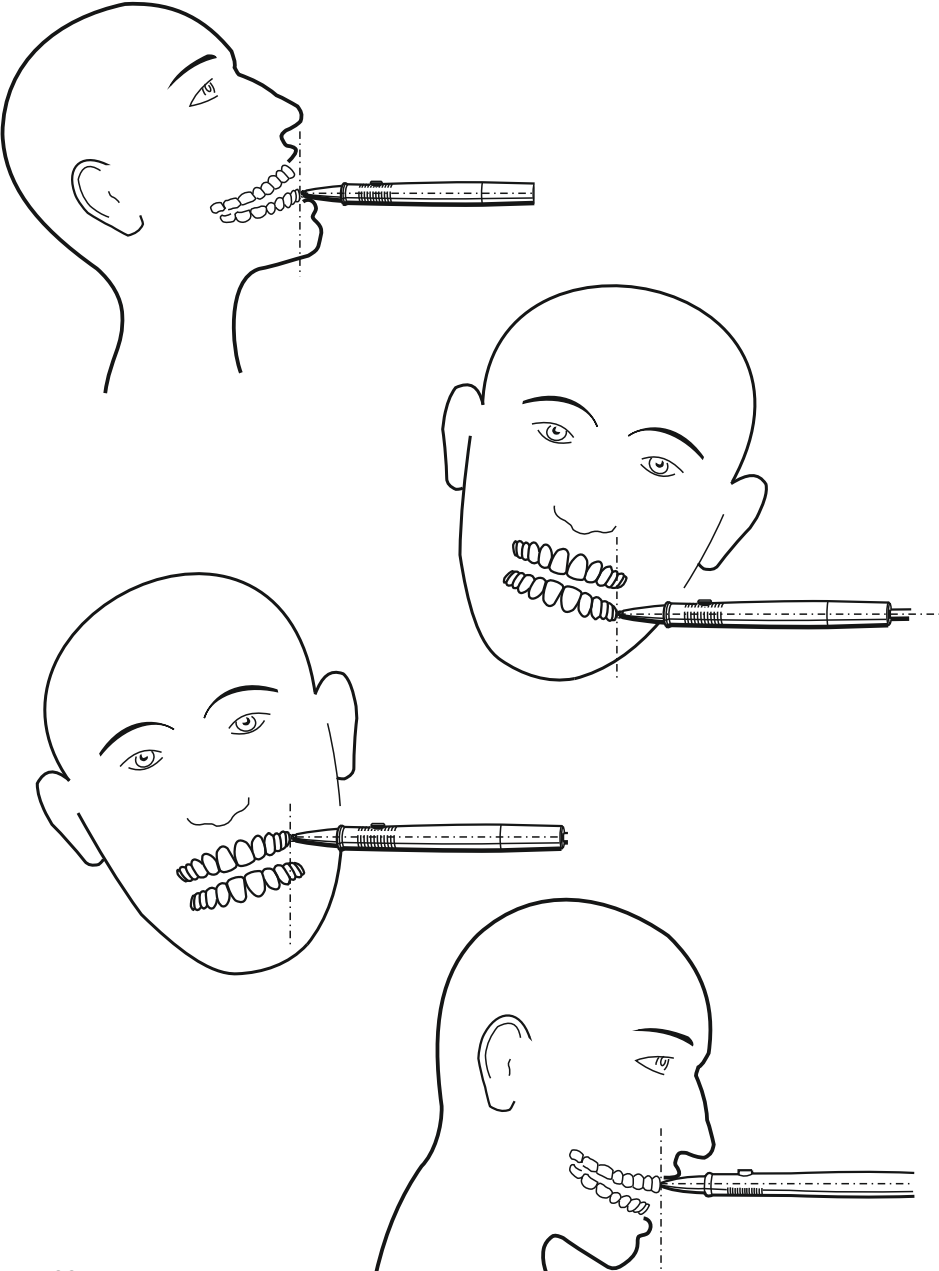


To measure dental implants, two measuring directions are relevant:

1. Accordingly to the measurement of natural teeth: Position of the handpiece from vestibularly in direction of lingually / palatinally. Mainly the lingual wall is measured.
2. Alternatively, if anatomically possible and accessible: Position of the handpiece from lingually / palatinally in direction of vestibularly. Mainly the vestibular wall is measured.

One-piece implants are measured at the upper end of the implant (ball head or similar). Two-piece implants are not measured at the implant itself, but at the implant abutment, the gingiva former or the final crown. The preferred hitting point is right above the gingiva.

Examples for measurements of natural teeth in maxilla and mandible, anterior tooth region and molar region.

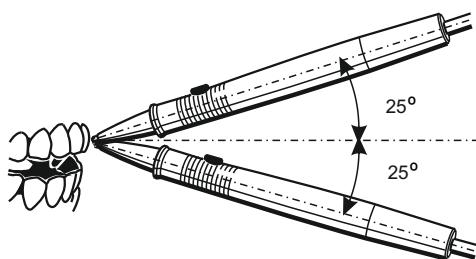


7.3 Posture of the handpiece

In order to get valid and reproducible readings, the Periotest classic handpiece must be held and positioned at the tooth / implant in a particular manner. Please observe the following instructions.

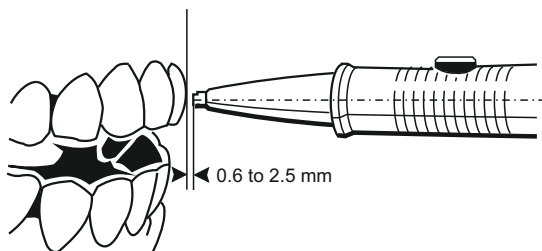
1. Horizontal posture of the handpiece

You only get valid readings if the handpiece is held (more or less) horizontally. A slight bending upwards or downwards (up to $\pm 25^\circ$) will be accepted. A little hint: If you think the handpiece is held horizontally, it is in fact often held already downwards. This is due to the perspective how the handpiece is held. It often helps to lift the tip of the handpiece a little bit.



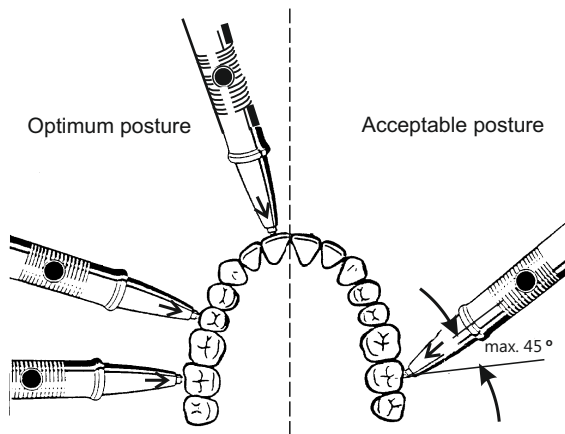
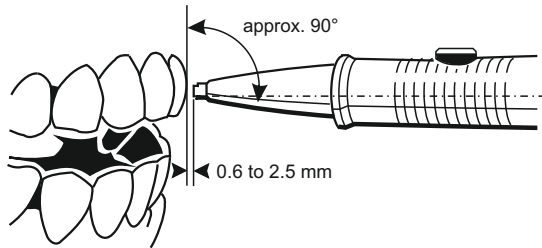
2. Distance between the tip of the handpiece and the tooth / implant

You need to have a certain distance between the tip of the handpiece and the tooth / implant. The valid distance is between 0.6 and 2.5 millimeters. If the handpiece is held more closely than 0.6 mm or more further away than 2.5 mm, there will be no valid reading. In the beginning it requires a little practice to meet the correct distance. We recommend to make some test measurements at demo tooth models or implants, before starting to measure „real“ teeth / implants.



3. Right angle between the handpiece and the tooth / implant

In order to get readings with the highest accuracy, place the handpiece in a right angle (handpiece horizontally, tooth / implant axis vertically). In the molar area, this is not always possible. Deviations up to 45° are acceptable but can lead to slightly different readings (+/- 1 Periotest value).



7.4 Measurement procedure

Switch on the Periotest classic and wait until the unit is ready to take measurements (approx. 3 seconds). Take the handpiece out of the handpiece holder. Start the measuring process by pressing briefly the button of the handpiece. The tapping head will hit the tooth / implant 16 times. For each valid impulse a low tone is emitted. For invalid impulses (for example, because the handpiece posture was not correct) a high tone is emitted. It is possible to correct the posture of the handpiece during the ongoing measurement process.

At least 4 of 16 impulses must be valid in order to get a valid reading. A valid reading is shown on the display and „spoken“. For example: The reading „15" is spoken as „One five“ and the reading „-2" is spoken as „minus two“.

If less than 4 impulses were valid, no reading will be indicated on the display. The display shows - - and there is no voice output.

To start a new measurement, press the handpiece button again. If you have finished the measurements, insert the handpiece into the handpiece holder and switch off the unit. If you do not switch off the unit manually, it switches off automatically after approx. 4 minutes. The unit can be switched on again by pressing the ON/OFF button.

7.5 Point in time of measurements at dental implants

You can take measurements in each stadium of the implantological process. Typical points in time are:

- Directly after implant insertion (measuring the primary stability)
- After the healing phase
- After the final crown is installed

7.6 Measurement of the occlusal load

To measure occlusal load, the patient should press his teeth together as if swallowing (to attain maximum intercuspitation). The measurement can be taken on the upper jaw with the teeth rows closed. To check occlusal adjustment, it is also possible to take measurements on the lower jaw.

8 Meaning of the Periotest values

General

The Periotest scale ranges from -8 to +50. The smaller the Periotest value, the higher the stability / damping degree of the tooth / implant.

ATTENTION

The Periotest classic is a measuring instrument which has been extensively tested and proven for many years. Nevertheless, it cannot be excluded that the device is not working properly and the readings are not correct. For legal reasons, we need to point out that before starting any medical treatment you must not rely solely on the measured Periotest value. You rather need to collect more data to assure your diagnosis.

Measurement of natural teeth

Clinical degree of tooth loosening	Periotest value
0	- 8 to 09
I	10 to 19
II	20 to 29
III	30 to 50

Furthermore, tables for natural teeth are available, showing Periotest values that can be expected in case of a healthy periodontium, for each tooth separately. Please see the professional literature for more information.

Measurement of dental implants

Nowadays, a wide range of implant systems is available on the market. In principle, the Periotest classic can be used at all of them. However, due to this multitude of implant systems, and the variation of the clinical situations, with regard to the meaning of the Periotest values, we can only give guideline values which represent a high and a low implant stability (osseointegration).

Periotest value range	Interpretation
-8 to 0	Good osseointegration; the implant can be loaded
01 to 09	Clinical examination is required; loading of the implant might or might not be possible, depending on implant type and clinical situation
10 to 50	Osseointegration is insufficient, the implant cannot be loaded

Generally, in the first days following implantation, implants lose a certain amount of stability. This is reflected by an increase in the Periotest values. After the healing phase, however, the Periotest values should be similar or lower to those immediately following implantation (primary stability). Persistent and significant higher Periotest values indicate either a destabilization of the implant, or a screw loosening, or an overloading of the implant, or an infection (e.g. periimplantitis). It is recommended to record the measured data, enabling to compare the different readings taken over time.

9 Care and cleaning

The unit and its accessories must be cleaned and disinfected prior to initial operation and before treating each patient. Unplug the power supply unit from the power outlet prior to cleaning or disinfection. Do not apply any liquids to the unit or spray them directly onto it. Never immerse the unit or its accessories in liquids. The packaging of the unit or its accessories must not be used as sterilization packages.

9.1 Cleaning and disinfection

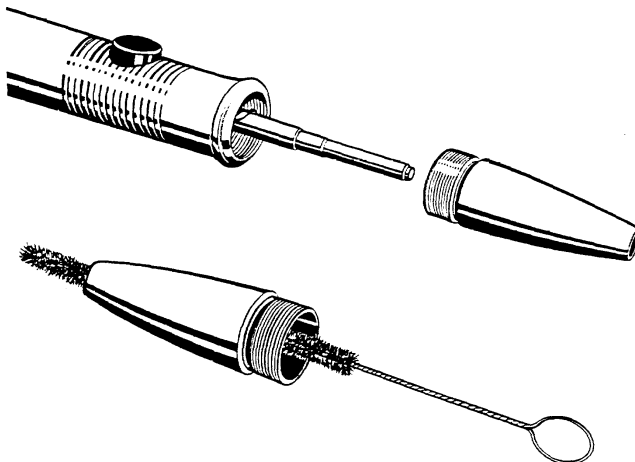
Cleaning and disinfecting the surfaces

The unit, the handpiece cable and the handpiece can be wiped off with a cloth moistened slightly with water. To remove stubborn dirt, use a piece of cloth moistened slightly with a neutral cleaning agent and then wipe it dry with a soft cleaning rag. Do not clean in an ultrasonic cleaning system. Never use any solvents or aggressive cleaning agents to clean the unit or the handpiece cable. Do not allow liquids to penetrate into the slots of the unit.

The unit, the handpiece cable and the handpiece can be wiped off with a cloth moistened slightly with a disinfectant. You must choose only disinfectants that comply with the valid requirements of the respective national regulatory body or whose bactericidal, fungicidal and virucidal properties have verifiably been tested and approved accordingly. You can use for instance: PlastiSept cleaning foam from Alpro.

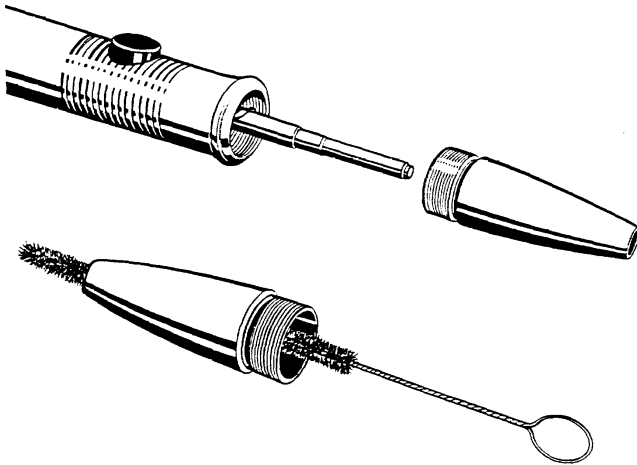
Disinfection of the tapping head

To disinfect the tapping head, unscrew the tip of the handpiece and wipe off the tapping head with disinfection wipes. Do not use soaking wet wipes. It is very important to avoid the disinfection fluid penetrate into the rear parts of the handpiece.



Cleaning the tip of the handpiece

The tip of the handpiece must always be clean inside. To clean it, unscrew the tip from the handpiece. Look inside. If you observe impurities, please use the supplied cleaning brush to remove it. After each use of the brush, it must be cleaned, too. Use disinfection foam or spray. The brush will wear out over time. After 10 applications, the brush should not be used any more. A new brush can be ordered, item number 5245758. If the impurities inside the tip of the handpiece are not too adhesive, you can use cotton buds instead of the brush.



ATTENTION

You should always observe the following instructions for cleaning the Periotest classic handpiece:

Do not allow liquids or oil to enter the inner parts of the handpiece. Do not spray liquids or oil into the handpiece, neither from the front, nor from the rear side. Repeated entry of such fluids will form a patina which prevents the tapping head from moving easily and results in malfunction. In the longer run, the contacts inside the handpiece and also in the handpiece cable will corrode which causes malfunction and can only be repaired by replacing the whole assembly.

9.2 Sterilization of the handpiece

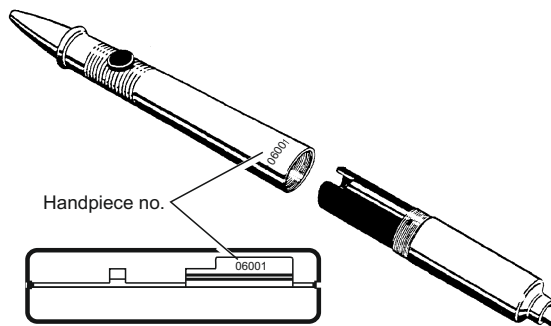
The Periotest classic handpiece can be sterilized if the following instructions are observed carefully:

Disconnect (unscrew) the handpiece from the handpiece cable. The handpiece can be sterilized by using a suitable sterilization bag ("wrapped" sterilization), and it can be sterilized without a sterilization bag ("unwrapped" sterilization). The unwrapped sterilization has the advantage that some deposits are removed from the tapping head (if they are not too adhesive), and so the sterilization process has also a cleaning function. After an unwrapped sterilization, however, the handpiece needs some time to dry out inside and outside before it can be used again. A wet handpiece can cause a malfunction. The drying may take 1 or 2 hours before it can be attached at the handpiece cable again. If you cannot wait that long, please sterilize the handpiece „wrapped“. If you sterilize „wrapped“, the handpiece can be used after its temperature has dropped below 40 °C (104 °F).

Sterilize the handpiece at a steam temperature of 134 °C (273 °F), 3 minutes holding time at 2.13 bar (30.88 psi) overpressure. Only steam sterilizers that fulfill the requirements of EN 13060, „Class B“, are suitable and approved for sterilization of the Periotest classic handpiece.

ATTENTION

The handpiece has a serial number which is indicated at the back of the Periotest classic housing. If you use several Periotest classic units, please do not mix the handpieces. This can lead to malfunction or wrong readings.



10 Battery

10.1 Charging the battery

The Periotest classic is equipped with a nickel-metal hydride (NiMH) storage battery.

WARNINGS

- Only use the supplied power supply unit FW7219 to charge the battery. If you use a different charger, the Periotest classic and the battery can be damaged.
- The Periotest classic must be switched off before the charging procedure begins.
- If any substances escape from the unit, please interrupt the charging procedure immediately and send the unit to your dental depot for a check. It is dangerous to use the unit with a defective battery.
- If the Periotest classic has not been used for a longer time, please lift out the battery (as described in section 10.2) and visually inspect it. If you observe deposits near the contacts, the battery might be defective and should not be charged or used. Send the battery or the whole unit to your dental depot for a check.

Always charge the battery if the unit „speaks“ **low battery**. You can charge the battery earlier, at any time, to assure permanent availability. There is no „memory effect“ of the battery. Regarding the frequency or the point in time when to charge the battery, there is nothing special to keep in mind.

The remaining battery voltage is indicated on the display, immediately after the unit is switched on. If the battery voltage is below 12 V, the battery should be charged to assure an uninterrupted work.

To charge the battery, first connect the charger with the Periotest classic and then with the wall socket. The charging process passes through different stages, indicated by different colours and flashing of the LED. In the beginning, the LED flashes yellow, then you see a fast green flashing (main charging), then a slow green flashing and finally you see a permanent green light (charging process finished). The charging process may be interrupted any time (e.g. if you want to use the Periotest classic again before the charging process is finished). If the battery is empty, it takes approx. 2 hours to charge it.

If after a full charging cycle the battery is quickly empty again, it has reached its end of life and needs to be replaced. A spare part battery (item / order number 5959677) can be ordered from your dental depot.

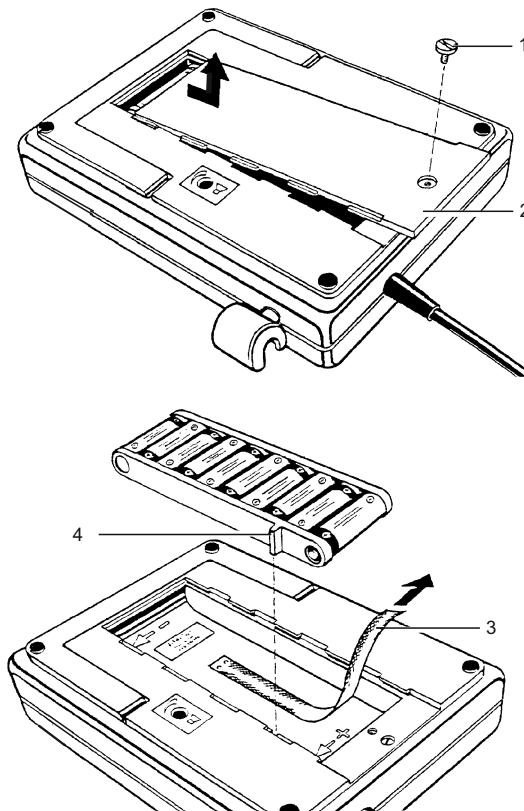
10.2 Changing the battery

To replace the nickel-metal hydride (NiMH) storage battery, use a screwdriver or a small coin to unscrew the screw (1) on the bottom side of the Periotest classic and remove the battery compartment cover (2) by sliding it out. Lift out the battery by using the fabric band (3). The battery has a cover with a „nose“ (4) which fits in the battery compartment and thus prevents the battery from wrong insertion. If you insert the new battery, please make sure that the battery contacts of the housing move to the side and not downwards.

WARNING

After the replacement of the battery, the battery compartment must be closed before the Periotest classic is put into operation again. The Periotest classic must not be used with an open battery compartment.

When replacing the battery, make sure that the old battery is disposed of in an environmentally safe manner.



11 Maintenance

The Periotest classic handpiece is maintenance-free. Please see the instructions in section 9 (Care and Cleaning). The tapping head must always be clean and dry. Never oil the handpiece, and do not allow any liquids to enter the inner parts of the handpiece.

The Periotest classic does not need to be recalibrated. Perform a functional test as described in section 6.3 to assure correct function and correct readings.

12 Electromagnetic compatibility

12.1 Electromagnetic emission


The UNIT is intended for operation in the electromagnetic environment specified below. The customer or user of the UNIT should make sure that it is used in such an environment.

Emission measurement	Conformity	Electromagnetic environment guidelines
RF emissions according to CISPR 11	Group 1	The UNIT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions according to CISPR 11	Class B	The UNIT is intended for use in all facilities, including residential areas and in any facilities connected directly to a public power supply providing electricity to buildings used for residential purposes.
Harmonics according to IEC 61000-3-2	not applicable Power output < 50 W	
Voltage fluctuations/Flicker according to IEC 61000-3-3	not applicable no significant flicker	

12.2 Interference immunity

The UNIT is intended for operation in the electromagnetic environment specified below. The customer or user of the UNIT should make sure that it is used in such an environment.

Interference immunity tests	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment guidelines
Electrostatic discharge (ESD) according to IEC - 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst according to IEC 61000-4-4	± 1 kV for input and output lines ± 2 kV for power cables	± 1 kV for input and output lines ± 2 kV for power cables	The quality of the line power supply should be that of a typical commercial or hospital environment.
Surge voltages according to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	The quality of the line power supply should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and variations of the power supply according to IEC 61000-4-11	< 5 % U_T for ½ period (> 95 % dip of U_T) 40 % U_T for 5 periods (60 % dip of U_T) 70 % U_T for 25 periods (30 % dip of U_T) < 5 % U_T for 5 sec. (> 95 % dip of U_T)	< 5 % U_T for ½ period (> 95 % dip of U_T) 40 % U_T for 5 periods (60 % dip of U_T) 70 % U_T for 25 periods (30 % dip of U_T) < 5 % U_T for 5 sec. (> 95 % dip of U_T)	The quality of the line power supply should be that of a typical commercial or hospital environment. If the user of the UNIT requires it to continue functioning following interruptions of the power supply, it is recommended to have the UNIT powered by an uninterrupted power supply or a battery.
Magnetic field of power frequencies (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Remarks: U_T is the AC supply voltage prior to application of the test level.			

Interference immunity tests	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment guidelines
Conducted HF interference IEC 61000-4-6	$3V_{\text{eff}}$ 150 kHz to 80 MHz ¹	$3V_{\text{eff}}$	<p>Portable and mobile radio equipment must not be used within the recommended working clearance from the UNIT and its cables, which is calculated based on the equation suitable for the relevant transmission frequency.</p> <p>Recommended working clearance:</p> $d = [1, 2] \sqrt{P}$ <p>$d = [1, 2] \sqrt{P}$ at 80 MHz to 800 MHz</p> $d = [2, 3] \sqrt{P}$ at 800 MHz to 2.5 GHz <p>Where P is the nominal transmitter output in watts (W) specified by the transmitter manufacturer and d is the recommended working clearance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey², should be less than the compliance level³ in each frequency range.</p> <p>Interference is possible in the vicinity of equipment bearing the following graphic symbol.</p> 
Radiated HF interference IEC 61000-4-3	$3V/m$ 80MHz to 800MHz ¹ . $3V/m$ 800MHz to 2.5GHz ¹ .	$3V_{\text{eff}}$ $3V_{\text{eff}}$	

1. The higher frequency range applies at 80 MHz and 800 MHz.

2. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast, cannot be predicted theoretically with accuracy. An investigation of the location is recommended to determine the electromagnetic environment resulting from stationary HF transmitters. If the measured field strength in the location in which the UNIT is used exceeds the applicable \square RF compliance level above, the UNIT should be observed to verify normal operation. If unusual performance characteristics are observed, it may be necessary to take additional measures such as reorientation or repositioning of the UNIT.

3. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

12.3 Working clearances

Recommended working clearances between portable and mobile HF communication devices and the UNIT

The UNIT is intended for operation in an electromagnetic environment where radiated HF interference is checked. The customer or the user of the UNIT can help prevent electromagnetic interference by duly observing the minimum distances between portable and/or mobile HF communication devices (transmitters) and the UNIT. These values may vary according to the output power of the relevant communication device as specified below.

Nominal transmitter output [W]	Working clearance according to transmission frequency [m]		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = [1, 2] \cdot \sqrt{P}$	$d = [1, 2] \cdot \sqrt{P}$	$d = [2, 3] \cdot \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters whose maximum nominal output is not specified in the above table, the recommended working clearance d in meters (m) can be determined using the equation in the corresponding column, where P is the maximum nominal output of the transmitter in watts (W) specified by the transmitter manufacturer.

Remark 1

The higher frequency range applies at 80 MHz and 800 MHz.

Remark 2

These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is influenced by their absorption and reflection by buildings, objects and persons.

We reserve the right to make any alterations which may be required due to technical improvements.

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