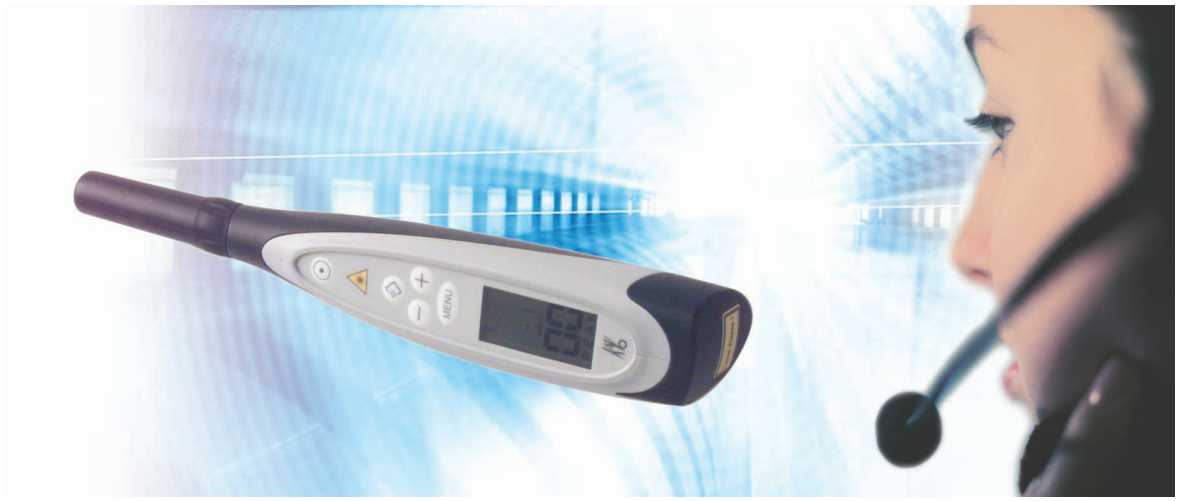
Instructions for use

DIAGNOdent pen 2190



Always be on the safe side.

KaVo. Dental Excellence.

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CE 0124

Table of contents

1 User instructions

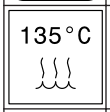
1.1 User guide

Requirement
Read these instructions prior to first use to avoid misuse and prevent damage.

1.1.1 Abbreviations

Abbre-viation	Explanation
IfU	Instructions for use
CI	Care instructions
AI	Assembly instructions
TI	Technician's instructions
SC	Safety checks
IEC	International Electrotechnical Commission
RI	Repair instructions
RK	Retrofitting kit
AS	Assembly set
EP	Enclosed parts
EMC	Electromagnetic compatibility
PI	Processing instructions

1.1.2 Symbols

	Refer to the chapter on Safety/Warning symbol
	Important information for users and service technicians
	Thermodisinfectable
	Suitable for steam sterilisation at up to 138 °C
	CE mark (European Community). A product bearing this mark meets the requirements of the pertinent EC directives, i.e. the standards applicable in Europe.
▶	Action request
	Laser warning sign hazard symbol
	Laser notification sign, classified in accordance with IEC 60825:2007

1.1.3 Target group

This document is for dentists and dental office staff.

1.2 Service

Please direct all questions regarding the product, service, and maintenance to the following addresses.
Please refer to the serial number of the product in all inquiries!
Service-Hotline:
+49 7351 56-1500
Service.Instrumente@kavo.com
For further information, please visit: www.kavo.com

KaVo Dental GmbH
Customer Service Center
Bahnhofstraße 20
D-88445 Warthausen
+49 (0) 7351 56-1500
www.kavo.com

1.3 Warranty terms and conditions

Within the scope of the applicable KaVo delivery and payment conditions, KaVo guarantees proper function, absence of defects in material and workmanship for a period of 12 months from the date of purchase as confirmed by the salesperson.
In case of justified complaints, KaVo will honour its warranty with a free replacement or repair.
The warranty does not cover defects and their consequences that arose or may have arisen due to natural wear, improper handling, cleaning or maintenance, non-compliance with operating, maintenance or connection instructions, corrosion, contaminated media supply or chemical or electrical influences deemed abnormal or impermissible in accordance with factory specifications.
The warranty does not usually cover lamps, light conductors made of glass and glass fibres, glassware, rubber parts and the colourfastness of plastic parts.
The warranty expires if defects or their consequences could possibly have arisen because the product has been modified or changed. Warranty claims can only be asserted when they are immediately reported to KaVo in writing.
This notification must be accompanied by a copy of the invoice or delivery note on which the manufacturing number is clearly visible. In addition to the guaranty, the statutory warranty claims of the purchaser also apply with a warranty period of 12 months.

1.4 Transportation and storage

1.4.1 Currently valid packaging regulations

Note
Only valid for the Federal Republic of Germany.

Dispose of and recycle the sales packaging appropriately in accordance with current packaging regulations, employing waste management or recycling companies. Comply with the comprehensive return system. KaVo has had its sales packaging licensed for this purpose. Please comply with the regional public waste-disposal system.

1.4.2 Damage in transit

In Germany

If the packaging is visibly damaged on delivery, please proceed as follows:

1. The recipient of the package must record the loss or damage on the delivery receipt. The recipient and the representative of the shipping company must sign this delivery receipt.
2. Leave the product and packaging in the condition in which you received it.
3. Do not use the product.
4. Report the damage to the shipping company.
5. Report the damage to KaVo.
6. Consult with KaVo first, before returning a damaged product.
7. Send the signed delivery receipt to KaVo.

If the product is damaged but there was no discernable damage to the packaging upon delivery, proceed as follows:

1. Report the damage to the shipping company immediately and no later than 7 days after delivery.
2. Report the damage to KaVo.
3. Leave the product and packaging in the condition in which you received it.
4. Do not use a damaged product.

Note

If the recipient fails to comply with any of the above-mentioned obligations, the damage will be considered to have arisen after delivery
(in accordance with the General German Freight Forwarders´ Terms and Conditions, Art. 28)
.

Outside Germany

Note

KaVo shall not be held liable for damage arising from transportation.
The shipment must be checked on arrival.

If the packaging is visibly damaged on delivery, please proceed as follows:

1. The recipient of the package must record the loss or damage on the delivery receipt. The recipient and the representative of the shipping company must sign this delivery receipt.
   Without this evidence, the recipient will not be able to assert a claim for damages against the shipping company.
2. Leave the product and packaging in the condition in which you received it.
3. Do not use the product.

If the product is damaged but there was no discernable damage to the packaging upon delivery, proceed as follows:

1. Report any damage to the shipping company either immediately or no later than 7 days after delivery.
2. Leave the product and packaging in the condition in which you received it.
3. Do not use a damaged product.

Note

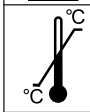
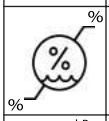
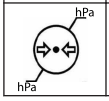
If the recipient fails to comply with any of the above-mentioned obligations, the damage will be considered to have arisen after delivery
(in accordance with CMR law, Chapter 5, Art. 30).

1.4.3 Information on the packaging: Storage and transportation

Note

Please keep the packaging in case you need to return the product for servicing or repair.

The symbols printed on the outside are for transportation and storage, and have the following meaning:

	Transport upright with the arrows pointing upwards!
	Fragile - protect against impact!
	Protect from moisture!
	Permissible stacking load
	Temperature range
	Humidity
	Air pressure

2 Safety

2.1 Description of safety instructions

2.1.1 Warning symbol

	Warning symbol

2.1.2 Structure

⚠ DANGER

The introduction describes the type and source of the hazard.
This section describes potential consequences of non-compliance.
- The optional step includes necessary measures for hazard prevention.

2.1.3 Description of hazard levels

Safety instructions distinguishing between three hazard levels are used in this document to prevent personal and property damage.

⚠ CAUTION

CAUTION
indicates a hazardous situation that can cause damage to property or mild to moderate injuries.

⚠ WARNING

WARNING
indicates a hazardous situation that can lead to serious or fatal injury.

⚠ DANGER

DANGER
indicates a maximal hazard due to a situation that can directly cause death or fatal injury.

2.2 Safety instructions

2.2.1 Product-specific

⚠ CAUTION

Injury/damage due to leaky battery.
Health damage and product damage.
- Use leak-proof batteries only!
- Remove the battery during long downtimes!
- Properly dispose of used batteries!
- Do not use rechargeable batteries!
- Do not touch battery contacts and patient at the same time!

⚠ CAUTION

Danger of injury from electric current

Electrical shock

- Do not use power supplies.
- Only supply the product with the specified voltage.

⚠ CAUTION

Hazard from improper use.

Injury and damage.

- The product may only be used by trained professionals.

⚠ CAUTION

Risks from electromagnetic fields.

Electromagnetic fields might interfere with the functions of implanted systems (such as pacemakers).

- Ask patients if they have a cardiac pacemaker or other system implanted before you start the treatment!

⚠ CAUTION

Blinding hazard from laser beam of laser class 1.

Eye injury.

- Do not look into the laser beam!
- Do not open the unit.

⚠ WARNING

Aspiration of the probe.

Danger of suffocation.

- Check the seating of the probe in the DIAGNOdent pen 2190 by pulling on it!

⚠ CAUTION

Leaky LCD.

Harmful to health.

- Turn off the unit when the LCD is damaged.
- Do not contact the liquid.
- In case of contact with liquid, immediately rinse with water.
- Consult a physician if any symptoms are manifested.

2.2.2 Protective equipment

Note

Since this is a class 1 laser medical device, no personal protective equipment needs to be worn according to the EC directive.

2.3 Electromagnetic compatibility

Note

Based on DIN EN 60601-1-2 concerning the electromagnetic compatibility of electromedical devices, we need to point out that:

• Medical electrical devices are subject to special measures regarding electromagnetic compatibility and must be operated in accordance with the requirements listed below.

• Portable and mobile high-frequency communications devices can influence medical electronics.

Note

KaVo cannot guarantee the compliance of accessories, cables, and other components not supplied by KaVo with the EMC requirements of IEC 60601-1-2 (DIN EN 60601-1-2).

See also:

9 Information about electromagnetic compatibility, Page 39

2.4 Disposal

Note

Any waste which is generated must be recycled or disposed of in strict compliance with all applicable national regulations in a manner which is safe both for people and the environment.

If you have any questions regarding proper disposal of the KaVo product, please contact the KaVo branch.

2.5 Disposal of electronic and electrical devices

Note

According to EC directive 2002/96 concerning used electrical and electronic devices, this product is subject to the cited directive and must be disposed of accordingly within Europe.

For more information, please visit www.kavo.com or contact your specialised dental supplier.

For final disposal, please contact:

In Germany

To return an electrical device, you need to proceed as follows:

1. On the homepage www.enretec.de of enretec GmbH, you can download a form for a disposal order under the menu item eom. Download the disposal order or complete it as an online order.
2. Enter the corresponding information to complete the order, and submit it as an online order or by fax +49 (0) 3304 3919-590 to enretec GmbH.
   The following contact options are also available for questions and for initiating a disposal order:
   Phone: +49 (0) 3304 3919-500
   Email: eom@enretec.de and
   Postal address: enretec GmbH, Geschäftsbereich eomRECYCLING®
   Kanalstraße 17
   D-16727 Velten

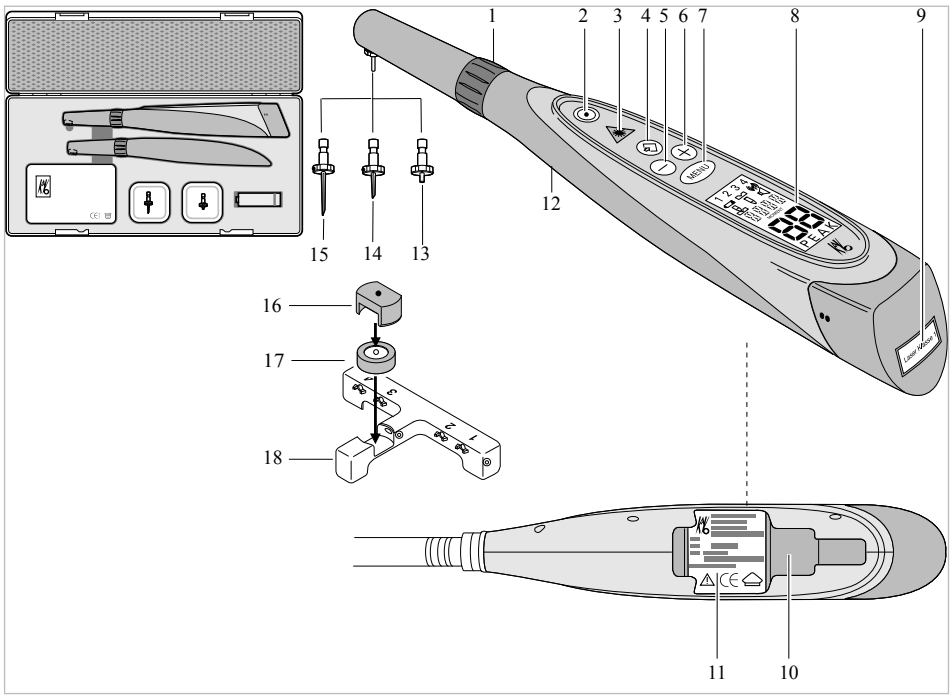
3. A unit that is not permanently installed will be picked up at the office.
   A permanently installed unit will be picked up at the curb at your address on the agreed date.
   The owner or user of the device will have to bear the cost of disassembly, transportation and packaging.

International

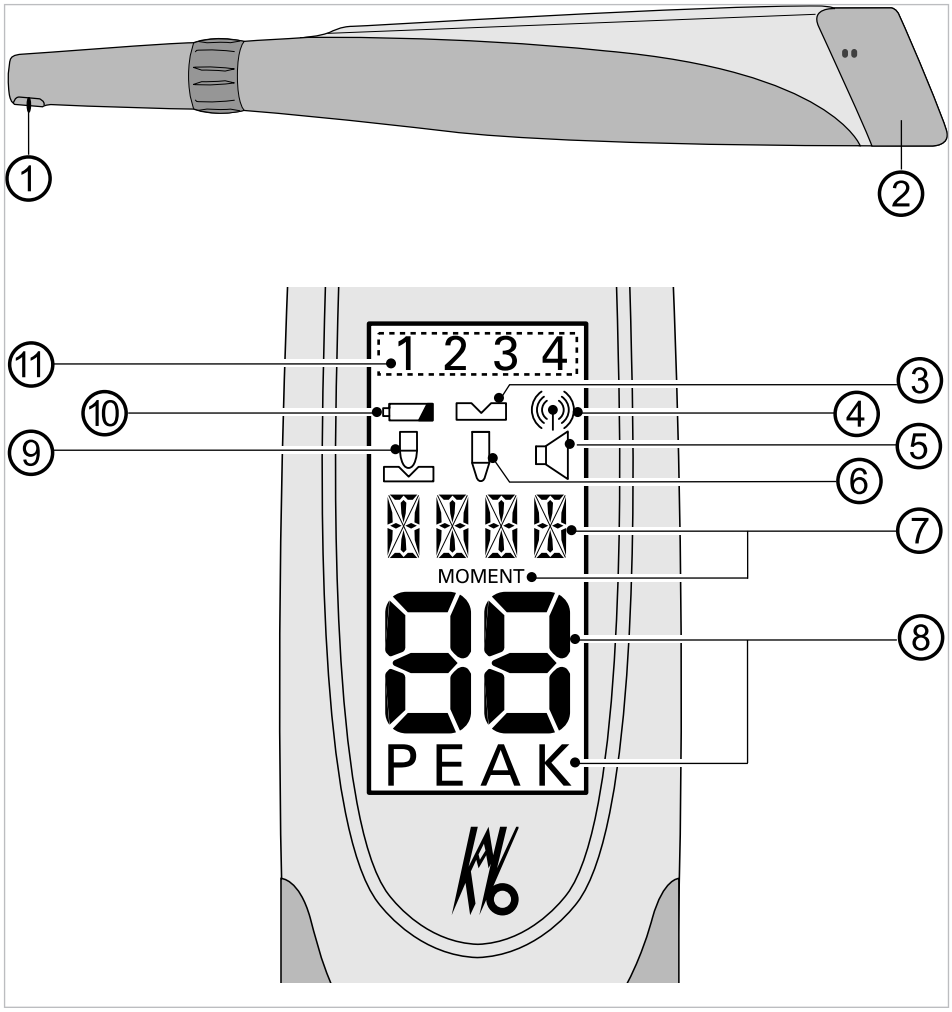
For country-specific information on disposal, contact your dental supplier.

3 Product description

3.1 DIAGNOdent pen 2190



① Ring switch
② The start button
③ Warning sign: danger, laser
④ Save button
⑤ Minus button
⑥ Plus button
⑦ Menu button
⑧ LCD display
⑨ Laser notification sign
⑩ Battery compartment
⑪ Rating plate
⑫ Grip sleeve
⑬ Fissure probe
⑭ Prox probe
⑮ Paro probe (optional accessory)
⑯ Guide to prox probe
⑰ Standard C with holder
⑱ Special holder for Steribox



① Laser beam exit
② Infrared beam exits at the black end cap
③ Reference value menu
④ Symbol for infrared data transmission
⑤ Volume menu
⑥ Probe memory menu
⑦ MOMENT display
⑧ PEAK display
⑨ Calibration
⑩ Battery warning symbol
⑪ Probe memory (1-4)

3.2 Purpose – Proper use

3.2.1 General

The overarching guidelines and/or national laws, national regulations and the rules of technology applicable to the startup and use of the KaVo product for the intended purpose are to be applied and complied with.
This KaVo product is intended only for use in the field of dentistry. The product may not be used for a purpose for which it was not intended.
"Proper use" includes following all the instructions for use and ensuring that all inspections and service tasks are performed.
Manipulations of the unit modifying it from its original condition are not permissible.
The use of this KaVo product is not permitted in areas subject to an explosion hazard.

The user must ensure that the unit works properly and is in satisfactory condition before each use.

The applicable national legal regulations must be observed during the use of the device, in particular the following:
- Applicable regulations governing the connection and start-up of medical devices.
- Current occupational safety regulations.
- Current accident prevention regulations.

Users have a duty to:
- Only use equipment that is operating correctly
- to protect himself, the patient and third parties from danger.
- to avoid contamination from the product

In Germany, operators, equipment managers and users are obliged to operate their equipment in accordance with the MPG regulations.
The services encompass all the test tasks required in accordance with § 6 of the medical devices operator ordinance (Medizinprodukte-Betreiberverordnung, MPBetreibV).

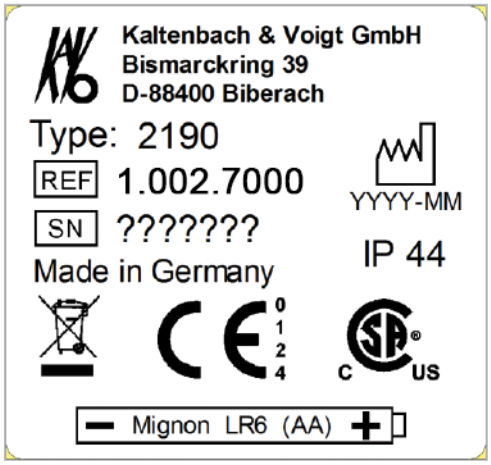
3.2.2 Product-specific

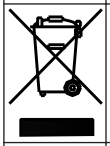
The DIAGNOdent pen 2190 is only for dental treatment within the context of dental medicine. It is to be used in a dentist's office or dental clinic.
The DIAGNOdent pen 2190 is a tool that helps dentist's detect concretions or caries in teeth that have been thoroughly cleaned.
The tooth substance is caused to fluoresce with a laser light. The DIAGNOdent pen 2190 recognises this fluorescence and the differences between healthy and diseased tooth substance is displayed by the DIAGNOdent pen 2190.
By using the installed infrared diodes, you can show the display values of the DIAGNOdent pen 2190 on the DIAGNOdent display 2191 to inform the patient. Further information can be found in the instructions for use of the DIAGNOdent display 2191.
The DIAGNOdent pen 2190 meets laser class 1 according to IEC 60825-1:2007.
The DIAGNOdent pen 2190 is a class IIa medical device according to EC Directive 93/42/EEC and meets the requirements of 2004/108/EC, etc. in regard to electromagnetic compatibility.

The following persons are authorised to repair and service the KaVo product:
- Technicians of KaVo branch offices after appropriate product training.
- Specifically KaVo-trained technicians of KaVo franchised dealers.

Safety checks are not necessary.

3.3 Rating plate



	CE mark
	CSA mark
	Classification (applied part type B)
	For disposal information, see Intended use
	Follow the instructions for use, icon is attached on the side of the unit
	Manufacturer
	Battery name
MM	Month manufactured
YYYY	Year manufactured
SN ??? ????	Sequential SN
REF	Material number
Type:	Device type
IP 44	Degree of protection against ingress of solid and liquid substances

3.4 Technical Specifications

Length	approximately 220 mm
Diameter	approximately 32 mm
Weight	110 g
Voltage 1 cell, mignon LR6 alkaline	1.5 V
Light output of the laser diode	<1 mW
Wavelength of the laser diode	655 nm
Beam strength of the infrared diode	<140mW/sr
Wavelength of the infrared diode	850 nm - 950 nm
Degree of protection	IP 44
Operating temperature	+10 °C to +30 °C
Calibration temperature	+22°C ±2°C
relative humidity	30% RH to 75% RH
Power consumption	<200 mA

Transportation and storage conditions

Transportation and storage temperature	-10 °C to +55 °C
relative humidity	5% RH to 90% RH
Air pressure	700 hPa to 1060 hPa

4 First use

⚠ CAUTION

Non-sterile gripping sleeve and probes.

Health damage.

- Sterilise the probes and gripping sleeves before first startup since they are delivered in non-sterile condition by the manufacturer!

See also:

6.1 Reprocessing methods according to DIN EN ISO 17664, Page 33

4.1 Insert the battery

⚠ CAUTION

Injury/damage due to leaky battery.

Health damage and product damage.

- Use leak-proof batteries only!
- Remove the battery during long downtimes!
- Properly dispose of used batteries!
- Do not use rechargeable batteries!
- Do not touch battery contacts and patient at the same time!

Note

Only use the type mignon LR6 alkaline cell.

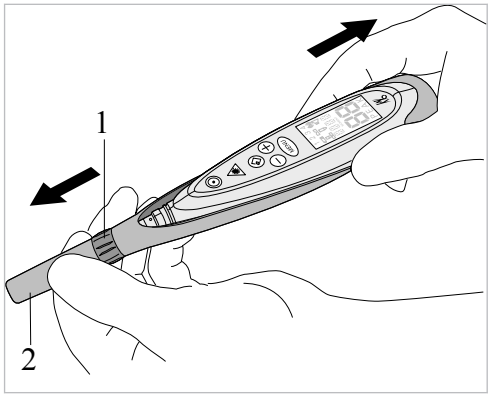
⚠ CAUTION

Product damage from misuse.

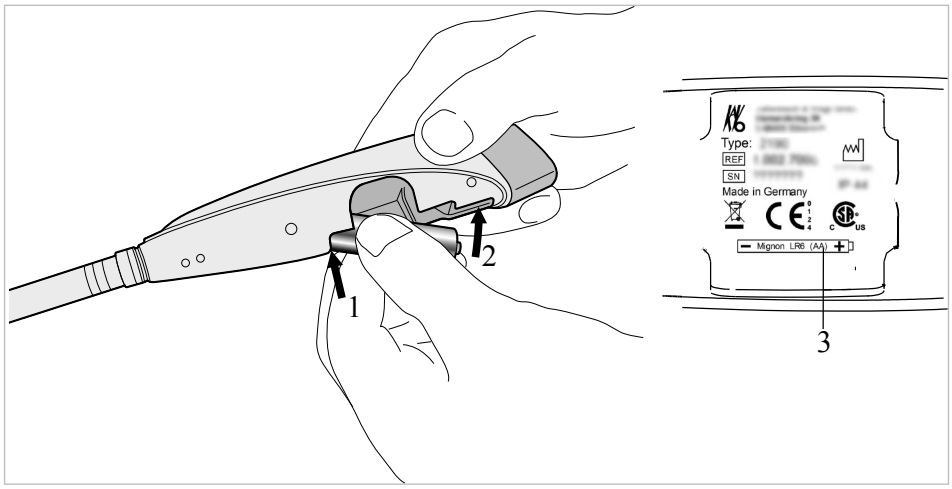
Damage to the contacts.

- Do not turn on the ring switch ① when removing and shoving on the grip sleeve②.

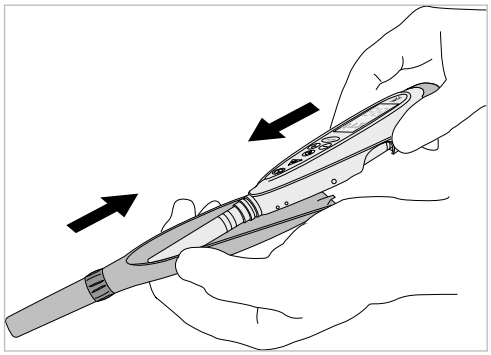
- Remove the grip sleeve



- Insert conventional mignon (LR6) alkaline cell matching the polarity ③.



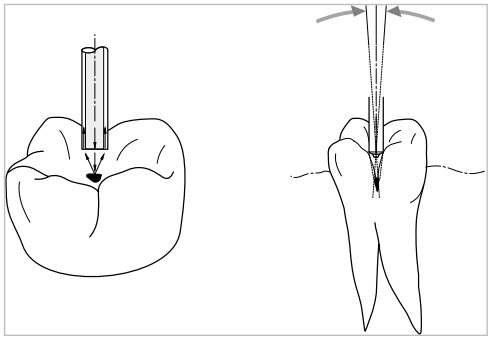
- Shove on the grip sleeve



5 Operation

5.1 Mode of operation of the DIAGNOdent pen 2190

Changed tooth substance emits fluorescent radiation when exposed to light of a certain wavelength. This radiation is detected and analysed.
A specific amount of light energy is supplied by the light probe that contacts and enters the tooth surface. If fluorescent light arises in the case of a pathological change, it is evaluated.
At a fissure, careful scanning is required since this allows very small defects to be detected. By moving the probe slightly back and forth over the base of the fissure, the detection sensitivity can be increased and the location of maximum florescence can be identified.



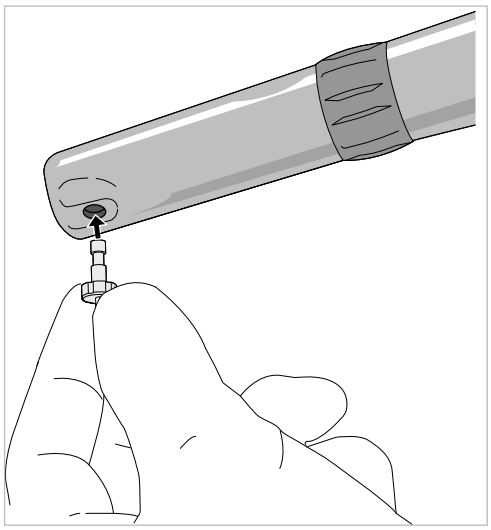
5.2 Inserting the probe

- Insert the probe until it snaps into place.

⚠ WARNING

Aspiration of the probe.
Danger of suffocation.

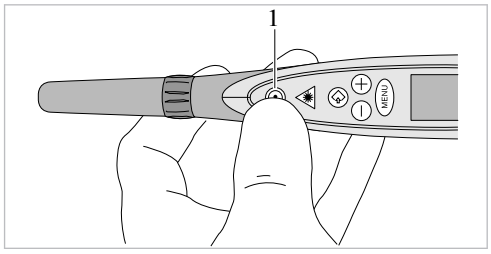
- Check the seating of the probe in the DIAGNOdent pen 2190 by pulling on it!



5.3 Turning on/off

5.3.1 Start up

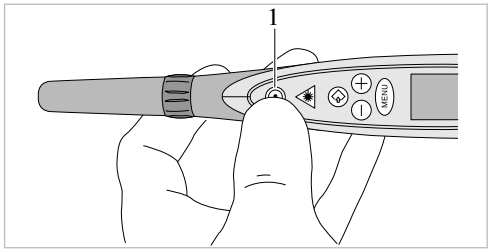
- Hold the start button ① for approximately 1 second until the signal sounds and the display appears.



5.3.2 Switch off

Note
After 90 seconds of non-use, the DIAGNOdent pen 2190 automatically turns off.

- Press start key ① for approximately 5 seconds until the DIAGNOdent pen 2190 turns off.

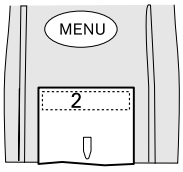


5.4 Menus

If there is no entry in the menu within three seconds, the device returns to display mode.

5.4.1 Select probe memory

A memory (1 - 4) can be selected for the probes to assign a specific device calibration to each probe, such as 1 for a proximal probe, 2 to a fissure probe, and 3 for the Paro probe.



- Press the menu key twice.

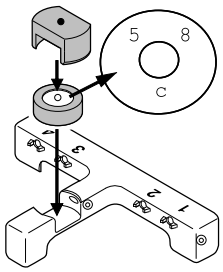
⇨ The probe symbol and set probe memory (such as 2) appear on the display.

- Set the desired value with the plus or minus button.

- Use the save button to save the set value.

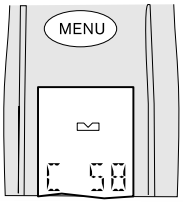
⇨ The product returns to display mode.
If the save button is not pressed for 3 seconds, the set value is automatically saved.
The DIAGNOdent pen 2190 returns to display mode.

5.4.2 Checking/setting the reference value



The reference value is engraved on the surface of the supplied reference (such as C 58).
This value is preset. When exchanging the reference, this new reference value can be set.

When exchanging the supplied reference (for example if it becomes damaged), it may only be replace with a reference with the same letter (such as C). The number (such as 58) of the new reference may differ from the old number.



- Press the menu key five times.

⇨ The reference value symbol appears with the set reference value (such as C 58).

- Set the desired value with the plus or minus button.

- Use the save button to save the set value.

⇨ The product returns to display mode.

Note
The save button must be pressed within 3 seconds since an error message otherwise appears and the old value remains set.

5.4.3 Calibrating the probes with a reference

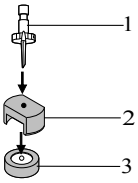
The display can change due to component aging and probe wear.

Calibration enables:
- the DIAGNOdent pen 2190 values to be observed over a longer period.
- the comparison of DIAGNOdent pen 2190 values from different DIAGNOdent 2190 pens.
- the use of different probes with individual values.

Calibration is required when the displayed value differs more than ± 3 from the reference value when the reference is held down.

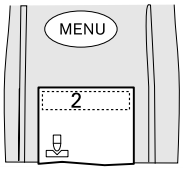
Note
During measurement, the reference must have a room temperature of 22°C ±2°C.

Note
The probes must be checked for damage before and after each use. They may only be used with the DIAGNOdent pen 2190 and only for the probe memory for which they were calibrated. The probe must not be scratched by scalpels, other probes, tweezers, etc. Do not drop the probe!



- Place the proximal attachment ② on the reference ③ only when calibrating the proximal probe ①.

⇨ Depending on the working direction of the probe, the values can differ slightly for technical reasons; however, it is generally not necessary to recalibrate during treatment.



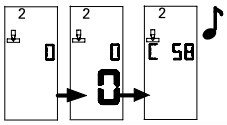
- Press the menu key.

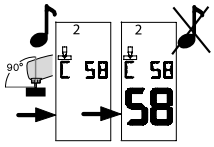
⇨ The calibration symbol appears.

Note
Do not point the probe toward light sources or reflective surfaces.

- Press the save key.

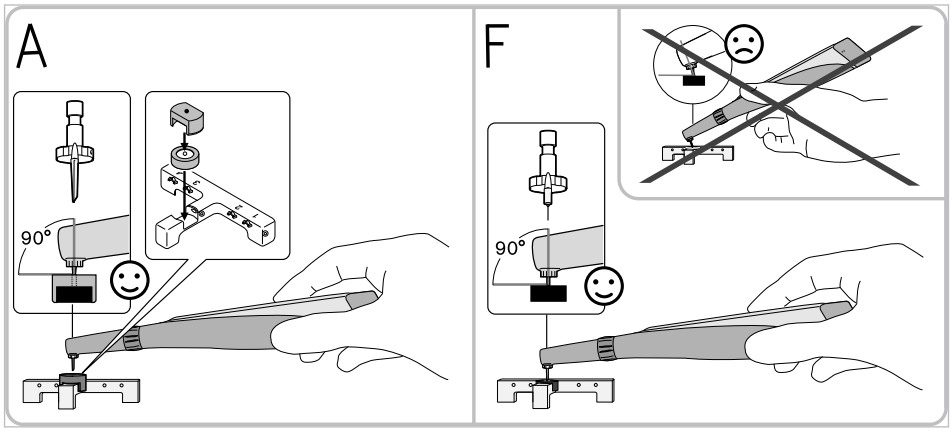
⇨ Calibration is started.





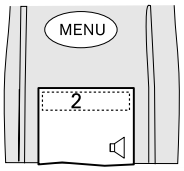
- Once you hear the signal, place the probe vertically on the reference.

⇨ As soon as the signal tone stops, calibration is over.
⇨ Calibration is successful when the value is the display agrees with the reference value (± 3).



5.4.4 Setting the volume

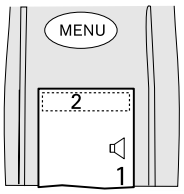
The volume can be set to three different levels (off, 1, 2).



- Press the menu key three times.

⇨ A volume symbol appears.

- Set the desired value with the plus or minus button.



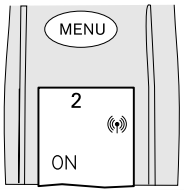
Possible settings: off, 1, 2

- Use the save button to save the set value.

⇨ The product returns to display mode.

5.4.5 Turning infrared data transmission on and off

The infrared data transmission can be turned on and off (ON,OFF).



- Press the menu key four times.

⇨ The infrared data transmission symbol appears.

- Use the plus or minus key to turn the infrared data transmission ON or OFF.

- Use the save button to save the set value.

⇨ The product returns to display mode.

Note

If a DIAGNOdent display 2191 Is not used, please turn the data transmission OFF to decrease power consumption.

5.5 Determine findings

5.5.1 General

Using the DIAGNOdent pen 2190 has advantages over minimally invasive therapy. Very small invisible changes up to a depth of 2 mm can be identified in the tooth substance and treated.
The values of the DIAGNOdent pen 2190 are not an automatic green light. When interpreting the values, other caries risk factors must be taken into consideration such as the caries history, frequency of sugar intake, presence of caries bacteria, and saliva production.
In numerous clinical studies, the thresholds of the DIAGNOdent pen 2190 corresponded with actual caries. In the table, we refer to the publication: Prof. Lussi et al., Quintessenz 10/2003. This publication can also be obtained as a special print from KaVo. These values are based on the fact that a zero value was first measured on at a healthy coronal location.
KaVo recommends the following therapies for the different ranges of values of the DIAGNOdent pen for fissure caries, smooth surface caries and proximal caries.

Fissure caries and smooth surface caries

DIAGNOdent pen values	Diagnosis - Therapy
0 to 12	Normal prophylaxis (such as fluoride toothpaste)
13 to 24	Intensive prophylaxis (such as fluoridation, KaVo HealOzone)
> 25	Minimally invasive restorative procedures Filling materials and intensive prophylaxis (such as KaVo HealOzone, RONDOflex, SONICflex) Classic restoration for large lesions depending on the risk and findings

Proximal caries

DIAGNOdent pen values	Diagnosis - Therapy
0 to 7	Normal prophylaxis (such as fluoride toothpaste)
8 to 15	Intensive prophylaxis (such as fluoridation, KaVo HealOzone)
> 16	Minimally invasive restorative procedures Composite filling materials and intensive prophylaxis (such as KaVo HealOzone, RONDOflex, SONICflex) Classic restoration for large lesions depending on the risk and findings

A diagnosis based on the values of the DIAGNOdent pen 2190 together with the caries risk factors enable caries to be identified in a timely manner or whether the tooth substance is healthy.
The DIAGNOdent pen 2190 is excellent for determining progression. In many cases in which a definitive diagnosis cannot be made, a non-invasive treatment such as fluoridation or KaVo HealOzone should be done. The progression can be observed in regular checkups.

1. Professional teeth cleaning
Calculus removal with the SONICflex, manual instruments, PROPHYflex powder jet device with PROPHYpearls, DURAtec 2933 polishing contra-angle handpiece

2. Examination with the DIAGNOdent pen						
Type of caries	Fissure caries	Proximal caries	Fissure caries	Proximal caries	Fissure caries	Proximal caries
Measured value	0 - 12	0 - 7	13 - 24	8 - 15	> 25	>16
Meaning	Healthy tooth substance		Initial demineralisation		Strong demineralisation	
Dental diagnosis	No findings		Monitoring		X-rays, caries bacteria test, saliva test	
Measures	Standard prophylactic measures Fluoride toothpaste, etc.		Intensive prophylaxis measures, local antibacterial measures such as fluoridation, KaVo HealOzone, chlorhexine		Minimally invasive treatment KaVo HealOzone, RONDOflex, SONICflex micro, composite filling materials and intensive prophylaxis	
Risk	Low		Medium		High	

5.5.2 Procedure

The patient's teeth must be clean before using the DIAGNOdent pen 2190. KaVo recommends the following procedure:

1. When the patient's teeth are being cleaned by a dentist or dental assistant, Scan the teeth after cleaning but before fluoridation.
2. Before scanning the teeth, the teeth and interdental spaces should be dry since saliva can deflect the light, especially in the interdental spaces.
3. The dentist diagnoses with elevated values.
4. The dentist prepares a plan of therapy.

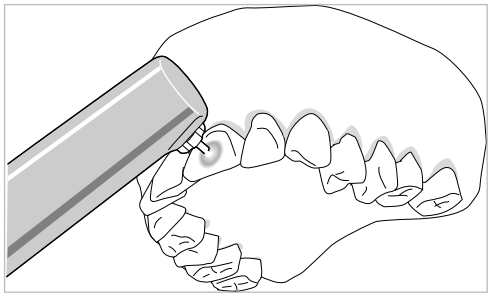
When interpreting the value of the DIAGNOdent pen 2190, false positive results can arise when the following points are not taken into account:

- Soiling
- Composite fillings that are fluorescent
- soiled edges of the composite fillings
- calculus/concretions
- Instances of higher values have been observed close to the pulp
- Food residue in the fissures
- Prophylaxis pastes
- remineralised caries
- strong natural fluorescence, discoloured teeth
- patients who have been exposed to radiation

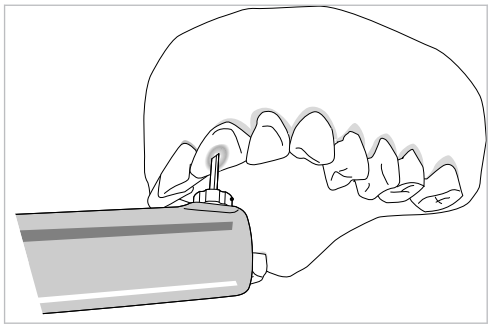
5.5.3 Individually adjust the DIAGNOdent pen 2190 to the patient

The teeth of different people have a different level of fluorescence. This is determined by eating habits, environmental conditions, etc. The teeth of each patient have the same fluorescence. It is therefore possible to individually adjust the 0 point of the DIAGNOdent pen 2190 to each patient.

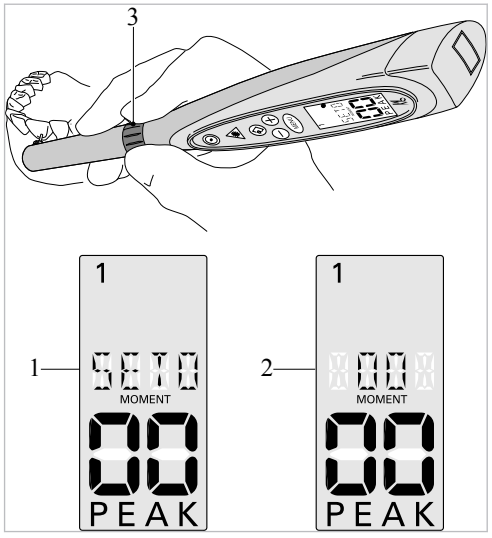
- Apply the probe to a healthy site of a tooth.



- Apply the prox probe to a healthy site of a tooth. The red dot on the probe must point toward the tooth.



- Turn on the ring switch ③ until you hear two beeps and the display ① appears.

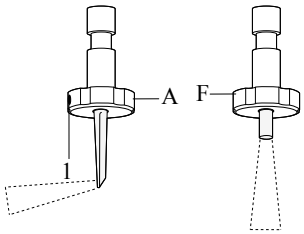


⇨ The device is individually adjusted to the patient.

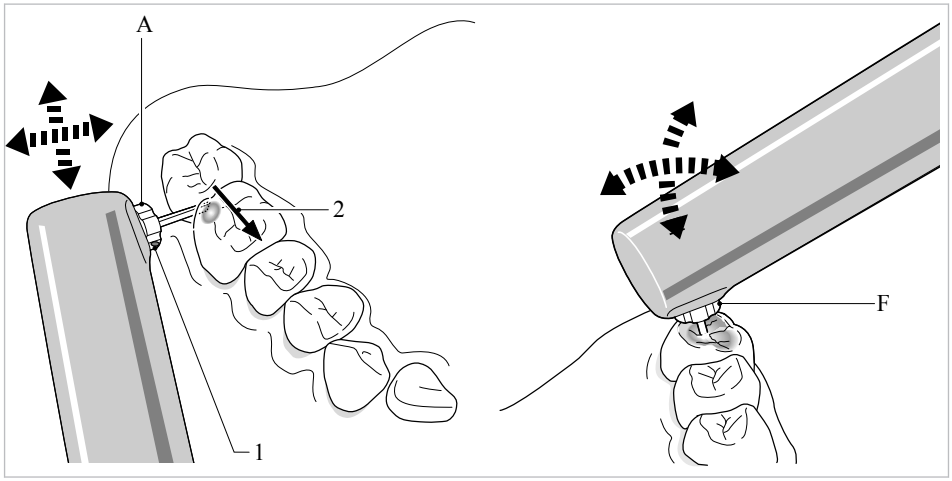
The displayed value lies between 00 and -9 when the probe does not contact the tooth, and +/- 1 when it contacts the tooth.

To reset the individual 0 point, the probe must be held in the air, and ring ③ must be actuated until you hear two beeps. The display shows 00 ②.

5.5.4 Scanning the tooth surface



Two different probes are available for detecting caries:
Fissure probe F (blue) for scanning smooth surfaces and fissures.
Prox probe A (black) for scanning the proximal area. Prox probe A can be rotated 360° and deflects the laser beam through a prism. The line of sight ② (red marking ①) can hence be changed in a mesial and distal direction.



Note
Guide the probe lightly without pressure over the tooth surface. Do not apply pressure.

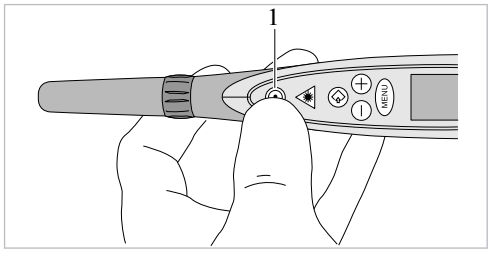
The MOMENT value is the current value.
The PEAK value is the maximum value since the last time the ring switch was pressed.

The tone sounds at a MOMENT display of 06. The higher the MOMENT value (06-99), the higher the frequency of the signal tone.

Note
Foreign light sources can cause problems with the detection system by illuminating the fibre tips. This is identified by a broad spread of MOMENT values. These outside disturbances must be identified and eliminated.
Tools for detecting plaque can cause an elevated fluorescence signal. The teeth therefore need to be cleaned beforehand.
Fluoride paste can distort the fluorescence signal. The fluorescence should therefore be measured before fluoride paste is used.
Seals, amalgam and composite fillings can change the fluorescence signal.

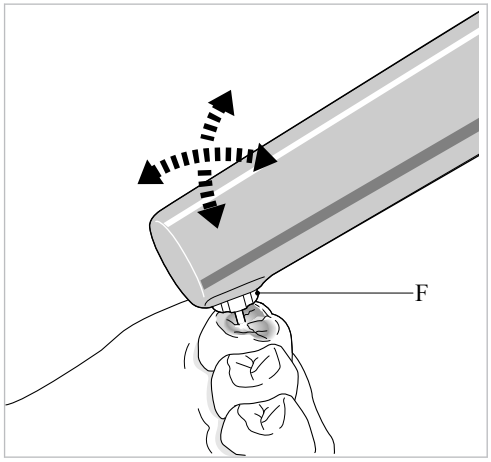
Scanning fissures and smooth surfaces

- Hold the start button ① for approximately 1 second until the signal sounds and the display appears.



⇨ The product is switched on, and the display shows ±0.

- Calibrate if necessary.
- Individually adjust the DIAGNOdent pen 2190 to the patient.
- Guide the DIAGNOdent pen 2190 over the tooth surface without applying pressure and pivot it in all directions to more precisely identify the max. values.

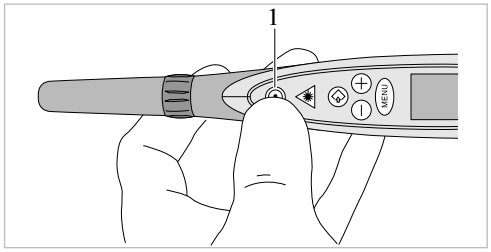


- Briefly press the ring switch when the value of the investigated tooth is elevated to reset the PEAK value.

Scan the proximal area

Note
Dry the proximal area before use.

- Hold the start button ① for approximately 1 second until the signal sounds and the display appears.



⇨ The product is switched on, and the display shows ±0.

- Align prox probe A in a distal or mesial direction with the dot.
- Calibrate if necessary.

See also:
5.4.3 Calibrating the probes against a reference, Page 22

- Individually adjust the DIAGNOdent pen 2190 to the patient.

See also:

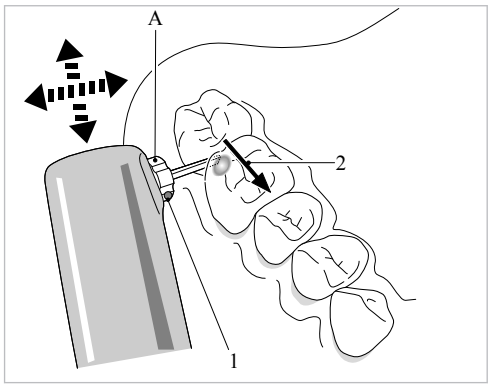
5.5.3 Adjust the DIAGNOdent pen 2190 to each individual patient, Page 26

- Insert the light probe into the interdental spaces contacting the teeth but without applying pressure.

⇨ The instrument shows deviations between healthy and fluorescent tooth substance.

Note

When inserting the probe into the interdental space, make sure that no leverage is exerted on the probe tip from canting since it can break, or fractures can arise in the prismatic tip.
If the patient makes sudden moves, the applied probe may be stressed and break.



KaVo recommends scanning by quadrant first mesial and then distal, or vice versa.

Interpretation of the obtained values in the proximal area

Not all of the proximal area can be reached, even when the prox probe is optimised. The areas directly around the contact point that are most likely to develop caries are more difficult to reach. The measured values are therefore usually lower than in a fissure area since they originate from areas that are less accessible.

5.5.5 Detect concretions and calculus with the paro probe (optional accessory)

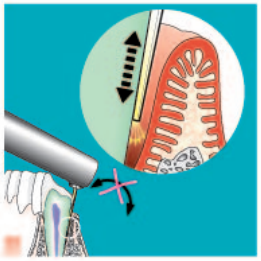
The DIAGNOdent pen 2190 is designed to be used in connection with the Perio probe to support the user in diagnosing calculus or concretions.
The Paro probe can be used to detect plaque in pockets up to 9 mm deep.
In connection with the Perio probe, the DIAGNOdent pen 2190 is used to detect calculus or plaque. It provides information to supplement visual observation and tactile probing by the dentist with conventional hand instruments. The DIAGNOdent pen 2190 can be used to determine the presence of concretions before and after the root surface is cleaned. This can provide valuable information on the success of cleaning. Only calculus or plaque can be detected that is directly accessible to the Paro probe. The detection of concretions in furcations or proximal concretions can be limited by restricted accessibility. The ability of the Paro probe to be inserted in the periodontal pocket can be restricted by soft tissue. When the probe tip is distant from concretions or calculus and the interdental space is filled with blood or sulcus fluid, detection can be restricted. Since root caries can also increase the values displayed by the DIAGNOdent pen 2190, the user must take this into consideration when making a diagnosis.

Before using the Period probe, the dentist should:
1. read the instructions for use.
2. properly store the probes.
3. follow the proper setup for the DIAGNOdent pen 2190.
4. Before every use, sterilise the grip sleeve and probes using a suitable sterilisation method.
5. check for root caries.
6. make sure that the distal end of the paro probe is undamaged, and that the crystal of the probe is not fractured.
7. make sure that the Perio probe is clean and that calculus or concretions are not on the probe.
8. individually adjust the 0 point of the DIAGNOdent pen 2190 to the patient, and clean the teeth before scanning.

Examination procedure

⚠ WARNING

The probe can break.
Injuries.
- Do not apply leverage to the probe!



- Insert the Paro probe into the PA pocket parallel to the tooth surface.

During the examination, the Perio probe of the DIAGNOdent pen 2190 must contact the tooth surface and be slowly moved across it. When the Paro probe approaches a questionable site and is moved an rotated over it at different angles, the change in the audible signal can help determine where the calculus or concretion is located.

DIAGNOdent pen 2190 values achieved with the Perio probe	Meaning
< 5	Clean PA pocket
5 - 40	Very small concretions Plaque next to the probe Possible root caries
> 40	Concretions are in the PA pocket.

The values measured with the Paro probe cannot be viewed as conclusive evidence of the presence, absence or degree of calculus or plaque. It should not be used as the sole basis for selecting a treatment. It needs to be used together with other diagnostic methods.

Note
Residual cleaning paste, tooth stains, restoration materials or caries can increase the MOMENT values of the DIAGNOdent pen 2190.

Note

Adhesive or fluorescent substances (including plaque or calculus) can adhere to the probe and influence the MOMENT values. The MOMENT values do not change even though the probe is moved in and out of the pocket. In this case, the probe should be cleaned.

Note

The changing signal tone of the DIAGNOdent pen 2190 during treatment can make patients nervous. The signal tone can be shut off.

6 Maintenance

The following persons are authorised to repair and service the KaVo product:

- Technicians of KaVo branch offices after appropriate product training.
- Specifically KaVo-trained technicians of KaVo franchised dealers.

Safety checks are not necessary.
The battery can be changed by the user and/or office personnel.

6.1 Setup methods according to DIN EN ISO 17664

The listed instructions for cleaning and sterilising were validated as suitable by the medical device manufacturer for preparing a medical device. The person preparing the device is responsible for the preparation achieving the desired result with the utilised equipment, materials and personnel in the preparation device. Normally, validation and routine monitoring of the process are required. Likewise, any deviation from the instructions by the person preparing the device should be carefully checked to see if it is effective, and potential negative consequences should be evaluated.

Note
Frequently setting up does not substantially influence these instruments. The product life normally ends due to wear and damage from use.

The following components must be treated:

- Unit surface
- Grip sleeve
- Probes
- Reference

⚠ WARNING

Product damage due to improper disinfection.

Malfunctions.

- ▸ Use disinfectant in accordance with the manufacturer's instructions!
- ▸ Do not immerse product in liquids!
- ▸ DEFINITELY NO spray disinfection!
- ▸ Disinfect by wiping only!
- ▸ NEVER use chlorine-containing disinfectants, KaVo recommends CaviWipes!

⚠ CAUTION

Damage due to penetrated liquids.

Malfunctions from penetrated liquids.

- ▸ Do not let any liquids enter the device!

⚠ CAUTION

Damage to device due to improper sterilisation.

Damage to the sterile device.

- ▸ No hot air sterilisation, no chemical cold sterilisation, do not sterilise with ethylene oxide!

⚠ CAUTION

Moisture.

Non-sterility.

- Ensure dryness. Autoclaves with a after-vacuum ensure dryness! In addition, drying can be accelerated through a 10 minute drying phase with the autoclave door open.

6.1.1 Preparations for cleaning

- Turn the DIAGNOdent pen 2190 off.

See also:

5.3.2 Turn off, Page 21

- Remove the probe and grip sleeve.

6.1.2 Cleaning

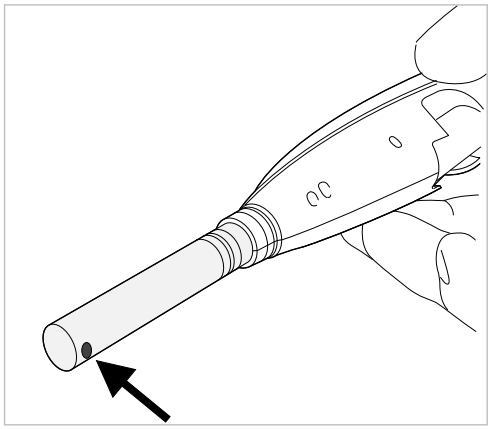
Note

Do not use solvents or aggressive chemicals.

- Remove major soiling directly after soiling with a single-use paper towel.

Manual cleaning

- Clean all outer surfaces of the DIAGNOdent pen 2190 with a soft cloth and with one of the indicated disinfectants.
- Clean the grip sleeve and probe under flowing water (tap water quality, temperature: 30°C +/- 5°C, flow: 2 l/min) for 30 seconds with a medium-hard toothbrush.
- When the inlet and outlet are soiled, clean it with isopropyl 70% and a Q-tip..



Machine cleaning

Not applicable.

6.1.3 Disinfection

Manual disinfection

KaVo recommends the following products based on material compatibility. The microbiological efficacy must be ensured by the disinfectant manufacturer:

- Mikrozid AF made by Schülke & Mayr (liquid or cloths)

- FD 322 made by Dürr

- For range of applications, please refer to the manufacturer's Instructions for Use.
- ▸ Wipe the surface, handpiece and probes with a soft cloth and permitted disinfectants.

Cleaning the probe

Note
To avoid fabric residue, the probes should be thoroughly cleaned before sterilisation and after each use.

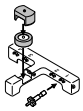
- ▸ Clean the outside with a cloth soaked in isopropanol 70% until no more residual contamination is visible.
- ▸ If the probe coupling is soiled, clean it with a Q-tip soaked in
  Clean with a Q-tip soaked in isopropanol 70%.
- ▸ Remove lint with dry air spray.

Automated disinfection

Not applicable.

6.1.4 Sterilization in a steam sterilizer in compliance with DIN EN 13060

sterilisation should directly follow cleaning.
Only the grip sleeve, reference and probes can be sterilised
Only sterilise the reference and probes in a special container in the steribox.



- ▸ Insert the probes in the probe holder in the steribox in the right probe storage space.

- ▸ Sterilising the probes in an autoclave:
- ▸ Use according to the manufacturer's instructions for use.

Note
When sterilising several instruments in a single sterilisation cycle, do not exceed the steriliserâ€™s maximum load.

6.1.5 Control and function test

General

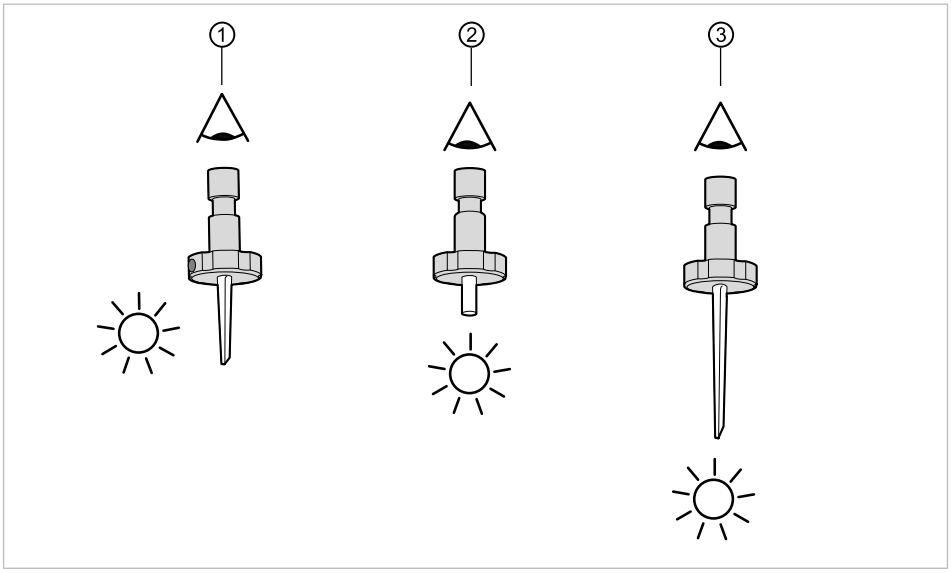
- ▸ Check for cleanliness.

Check light probes

- ▸ Remove the probe from the DIAGNOdent pen 2190 and hold it against a light source (such as daylight).

⇨ The end surfaces must shine brightly. The different geometries of the probes produce different shading.

⇨ When the surface is scratched on the light exit side, exchange the probe.



① Prox probe

② Fissure probe

③ Paro probe (optional accessory)

- Insert the probe into the DIAGNOdent pen 2190 and direct the red laser beam onto a white piece of paper when the device is turned on.

⇨ Use the image on the paper to evaluate the probe.

- Investigate the prismatic end of the proximal probe for fractures using a magnifying glass.

⇨ The probe must not be inserted in the DIAGNOdent pen 2190 while you do this.

6.1.6 Packaging and storage

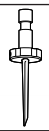
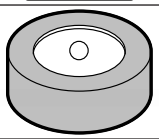
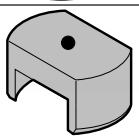
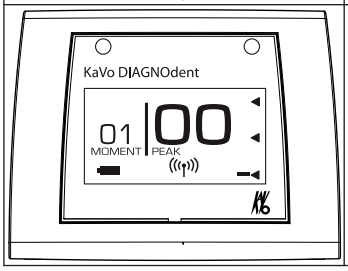
- Store the reference and probes in the probe holder of the steribox for sterilisation and subsequent storage.

7 Troubleshooting

Malfunction	Cause	Remedy
The device cannot be turned on	No power.	▸ Insert the battery properly. Insert a new battery.
Battery icon on	Battery weak.	▸ Insert a new battery as soon as "BATT" is displayed.
Display: BATT	Battery is dead.	▸ Insert a new battery.
Device switches to error and/or incorrect display.	Laser beam interrupted.	▸ Check the seating of the probe. ▸ Clean the laser exit opening.
	Broken or scratched probe.	▸ Replace the probe.
	The given order/sequence was not followed during the adjustment.	▸ Repeat the adjustment.
Display shows: ERR1	Checksum of program memory is incorrect.	▸ Turn on the instrument again. If this error repeats, send the unit to KaVo for repair.
Display shows: ERR 4	Laser power consumption too high.	▸ Do not turn the instrument on again. Send the instrument to KaVo for repair.
Double audio signal after start sound	No acknowledgement signal from LCD display.	▸ Send the instrument to KaVo for repair.
Product gets stuck in turned-on state.	Ring switch contacts are dirty or wet.	▸ Pull off and dry the gripping sleeve and clean and dry the ring switch contacts.

8 Accessories

The following additional accessories are approved by KaVo:

Presentation	Material summary	Mat. No.
	Light probe, prox saphir mont.	1.002.6970
	Light probe, fissure saphir mont.	1.002.6967
	Light probe, Perio sapphire mont.	1.002.8568
	Gripping sleeve	1.002.7003
	Sterile cassette DIAGNO-dent pen 2190	1.002.7011
	Standard C with holder	1.002.7020
	Guide to prox light probe	1.002.7023
	DIAGNOdent display 2191	1.004.8400

9 Information on electromagnetic compatibility

Electromagnetic Transmissions

The DIAGNODENT pen type 2190 is for use in an environment like the one cited below. The customer or user of the DIAGNOdent pen type 2190 should ensure that it is used in the correct environment.

Measurements of noise transmissions	Conformance	Electromagnetic environment - guidelines
HF transmission according to CISPR 11	Group 1	The DIAGNOdent pen type 2190 uses HF energy only for its internal operation. Its HF transmission is therefore very low, and it is improbable that neighbouring electronic devices will be disturbed.

Resistance to electromagnetic interference

The DIAGNODENT pen type 2190 is for use in an environment like the one cited below. The customer or user of the DIAGNOdent pen type 2190 should ensure that it is used in the correct environment.

Interference immunity tests	IEC 60601 test levels	Compliance level	Electromagnetic environment - Guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV atmospheric discharge	± 2/4/6 kV contact discharge ± 2/4/8 kV atmospheric discharge	Floors should be made of wood or concrete or be fitted with ceramic tiles. If the floor is fitted with synthetic material, the relative humidity must be at least 30 %.

NOTE: V_T is the alternating mains voltage before the test level is used.

Resistance to electromagnetic interference

The DIAGNODENT pen type 2190 is for use in an environment like the one cited below. The customer or user of the DIAGNOdent pen type 2190 should ensure that it is used in the correct environment.

Immunity tests	IEC 60601 test level	Conformance level	Electromagnetic environment - guidelines
Radiated HF disturbances according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile radio devices should not be used closer to the DIAGNOdent pen type 2190 including the electrical lines than the recommenced safe distance calculated using the equation for the transmission frequency. Recommended safe distance: $d=1.17\sqrt{P}$ $d= 1.17\sqrt{P}$ for 80 MHz to 800 MHz $d= 3.33\sqrt{P}$ for 800 MHz to 2.5 GHz with P as the maximum rated power of the transmitter in Watts (W) according to the transmitter manufacturer, and d as the recommended safe distance in meters (m). [b]The field strength of stationary radio transmitters should be less than the conformance level at all frequencies in an on-site check[c]. [d]Disturbances are possible close to devices that have the following symbol.

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

NOTE 2: These guidelines may not be applicable in every case. The spread of electromagnetic waves is absorbed and reflected by buildings, objects and people.

[a]The ISM frequency bands (for industrial, scientific and medical applications) 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.

[b] The conformance levels in the ISM frequency bands between 150 kHz and 80 MHz and the frequency range of 80 MHz and 2.5 GHz are intended to reduce the probability that mobile and portable communications equipment will produce disturbances when they are unintentionally brought near the patient. For this reason, the additional factor of 10/3 is used when calculating the recommended safe distances within these frequency ranges.

[c]The field strength of stationary transmitters such as base stations of mobile telephones and land mobile radio devices, amateur radio stations, AM and FM, radio and television broadcasters cannot be theoretically predetermined. To determine the electromagnetic environment of stationary transmitters, a study of the location should be considered. When the measured field strength at the site where the DIAGNOdent pen type 2190 is used exceeds the above conformance level, the DIAGNOdent pen type

2190 should be monitored to demonstrate proper function. When unusual performance features are observed, additional measures may be necessary such as realigning or moving the DIAGNOdent pen type 2190.
[d] Within the frequency range of 150 kHz to 80 MHz, the field strength should be less than $3V_{eff}$ V/m.

Recommended safe distance between portable and mobile HF telecommunications equipment and the DIAGNOdent pen type 2190

The DIAGNOdent pen type 2190 is intended for use in an electromagnetic environment in which HF disturbances are controlled. The customer or the user of the DIAGNOdent pen type 2190 can help prevent electromagnetic disturbances by maintaining the minimum distance between portable and mobile HF telecommunications devices (transmitters) and the DIAGNOdent pen type 2190 depending on the output of the communication device as indicated below.
The table shows the necessary safe distance depending on the transmission frequency in m:

Rated power of the transmitter in W	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d=0.17\sqrt{P}$	800 MHz to 2.5 GHz $d=2.33\sqrt{P}$
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.70	3.7	7.4
100	11.70	11.7	23.3

For transmitters whose maximum rated power is not in the above table, the recommended safe distance d in meters (m) can be calculated using the equation for the respective gap, where P is the maximum rated power of the transmitter in Watts (W) according to the manufacturer's information.
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not be applicable in every case. The spread of electromagnetic waves is absorbed and reflected by buildings, objects and people.

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