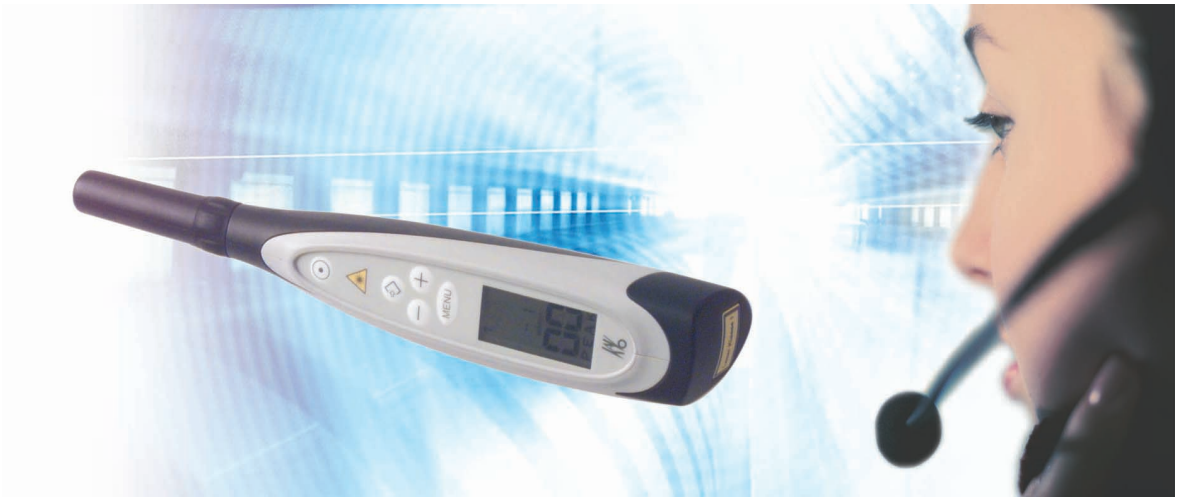
Instructions for use
DIAGNOdent pen 2190



Always be on the safe side.

KaVo. Dental Excellence.

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CE 0124

Table of contents

1 User instructions

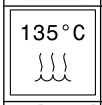
1.1 User guide

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

1.1.1 Abbreviations

Abbre-viation	Explanation
GA	Instructions for use
PA	Care instructions
MA	Assembly instructions
TA	Technician's instructions
STK	Safety check
IEC	International Electrotechnical Commission
RA	Repair instructions
EMC	Electromagnetic compatibility

1.1.2 Symbols

	Refer to chapter Safety/Warning
	Important information for users and technicians
	Thermodisinfectable
	Sterilisable up to 135°C
	CE mark (Communauté Européenne). A product with this mark meets the requirements of the relevant EC directives, i.e. the applicable standards in Europe.
▶	Action request
	Laser warning sign hazard symbol
	Laser notification sign

1.1.3 Target group

This document is for dentists and office personnel.

1.2 Service

Direct questions regarding the product, service and maintenance to the following address.
Please indicate the product serial number in all requests.
Service hotline:
+49 7351 56-1500
Service.Instrumente@kavo.com
Additional information can be obtained at: www.kavo.com

KaVo Dental GmbH
Customer Service Center
Bahnhof Strasse 20
D-88445 Warthausen
07351-56 1500
www.kavo.com

1.3 Warranty terms and conditions

Within the framework of applicable KaVo delivery and payment conditions, KaVo guarantees proper function, freedom from flaws in material and manufacturing for a period of 12 months from the date of purchase demonstrated by the purchaser. 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 when defects or their consequences can arise from manipulations or changes to the product. 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 ordinance

Note
Only valid for the Federal Republic of Germany.

Properly dispose of and recycle the sales packaging according the applicable packaging ordinance through waste management businesses or recycling companies within a comprehensive return system. KaVo has licensed its sales packaging in accordance with this directive. Please follow 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. You must contact KaVo 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

Failure on the part of the recipient to comply with one of the above obligations will mean that the damage will be considered to have arisen following delivery (in accordance with ADSp. Art. 28).

Outside of Germany

Note

KaVo is not liable for damage arising from transportation.
Immediately inspect the delivery after receipt!

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 the damage immediately or at least 7 days after the delivery to the delivery company.
2. Leave the product and packaging in the condition in which you received it.
3. Do not use a damaged product.

Note

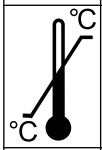
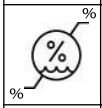
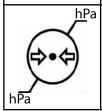
Failure on the part of the recipient to comply with one of the above obligations will mean that the damage will be considered to have arisen following delivery (in accordance with CMR law, Chapter 5, Art. 30).

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 danger.** This section portrays the possible consequences of non-observance. ▸ The optional step covers necessary measures for avoiding hazards.

2.1.3 Description of danger levels

Safety instructions with three hazard levels are used in this document for avoiding personal and property damage.

	⚠ CAUTION CAUTION indicates a hazardous situation that can cause damage to property, or mild or moderate physical harm.

	⚠ WARNING WARNING indicates a hazardous situation that can cause death or serious injury.

	⚠ DANGER DANGER indicates the maximum hazard level. indicates a directly hazardous situation that can cause death or serious injury.

2.2 Purpose – Proper use

2.2.1 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.

The KaVo product is not permitted to be used in areas subject an explosion hazard.

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

During use, national legal regulations must be observed, in particular:
- the applicable health and safety regulations
- the applicable 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 operator ordinance (MPOperator V).

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 that accessories, lines and transformers not delivered by KaVo will correspond with EMC requirements of EN 60601-1-2.

See also: 9 Information on electromagnetic compatibility, Page 39

Disposal

Note

Any waste which is generated must be recycled or disposed of in a manner which is safe both for people and for the environment. This must be done in strict compliance with all applicable national regulations.
Questions on proper disposal of the KaVo product can be answered by the KaVo branch.

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.
Before disassembling / disposing of the product, it must be completely processed (disinfected, sterilized) according to the section "Preparation methods"
Additional information can be obtained from KaVo (www.kavo.com) or your dental supplier.

For final disposal, contact:

Germany

To return an electrical device, proceed as follows:

1. At the homepage www.enretec.de of enretec GmbH, you can download a form for a disposal request under the menu item eom, or you can use it as an online request.
2. Fill out the request with the corresponding information, and send it as an online request or by fax (+49(0)3304 3919 590) to enretec GmbH.
   The following avenues are also available for questions and for initiating a disposal request:
   Telephone: +49 (0) 3304 3919 500
   E-mail: pickup@eomRECYCLING.com and
   Post: enretec GmbH, eomRECYCLING Department
   Kanalstraße 17
   16727 Velten
3. Your**movable**device will be picked up in your practice, and your**permanently installed**unit will be picked up at the curb at your address on the agreed deadline. The owner or user of the device will bear the costs for disassembly, transportation and packaging.

International (EU)

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

2.2.2 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 60825-1:1993 + A1:1997+ A2:2001.

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.

Safety checks are not necessary.

2.3 Safety instructions

2.3.1 Product-specific

⚠ CAUTION

Injury or damage from a leaky battery.
Damage to health and product damage.

- Only use leak-proof batteries.
- Remove the battery during long downtimes.
- Properly dispose of used batteries.
- Do not use rechargeable batteries.

⚠ 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.
The functions of implanted systems (such as pacemakers) can be influenced by electromagnetic fields.

- Ask patients before treatment!

⚠ CAUTION

Blinding hazard from the laser. Laser class 1.
Eye damage.

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

⚠ CAUTION

Aspiration of the probe.
Danger of suffocation.

- Check the seat of the probe in the **DIAGNOdent pen 2190** by pulling 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.

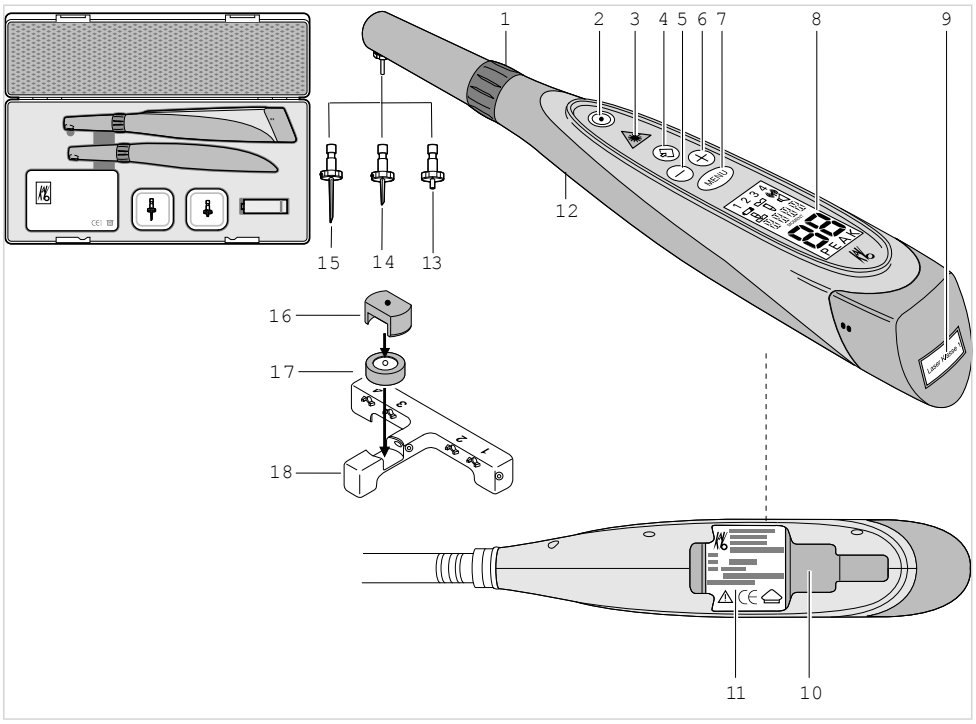
2.3.2 Protective equipment

Note

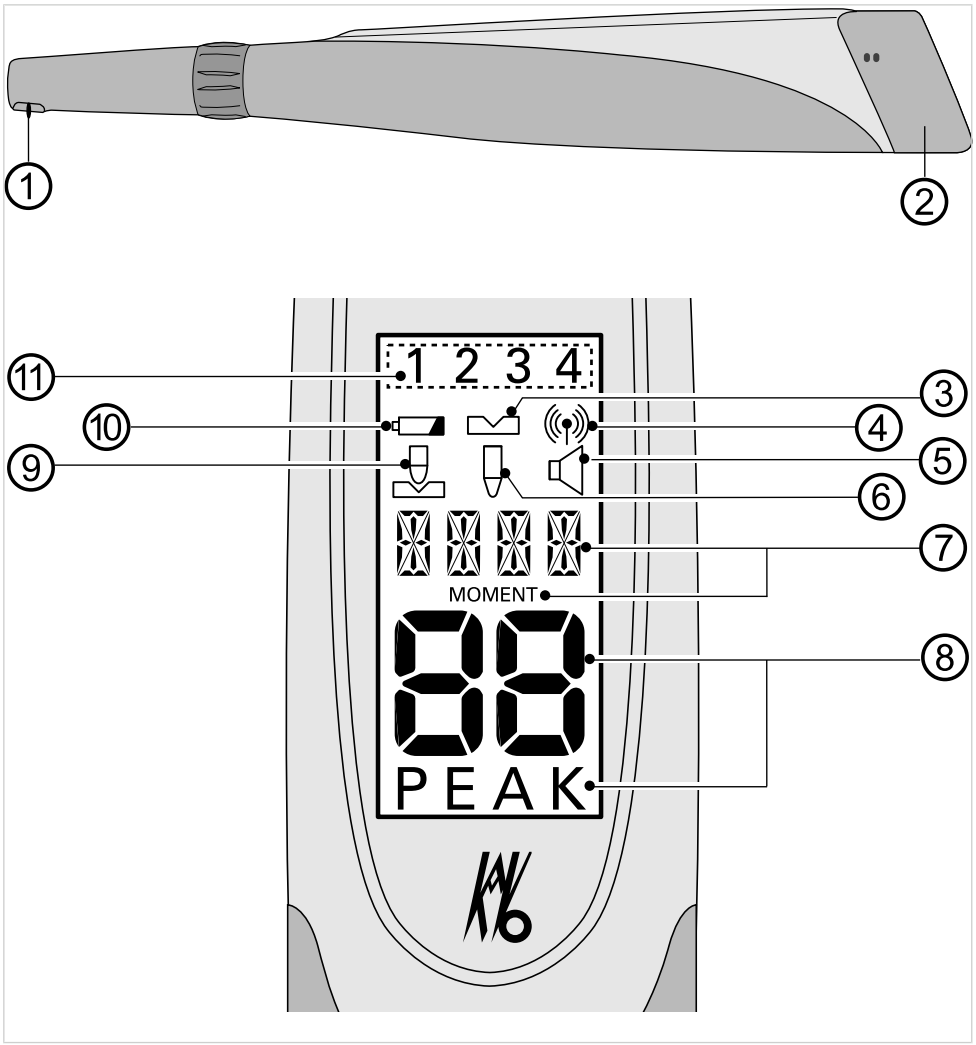
Since this is a class 1 laser medical device, no personal protective equipment must be worn according to the EC directive.

3 Product description

3.1 DIAGNOdent pen 2190

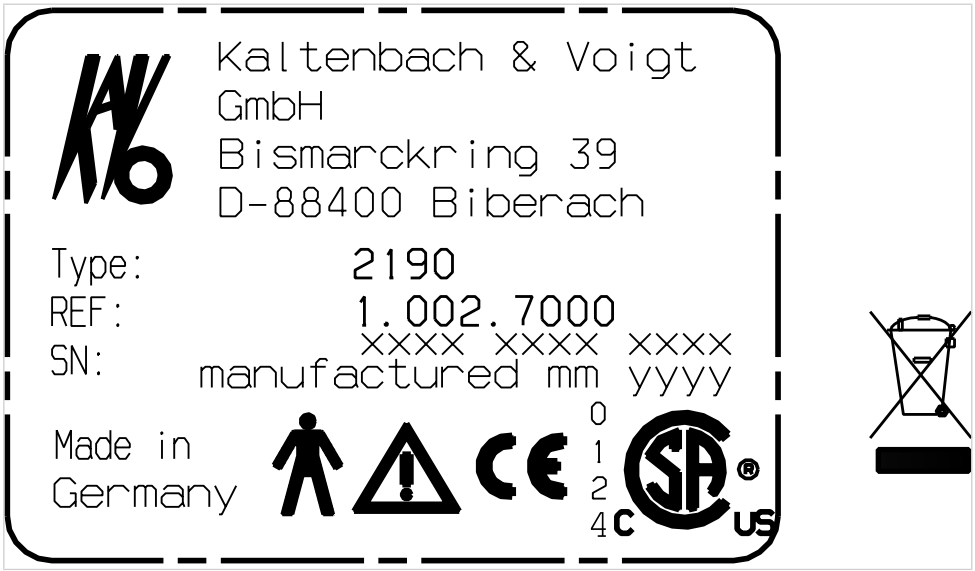


① Ring switch
② The start button
③ Warning sign: danger, laser
④ Save button
⑤ Minus button
⑥ Plus button
⑦ Menu button
⑧ LCD display
⑨ Laser notification sign
⑩ Battery compartment
⑪ Rating plate
⑫ Grip sleeve
⑬ Fissure probe
⑭ Prox probe
⑮ Paro probe (optional accessory)
⑯ Guide to prox probe
⑰ Standard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

3.1.1 Rating plate



CE 0124	CE mark
C SA US	CSA mark
	Application part type B
	Read and note the content of accompanying documents.
mm	Month manufactured
yyyy	Year manufactured
SN:	Serial number
REF:	Material number
Type:	Device type
	For disposal information, see use in accordance with intended purpose

3.2 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
Protection class	IPX0

Operating temperature	+10 °C to +30 °C
Calibration temperature	+22°C ±2°C
relative humidity	30% RH to 75% RH

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

Unsterile grip sleeves and probes
Harmful to health

- Sterilise the probes and grip sleeves before first startup since they are delivered unsterile from the manufacturer.

See also: 6.1 Setup methods according to DIN EN ISO 17664, Page 32

4.1 Insert the battery

⚠ CAUTION

Injury or damage from a leaky battery.
Damage to health and product damage.

- Only use leak-proof batteries.
- Remove the battery during long downtimes.
- Properly dispose of used batteries.
- Do not use rechargeable batteries.

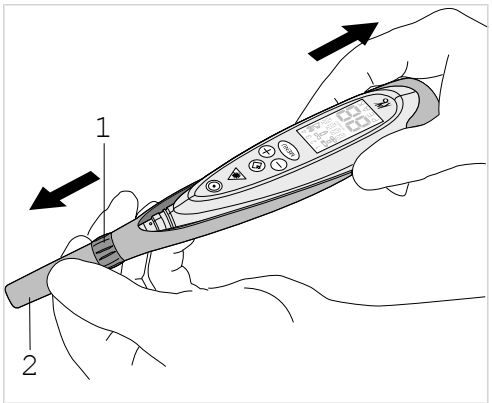
Note
Only use the type mignon LR6 alkaline cell.

⚠ CAUTION

Product damage from misuse.
Damage to the contacts.

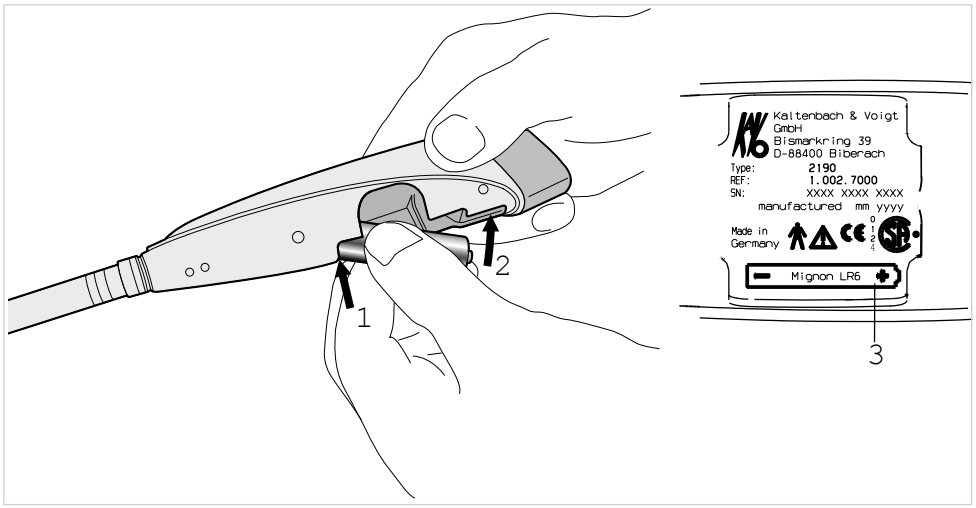
- Do not turn on the ring switch ① when removing and shoving on the grip sleeve②.

- Remove the grip sleeve

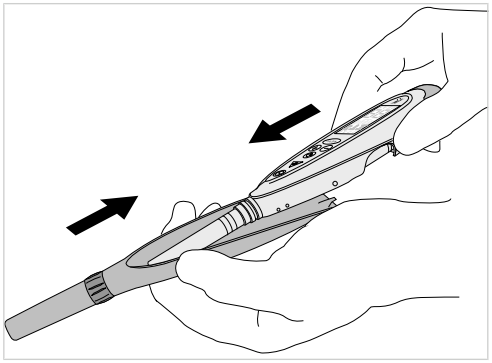


Note
Turn off device before changing the battery.
Do not use a rechargeable battery.

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



- Shove on the grip sleeve

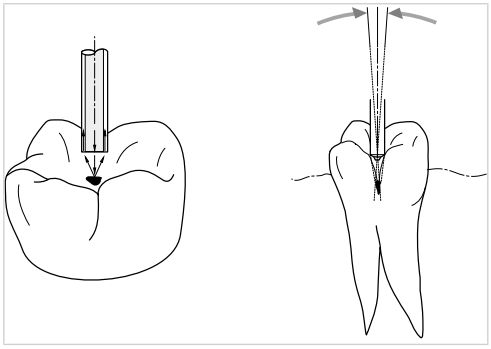


5 Operation

5.1 Mode of operation of the DIAGNOdent pen 2190

Altered tooth substance emits fluorescent light when irradiated at a specific wavelength. This is detected and evaluated.

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.



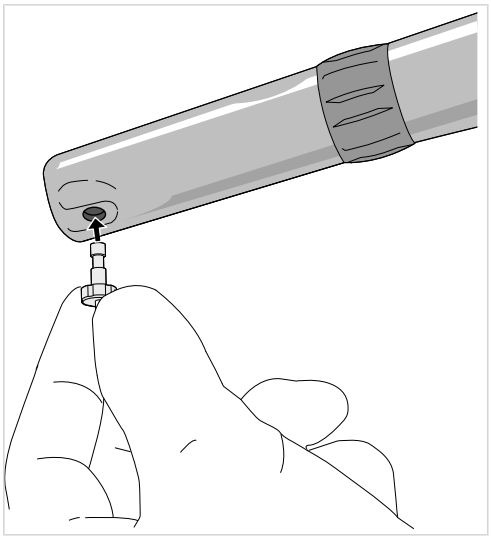
5.2 Inserting the probe

⚠ CAUTION

Aspiration of the probe.
Danger of suffocation.

- Check the seat of the probe in the **DIAGNOdent pen 2190** by pulling it.

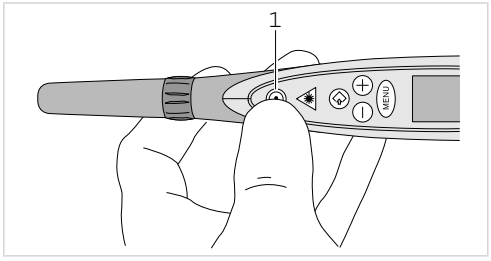
- Insert the probe until it locks into place



5.3 Turning on/off

5.3.1 Start up

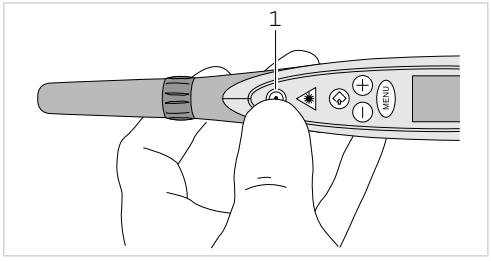
- Hold the start button ① for approximately 1 second until the signal sounds and the display appears.



5.3.2 Switch off

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

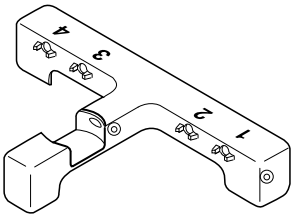
- Press start key ① for approximately 5 seconds until the DIAGNOdent pen 2190 turns off.



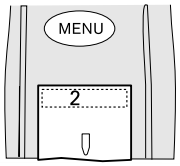
5.4 Menus

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

5.4.1 Select probe memory

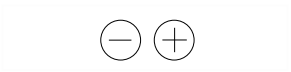


A memory (1 - 4) can be selected for the probes to assign a specific device calibration to each probe, such as 1 for a proximal probe, 2 to a fissure probe, and 3 for the Paro probe.



- Press the menu key twice.

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



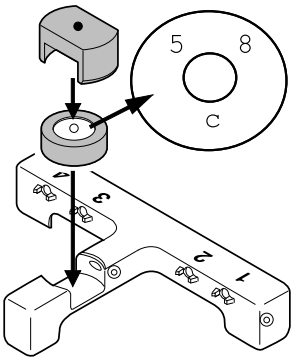
- Set the desired value with the plus or minus button.

- Use the save button to save the set value.

  The product returns to display mode.

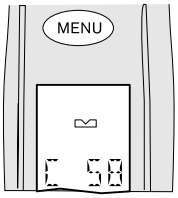
If the save button is not pressed for 3 seconds, the set value is automatically saved. The DIAGNOdent pen 2190 returns to display mode.

5.4.2 Checking/setting the reference value



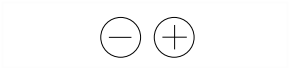
The reference value is engraved on the surface of the supplied reference (such as C 58).
This value is preset. When exchanging the reference, this new reference value can be set.

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.

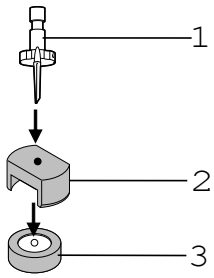
Calibration is required when the displayed value differs more than ± 3 from the reference value when the reference is held down.

Note

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

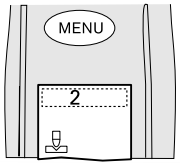
Note

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.



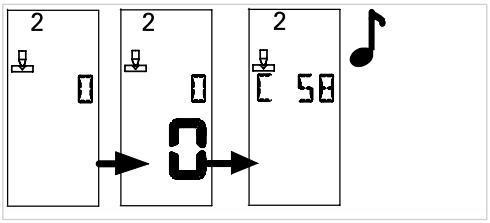
- Press the menu key.

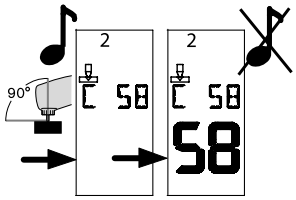
  The calibration symbol appears.

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

- Press the save key.

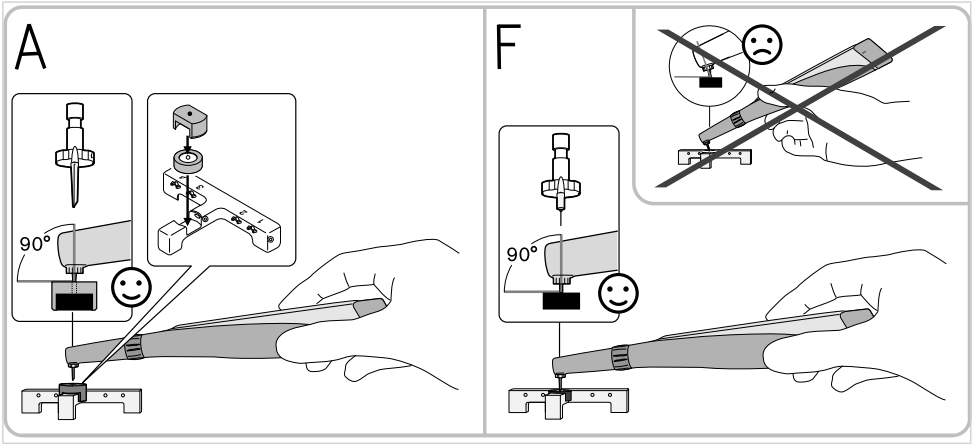
  Calibration is started.





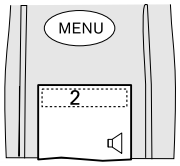
- Once you hear the signal, place the probe vertically on the reference.

  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).



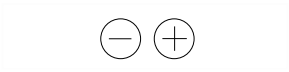
5.4.4 Setting the volume

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

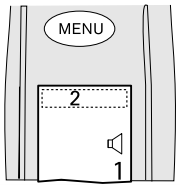


- Press the menu key three times.

  A volume symbol appears.



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



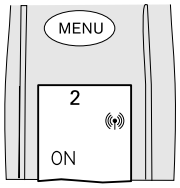
Possible settings: off, 1, 2

- Use the save button to save the set value.

  The product returns to display mode.

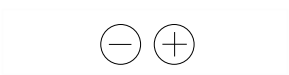
5.4.5 Turning infrared data transmission on and off

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 anti-bacterial measures such as fluoridation, KaVo HealOzone, chlorhexine	Minimally invasive treatment KaVo HealOzone, RONDOflex, SONIC-flex 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.

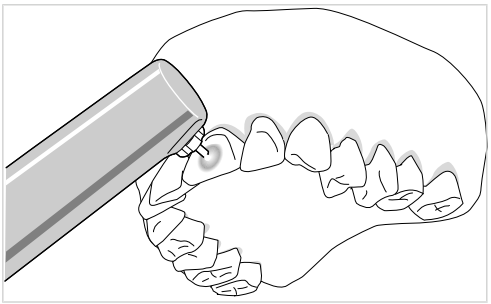
When interpreting the value of the DIAGNOdent pen 2190, false positive results can arise when the following points are not taken into account:

- 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

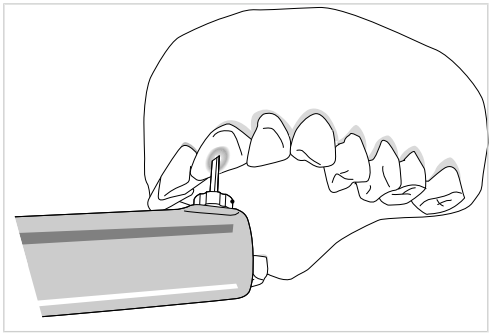
5.5.3 Individually adjust the DIAGNOdent pen 2190 to the patient

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.

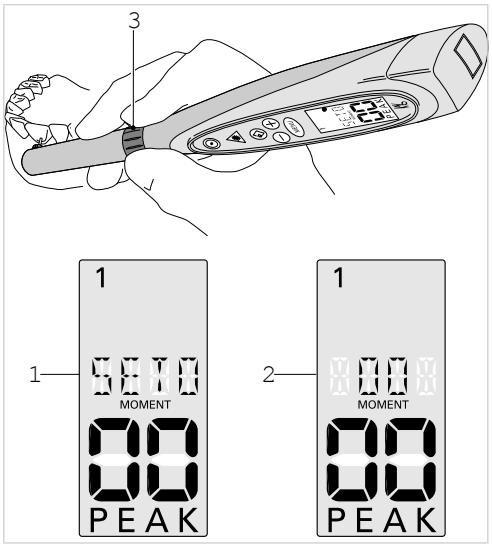
▸ Apply the probe to a healthy site of a tooth.



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



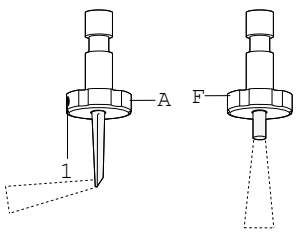
- Turn on the ring switch ③ until you hear two beeps and the display ① appears.



The device is individually adjusted to the patient.

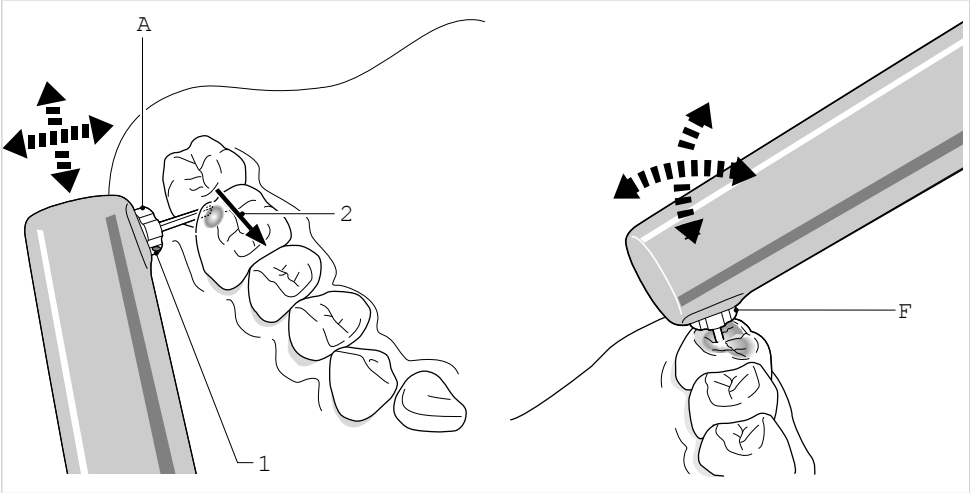
The displayed value lies between 00 and -9 when the probe does not contact the tooth, and +/- 1 when it contacts the tooth.
To reset the individual 0 point, the probe must be held in the air, and ring ③ must be actuated until you hear two beeps. The display shows 00 ②.

5.5.4 Scanning the tooth surface



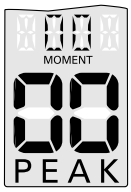
Two different probes are available for detecting caries:
Fissure probe F (blue) for scanning smooth surfaces and fissures.

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.

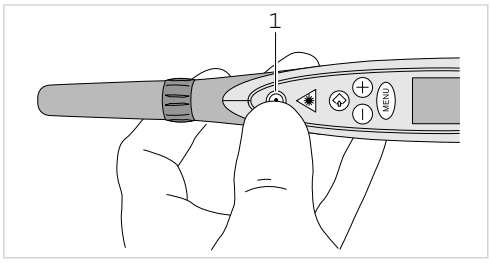
The tone sounds at a MOMENT display of 06. The higher the MOMENT value (06-99), the higher the frequency of the signal tone.

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.

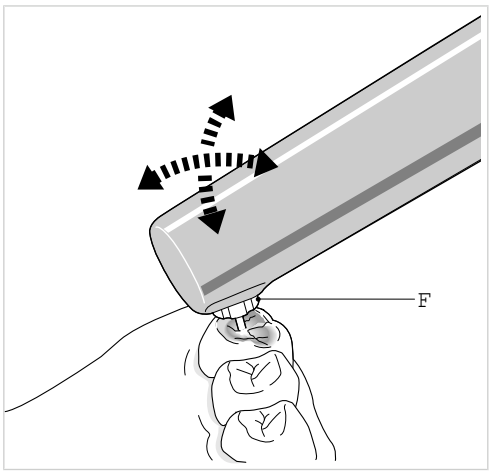
Scanning fissures and smooth surfaces

- 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.

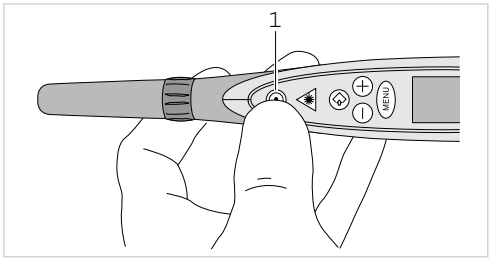


- Briefly press the ring switch when the value of the investigated tooth is elevated to reset the PEAK value.

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 with a reference, Page 21

- Individually adjust the DIAGNOdent pen 2190 to the patient.

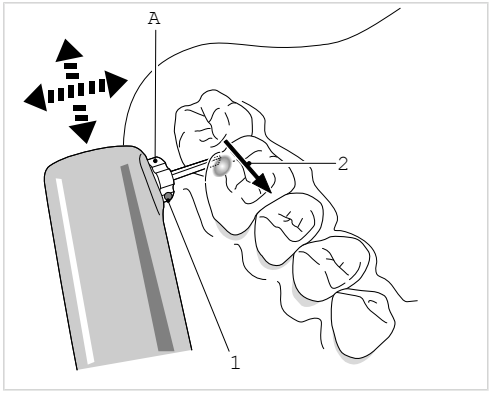
See also: 5.5.3 Individually adjust the DIAGNOdent pen 2190 to the patient, Page 25

- 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.

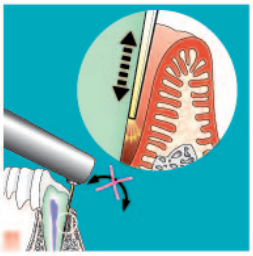
Before using the Period probe, the dentist should:
1. read the instructions for use.
2. properly store the probes.
3. follow the proper setup for the DIAGNOdent pen 2190.
4. Before every use, sterilise the grip sleeve and probes using a suitable sterilisation method.
5. check for root caries.
6. make 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

⚠ CAUTION

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

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

	**⚠ CAUTION** **Product damage due to improper disinfection.** Malfunctions. ▸ Use disinfectant in accordance with manufacturer's instructions. ▸ Only disinfect by wiping. ▸ Do not immerse product in liquids.

	**⚠ CAUTION** **Damage due to penetrated liquids** Malfunctions from penetrated liquids. ▸ Do not let any liquids enter the device.

	**⚠ CAUTION** **Product damage due to improper sterilisation.** Damage to the sterile product. ▸ No hot air sterilisation, no chemical cold sterilisation, do not sterilise with ethylene oxide!

	**⚠ CAUTION** **Moisture** Non-sterility ▸ Ensure dryness. Autoclaves with a subsequent vacuum ensure dryness. In addition, drying can be accelerated with a 10 minute drying phase with the autoclave door open.

6.1.1 Cleaning preparations

- Turn off the **DIAGNOdent pen 2190**.

See also: 5.3.2 Switch off, Page 19

- Remove probe and grip sleeve.

6.1.2 Cleaning

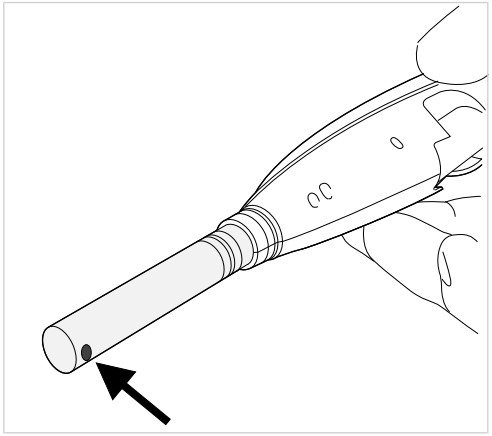
Note
Do not use solvents or aggressive chemicals.

- 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.
- Microcide AF by Schülke&Mayr (liquid or cloths)
- FD 322 by Dürr
  Follow 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.

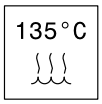
- ▸ Clean the outside with a cloth soaked in isopropanol 70% until no more residual contamination is visible.
- ▸ If the probe coupling is soiled, clean it with a Q-tip soaked in
  Clean with a Q-tip soaked in isopropanol 70%.
- ▸ Remove lint with dry air spray.

Automated disinfection

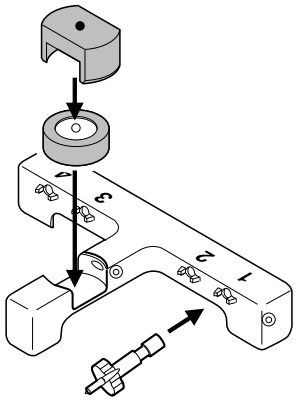
Not applicable.

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.



The KaVo products released for sterilisation have a maximum temperature resistance of 138 °C.
KaVo recommends for example
- STERIclave B 2200/ 2200P by KaVo
- Citomat/ K-series by Getinge



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

- Sterilising the probes in an autoclave:

Procedures	Duration/Temperature
Autoclave three times with an initial vacuum for	Min. 4 minutes/134℃ ±1
Autoclave using the gravitation method	Mind. 10 Minuten / 134 ℃ ±1
Autoclave using the gravitation method	Min. 60 minutes/121℃ ±1

- 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

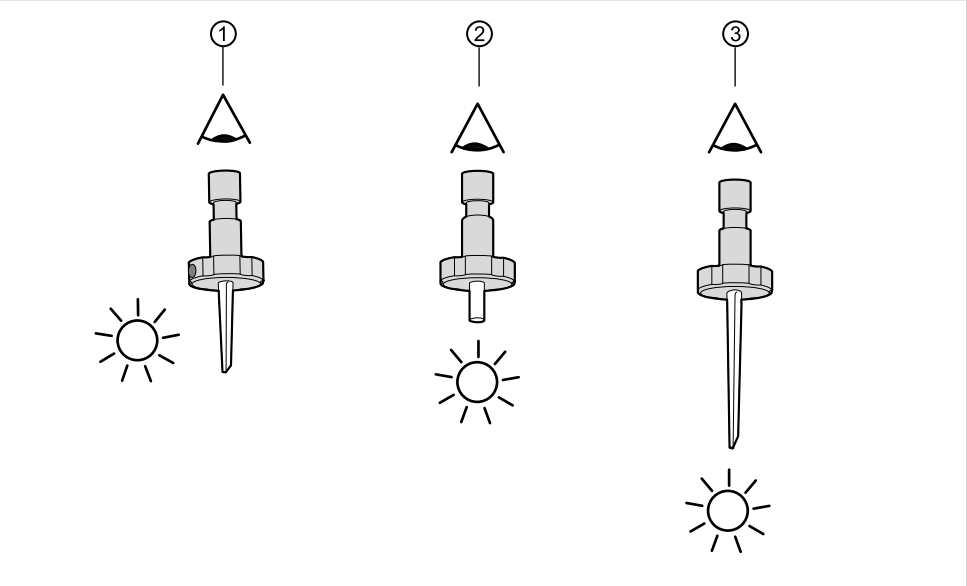
General

- 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.

6.1.6 Packaging and storage

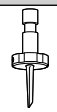
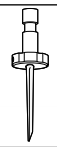
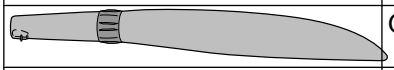
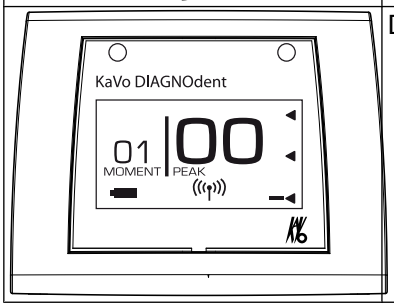
- Store the reference and probes in the probe holder of the steribox for sterilisation and subsequent storage.

7 Troubleshooting

Malfunction	Cause	Remedy
The device cannot be turned on	No power.	▸ Insert the battery correctly. Use a new battery.
Battery symbol on	Low battery.	▸ Insert a new battery at the latest when you see the display "BATT".
Display: BATT	Battery is dead.	▸ Use a new battery.
The device shows and error or the wrong display.	Laser beam interrupted.	▸ Check the seat of the probe.
		▸ Clean the laser exit.
	Broken or scratched probe.	▸ Exchange probe.
	The sequence is not maintained during calibration.	▸ Recalibrate.
Display: ERR1	The checksum of the program memory is wrong.	▸ Turn on the instrument again. If this problem repeats, send the unit to KaVo for repair.
Display: ERR 4	The laser power consumption is too high.	▸ Do not turn on the instrument. Send the instrument to KaVo for repair.
Two beeps after the start tone	No acknowledgement signal of the LCD display.	▸ Send the instrument to KaVo for repair.
The product remains turned on.	The contacts of the ring switch are dirty or wet.	▸ Remove the grip sleeve, dry it and clean and dry the ring switch contacts.

8 Accessories

The following 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
	Grip sleeve	1.002.7003
	Steri cassette for the DIAGNOdent 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.

Immunity tests	IEC 60601 test level	Conformance 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 have ceramic tiles. When the floor is made of 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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