Clinical Guidelines and Brief Operating Instructions
KaVo DIAGNOdent®

NEW!!
EZ-Cal
Faster Calibration

Listen! It's caries.
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INTRODUCTION

The DIAGNOdent is intended for use as an aid in detecting caries. It provides information to supplement the clinician’s visual observations, consideration of patient histories, and information from other diagnostic modalities, resulting in an overall risk assessment and a treatment determination. It is not a stand alone diagnostic tool. DIAGNOdent may also be used as an aid in monitoring progression or arrestment of caries by comparing a patient’s readings from visit to visit. All DIAGNOdent readings must be evaluated in the context of other diagnostic information.

Only caries on occlusal or flat surfaces of teeth, which are accessible to the probes, can be examined for caries. The DIAGNOdent does not detect interproximal caries, subgingival caries, or secondary caries under crowns, inlays, or composite/amalgam restorations.

INDICATIONS FOR USE

The DIAGNOdent is intended for use as an aid in detecting caries on thoroughly cleaned teeth and in monitoring progression or arrestment of caries by comparing a patient’s readings from visit to visit.

PRIOR TO USE OF THE DIAGNOdent, THE DENTIST SHOULD:

- Take a medical history and obtain information regarding diet, oral hygiene and past caries history. Examine radiographs, if available.
- Perform an initial dental examination, which includes a visual examination, using, if possible, magnification and an intraoral camera.
- Form a risk assessment of the patient from this information.
- Clean the teeth using a prophy brush or powder jet cleaner, e.g. KaVo PROPHYflex II, or other acceptable means. Dry the teeth.
- Identify suspicious tooth surfaces requiring further examination with DIAGNOdent.
Instructions for use

INSTRUCTIONS FOR USE

The DIAGNOdent should be used on suspicious sites identified after careful visual examination and thorough cleaning and drying of the teeth.

Prior to use; the DIAGNOdent must be calibrated with the selected probe tip and a patient-specific zero base line must be established. Please refer to these topics in the Brief Operating Instructions section of this booklet.

During examination of suspicious sites, the tip of the handpiece should be in light contact with the surface of the tooth and should be slowly rotated or rocked in a pendulum-like manner when contacting fissures or areas of concern, e.g., discoloration, enamel defects or areas that produce a sharp change in the audible signal. The higher the reading the greater the fluorescence of the site. The highest reading obtained can be referenced in the context of treatment considerations.

It is important to clean and dry the teeth prior to using the DIAGNOdent. Powder jet cleaners are rapid and effective in removing stain and debris from complex occlusal anatomy. Prophy paste residue can be difficult to remove from deep grooves and fissures.1
Seemingly intact molar, as perceived visually and radiographically. Corresponding histological cross-sections reveal actual extent of caries. (taken from Lussi 1993).
Correlation of DIAGNOdent values to possible course of action

<table>
<thead>
<tr>
<th>DIAGNOdent Values</th>
<th>No Action</th>
<th>Preventive Therapy</th>
<th>Record &amp; Monitor</th>
<th>Sealant</th>
<th>Preparation</th>
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<tr>
<td>0-5</td>
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<td>5-10</td>
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<td>10-15</td>
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<td>20-25</td>
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<td>•**</td>
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<td>25-30</td>
<td>•***</td>
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<td>30+</td>
<td>•***</td>
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</table>

Table 1-1

* Taken from Lussi; See “Research Supporting DIAGNOdent Scale Readings,” (page 6).
** In unusual cases of virulent disease, preparation may be a course of action when a value between 20 and 30 is recorded.
 *** Regardless of course of action taken to treat a specific lesion, preventive therapy may be indicated based upon caries risk.

Please note:

Alloy restorations (amalgam/gold) exhibit little or no fluorescence values. Composites/ceramics/cements emit their own fluorescence values. Therefore, it should be understood that any restorative material can misrepresent the health of the underlying tooth structure.

Plaque, tartar and discolorations generally exhibit very high fluorescence values. All deposits must be removed to permit better evaluation.
1. The DIAGNOdent should be used only after the teeth have been thoroughly cleaned and dried.

2. The device detects fluorescence of a chromophore, not necessarily bacteria, which is a surrogate marker that correlates with the grade of caries development.

3. False positives may arise because of fluorescence due to plaque or calculus in fissures or to discoloration, tartar, food and similar materials which may be lodged in or on the surface of the teeth. The DIAGNOdent may also respond to some restorative materials which include but are not limited to composite resins, sealants and ceramic restorations due to fluorescent components of these restorations. A distinction among these possible causes of a signal based solely on the displayed value is not possible; the dentist must assess each suspicious site to determine whether caries is present.

4. Very high readings, e.g., greater than 80, may indicate that the teeth are not thoroughly cleaned or free of debris. In such situations it is suggested that the tooth or area(s) be cleaned, dried and re-examined.

5. Arrested caries MAY be indicated by readings which are the same, nearly the same, or lower, over a series of examinations. Final assessment is dependent upon an examination of such sites by the dentist by other diagnostic modalities.

6. If the overall clinical assessment, taking into account all information other than that provided by the DIAGNOdent, leads to a conclusion that restoration is indicated, conservative methods should be used to determine the depth of the suspected caries. THE DIAGNOdent IN NO CASE SHOULD BE VIEWED AS AN INDICATOR OF THE DEPTH TO WHICH THE CLINICIAN SHOULD EXCAVATE!

7. The changing sound during an examination may cause anxiety in some patients. In such cases, the audible signal can be turned as low as possible or turned off completely at the discretion of the dentist. Refer to page 9 of this booklet for instructions on changing the tone control.
Extensive pre-clinical research establishes that laser-induced fluorescence is correlated with materials in carious lesions,\(^2\) and that the scale readings obtained by the DIAGNOdent correlate with grades of carious lesions.\(^3,4,5\) Results obtained by DIAGNOdent compare favorably to results achieved by other means of detection.\(^6\)

Clinical research supports the value of the DIAGNOdent as an aid to diagnosis of caries.\(^7,8,9,10,11,12\)

While the scale readings given by the device are valuable information, they should be used in the context of the other information obtained by the clinician by means of visual examination, patient histories, radiographs and other diagnostic modalities. They should not be relied on as a sole diagnostic tool. The chart “Correlation of DIAGNOdent Values to Possible Courses of Action” (page 4) is based on the research and suggestions of Lussi.\(^13\) Specifically, making the following correlations based upon in vivo studies:

<table>
<thead>
<tr>
<th>Scale Reading</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>0 - 14</td>
<td>no caries, or histological enamel caries limited to the outer half of the enamel thickness.</td>
</tr>
<tr>
<td>15 - 20</td>
<td>histological caries extending beyond the outer half, but confined to the enamel.</td>
</tr>
<tr>
<td>21 - 99</td>
<td>histological dentinal caries</td>
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</table>

and provide the following treatment recommendations:

<table>
<thead>
<tr>
<th>Scale Reading</th>
<th>Recommendation</th>
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<tbody>
<tr>
<td>0 - 14</td>
<td>no active care is advised.</td>
</tr>
<tr>
<td>15 - 20</td>
<td>preventive care is advised.</td>
</tr>
<tr>
<td>21 - 30</td>
<td>preventive or operative care is advised depending on the patient’s caries risk, the recall interval etc.</td>
</tr>
<tr>
<td>&gt;30</td>
<td>operative and preventive care is advised.</td>
</tr>
</tbody>
</table>

THE SCALE READINGS FROM DIAGNOdent SHOULD NOT BE VIEWED AS CONCLUSIVE OF THE PRESENCE, ABSENCE, PROGRESSION, ARRESTMENT, OR GRADE OF CARIES, OR BE DETERMINATIVE OF THE CHOICE OF TREATMENT, BUT SHOULD BE INTERPRETED IN THE CONTEXT OF OTHER DIAGNOSTIC INFORMATION!
KaVo DIAGNOdent 2095

Brief operating instructions

ASSEMBLY

NOTES

Please note the following points

■ Load battery pack. Batteries must be correctly inserted into battery compartment. Polarity is important, note diagram on battery pack.

■ Insert battery pack into rear of unit, arrow down, ensuring that battery pack is secure.

■ Insert handpiece rest in the vertical or horizontal socket position.

■ Remove protective caps and insert optical tubing into the unit; insert plug end of optical tubing into tubing socket on back of unit. Use care to align pins! Firmly secure tubing with threaded lock nut.
KaVo DIAGNOdent 2095

Assembly

■ Remove protective cap from handpiece end of tubing. Slide the gripping sleeve over the end of handpiece with light axial pressure, clicking into place, aligning KaVo logo with embossed arrow symbol. (➡️)

■ Gently seat light probe tip onto the gripping sleeve and snap into place with a slight axial pressure. When seated properly the A or B symbol on the tip will align with KaVo logo on gripping sleeve.

■ Ensure proper connection of handpiece.

■ To remove the gripping sleeve and the laser probe tip, gently rotate radially. Do not pull!

■ Place handpiece correctly in the handpiece rest! (magnetic holder)
KaVo DIAGNOdent 2095

Function

**Switching on**
Operate ring switch on handpiece with gentle squeeze.

The DIAGNOdent automatically switches off when not in use after approximately 2 minutes. The user cannot switch off the unit.

**Speaker Control**
The volume of the acoustic signal can be adjusted in four steps using the key with the loudspeaker symbol.

Adjust volume from step 1 to 4.

Speaker off.
KaVo DIAGNOdent 2095

Calibration

Switch unit on.
Select tip.

Device must be calibrated before use, with desired probe tip in place.

Ensure that the LED on control panel is in the correct position which corresponds with tip selected.

Press the CAL key and release. A zero will appear in the Moment display followed by a second zero in the Peak display.

The display changes to a two-digit number and a letter e.g. "67b or 58c", etc. Simultaneously, the unit begins to emit an audible tone. Gently place the probe tip on the center of the circular calibration disc, which is affixed inside the sterilization cassette.* While holding the tip in place, the two digit number will also appear under the Moment display and the audible tone will cease. This indicates that the probe tip calibration process is complete and the device is ready for use.

Tip A: conical shape for fissure areas.
Tip B: broad, flat design for flat surfaces.

*Note: The two-digit number indicates the device calibration standard, which should match the number printed on the circular disc found in the sterilization cassette (see page 15).
Check the calibration frequently using the ceramic standard disc provided in the sterilization cassette. In the event of a deviation greater than +/- 3 from the reference value of the ceramic standard, a new calibration must be performed.

NOTE: Due to influences which affect the optical properties of the probe tips e.g. wear and sterilization, it is recommended that calibration should be performed routinely with probe tip changes. The additional time required to recalibrate will result in optimal performance of the DIAGNOdent.

EXAMINING TOOTH SURFACES

Clean and dry the teeth.

ESTABLISH ZERO BASE LINE

Due to slight, natural variances in the fluorescence of healthy tooth structure, it is recommended to establish a zero base line, specific to each patient. Prior to scanning tooth surfaces, select one anatomical reference point on a tooth surface which is apparently healthy. The middle third, facial surface of a non-restored tooth is ideal.

Hold the probe tip against the tooth at right angles to the surface, while gently maintaining squeeze pressure on gray ring switch of the handpiece. “Set 0” will appear on the display, also confirmed by a second audible beep, indicating that the zero base line is established.

The anatomical location where the zero base line was established should be documented in the patient's dental record for future reference e.g. DIAGNOdent zero base line: mid facial #8.

After scanning tooth surfaces it is important to eliminate the influence of the patient-specific zero base line from the device. Simply hold the tip in the air and hold the gray ring switch until “Set 0” appears on the display also confirmed by the second audible beep.
Scanning teeth

Place probe tip on tooth surface with light contact. If the audible signal is enabled, the tone will sound when the DIAGNOdent reaches a minimum value threshold and continues to increase proportionately with increased values.

In fissure areas, the tip must be slowly rocked in a pendulous motion as to carefully scan the adjacent periphery of the site at various angles.

The operator will observe the values on the display: the Moment display indicates the real-time value that the probe tip is measuring, continuously changing as the probe tip moves. The Peak display captures the maximum value measured in the sequence. The Peak value is reset by the operator by actuating the ring switch with a brief squeeze.

In practice, the operator will scan tooth surfaces while monitoring the audible signal. An increase in tone pitch will alert the operator to observe the display values. This will allow the operator to pin-point the exact site which corresponds to the elevated values.
These brief Operating Instructions cover only the important operating functions. Before starting the unit for the first time and when the handling of this medical product, it is essential to read the instructions for use included in the delivery.
DENTAL HISTORY

DENTAL EXAMINATION

CLEAN TOOTH SURFACE WITH PROPHYLAXIS

IDENTIFY SUSPICIOUS TOOTH SURFACES

SCAN TOOTH SURFACES WITH DIAGNOdent

RISK ASSESSMENT AND DETERMINE COURSE OF TREATMENT
Refer to Table 1-1 for correlation of numeric values

OBSERVATION

PREVENTION

RESTORATION

MONITOR

MONITOR

MONITOR
CHECKING THE STANDARD VALUE

Note: The standard value displayed in the DIAGNOdent must match the standard (cassette) used to calibrate the probe tips. In the event that multiple or replacement cassettes are used with the device, the standard value must be reprogrammed in the DIAGNOdent to match the respective value standard (cassette) used for probe tip calibration.

Switch unit on.

Press key.

The display shows e.g. c... and two digits. The letter and the two digits must be identical to the ones printed on the ceramic standard disc [1] provided in the sterilization cassette used for calibration.

CHANGING THE STANDARD VALUE

Switch unit on.

Press the “up/down arrow” key to view standard value.

Actuate gray ring on handpiece to change standard value.

Press the “up/down arrow” key again to enter new standard value.
BATTERY INDICATOR

Indicator flashes at a power of approx. 20%

When the power falls below 20% the display shows ACC then LO.

At the same time, an acoustic signal is heard and the unit switches off.

TROUBLESHOOTING

Refer to Operating Instructions delivered with product.
1. What is the DIAGNOdent actually measuring?
A. The DIAGNOdent measures laser fluorescence within tooth structure. As the incident laser light is propagated into the site, two-way handpiece optics allows the unit to simultaneously quantify the reflected laser light energy. At the specific wavelength that the DIAGNOdent laser operates, clean healthy tooth structure exhibits little or no fluorescence, resulting in very low scale readings on the display. However, carious tooth structure will exhibit fluorescence, proportionate to the degree of caries, resulting in elevated scale readings on the display.

2. What is the difference between the Moment and Peak?
A. The Moment is the number that is occurring at that exact spot on the tooth and changes as you move across the tooth. The Peak is the highest number recorded before the unit is reset. As you are doing your examination it is the Peak number which you should look at.

3. What do you mean by a clean tooth?
A. To get consistent readings it is essential to have a clean tooth. This is especially important when monitoring values at future examinations. We suggest that the teeth are cleaned thoroughly using any acceptable means. The use of a powder jet cleaner, e.g. KaVo PROPHYflex 2, is a rapid and effective method to clean stain and debris from complex occlusal anatomy.

4. Can the unit diagnose inter-proximal caries?
A. No. Limited accessibility to the embrasure prevents accurate reading of approximal surfaces.

5. Can the unit be used around existing composite resin restorations?
A. No. Because composite resins can fluoresce, prompting elevated readings, the DIAGNOdent should not be used on these materials.

6. Can the unit read caries under an existing amalgam?
A. If there is caries at the margin it will give an accurate reading; however if the caries is under the floor of the amalgam the reading will not be accurate.

7. If I see stain under a sealant will the unit tell me if this is decay or not?
A. No. The sealant must first be removed and then an accurate reading can be taken.

8. Can the DIAGNOdent be used to determine if caries excavation is complete?
A. Not always; some conservative preparation designs, particularly those with small access openings, limit proper tip angulations within a preparation. Furthermore, independent research indicates that when used in deep preparations, in close proximity to the pulp, elevated values may be obtained, possibly resulting from fluorescence of underlying pulp and not necessarily as a result of caries. Therefore, the use of other methods to determine extent of affected tooth structure should be employed in these situations.
9. What do you mean by risk assessment?  
A. It is necessary to consider a patient’s dental history, dietary sugar intake, oral hygiene, history of maintaining regular recalls, caries status (the number of carious teeth in their mouth), as well as any other information such as that from radiographs or other diagnostic modalities.

10. What does a very high number mean?  
A. This may occur when there is an open lesion at the surface or if there is a lot of debris where the reading is being taken. The tooth should be cleaned thoroughly and a second reading taken.

11. Can the unit be used on both primary and permanent teeth?  
A. Studies have shown the unit is equally accurate in both primary and permanent teeth.

12. How much change in the reading between visits is considered significant?  
A. The margin of error is (+) or (-) 3 so a change greater than this would be necessary before the tooth should be considered to exhibit a changing condition.

13. Can the tone be used to identify caries?  
A. No. The audible tone function is an operator convenience, which allows the dentist to focus on the tooth while scanning, only sounding variably as different value thresholds are reached. The signal is intended to direct the operator to the visual display. Tone volume can be changed or altogether switched off as desired.

14. I cannot calibrate the unit, I continuously get an error message on the display.  
A. Nearly all calibration errors are attributed to user error. It is necessary to follow calibration instructions carefully. If error persists, contact KaVo Customer Service.

15. As the device is a laser, is protective eyewear required?  
A. No. The device is harmless when used as directed.

16. How deep does the laser penetrate the tooth?  
A. Approximately 2mm.

17. Which tip should I use, A or B?  
A. Tip A is conical in shape and designed for fissure areas. Tip B is broader and designed for flat surfaces.

18. What is the recommended asepsis protocol for the DIAGNOdent?  
A. Clean the control unit and the tubing these surfaces with a soft cloth dampened with a mild soap solution. The remaining handpiece sheath and tips can be steam sterilized. Chemical vapor sterilization is also acceptable, however, components will eventually discolor and degrade at an accelerated rate. Many clinicians sterilize the tips but prefer to barrier protect the sleeve portion. Other clinicians fit barriers over the entire sleeve and tip assembly to eliminate the need for tip sterilization. When tips are barrier protected, unit must be calibrated with barrier in place. Tips can be cleaned with a soft cotton swab moistened with water. Do not use surface disinfectants on the trip or sleeve components! See Operating Manual for additional cleaning information.

19. Does ambient light affect DIAGNOdent readings?  
A. The photo-optic measuring system in the DIAGNOdent has filters to eliminate the influences of most ambient light. However, when calibrating the device, avoid exposing the probe tip to direct halogen light.
References


CAUTION!
Class II laser product
Visible laser radiation
DO NOT STARE INTO BEAM
DO NOT OPEN CASE
Laser aperture at handpiece

CAUTION: Federal (US) Law restricts the sale or use of this device to qualified professionals.

This product is certified to comply with regulation 21 CFR 1040