DEXIS

DEXIS Platinum Sensor Manual
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The DEXIS Platinum sensor includes the USB interface component copyrighted by the Cypress Semiconductor Corporation.

Language

The original language of this manual is English.
1 Introduction ............................................................... 1
1.1 A WORD ABOUT THE DEXIS PLATINUM SENSOR ......................... 1
1.2 ESSENTIAL PERFORMANCE ................................................. 2
1.3 INTENDED USE OF THE DEVICE .......................................... 2
1.4 PRODUCT DESCRIPTION .................................................... 3
1.5 PROFICIENCY WITH THE DEXIS PLATINUM SENSOR ...................... 3
1.6 CONVENTIONS USED IN THE MANUAL .................................... 4
1.7 THE DEXIS MISSION .......................................................... 4
2 INSTALLATION, CARE, AND MAINTENANCE ................................. 5
2.1 OVERVIEW OF THE DEXIS PLATINUM SENSOR SYSTEM ................... 5
2.1.1 TIER ONE CONTENTS: SOFTWARE AND DOCUMENTATION ............... 6
2.1.2 TIER TWO CONTENTS: SENSOR AND SENSOR ITEMS ..................... 6
2.1.3 TIER THREE CONTENTS: ACCESSORIES .................................... 6
2.2 DESCRIPTION OF PRODUCT SYMBOLS .................................... 7
2.3 HARDWARE REQUIREMENTS .................................................. 7
2.3.1 CAUTION: HARDWARE UPGRADES ........................................ 7
2.4 INSTALLING THE DEXIS PLATINUM SENSOR ................................ 9
2.4.1 CONNECT THE DEXIS PLATINUM SENSOR .................................. 9
2.4.2 LOAD DEXIS PLATINUM SENSOR FILE(S) .................................... 9
2.4.3 MOUNT THE SENSOR GARAGE ............................................. 10
2.5 ADJUSTING THE X-RAY SOURCE ........................................... 10
2.5.1 COMFORMANCE TO STANDARDS ......................................... 10
2.5.2 SAFETY CONSIDERATIONS ............................................... 11
2.5.3 X-RAY GENERATOR SETTINGS ............................................. 12
2.5.4 DISTANCE OF X-RAY SOURCE TO SENSOR ................................ 13
2.6 PROPER CARE OF THE DEXIS PLATINUM SENSOR .......................... 13
2.7 PROPER CARE OF THE DEXIS PLATINUM SENSOR HOLDERS .................. 16
2.8 IMAGE QUALITY ASSURANCE ................................................ 17
Welcome to the exciting world of DEXIS! And thank you for your recent investment in the DEXIS Platinum sensor system. We hope you will have an extraordinary experience with our products and services.

1.1 A word about the DEXIS Platinum sensor

The sensor is a USB-driven digital sensor designed from the outset with you, the clinician, in mind. It has been designed specifically for health care professionals already acquainted with the standard procedures for acquiring dental intra-oral radiographs. (Refer to Appendix B for the sensor specification which includes the definition of the intended use.)

The sensor design uses advanced ergonomic principles. Four beveled corners, a moderate profile, and a rounded casing provide enhanced comfort for your patients. The sensor is positioned in the patient’s mouth similar to how intra-oral film is positioned.

**WARNING**

No modification of this equipment is allowed.

There is no electrical or physical connection between the sensor and the X-ray generator. The sensor creates a digital image from X-ray doses perceptible by the sensor. The digital image created is immediately visible on the screen of the personal computer connected to the sensor through the standard USB port.

With imaging software, acquired images can be optimized for specific diagnostic tasks, archived as image files, and printed out on a suitable printer if desired. The DEXIS software is one example of a dedicated software that provides a number of utilities for optimizing viewing and printing of images.
1.2 **Essential Performance**

The essential performance of the DEXIS Platinum sensor systems comprises:

- The ability of the sensor to capture X-ray images suitable for recognition of normal anatomical structures, dental pathologies, and abnormal conditions, where inadequate images may result in misdiagnosis, subjecting the patient to incorrect or unnecessary dental procedures that would present an unacceptable risk to the patient;

- The ability of the sensor holder to align the sensor with the X-ray source for imaging the desired anatomy, where inadequate alignment may result in repeated X-ray exposures, subjecting the patient to additional ionizing radiation that would present an unacceptable risk to the patient;

- The ability of the single use sensor sheaths to isolate the sensor from the patient, where cross-contamination could present an unacceptable risk to the patient.

1.3 **Intended Use of the Device**

The DEXIS sensor is a USB-driven digital sensor which is intended to acquire patient dental intra-oral radiography images. The DEXIS sensor shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intra-oral radiographs. Digital X-ray imaging is an aide for diagnosis and should always be confirmed by the doctor using additional procedures and / or other diagnostic aides for confirmation.

The DEXIS sensor can be used either in combination with special positioning devices to facilitate positioning and alignment with the x-ray beam or it may also be positioned by hand with the assistance of the patient.

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**WARNING**

Take the necessary steps to protect yourself from radiation. For proper operator positioning, refer to the ‘Instructions for Use’ of your intraoral X-ray equipment.
1.4 **PRODUCT DESCRIPTION**

An X-ray image sensor (CMOS) is positioned in the patient’s mouth just like intraoral film. There is no electrical or physical connection between the DEXIS Platinum sensor and the X-ray generator. Images are automatically acquired when X-rays are present in a dose which is perceptible to the sensor.

Digital X-ray images are quickly displayed on the screen. Images can be optimized for viewing via imaging software, stored as image files, and printed out on a suitable printer if desired.

The DEXIS Platinum sensor must be connected to a PC running on a Windows operating system through the standard USB port (Universal Serial Bus).

1.5 **PROFICIENCY WITH THE DEXIS PLATINUM SENSOR**

The user must be able to read and understand the written language of this manual. Please become acquainted with your DEXIS Platinum sensor. The sensor is your tool. Learn to use it well and it will become an effective aid in your diagnosis, treatment and treatment planning process.

As with all new clinical tools, it is necessary to invest a certain amount of time for practice in order to become proficient with the sensor.
We highly recommend that you register for in-office training with a certified DEXIS instructor and that you and all of your clinical team set aside time to learn the system together. This manual is not intended to serve as a substitute for this training. However, as preparation for the training, we do encourage you to read the manual thoroughly and practice with your equipment safely and carefully for at least one week prior to your training date.

Please note that this manual assumes that new users possess basic computer skills and an understanding of the Windows® operating system. Absent this experience, we highly recommend that you obtain these skills through a computer course, video, or textbook. Your DEXIS representative may be able to suggest (although not endorse) one or more of these computer learning resources.

1.6 **CONVENTIONS USED IN THE MANUAL**

The following conventions are used to bring the operator’s attention to important information:

| **WARNING** | Alerts the operator that failure to follow the procedure could cause bodily injury or death. |
| **CAUTION** | Alerts the operator that failure to follow the procedure could cause damage to the equipment or cause loss of data. |
| **Important:** | Provides advice for the operator regarding use of the device or a process. |
| **Please note:** | Highlights important or unusual points. |

1.7 **THE DEXIS MISSION**

Our mission at DEXIS is to develop and support the Digital Radiography community around the world. We seek to build strong partnerships with our doctors and their teams based on long-term, interactive relationships.

Let’s start your journey into the world of DEXIS Digital X-ray!
Most telephone calls for assistance received by the DEXIS Customer Care specialists stem from inadequate attention to hardware installation. Poor care of the DEXIS Platinum sensor can result in damage to or destruction of the fragile electronic components. Also, inattention to basic maintenance procedures, including adjustment of the X-ray source, can lead to unacceptable image quality.

We recommend that you engage a qualified computer specialist or network technician and develop a permanent relationship for your ongoing computer needs. We understand the prospective of “saving money” by implementing a seemingly more cost-effective solution; however, it is our experience that while this may be true in the short term, such decisions are considerably more expensive in the long run.

Naturally, turnover and attrition in a dental office will see team members come and go. The DEXIS Platinum sensor is a highly sophisticated piece of equipment that must be handled with care and maintained in accordance with the manufacturer’s recommendations. Despite the pressures of a busy schedule, please take the time to ensure that all new team members become familiar with the equipment and the care that it requires.

When calling Technical Support for assistance, please make sure that you have access to the computer on which the DEXIS sensor is used and on which the manual may be displayed. You will be instructed where to find answers and solutions for your particular questions. This allows optimal “over the phone” assistance.

2.1 Overview of the DEXIS Platinum Sensor System

The system includes the DEXIS Platinum sensor, a full set of sensor holders, installation software, and other consumables.
2.1.1 Tier One Contents: Software and Documentation

- Getting Started With DEXIS booklet (PLU778002)
- DEXIS Platinum Sensor Training CD (PLU778003)
- DEXIS Platinum Sensor Manual (PLU815)
- DEXIS Software Installation CD (PLU348)
- DEXIS Software Training CD (PLU778011)
- DEXIS Software Manual (PLU824-EN)
- DEXIS Software Quick Reference Guide (PLU802)
- System Requirements Sheet (PLU151)

2.1.2 Tier Two Contents: Sensor and Sensor Items

- DEXIS Platinum Sensor - Direct USB intra-oral digital X-ray sensor
- Sensor Garage - To store and protect sensor when not in use (PLU623)
- DEXIS Platinum Sensor File CD - Sensor-specific file to be installed on each computer where the sensor will be used
- Sensor Cable Clip - Used to attach sensor cable to apparel (PLU620)
- Cable Clip Set (3) - Used to attach sensor cable to the bar (PLU622)
- USB Extender, 3 Feet (1 m) - For easy access to computer's USB port (PLU778005)
- Sensor Sheaths 100 Sample Pack - Hygienic barrier for the sensor (PLU975019, Bag of 100)

2.1.3 Tier Three Contents: Accessories

- Anterior Holders (2) (PLU795005)
- Posterior Holders (2) (PLU795008)
- Horizontal Bitewing Holders (2) (PLU795011)
- Vertical Bitewing Holders (2) (PLU795012)
- Vertical Hand-held Holders (1 set of 2) - Held by patient to capture anteriors (PLU795013)
Installation, Care, and Maintenance

- Horizontal Hand-held Holders (1 set of 2) - Held by patient to capture posteriors (PLU795010)
- Rings and Bars Kit (PLU604)

**Important:** Previous versions of the DEXIS holders, distinguishable by their white color, are NOT compatible with the DEXIS Platinum Sensor. Likewise, the previous sensor is NOT compatible with the new holders. The DEXIS Platinum Sensor and Holders are designed for a custom fit.

2.2 Description of Product Symbols

Please refer to “Product Symbols” on page 37.

2.3 Hardware Requirements

**Important:** For regulatory reasons, all IT components used in connection with the DEXIS Platinum sensor need to be in compliance with the applicable safety standards. Refer to Appendix B, “Conformance to Standards,” on page 30.

Our current hardware system requirements are available in the support section on our web site www.dexis.com, from your representative, and from our Customer Care Center. As technology changes, our requirements are updated to reflect such changes. Please consult current DEXIS systems requirements before the purchase of any hardware.

Note that systems meeting only the minimum requirements may fail to deliver a satisfactory experience. Systems with faster processors, more memory, and bigger, faster hard drives will significantly enhance performance.

2.3.1 Caution: Hardware Upgrades

Every change in hardware exposes your business to risk. Computers containing patient records are “mission critical.” Careful consideration is required in order to minimize risk before changes are made to any system that is currently in use. Whether the change is to be made to hardware or to the operating system, you should be prepared to deal with an unexpected outcome including a catastrophic loss of data. For this reason, we offer the following suggestions for use with mission-critical systems:
Instead of upgrading hardware or the operating system, consider purchasing a new pre-configured system. Computers are amazingly inexpensive today; bringing-up a new system in parallel with an existing system is a good way to avoid placing the existing system at risk. The existing system will remain productive while the new system is qualified and readied for full service. Consider the new computer as cheap insurance, but it's even better than insurance because you get to keep it.

If you must upgrade your existing system, consider purchasing an additional hard drive and making a bootable, literal copy of the existing hard drive. Remove the original hard drive and make the changes to the newer (and probably larger) hard drive. With the original hard drive removed from the computer, it is not at risk and all of your data will be safeguarded. If the new changes are found to be unsatisfactory after a suitable evaluation period, you can always re-install the old hard drive and fully restore your previous environment.

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**CAUTION**

Always back-up your data and store it off site. Before assuming that your back-up efforts have been successful, make sure that you understand the backup process and practice the restore process at least once on a test system. Verify that both the operating system and data have been preserved.
2.4 Installing the DEXIS Platinum Sensor

Please note: The Platinum Sensor does not require calibration.

Installation includes

- Connecting the sensor to your computer
- Load the file specific to the sensor

2.4.1 Connect the DEXIS Platinum sensor

1. Make sure the computer to which you are connecting the sensor has a compatible version of the software installed.

2. Carefully plug the USB end of the sensor cable into the PC USB port. Do not use force; ensure that the plug is properly oriented with the PC port. Try rotating the USB plug if it does not easily insert into port.

3. Follow the installation instructions appearing on the screen.

2.4.2 Load DEXIS Platinum Sensor File(s)

Please note: Each sensor includes a specific optimization file designed to optimize the X-ray images from that particular sensor. This optimization file is provided on the serial-numbered CD and sensor file USB, labeled DEXIS Platinum Sensor File. The sensor file must be installed on every computer where you intend to use that sensor. Failure to install the correct sensor file will result in fuzzy or blurred images.

1. Insert the DEXIS Platinum Sensor File CD into the disk drive or sensor file USB, if you have a Mac.

2. Follow the loading instructions.

3. Ensure that destination location for the sensor file is the same one chosen as the default folder when the software was installed (usually C:\DEXIS).
2.4.3 Mount the Sensor Garage

Install the sensor garage in a place that is convenient and does not exceed the maximum length of the USB cable, which is 10 ft. (3 m). The sensor garage should also be positioned so that the cable from the sensor does not create a tripping hazard. To install the sensor garage, clean the mounting surface, remove the backing from the double sided-tape, then firmly press the sensor garage against the mounting surface.

2.5 Adjusting the X-ray Source

The DEXIS Platinum sensor is generally compatible with any dental X-ray unit and generator capable of supplying the required range of exposure times and doses.

Digital sensors normally require much smaller exposure times than film sensors thanks to the high sensitivity of the technology used with the sensor. This is why direct current X-ray generators are recommended (“DC,” “high frequency,” or “average frequency,” “with electronic convertor”). These generators can normally provide stabilized tube voltage (kV) and reproducible exposure doses even with very short exposure times. Please refer to your X-ray generator manual for the recommended exposure times for digital sensors.

Important: X-ray machines, even the same brands and types purchased at the same time, differ widely in their performance. In addition, on newer X-ray machines, the “digital” setting on your dial or keypad may not be the ideal setting.

2.5.1 Conformance to Standards


The DEXIS Platinum sensor conforms to safety standard IEC 60601-1.

All IT components electrically connected to the DEXIS Platinum sensor must conform to IEC 60950-1.
Normally, the IT components are placed OUTSIDE the patient environment. IT components placed INSIDE the patient environment, due to customer site requirements, must also conform to IEC 60601-1.

IEC 60601-1 defines the “Patient environment” as “any volume in which intentional or unintentional contact can occur between a Patient and parts of the ME Equipment or ME System or between a Patient and other persons touching parts of the ME Equipment or ME System.”

**CAUTION**

US Federal law restricts this device to sale by or on the order of a dentist or other licensed practitioner.

### 2.5.2 Safety Considerations

All external surfaces of the sensor, sensor cable, sensor holders and the sensor sheaths are considered to be applied parts and are safe for normal or accidental patient contact during use.

The DEXIS Platinum sensor has no serviceable parts. Do not open the device to service it. All aspects of the sensor that are meant to be attended to by the operator are accessible without opening the internal components of the device. If there is a service problem, contact a qualified dealer service representative or DEXIS Technical Support.

**Mains Isolation**

Disconnection from the supply mains occurs at the input to the computer. The sensor can also be disconnected from the computer.

**X-ray Protection**

The rules of dental radiography still apply to digital X-ray systems. Please continue to use protection for your patients. As a clinician, clear the immediate area when exposing the sensor.
Prevention of Cross-Contamination

To help prevent cross-contamination between patients, place a new hygienic barrier on the sensor for each new patient. The hygienic barrier must cover the sensor and at least 3-4 in. (7-10 cm) of the cable.

For information about cleaning the sensor, refer to “Proper Care of the DEXIS Platinum Sensor” on page 13.

Prevention of Environmental Contamination

Dispose of sheaths and other consumable products following the normal dental office procedure for biomedical waste. Improper disposal of biomedical waste can lead to the spread of illness or disease.

Properly dispose of the sensor when it has reached its end of life. For information, refer to the explanation of this symbol on page 37.

Sensor Inspection

Always inspect the sensor, cable, and positioning devices for physical damage prior to every use. See “Proper Care of the DEXIS Platinum Sensor” on page 13.

WARNING

Remove sensor from service if damage to the cable or housing is observed, otherwise exposure to elevated surface temperature or electrical energy may result.

2.5.3 X-ray Generator Settings

The radiation of X-ray tubes is controlled by the settings of:

- Exposure time (msec) or pulses
- Voltage (kV or kVp)
- Current (mA)

Some controls allow for the modification of all of the above, some have fixed settings for current and voltage.
Follow the instructions of the X-ray generator to set the desired dose range.

2.5.4 **Distance of X-ray Source to Sensor**

There is a correlation between the distance of the cone to the sensor and the dose received by the DEXIS Platinum sensor. The radiation that reaches the sensor decreases with the square of the distance. If you double this distance, you receive only $\frac{1}{4}$ of the radiation.

2.6 **Proper Care of the DEXIS Platinum Sensor**

Prior to taking X-rays, each staff member should be fully trained and have a complete understanding of how to care for the sensor. Not adhering to the following rules to protect the sensor may potentially result in malfunction or permanent damage.

- Store the sensor in the sensor garage when not in use.
- Do not allow the patient to bite down on the sensor or cable.

**CAUTION**

Biting down on the sensor or cable will damage the housing and/or cable and lead to a sensor malfunction. We highly recommend using the DEXIS Platinum sensor holders as they are designed to protect the sensor. However, should you choose to NOT use a DEXIS Platinum sensor holder, you must protect the sensor and the cable.

- Do not roll over the cables with any wheeled items such carts or chairs.
- Do not allow the sensor cable to be pinched in a drawer, door, or cabinet.
- Do not twist, coil, or wrap the sensor cable tightly around any object.
- Do not insert foreign objects into the sensor cable connector.
- Do not drop the sensor.
- Do not clamp the sensor with devices that exert excessive force (for example, hemostats or clamps of any type).
• Do not autoclave the sensor.

**CAUTION**

Do not autoclave sensor. Autoclave sterilizers will permanently damage the sensor.

• Decontaminate the sensor and cable in accordance with CDC – or your country’s (e.g., OSAP) standards – for infection control. DEXIS recommends wiping the DEXIS Platinum sensor with one of the following cleaning agents:
  - Precise Foam (Manufactured by Caltech Industrials Inc.)
  - CaviCide® (Manufactured by Metrex)
  - CaViWipes™ (Distributed by Kerr)
  - Sani-Cloth® Plus (Distributed by Crosstex)
  - Dürr System-Hygiene FD 350 Disinfection Wipes Classic (Manufactured by Dürr)
  - 70% Isopropyl Alcohol
  - FD 322 (manufactured by Dürr)

**CAUTION**

The sheath must be removed after each patient. The sensor must be cleaned and disinfected after each patient by rubbing with isopropyl alcohol (70%).
CAUTION

Do NOT use any of the cleaning agents listed above for previous versions of DEXIS sensors except Precise Foam.

The slightly different design of the cable attachment on those sensors will help you to distinguish them from the DEXIS Platinum sensors. In addition, with the previous version, the connection to the PC is through a controller. (The DEXIS Platinum sensor connects directly to one of the USB ports on the PC.)

Please note: DEXcare and Basic Care service level agreements do not cover visible damage to any of the DEXIS hardware components! Abuse or misuse of DEXIS components will result in voiding the warranty and DEXcare or Basic Care coverage.
2.7 Proper Care of the DEXIS Platinum Sensor Holders

The DEXIS Platinum sensor holders can be disinfected in a steam autoclave using distilled water at temperature of 273°F (134°C) at 216 kPa for 12 minutes. However, certain restrictions apply:

- Run the appropriate autoclave cycle according to the manufacturer’s specifications for your specific unit.
- Always avoid direct contact of the holders with metal trays, instruments, and heating elements.
- Always place holders in autoclave bags.
- Always situate bagged holders into the autoclave so that they are furthest from the heat source.
- Do not use a chemical autoclave.

Exposing the holders to hot metal and placing them close to heating elements will reduce the lifetime of the holders.

CAUTION

Holders should be disinfected in an autoclave or with a cleaning agent after each patient.

If the infection control guidelines for your country permit, the holders can be disinfected using the cleaning agents below, following the manufacturer’s instructions.

- CaviCide® (Manufactured by Metrex)
- CIDEX OPA (Ortho-Phthalaldehyd, Distributed in the US by Advanced Sterilization Products)
- Asepticare (Manufactured by Ecolab)
- FD322 (Manufactured by Dürr Dental)
- 70% Isopropyl Alcohol
- Procide D (distributed by Kerr)
- Procide D Plus (distributed by Kerr)
- CIDEX (distributed in the U.S.A. by Advanced Sterilization Products)
Please note: Previous versions of DEXIS holders, distinguishable by their white color, are more sensitive to overheating. Disinfect those holders in an autoclave at a temperature no greater than 257°F (125°C) or by soaking in a cold sterile solution. It is important to always consult the manufacturer’s recommendations for the solution you are using.

2.8 Image Quality Assurance

Image quality of the DEXIS Platinum sensor depends on several factors:

- the quality of the X-ray source (kV, focal spot size, distance)
- the alignment of the X-ray source to the anatomic region
- the applied X-ray dose / exposure time
- the patient remaining still during exposure period
- the settings of the computer monitor

It is recommended that you establish a procedure for periodic review of the image quality. If image quality is not satisfactory, or degrading, please check the contributing system parts as outlined below:

X-ray Dose / Exposure Time Settings

The DEXIS Platinum sensor has been designed to be used with a wide range of dose settings between 20 μGy and 2,000 μGy, to allow adjustments of the dose to the specific diagnostic task, and to compensate for under- and over-exposure. As a general recommendation, start by using dose / exposure time settings recommended by your X-ray source manufacturer for digital X-ray sensors.

The DEXIS Platinum sensor can be used with much lower dose / exposure time settings. Nevertheless, low dose operation of a digital sensor in general can result in a grainy image appearance. If the image of the DEXIS Platinum sensor appears grainy, increase the dose settings. If you obtain good results with a particular setting, you might try a lower dose setting to see if you still gain good results.

The DEXIS Platinum sensor can work at higher dose / exposure time settings, if needed for a particular diagnostic task. At high dose / exposure time settings, it might not be possible to distinguish air from soft tissue.
Such regions may appear overexposed. If air and soft tissue regions in the image appear overexposed, reduce the dose settings.

Remember, as with standard film, you will need to adjust the duration setting to compensate for tooth type (central incisor to molar) and patient body type (larger adult to small child). Ultimately, the settings you choose should be what you consider to be suitable for your diagnostic needs.

X-ray Sharpness / Contrast

Many parts of the X-ray imaging system contribute to the sharpness and contrast of the image. It is recommended that you use a dental phantom for a periodic (at least annual) assessment of the image quality by performing a side-by-side comparison of an initial dental phantom image to a current dental phantom image to ensure that the images have sufficient quality for diagnostic purposes in your application.

Dental phantom images should be acquired with fixed settings for X-ray dose (kV, mA, distance), and a fixed and reproducible alignment of the X-ray source and the dental phantom to the DEXIS Platinum sensor.

Please note: Contact DEXIS technical support for recommendations about commercially available dental phantoms.

Display Image

Refer to the software manual for guidance on how to ensure good display settings and image display properties. It is recommended to view images on an SVGA monitor with at least 1,024 x 768 pixel resolution at 0.25 to 0.26 dot pitch or better and 24 bit true color (3d bit preferred), in native resolution.
Clinical Use of the DEXIS Platinum Sensor Holders

Please become acquainted with your DEXIS Platinum sensor. The sensor has a unique design using advanced ergonomic principles. It features four beveled corners, a moderate profile, and a rounded casing. This design, along with proper placement, translates into enhanced patient comfort.

If you have not done so, please take some time to review the proper handling guidelines in “Proper Care of the DEXIS Platinum Sensor” on page 13 before attempting to use your DEXIS Platinum sensor with the holders.

3.1 DEXIS Platinum Sensor Holders

The DEXIS Platinum sensor system includes these parts:

1. Rings and bars (not shown)
   a. Two universal
   b. One bitewing

2. Two anterior holders

3. Two posterior holders

4. Biteblock holders
   a. Two horizontal
   b. Two vertical

5. Hand-held holders
   a. One horizontal set
   b. One vertical set
3.2 Assembly

- Assemble the rings, bars and holders so that the entire sensor area is visible through the ring. This applies to horizontal or vertical bitewing holders, periapical (anterior or posterior) holders, and hand-held holders.

**WARNING**

To help prevent cross-contamination between patients, place a new hygienic sheath on the sensor for each new patient.

- Place the sheath over the sensor.
- Attach the sensor to the positioner. The sensor will only fit into the holder one way.
- Place the cable into the groove on the holder whenever possible. This protects it when the patient closes. Should you choose to use the cable clip, place the square hole on the end of the bar and place the sensor cable into the clip. Please see “Cable Protection” on page 27 and the Positioning Tutorial for complete information on cable protection.

**Please note:** The DEXIS Platinum sensor is not compatible with previous DEXIS sensor holders.
3.3 Correct Placement Using the Paralleling Technique

We recommend using the sensor holders included with your new DEXIS Platinum sensor. Correct placement of the sensor in the patient’s mouth is essential for obtaining acceptable X-ray image quality. These holders have been specially designed to work with the DEXIS Platinum sensor and the DEXray software.

The DEXIS Platinum sensor, in combination with the supplied rings and holders, use the paralleling technique originally developed by the Rinn Corporation. This technique places the sensor in the mouth so that it is parallel to the long axis of the tooth and perpendicular to the interproximal spaces. By drawing an imaginary line through the occlusal/incisal surfaces (occlusal line) of the teeth to be X-rayed, and placing the sensor parallel to this line, it will be perpendicular to the interproximal spaces. To achieve parallel positioning, the sensor/holder must be positioned away from the lingual/palatal surface and located in the deeper areas of the mouth in all areas except for mandibular molars.

**Mandibular Incisor, Canine, or Cuspid**

Position the sensor/holder so that it is parallel to the roots of the teeth. Place either under the tongue or over the tongue, whichever is most comfortable for the patient. If large mandibular tori are present, position the sensor/holder behind the tori, even if it is in the first molar area. Ask the patient to close end-to-end in order to maintain the placement. In the event that the holder does not remain parallel to the roots of the incisors, bisect your angle. Should the incisal edges routinely be missing from your images, place a cotton roll or flap between the tooth and the holder and/or verify that the sensor holder is parallel to the roots.
Mandibular Bicuspid, Premolar, or Molar

Position the sensor/holder so that it is parallel to the roots of the teeth. Place either under or over the tongue, whichever is most comfortable for the patient. Once you establish that the sensor/holder is parallel to the roots and parallel to the occlusal line, move the sensor/holder to the mid-line. Ask the patient to close. In the event that the holder does not remain parallel to the roots of the premolars, bisect your angle.

Maxillary Incisor, Canine, or Cuspid

Position the sensor/holder so that it is parallel to the roots of the teeth. Once you establish that the sensor/holder is parallel to the roots, move the sensor/holder toward the center of the palate. Ask the patient to close end-to-end in order to maintain the placement. In the event that the holder does not remain parallel to the roots, bisect your angle. If a large maxillary torus is present and you are unable to place the sensor/holder in a traditional position, the sensor/holder must be placed on the torus as you would place traditional film and you must bisect your angle. Should the incisal edges be routinely missing from your images, place a cotton roll or flap between the tooth and the holder and/or verify that the sensor/holder is parallel to the roots.

Maxillary Bicuspid, Premolar, or Molar

Position the sensor/holder so that it is parallel to the roots of the teeth. Once you establish that the sensor/holder is parallel to the roots and parallel to the occlusal line, move the sensor/holder toward the center of the palate. Ask the patient to close. In the event that the holder does not remain parallel to the roots, bisect your angle. If a large maxillary torus is present and you are unable to place the sensor/holder in a traditional position, the sensor/holder must be placed on the torus as you would place traditional film and you must bisect your angle.
Clinical Use of the DEXIS Platinum Sensor Holders

Bitewing — Bicuspid, Premolar, or Molar

Position the sensor/holder so that it is parallel to the occlusal line, move the sensor/holder toward the midline. Ask the patient to close.

Hand-held Holders

You may use the bitewing bar and ring with the hand-held holder to use the paralleling technique. Position the sensor/holder so that it is parallel to the root of the tooth and toward the midline. Ask the patient to grasp the handle after you have placed the sensor in the appropriate position. The patient may close to stabilize if position permits. The patient will not be able to close completely due to the design of the holder. Should you choose not to use the paralleling technique, bisect your angle.

3.4 Pedodontic Placement Techniques

When you are placing a sensor in the mouth of a child, you will often face the same challenges that you face with placing film in their mouths. Keep in mind that although the sensor is larger than a film pack, it is also smoother. This will work to your advantage.

Here are some techniques that will help you succeed in using the sensor in children when standard techniques fail. You may be familiar with many of them, since they work not only for the DEXIS Platinum sensor, but for film as well.

To begin, you should set the child up for X-rays both physically and psychologically; that is, ready their mouths and their minds. Use diversion when necessary. In addition, consider the size of the pedo film relative to the sensor. Also consider what information you need to gather from the X-ray and use that part of the sensor that will enable you to capture the information you need.

- Avoid saying the word tongue, since it might cause the tongue to act involuntarily.
• Have the child focus on the end result — an instant image of their teeth. If they can see the monitor, this will give them incentive to cooperate. Most children are very comfortable with computers and will be impressed to see an X-ray of their teeth on the screen.

• Place your finger in the areas where you plan on placing the sensor.

• Let the patient hold the sensor in the mouth (without biting it) to get used to the feel of it.

• Physically divert focus to something other than the sensor. Have the child place his or her finger on their arm, hold the holder, or make a certain sound.

3.4.1 Periapical X-rays

Offset Bitewing Tab

It is always best to use the DEXIS Platinum sensor holders provided. However, if you are taking a periapical X-ray and you cannot use the standard periapical DEXIS biteblock, try using a bitewing tab, cover, sticky, or foam. Place it above or below the center line of the sensor. Note that the entire sensor does not need to be placed in the arch, only that part that gives you the information you need.

Important: Use a cotton roll to protect the cable. Note also that when using holders other than the DEXIS Platinum sensor holders, you must always protect the cable.

Also consider using the endo (hand-held) holders. Whether you use a bisecting-angle or a modified occlusal technique, the child’s focus can be diverted to holding the holder. Allow them to remove it after the image is taken. Children tend to be less fearful and more cooperative if they feel they are helping. Again, their focus is on helping you.
Bisecting-Angle Technique
Place the holder against the palate and use the standard Bisecting Angle technique.

Modified Occlusal Technique
Place the sensor parallel to the occlusal plane and add a cotton roll for protection, comfort, and support. Ask the child to close gently. Use the standard bisection angle technique to capture the image.
3.4.2 **Bitewing X-rays**

When you are taking bitewings and your goal is to see the crowns of the primary teeth, you will find that often the child will not need to close all the way. Place the sensor in the center of the palate first. (When the sensor is placed in the mandible, the child is more likely to try to manipulate the sensor.) Next, have the child close down an appropriate amount. Then, ask the child to focus on saying “eeeeee” to allow better vision into the mouth and aid in producing a well-placed image.

Use the bitewing biteblock, with or without the ring and bar. If this is not possible, using a bitewing tab, cover, sticky or foam.

**Important:** Use a cotton roll to protect the cord. Again, note that when using holders other than the DEXIS Platinum sensor holders, you must always protect the cord.

3.4.3 **Occlusal X-rays**

Occasionally, you may need an occlusal view.

**Single-exposure Image**

For a small child, you may be able to use the sensor placed lengthwise from right to left and capture the necessary information in one exposure.
Two-exposure Images
In some cases, you may need to place the sensor width wise, from anterior to posterior, on half of the arch, and then repeat for the other half.
In both cases, the sensor is placed parallel to the occlusal plane and a cotton roll is added for protection, comfort, and support. Ask the child to close gently. Use the standard occlusal technique to capture the image.

3.5  AFTER EXPOSURE
1. Carefully remove the sensor from the oral cavity following the exposure.
2. Grasp the sensor and positioning device and remove the sensor from under the retaining clips.
3. If needed, grasp the USB connector and pull it straight out of the port on the computer.

3.6  CABLE PROTECTION
There is a groove on the underside of the periapical holders and a slightly different groove in the bitewing holders. Place the sensor cable into this groove for protection. This works well when the sensor is placed into the holder and then the entire assembly is sleeved.
On those occasions where it is necessary to sleeve the sensor before placing in the holder, due to the thickness of the barrier, the cable may not stay in the groove. In this case, verify that the cable is adjacent to the holder, either to the side that is to the anterior or posterior of the holder. Since the holder will not allow for full closure, the cable is protected. Again, please verify that the cable is not between the holder and the teeth as it may become crimped upon the patient closing.
We highly recommend the use of the DEXIS Platinum sensor holders as they are designed to protect the sensor and cable. However, if you choose not to use these holders, you must take steps to protect the sensor and the cable. The use of a sponge bw tabs may offer additional protection. However, no matter the barrier or bw tab, you must protect the cable.

You must always ask patients to close lightly so that they have only the slightest of contact. Do not allow patients to bite down on the cable. If you feel that you will not have the patient’s full cooperation, place an object such as a folded gauze or cotton roll on the tab, to hold the teeth open just enough to keep the cable from harm. You may also place the cable in an area where there are missing teeth or in an area where, anatomically, there is an open space or lack full occlusion.

To help maintain better control of your sensor when it is out of your hands, use the cable clip to clip the sensor to the patient’s clothing. In the event that the patient ejects the sensor, it will not land on the floor. If necessary, twist the ends of the clip to form an alligator-style clip.

Take hold of the sensor cable approximately 18–24 inches (45–60 cm) from the sensor. Gently slide the cable through the opening. Place the cable into the groove.

Clip the holder on to the patient’s clothing as shown. You may also clip the cable to your own clothing when you move the sensor from one operatory to another.
Appendix A
Additional Help and Support

DEXIS on the Internet
www.dexis.com

The DEXIS Platinum sensor described herein does not contain parts which can be serviced (subject to clause 6.8.3.c IEC 60601-1-2nd).

DEXIS Customer Care Center (United States and Canada)
Tel: 1-888-883-3947
Fax: 1-888-833-3947
E-mail: support@dexis.com
We are happy to assist you from Monday–Friday, 8:00 am to 8:00 pm, EST.

Outside North America

Kaltenbach & Voigt GmbH
Bismarckring 39
D-88400 Biberach, Germany
+49 (0) 73 51 / 56-0
Appendix B
Specifications and Standards

Intended Use
The DEXIS Platinum sensor is a USB-driven digital sensor which is intended to acquire dental intra-oral radiography images.

The sensor shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intra-oral radiographs.

The sensor can be used either in combination with special positioning devices to facilitate positioning and alignment with the x-ray beam or it may also be positioned by hand with the assistance of the patient.

DEXIS Platinum Sensor Specifications

| SENSOR ARCHITECTURE | Indirect converting dental IO X-ray sensor  
|                     | 1692 by 1324 pixels  
|                     | 19.5 µm pixel pitch  
|                     | 20+ visible lp/mm  |
| X-RAY PARAMETERS | Sensor can be used with dental X-ray generators in the range of 60 to 70 kV; at minimal 40 µGy incident dose  |
| SW ARCHITECTURE | USB 2.0/1.1 compliant USB interface + application interface to dental imaging software products  
|                  | Operation system:  
|                  | - Microsoft Windows XP© with actual service pack  
|                  | - Microsoft Windows Vista© with actual service pack  |
| ELECTRICAL RATING | DC 5V, 350 mA max  |
| CONNECTION TO pc | USB 2.0 Standard  |
| PROTECTION AGAINST SHOCK | Class II type BF applied part  |
| MODE OF OPERATION | Continuous  |
| METHOD OF STERILIZATION | Sensor not suitable for sterilization  |
### APPENDIX B

<table>
<thead>
<tr>
<th>ENVIRONMENTAL CONDITIONS</th>
<th>Humidity</th>
<th>Air Pressure</th>
<th>Ambient Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>USAGE</td>
<td>30% to 95%</td>
<td>700 to 1060 hPa</td>
<td>5° to 30°C</td>
</tr>
<tr>
<td>DEXIS Platinum sensor is not suitable to be operated in oxygen rich and/or explosive environments</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TRANSPORTATION AND STORAGE</td>
<td>10% to 95%</td>
<td></td>
<td>-40° to 70°C</td>
</tr>
<tr>
<td>Transport in the supplied protective package</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EU CLASSIFICATION</td>
<td>Class Iia medical device according to MDD 93/42/EWG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protection against water/matter – IP 68</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
B.1 Detective Quantum Efficiency (DQE)

The following data regarding DQE versus spatial frequency as a function of dose is provided to allow the contribution of the DEXIS Platinum to overall imaging performance matrix to be considered.

Shown above is the X-ray sensor DQE as a function of spatial frequency, for a range of X-ray doses from 50 to 600 uGy. The curves indicate that there is no significant change in DQE performance going from 50 uGy to 600 uGy. This implies that the sensor operates quantum-limited over that dose range, indicating that all photons are being used effectively and that noise does not degrade performance at low doses. The curve also indicates that device can resolve detail down to 20 lp/mm (over all doses). This means that the X-ray sensor exhibits no reduction in resolution over the input dose range from 50 to 600 uGy.
APPENDIX C

EMC Information

The DEXIS Platinum sensor is, like any electronic medical device, subject to electromagnetic interactions with other electronic devices. The information in this chapter addresses this issue.

The EMC information in this chapter is provided for the medical system established by connecting the DEXIS Platinum sensor to a computer. This computer must be compliant with IEC 60950-1 (if located outside the patient environment) or IEC 60601-1 (if located inside the patient environment). Please consult the documentation of the computer for completing the EMC information.

**Important:** Portable/mobile radio frequency communications equipment can affect the function of the DEXIS Platinum sensor as well as any other electronic medical equipment.

DEXIS is a USB compliant device and shall be used with USB compliant cables suitable for high speed/USB 2.0 cables. Such cables are either marked “USB 2.0” or “USB high speed.” USB certified hubs can be used to extend the distance to the USB host/computer. The length of the cable connection to the hub or between hubs shall not exceed 5 m.

**CAUTION**

Using non-USB compliant cables or hubs, or exceeding the maximum count of USB hub devices for extending the distance, can degrade the immunity of the DEXIS Platinum sensor to electromagnetic fields or increase the emission of electromagnetic fields from DEXIS.
Appendix C

Guidance and manufacturer's declaration - electromagnetic emissions

The DEXIS Platinum sensor, used with a compliant computer, is intended for use in the electromagnetic environment specified below. The customer or the user of the DEXIS Platinum sensor should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The sensor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>The sensor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Class B (*)</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td>
<td>Complies (*)</td>
<td></td>
</tr>
</tbody>
</table>

(*) Computer used with the DEXIS Platinum sensor must meet this rating.
 Guidance and manufacturer's declaration - electromagnetic immunity

The DEXIS Platinum sensor, used with a compliant computer, is intended for use in the electromagnetic environment specified below. The customer or the user of the DEXIS Platinum sensor should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>+/-6 kV contact</td>
<td>Complies (*)</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td>+/-8 kV air</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>+/-2 kV for power supply lines</td>
<td>Complies (*)</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td>+/-1 kV for input/output lines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>+/-1 kV differential mode</td>
<td>Complies (*)</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
<td>+/-2 kV common mode</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply lines</td>
<td>5% U_T (95% dip in U_T) for 0.5 cycle</td>
<td>Complies (*)</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the sensor requires continued operation during power mains interruptions, it is recommended that the sensor be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
<td>40% U_T (60% dip in U_T) for 5 cycles</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>70% U_T (30% dip in U_T) for 25 cycles</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5% U_T (95% dip in U_T) for 5 sec.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td>3A/m</td>
<td>Complies (*)</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NOTE 1 U_T is the a.c. mains voltage prior to application of the test level.

(*) Computer used with the DEXIS Platinum sensor must meet this rating.
Guidance and manufacturer's declaration - electromagnetic immunity

The DEXIS Platinum sensor, used with a compliant computer, is intended for use in the electromagnetic environment specified below. The customer or the user of the DEXIS Platinum sensor should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 61000-4-3 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
</table>
| Conducted RF        | 3 Vrms                   | 3 V              | Portable and mobile RF communications equipment should be used no closer to any part of the DEXIS Platinum sensor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
| IEC 61000-4-3       | 150 kHz to 80 MHz        |                  | $d = 1.2\sqrt{P}$                      |
| Radiated RF         | 3 V/m                    | 3 V/m            | 80 MHz to 800 MHz                      |
| IEC 61000-4-6       | 80 MHz to 2,5 GHz        | 3 V/m            | $d = 1.2\sqrt{P}$                      |
|                     |                          |                  | 800 MHz to 2,5 GHz                     |
|                     |                          |                  | $d = 2.3\sqrt{P}$                      |

where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,\(^a\) should be less than the compliance level in each frequency range.\(^b\)

Interference may occur in the vicinity of equipment marked with the following symbol:

![Interference symbol]

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

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

\(^a\) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the DEXIS Platinum sensor is used exceeds the applicable RF compliance level above, the DEXIS Platinum sensor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the DEXIS Platinum sensor.

\(^b\) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m
The DEXIS Platinum sensor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DEXIS Platinum sensor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DEXIS Platinum sensor as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter W</th>
<th>Separation distance according to frequency of transmitter m</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

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

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

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

## Product Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Title of the Symbol</th>
<th>Reference Number</th>
<th>Standard Containing the Symbol</th>
<th>Function / Description per Standard</th>
<th>Manufacturer Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Type BF applied part]</td>
<td>Type BF applied part</td>
<td>5333</td>
<td>IEC 60417</td>
<td>To identify a type BF applied part complying with IEC 60601-1</td>
<td>To identify a type BF applied part complying with IEC 60601-1</td>
</tr>
<tr>
<td>![Direct Current]</td>
<td>Direct Current</td>
<td>5031</td>
<td>IEC 60417</td>
<td>To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals</td>
<td>Direct Current</td>
</tr>
</tbody>
</table>
| ![Intertek ETL Listed (Canada & USA)] | Intertek ETL Listed (Canada & USA) | N/A | N/A | The Marks are evidence that the model/product conforms to applicable standards and that there is a program of ongoing factory inspections | This ETL listed mark guarantees that Intertek has certified the product described herein under control number 3187969 to be in compliance with the applicable regulations. Intertek is:  
• a Nationally Recognized Testing Laboratory by the Occupational Safety and Health administration (OSHA) in the United States.  
• a Certifying Body in Canada by the Standards Council of Canada. |
| ![CE Mark] | CE Mark | N/A | N/A | The product meets all the legal requirements for CE marking and can be sold throughout the European Economic Area | The CE symbol ensures that the product herein specified meets the provisions of European Council Directive 93/42 EEC concerning medical devices. |
| ![General Warning Sign] | General Warning Sign | W001 | ISO 7010 | To signify a general warning | Warning |
### Appendix D

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Title of the Symbol</th>
<th>Reference Number</th>
<th>Standard Containing the Symbol</th>
<th>Function / Description per Standard</th>
<th>Manufacturer Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Warning; Radioactive material or ionizing radiation" /></td>
<td>Warning</td>
<td>W003</td>
<td>ISO 7010</td>
<td>To warn of radioactive materials or ionizing radiation</td>
<td>Warning</td>
</tr>
<tr>
<td><img src="image" alt="Caution" /></td>
<td>Caution</td>
<td>0434B</td>
<td>ISO 7000</td>
<td>To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.</td>
<td>Please refer to the written instructions of this manual.</td>
</tr>
<tr>
<td><img src="image" alt="Do not reuse" /></td>
<td>Do not reuse</td>
<td>1051</td>
<td>ISO 7000</td>
<td>To indicate that the item is for single use only and must not be used more than once, for example on packages of medical disposables.</td>
<td>Indicates the product should be used only once.</td>
</tr>
<tr>
<td><img src="image" alt="Marking of electrical and electronic equipment" /></td>
<td>Marking of electrical and electronic equipment</td>
<td>N/A</td>
<td>BS EN 50419</td>
<td>This symbol on the products and/or accompanying documents means that used electrical and electronic products should not be mixed with general household waste.</td>
<td>The DEXIS sensor contains a small amount a lead, similar to the lead foil used in a dental intra-oral X-ray film. Please contact your dealer or supplier for further information about product disposal at the end of the product’s lifetime.</td>
</tr>
<tr>
<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer</td>
<td>3082</td>
<td>ISO 7000</td>
<td>To identify the manufacturer of a product. This symbol shall be used filled in all applications to differentiate it from ISO 7000-2497.</td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image" alt="Date of manufacture" /></td>
<td>Date of manufacture</td>
<td>2497</td>
<td>ISO 7000</td>
<td>To indicate the date on which a product was manufactured.</td>
<td>Date of manufacture</td>
</tr>
<tr>
<td><img src="image" alt="Catalogue number" /></td>
<td>Catalogue number</td>
<td>2493</td>
<td>ISO 7000</td>
<td>To identify the manufacturer’s catalogue number, for example on a medical device or the corresponding packaging. The catalogue number shall be placed adjacent to the symbol.</td>
<td>Catalog number</td>
</tr>
<tr>
<td>Symbol</td>
<td>Title of the Symbol</td>
<td>Reference Number</td>
<td>Standard Containing the Symbol</td>
<td>Function / Description per Standard</td>
<td>Manufacturer Interpretation</td>
</tr>
<tr>
<td>--------</td>
<td>---------------------</td>
<td>------------------</td>
<td>--------------------------------</td>
<td>------------------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>SN</td>
<td>Serial number</td>
<td>2498</td>
<td>ISP 7000</td>
<td>To identify the manufacturer's serial number, for example on a medical device or its packaging. The serial number shall be placed adjacent to the symbol.</td>
<td>Serial number</td>
</tr>
<tr>
<td></td>
<td>Operator's manual; operating instructions</td>
<td>1641</td>
<td>ISO 7000</td>
<td>To identify the location where the operator's manual is stored or to identify information that relates to the operating instructions. To indicate that the operating instructions should be considered when operating the device or control close to where the symbol is placed.</td>
<td>Follow Operating Instructions for Use</td>
</tr>
<tr>
<td></td>
<td>Class II equipment</td>
<td>5172</td>
<td>IEC 60417</td>
<td>To identify equipment meeting the safety requirements specified for Class II equipment according to IEC 61140.</td>
<td>Protection against electrical shock: Class II Equipment.</td>
</tr>
<tr>
<td>IP68</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Protection against dust and continuous immersion in water.</td>
</tr>
<tr>
<td></td>
<td>Atmospheric pressure limitation</td>
<td>2621</td>
<td>ISO 7000</td>
<td>To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage.</td>
<td>Atmospheric pressure limitation</td>
</tr>
<tr>
<td></td>
<td>Humidity limitation</td>
<td>2620</td>
<td>ISO 7000</td>
<td>To indicate the acceptable upper and lower limits of relative humidity for transport and storage.</td>
<td>Humidity limitation</td>
</tr>
<tr>
<td></td>
<td>Temperature limit</td>
<td>0632</td>
<td>ISO 7000</td>
<td>To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used.</td>
<td>Temperature limitation</td>
</tr>
<tr>
<td></td>
<td>This way up</td>
<td>0623</td>
<td>ISO 7000</td>
<td>To indicate correct upright position of the transport package.</td>
<td>This end up</td>
</tr>
</tbody>
</table>
## Appendix D

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Title of the Symbol</th>
<th>Reference Number</th>
<th>Standard Containing the Symbol</th>
<th>Function / Description per Standard</th>
<th>Manufacturer Interpretation</th>
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<tbody>
<tr>
<td>12</td>
<td>N/A</td>
<td>N/A</td>
<td>ISO 7000</td>
<td>N/A</td>
<td>Stacking unit</td>
</tr>
<tr>
<td></td>
<td>Keep away from rain</td>
<td>0626</td>
<td>ISO 7000</td>
<td>To indicate that the transport package shall be kept away from rain and in dry conditions.</td>
<td>Keep dry</td>
</tr>
<tr>
<td></td>
<td>Fragile; handle with care</td>
<td>0621</td>
<td>ISO 7000</td>
<td>To indicate that the contents of the transport package are fragile and the package shall be handled with care.</td>
<td>Fragile handle with care</td>
</tr>
</tbody>
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## Appendix E

### Accessories

<table>
<thead>
<tr>
<th>Part number</th>
<th>Part</th>
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</thead>
<tbody>
<tr>
<td>PLU975019</td>
<td>DEXIS 100ct Sensor Covers</td>
</tr>
<tr>
<td>PLU620</td>
<td>Sensor Cable Clip</td>
</tr>
<tr>
<td>PLU622</td>
<td>Cable Clip (3)</td>
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<tr>
<td>PLU623</td>
<td>Sensor Garage</td>
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<tr>
<td>PLU778005</td>
<td>USB cable extender (3 ft)</td>
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## Appendix E

<table>
<thead>
<tr>
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<th>Part</th>
<th>Kit consists of items below</th>
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<tbody>
<tr>
<td>PLU795041</td>
<td>DEXIS Platinum Holders KIT</td>
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<tr>
<td>PLU795005</td>
<td>DEXIS Platinum Anterior Holder</td>
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<td>PLU795008</td>
<td>DEXIS Platinum Posterior Holder</td>
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<td>PLU795011</td>
<td>DEXIS Platinum Horizontal Biteblock Holder</td>
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<tr>
<td>PLU795012</td>
<td>DEXIS Platinum Vertical Biteblock Holder</td>
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<tr>
<td>PLU795010</td>
<td>DEXIS Platinum Horizontal Hand-Held Holders (set of 2)</td>
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<tr>
<td>PLU795013</td>
<td>DEXIS Platinum Vertical Hand-Held Holders (set of 2)</td>
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<td>Part number</td>
<td>Part</td>
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<tr>
<td>1.010.3775</td>
<td>Holder Universal Ring</td>
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<tr>
<td>PLU646</td>
<td>Holder Universal Aiming Bar</td>
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<tr>
<td>PLU641</td>
<td>Holder Bitewing Aiming Bar</td>
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<tr>
<td>PLU795014</td>
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<td>PLU795036</td>
<td>DEXIS Endo Holder Horizontal UL-LR</td>
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### Appendix E

<table>
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<tbody>
<tr>
<td>PLU795037</td>
<td>DEXIS Endo Holder Horizontal LL-UR</td>
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<tr>
<td>PLU795038</td>
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<td>PLU795039</td>
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<tr>
<td>PLU795045</td>
<td>Endodontic Aiming Bar</td>
</tr>
</tbody>
</table>
A
Anterior holder 19
Autoclave 16
B
Bisecting angle technique 25
Bitewing holders 19
C
Cable protection 24, 26, 27
Care of
  sensor 13
  sensor holders 16
H
Hardware requirements 7
Holder
  anterior 19
  bitewing 19
  hand-held 19, 23
  posterior 19
I
Installation 9
O
Occlusal view 25, 26
P
Paralleling technique 21
Pedodontic placement 23
Placement
  pedodontic 23
Placement of sensor 21
Positioning 21
  bisecting angle technique 25
  occlusal view 25, 26
  pedodontic 23
Posterior holder 19
Protection
  of cable 24, 26, 27
S
Sensor
  care of 13
  description 1
  pedodontic placement 21
  placement 21
  proficiency with 3
Sensor holders
  care of 16
Sterilization sheaths 12
U
Upgrades 7
X
X-ray source 10, 13
  settings 12