

DEXIS CariVu

Caries Detection Device

User Manual
Manuel de l'utilisation



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Language

The original language of this manual is English.

CHAPTER 1

Introduction

Welcome to the exciting world of DEXIS! And thank you for your recent investment in the DEXIS CariVu caries detection system. We hope you will have an extraordinary experience with our products and services.

A WORD ABOUT THE DEXIS CARIVU

DEXIS CariVu is a handheld device for caries detection used in conjunction with the DEXcapture software module (refer to the DEXcapture Software manual). The DEXIS CariVu device is intended for use in dentistry only. Any other type of use is prohibited. Proper use includes compliance with all instructions for use and inspection and maintenance intervals.

INTENDED USE

The DEXIS CariVu is a diagnostic aid for the detection of open or incipient carious lesions above the gingiva and for monitoring the progress of such lesions.

Indications:

- Detection of smooth surface caries
- Detection of occlusal caries
- Detection of proximal caries
- Detection of initial caries
- Detection of secondary caries
- Detection of cracks

CONTRAINDICATIONS FOR USE

Use of the device is limited as follows:

- Diagnosis is extremely limited by restorations (such as crowns) and very large fillings.
- Subgingival caries cannot be diagnosed.



PROFICIENCY WITH THE DEXIS CARIVU DEVICE

Please become acquainted with your DEXIS device. The device is your tool. 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 device. Learn to use it well and it will become an effective aid.

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. The user must be able to read and understand the written language of this manual.

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 serious bodily injury or death.
 CAUTION	Alerts the operator that failure to follow instructions may result in minor or moderate bodily injury or damage to the device.
Please Note:	Highlights important or unusual points.

SYSTEM REQUIREMENTS

The DEXIS CariVu device and supporting DEXcapture software module works on all computers that can run DEXIS Imaging software. Current hardware system requirements and the DEXcapture software module are available in the support section on our web site www.dexis.com, from your representative, and from our Customer Care Center.

CONNECT CARIVU TO THE COMPUTER

Please Note: To prevent interference, use a computer without a web cam.

1. Ensure the computer conforms to IEC 60950.
2. Insert the CariVu USB cable into the USB port of the computer.
3. Place the CariVu device in the holder with the corded end facing down.

CHAPTER 2

DEXIS CariVu Description

DEVICE DESCRIPTION

The DEXIS CariVu (caries detector, laser light, transmission) is a handheld laser fluorescence caries detection device according to 21 § CFR 872.1745.

The device uses DIFOTI technology (Digital Imaging Fiber Optic Transillumination). DEXIS CariVu produces images reminiscent of X-ray images, but which are completely radiation free, by means of a light that is especially adapted to this examination method.

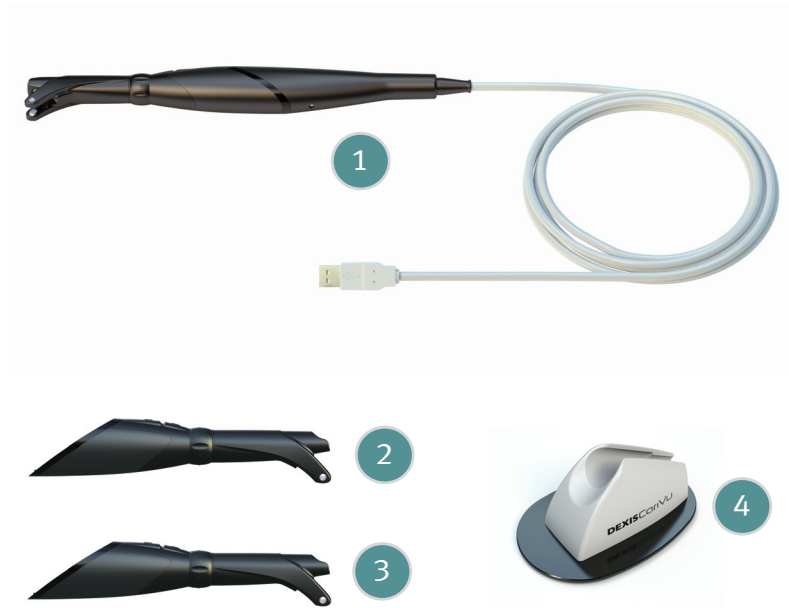
The tooth structures allow the passage of light from the entry site to the device. Areas that block light transmission (such as carious lesions) show up clearly as well delimited, dark areas. A digital camera captures the image and makes it visible in real-time on the computer screen.

The DEXIS CariVu device connects to the computer by a USB 2.0 cable. Compatible DEXIS software must be installed on the computer, with the add-on CariVu acquisition software.

- Ensure that the connection method is USB 2.0 compliant.
- Only use extender cables that are clearly marked as USB 2.0 compliant.
- Maximum length for a non-powered extender is 2.5 meters. The total length of the device cable and a non-powered extender must be 5.0 meters or less.

The CariVu acquisition software acquires images and stores them in the intra-oral camera section of the DEXIS database for future use. The previously saved images (transillumination images, intra-oral radiographs, intra-oral photographs) can be used for comparison with the newly acquired images.

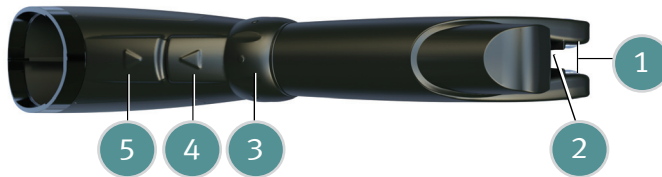
CARIVU COMPONENTS



Package Contents

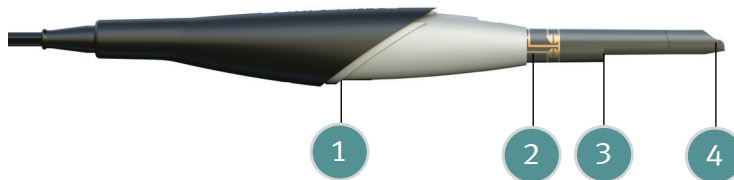
Number	Description	Quantity
1	Handpiece with USB 2.0 cable with anti-kink sleeve and DC/DC voltage transformer	1
2	Large occlusal tip (adult)	1
3	Small occlusal tip (child)	1
4	Holder	1
Not shown	Operator manual	1

TIP COMPONENTS



1	Optical fibers for laser beam
2	Opening for probe window
3	Ring Switch When device is off, press briefly to turn on. When device is on, press briefly to create a still image. The image is either saved immediately or after the Ring Switch is pressed again for three seconds, depending on the selected mode in the CariVu acquisition software Preferences.
4	Control Button 1 - press to select next tooth in the Tooth Chart (clockwise direction)
5	Control Button 2 - press to select previous tooth in the Tooth Chart (counterclockwise direction)

HANDPIECE COMPONENTS



1	Contact groove for tip identification
2	Contact surface for the ring switch
3	Fiber optic interface for tip
4	Window for camera lens

LABELS AND SYMBOLS



Ensures that the product herein specified meets the provisions of European Council Directive 93/42 EEC concerning medical devices.



Model number



Serial number



Used electrical and electronic products should not be mixed with general household waste.



Consult Operating Instructions for Use



Caution. Consult written instructions in this manual.



Classification BF (IEC 601.1 - 1988 and Amendments)



Indicates that the device is certified for both the US and Canadian markets, to the applicable US and Canadian standard.



Date of Manufacture



Direct Current



Manufactured For

SERVICE AND PROPER DISPOSAL

Consult the device warranty for information. Properly dispose of the device at the end of its useful life. Do not mix with general household waste.

SAFETY CONSIDERATIONS

All external surfaces of the device are considered to be applied parts and are safe for normal or accidental patient contact during use.

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

IMPORTANT SAFETY PRECAUTIONS**WARNING**

Failure to follow instructions may result in serious bodily injury or death.

- Danger of injury from electric current.
 - Do not use a damaged device on a patient. Stop using the device if it becomes damaged.
 - Connect the device only to a computer that is approved according to IEC 60950.
 - Do not use the device on patients or place it near patients with the tip removed.
 - Do not use the device after it has been dropped.
 - Danger of suffocation.
 - Vomiting can be triggered by inserting the device too far. Aspiration of vomit. Keep the device away from the patient's throat.
 - Blinding hazard from invisible laser. Eye damage.
 - Do not point the device toward the eyes when the laser is on.
 - Do not operate the device when the housing is damaged or open.
 - Do not use the device on patients or place it near patients with the tip removed.
 - Do not look into the handpiece aperture when the tip is removed.
-

- Hazard from electromagnetic radiation. Interference with other devices.
 - Do not use the device on patients with pacemakers.
 - To prevent interference, turn off devices located in the treatment room that are sources of electromagnetic radiation, such as X-ray machines, lasers, and rotating instruments.
- No modification of this device is allowed.



CAUTION

Failure to follow instructions may result in minor or moderate bodily injury or damage to the device.

- US Federal law restricts this device to sale by or on the order of a health care professional/dentist. For dental use only.
- To help prevent cross-contamination between patients, decontaminate the device handpiece and tips after every use.
- Kinking or pinching the USB cable may cause irreversible breakage of the electrical lines in the USB cable. Do not pull on the USB cable.
- To prevent damage to the device, make sure that the insert track of the tip mates with the opening in the contact groove when attaching the tip.
- Do not actuate the ring switch and control buttons when removing and attaching the tips.
- Do not lean on the device while it is situated in the holder.
- The pulp cavity may become heated from the laser. Restrict use to a maximum of one minute per tooth.
- Do not use the device on wounds / exposed tissue.
- Always inspect the device and cable for physical damage prior to every use.
- Do not immerse device in liquids or allow any liquids to penetrate the device. Do not use solvents or caustic chemicals. Use only the recommended disinfectants according to the manufacturer's instructions.

CHAPTER 3

Using DEXIS CariVu Device

ATTACHING AND REMOVING A TIP

There are two tip sizes: large (adult) and small (child), with the difference being the distance between the probe window opening and end of the tip spacers. Sizes are marked on the tips.

Slide Tip onto the Handpiece

Do not force or twist the tip when attaching to the handpiece. Tips must be slid to the limit stop on the handpiece. Otherwise, areas within the picture may remain covered.

1. Slide the tip evenly to the stop.
2. Make sure that the insert track on the inside of the tip mates with the opening in the contact groove.



Pull Tip off the Handpiece

Do not twist the tip when removing from the handpiece. Do not touch the control buttons when removing the tip.

1. Pull the tip off handpiece while applying a moderate amount of force.
2. Do not touch the control buttons.



TURNING THE DEVICE ON/OFF

1. To turn the device on, remove it from the holder. Alternately, briefly press the ring switch.
2. To turn the device off, place it in the holder. Keep device in the holder when not in use.

Please Note: The device turns off automatically if not used for 10 minutes.

WORK FLOW OVERVIEW

Below is an outline of the CariVu work flow. The work flow details are described in the remaining paragraphs.

- Start the DEXIS imaging program.
- Create or select a patient in DEXIS.
- Start the CariVu acquisition software.
- Take the device off the holder.
- Select the tooth in the Tooth Chart.
- Position the device on the tooth.
- Capture one or more still images of the tooth.
- Repeat the procedure for additional teeth that are to be examined.
- Review the images and discard unwanted images that are not to be added to the DEXIS database.
- Place the device into the holder.
- Close the CariVu acquisition software to move the acquired image to the DEXIS database.

CHAPTER 4

User Maintenance and Troubleshooting

CLEANING AND DISINFECTING

Prior to cleaning

- Shut down the DEXIS software.
- If connected, disconnect the USB cable from the computer.
- Remove the tip from the device.

Recommended Disinfectant

- Cavicide

Cleaning Instructions



CAUTION

Do not immerse device in liquids or allow any liquids to penetrate the device. Do not use solvents or caustic chemicals. Use only the recommended disinfectants according to the manufacturer's instructions.

Clean the device and tips after every use.

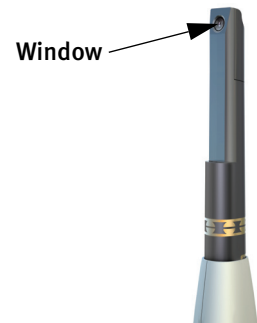
- Remove major soiling immediately after soiling occurs with a single-use paper towel.
- Clean all outer surfaces on the device and tips with a soft cloth and the recommended disinfectant.
- If probe window is soiled, clean gently with isopropanol 70% and a cotton swab. Excessive force may damage the window.

STERILIZING



CAUTION

Do **not** use the following sterilization methods: hot air, chemical cold sterilization, or ethylene oxide. Do not place tips in an ultrasonic bath.



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

Please Note: Only the tips can be sterilized. The tips have a maximum temperature resistance of 138° C (280° F).

1. Clean and disinfect the tips prior to sterilization.
2. Place tips in a bag.
3. Autoclave using one of the following methods:
 - Autoclave with pre-vacuum at least 3 minutes at 135° C (275° F)
Drying time: 10 minutes
 - Autoclave using the gravity method at least 10 minutes at 135° C (275° F)
Drying time: 10 minutes
4. Store tips in a bag.

FUNCTIONAL CHECKS

- Check device for cleanliness prior to each use.
- Hold tips against a light source (such as daylight) and check the optical fibers for build up and defects.

TROUBLESHOOTING

- If the device is unplugged from the computer while the software is running, error messages may be displayed at the next start up. Always close the software before unplugging the device.
- If error messages are displayed at start up, close all programs and reboot the computer.
- Do not continue to use the DEXIS device if there is visible damage to the device handpiece, tip, and/or USB cable.
- Ensure that the maximum length of a non-powered cable extender is not more than 2.5 meters and is USB 2.0 compliant.

CHAPTER 5

Specifications and Standards

TECHNICAL SPECIFICATIONS

Device Data	
Power consumption	0.5 A maximum
Supply voltage	5 V
Cable length	2.5 meters
Weight	190 g
Length	Approximately 245 mm
Diameter	30 mm
Protection class	IP 44*
* Indicates the housing provides protection against ingress of solid foreign matter greater than or equal to 1 mm in diameter and against splashing water.	
Image Detector	
Type	CMOS
Format	1/4"
Monochrome	8 bit
Resolution	640 W x 480 H
Optical System	
Image angle	105°
Viewing direction	80°
Focusing distance	4.5 mm
Illumination	
Type	Laser diode
Number	2
Wavelength	780 nm

Optical power	15 mW
Optical power according to IEC 60825-1 downstream of the occlusal tips	Max. 1 mW
Operating Conditions	
Ambient temperature	+10 to +30° C
Air pressure	80 to 106 kPa
Relative humidity	5 to 95% non-condensing
Max. elevation for operation	Max. 2000 m
Storage and Transportation Conditions	
Ambient temperature	-10 to +55° C
Air pressure	70 to 106 kPa
Relative humidity	5 to 95% non-condensing

ACCESSORIES

Part Number	Item
1.010.5561	Occlusal tip, large
1.005.5560	Occlusal tip, small

EQUIPMENT STANDARDS

The device was tested and/or evaluated against and found compliant to the following standards/requirements:

IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)

IEC 60601-1-6: 2010 (3rd Edition) for use in conjunction with IEC 60601-1: 2005 (3rd Edition) and IEC 62366: 2007 (1st Edition)

EN 60601-1-2: 2007 (CISPR 11:2009/A1: 2010)

Medical Device Directive 93/42/EEC

MANUFACTURER'S DECLARATION

The DEXIS device 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 device 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.



WARNING

The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Please Note: Portable/mobile radio frequency communications equipment can affect the function of the DEXIS device 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 device to electromagnetic fields or increase the emission of electromagnetic fields from DEXIS.

Guidance and manufacturer's declaration - electromagnetic emissions		
<p>The DEXIS device, used with a compliant computer, is intended for use in the electromagnetic environment specified below. The customer or the user of the DEXIS device should assure that it is used in such an environment.</p>		
Emissions Test	Compliance	Electromagnetic environment - guidelines
HF emissions CISPR 11	Group 1	<p>The device 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.</p>
HF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The DEXIS device, used with a compliant computer, is intended for use in the electromagnetic environment specified below. The customer or the user of the DEXIS device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ±8 kV air	± 2/4/6 kV contact ± 2/4/8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE 1 U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The DEXIS device, used with a compliant computer, is intended for use in the electromagnetic environment specified below. The customer or the user of the DEXIS device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted HF IEC 61000-4-6	3 V _{eff} 150 kHz to 80 MHz outside the ISM bands ^a	3 V _{eff}	<p>Portable and mobile HF communications equipment should be used no closer to any part of the DEXIS device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = 1.17\sqrt{P}$
Radiated HF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.17\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ for 800 MHz to 2.5 GHz <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).</p> <p>^b Field strengths from fixed HF transmitters, as determined by an electromagnetic site survey,^c should be less than the compliance level in each frequency range.</p> <p>^d Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

^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 compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range from 80 MHz to 2.5 GHz are intended to reduce the probability of mobile/handheld communications facilities causing interference when they are inadvertently introduced into the patient area. For this reason, the additional factor of $10/3$ is applied in the calculation of the recommended safe clearances in these ranges of frequencies.

^c The field strength of stationary transmitters, such as, e.g. base stations of mobile phones and mobile terrestrial radio devices, amateur radio stations, AM and FM radio and television transmitters, cannot be determined exactly based on theoretical considerations. A site study should be considered to determine the electromagnetic environment in terms of stationary transmitters. If the measured field strength at the site, at which the device is used, exceeds the compliance levels shown above, the device should be monitored to demonstrate proper function. If any uncommon performance characteristics are observed, additional measures may be required, such as, e.g. changing the orientation or using a different location for the device.

^d In the frequency range 150 kHz to 80 MHz, the field strength should be less than $3 V_{\text{eff}}/\text{m}$.

**Recommended separation distances between
portable and mobile HF communications equipment and the DEXIS device**

The DEXIS device is intended for use in an electromagnetic environment in which radiated HF disturbances are controlled. The customer or the user of the DEXIS device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communications equipment (transmitters) and the DEXIS device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=1.17\sqrt{P}$ m	80 MHz to 800 MHz $d=1.17\sqrt{P}$ m	800 MHz to 2,5 GHz $d=2.33\sqrt{P}$ m
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3

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 A

Additional Help and Support

DEXIS on the Internet

www.dexis.com

CariVu Acquisition Software Downloads

- DEXcapture
- CariVu 2.0
- CariVu 1.5

DEXIS Customer Care Center (United States and Canada)

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