Sonochart

Safety, Regulatory and Technical Specification User Guide

Notice

The Safety, Regulatory and Technical Specifications User Guide includes information on the safety instructions, regulatory information, and the technical specifications of the devices. We recommend that you thoroughly familiarize yourself with this guide to make the most effective use of your system.

The information contained in this guide may be subject to modification without notice, justification or notification to the persons concerned.

This document is originally written in English.

The Sonochart product and its accessory are intended for medical professional use only.
U.S. Federal law restricts this device to sale by or on the order of a dental healthcare professional.

Manual Name: Sonochart Safety, Regulatory, and Technical Specifications User Guide
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Contents

Safety Information

Indications for Use

Sonochart is an intraoral ultrasonic system intended to be used by dental healthcare professionals to provide measurements of periodontal soft tissues for diagnostic support of adult patients.

Clinical benefits and performance characteristics

SonoChart device benefits dental healthcare professionals by providing them safe, non-intrusive, accurate and repeatable periodontal measurements. The outcomes allow the dental healthcare professional to support periodontal diagnosis, establish relevant periodontal treatment plan and thus improve the clinical patient management. The clinical benefit of Sonochart device brings positive impact to patient management.

The clinical performances of SonoChart device stem from the technical characteristics of the ultrasound equipment defined in IEC 60601-2-37 and IEC 60601-2-18 standards:

IEC 60601-2-18 Essential performances

- Unexpected impact of the probe head orientation on the measurements
- Live acquisitions during patient procedure (no recorded data replayed)

IEC 60601-2-37 Essential performances

- Unexpected noise on a waveform or artefacts or distortion in an image or error of a displayed numerical value which cannot be attributed to a physiological effect, and which may alter the diagnosis
- Unexpected display of incorrect numerical values associated with the diagnosis to be performed
- Unexpected incorrect safety-related indications display
- Unexpected unintended or excessive ultrasound output
- Unexpected unintended or excessive transducer assembly surface temperature

Conventions in this Guide

The following special messages emphasize information or indicate potential risk to personnel or equipment:

WARNING: Warns you to avoid injury to yourself or others by following the safety instructions precisely.

Important: Alerts you to a condition that might cause problems.

Note: Emphasizes important information.

Tip: Provides extra information and hints.

Warning and Safety Instructions

There are no contra-indications identified for the Sonochart device. When operating the unit, observe the following warning and safety instructions:

DANGER OF ELECTRIC SHOCK
This is an electrical unit. Do NOT expose it to water spray. Such action can cause an electric shock or a malfunction of the unit

IMPORTANT: All known residual risks, or undesirable side effects are listed in this guide. If any serious incident occurs in relation to the device, you must report it to Carestream Dental and to the competent authority of your Member State in the European Union.

IMPORTANT: You must wear gloves when using the SonoChart device

WARNINGS:

1. Any other equipment not complying with IEC 60601 shall be kept at least 1.83 meters away from the patient.
2. Operation where chemical substances are involved are done under aspiration and a medical control is done on operators who are in contact with toxic substances
3. DO NOT maintain or service the device while it is in use on the patient.
4. You MUST use an adequate intraoral ultrasound gel.
5. Parts of Sonochart device that come into contact with the patient and the operator must be cleaned and disinfected between patients.
6. DO NOT put Sonochart probe cover in direct contact within the patient's mucosa.
7. You MUST be trained on risk related to electric shock.
8. In the event of a cell leaking, do not allow the liquid to come in contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.
9. The product and packaging shall be stored in the following conditions:

   Temperature: -10°C to +60°C for storage.

   Relative Humidity: 10 - 90%.

   Atmospheric pressure: 700 to 1060 hPa.

   Altitude up to 3000 m.
10. The unit shall operate in the following environment:

    Temperature: 10°C to 30°C.

Relative Humidity: 30 - 80%.

Atmospheric pressure 700 to 1060 hPa.

Altitude up to 3000 m.

11. We highly recommend the training of users to the ultrasonic imaging technology

12. It is required to train users to the system**.**

13. You MUST maintain a good positioning of the probe during the whole procedure.

14. You should use consumables according to the manufacturer instructions for use**.**

15. The hydrogel couplant is designed and tested for the Sonochart system. Only use the hydrogel couplant accessory with the Sonochart system**.**

16. You should handle the consumables according to standard operating procedures for the disposal of contaminated medical waste**.**

17. Millimeter metric is used throughout the Sonochart system (mobile application and handpiece's display screen).

18. Check that the hydrogel couplant is not expired before use.

19. The expiry date format, readable on the hydrogel couplant primary packaging, is YYYY-MM.

20. In case of damaged packaging or damaged hydrogel couplant, do not use the hydrogel couplant.

21. The hydrogel couplant is a single use. Do not reuse the hydrogel couplant between patients.

22. Do not sterilize the hydrogel couplant prior use. Sterilization procedures, including autoclaves, could affect the hydrogel couplant properties.

23. Unless recommended or validated for the Sonochart system, do not use other ultrasonic couplant available on the market.

24. Do not swallow the hydrogel couplant.

25. Do not use the hydrogel couplant in combination with additional chemistry during the procedure.

26. After each procedure, the patient must rinse out his mouth.

27. Rinse the hydrogel couplant under clear water before use to limit the hydrogel couplant salty taste.

28. Keep the hydrogel couplant wet throughout the patient procedure.

29. Once the hydrogel couplant primary packaging opened, keep the hydrogel couplant in his packaging prior usage and use the hydrogel couplant in the following 10 hours.

Disposal

This equipment contains certain materials and chemical compounds incidental to the manufacture of electrical and electronic equipment, and improper "end-of-life" disposal of such equipment can result in environmental contamination. Therefore, this equipment should not be disposed of as ordinary household waste but should instead be delivered to a designated electrical and electronic waste disposal or recycling center. For further information on disposing of electrical and electronic waste, contact the cognizant authority within the local jurisdiction.

Dispose of the Sonochart probe head and/or battery according to standard operating procedures or local regulations for the disposal of contaminated medical waste. Dispose of the Sonochart probe head and/or his battery according to standard operating procedures or local regulations for the disposal of contaminated medical waste. For additional SonoChart head, contact your representative.

Precautions Before Use

Perform the following activities on your device and accessories before use:

A. Cleaning and Disinfecting

To ensure maximum hygienic safety for the patient and to minimize the risk of cross-contamination, carefully perform the following maintenance activities on your Sonochart device.

After each patient, clean and disinfect:

- The probe head. See section **"Cleaning and disinfecting the probe head"**

B. Visually Inspecting Sonochart device for damage

Visually inspect the device for damage or signs of deterioration by doing the following:

- Inspect the probe's acquisition window
- Inspect around the probe buttons and contact points.
- Inspect the hydrogel before putting it on the probe head

If damage is noticed, do not use the device, and contact your representative.

Hygiene and Disinfection

Cleaning and disinfecting the probe head

WARNINGS:

- **Disinfect the probe head after each patient.**
- **Never place the probe head in an autoclave as this could result in serious damage to the device.**
- **Do not use UV disinfection nor ultrasound cleaning as this could result in serious damage to the sensor.**
- **You must first clean the probe head before disinfecting it.**
- **You must use the disinfectant according to the manufacturer instructions.**
- **You must wear gloves during the whole cleaning and disinfecting procedure**

You must first clean the probe head before disinfecting it. To do so, follow these steps:

1. Remove debris or organic matter from the probe head surface with a disposable wipe or surface brush.
2. Inspect the probe head for debris. Repeat cleaning if there is any debris left.
3. Disinfect the probe head with disinfecting wipes or soak it in a disinfecting solution with high-level hospital disinfectant with label claims of tuberculocidal activity (for example: a chlorine containing product, a quaternary ammonium compound with alcohol, a phenolics, an iodophors, an EPA-registered chlorine-base product). **You MUST follow the instructions for use**.

Carestream Dental LLC recommends the use of the FDA cleared Tristel Duo ULT high-level disinfectant foam, to disinfect the probe head. To ensure disinfection quality, Carestream Dental LLC recommends following disinfectant foam manufacturer recommendations and apply the foam on the probe head during at least 10 minutes.

Probe head swap

Refer to user guide, section maintenance

Maintenance

Refer to user guide, section maintenance

Accessories and consumables

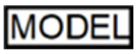
The hydrogel accessory is a latex free product.

For hydrogel product composition, properties and associated operating risks, please refer to the hydrogel Safety Data Sheet.

For Hydrogel operation, refer to Sonochart User & Installation Guide (SMA86), section 8 “Setting up the Handpiece, Using the Hydrogel”.

Marking and Labeling Symbols for Sonochart product

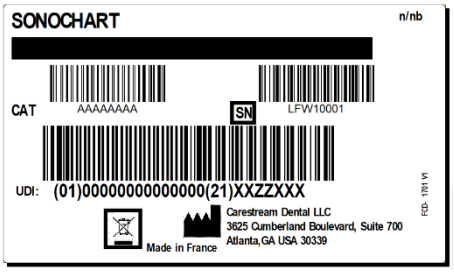
	Type BF device symbol complying with the IEC 60601-1 standard.
	In the European Union, this symbol indicates: Do NOT discard this product in a trash receptacle; use an appropriate recovery and recycling facility. Contact your local sales representative for additional information on the collection and recovery programs available for this product.
	Direct current
	Caution
	Refer to instruction manual/booklet
	Consult the instructions of use or consult the electronic instructions for use/ eIFU indicator
	Temperatures limits
	Humidity limitation
	Atmospheric pressure limitations
	Date of Manufacture.
	Country of manufacture
	Manufacturer’s address.

	Medical Device
	Name of the European authorized representative and address of the registered place of business
	Name of the Responsible Person in the United Kingdom and address of the registered place of business
	Defines the unit's model
	Name of the Swiss authorized representative and address of the registered place of business
	Batch code
	Use-by date
	Unique device identifier
	Do not re-use
	Do not use if package is damaged and consult instructions for use
	No-sterile

Label Locations

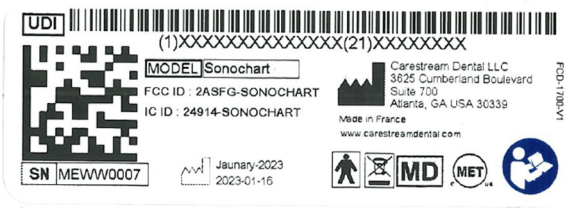
The following figures illustrate the label locations of the Sonochart product:

Sonochart shipping label:

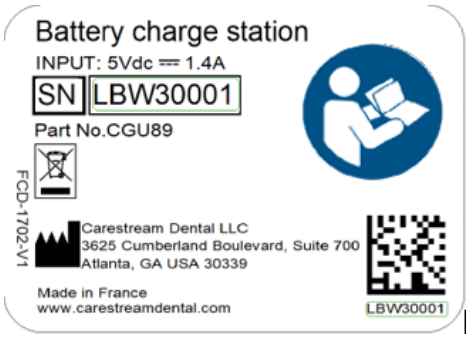


Sonochart Product label:

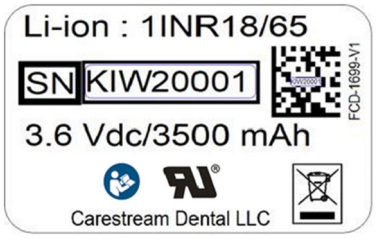
Sonochart handpiece label



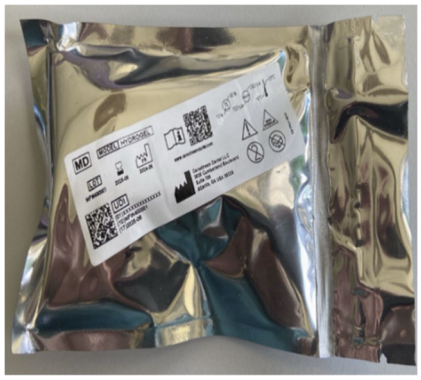
Battery charge station:

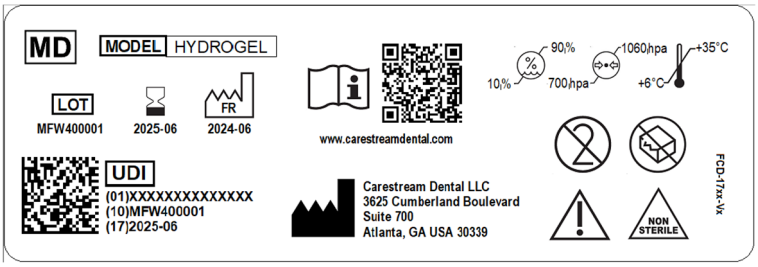


Battery label:



Hydrogel label:





Regulatory Information

General Regulatory Requirements

IEC 60601-1	Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance
ANSI AAMI 60601-1	Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance
CAN /CSA C22.2 N°60601-1	Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance
ANSI AAMI IEC 60601-1-2	Medical Electrical Equipment, Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Disturbances – Requirements and tests.
IEC 60601-1-6	Medical Electrical Equipment, Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
IEC 60601-2-18	Medical electrical equipment –Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
IEC 60601-2-37	Medical electrical equipment –Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
EN 62366-1/IEC 62366-1	Medical devices - Application of usability engineering to medical devices
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
EN ISO 20417	Medical devices - Information to be supplied by the manufacturer
IEC 62304	Medical device software - Software life cycle processes
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ETSI EN 300 328	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonized Standard for access to radio spectrum
ETSI EN 301 489-1	Electromagnetic compatibility (EMC) standard for radio equipment and services. Part 1: Common technical requirements. *Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU*
ETSI EN 301 489-17	Electromagnetic Compatibility (EMC) standard for radio equipment and services. *Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU*

IEC 62133-2	Secondary cells and batteries containing alkaline or other non-acid electrolytes. Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications. Part 2: Lithium systems
UL ANSI 2900-2-1	Software Cybersecurity for Network-Connectable Products, Part 1-2: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems

Classification in accordance with EN/IEC 60601-1	
Type of protection against electric shock	INTERNALLY POWERED ME EQUIPMENT
Degree of protection against electric shock	Type BF
Protection against harmful ingress of water	IPX1 (for probe head)
Operation mode	Continuous operation
Flammable anesthetics	Not suitable for use in presence of flammable anesthetics or a mixture of flammable anesthetics with air or oxygen or nitrous oxide

Conformity with EN/IEC 60601-1-2

Electromagnetic Compatibility Precautions

WARNINGS:

- **Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC).**
- **Sonochart product is intended to be used in a professional healthcare facility environment.**
- **Sonochart product must be installed and put into service according to the EMC information provided in this document.**
- **Communication Equipment: Portable and mobile Radio Frequency (RF) communications equipment can affect the Electromagnetic Compatibility of Sonochart product**
- **Sonochart product may be interfered with other equipment even if that other equipment complies with CISPR emission requirements.**

WIFI

This equipment complies with radio frequency exposure limits set forth by the RED for an uncontrolled environment.

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s) and complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation of the device.

Changes or modifications made to this equipment not expressly approved by Carestream Dental may void the FCC authorization to operate this equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.
—Increase the separation between the equipment and receiver.
—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
—Consult the dealer or an experienced radio/TV technician for help.

The device is for indoor use only and supports dual-band Wi-Fi with 802.11a/b/g/n operation in the 2.4 GHz and 5 GHz radio bands. The module is designed to operate in only one frequency band at a time.

	BLE	Wifi 2.4	Wifi 5
Frequency Bands:	2400-2483.5 Mhz	2400-2483.5 Mhz	5150-5250 Mhz 5250-5350 Mhz 5470-5725 MHz
Maximum Output Power:	< 10 dBm	< 20 dBm	< 20 dBm

SAR: Worn or Body Supported Device: 0.276 W/kg, 1g

Radiofrequency radiation exposure Information:

For body-worn, head and limb-worn operation this device has been tested touched to the phantom and meets FCC and ISED RF exposure guidelines. Nevertheless, the device should be used in such a manner that the potential for human contact during normal operation is minimized.

Guidance and manufacturer's declarations

Sonochart product Components
Handpiece
Battery charge station
Battery
Battery charge station USB cable

WARNINGS:

- **Use limitation: The use of accessories, cables, or transducers other than those specified in the user guide with the exception of cables, accessories or transducers recommended by Carestream Dental LLC as replacement parts of internal components may result in increased emissions or decreased immunity of Sonochart device**
- **Sonochart product should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, Sonochart should be observed to verify normal operation in the configuration in which it will be used.**

Sonochart product is intended for use in the electromagnetic environment specified below. The customer or the user of Sonochart should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	Sonochart use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Sonochart 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.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Sonochart are intended for use in the electromagnetic environment specified below. The customer or the user of Sonochart should assure that they are used in such an environment.

The essential performance of the Sonochart is defined by IEC 60601-2-37, Table 201.102.

Immunity Test	IEC 60601 Test Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 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	Not Applicable for Sonochart	For battery charging, mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Not Applicable for Sonochart	For battery charging, 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	Not Applicable for Sonochart	Sonochart is internally powered only.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Proximity magnetic fields IEC 61000-4-39	8 A/m on the frequency 30 kHz 65 A/m on the frequency 134.2 kHz 7.5 A/m on the frequency 13.56 MHz	Professional healthcare facility environment

Guidance and Manufacturer's Declaration - Electromagnetic Immunity **(IEC 60601-1-2)**

Sonochart product is intended for use in the electromagnetic environment specified below. The customer or the user of Sonochart should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	Not Applicable for Sonochart Battery charging: 3 Vrms 150 kHz to 80 MHz and 6V at ISM Frequencies and amateur radio frequencies	Environment of a care facility professional health.

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

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz Test levels and frequencies according to table 9 from IEC 60601-1-2: 2014	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Sonochart product. Otherwise, degradation of the performance of this equipment could result

Note: 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 Sonochart system is used exceeds the applicable RF compliance level above, the Sonochart should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Sonochart product.

Note: Uninterrupted communication is essential for electromagnetic compatibility.

Compliance with International Regulations

Directive 2011/65/EU on the Restriction of the use of certain Hazardous Substances in electrical and electronic equipment (RoHS), as amended by Directive (EU) 2015/863.

Medical Devices Regulations 2002 (SI618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478), Class IIa.

Radio Equipment Directive (2014/53/EU)

FDA Center for Devices & Radiological Health (CDRH-CFR title 21 chapter 1) (USA)

Technical Specifications

Model: Sonochart

Sonochart Technical Specifications	
Sensor Technology (Ultrasonic Transducer)	**Piezoelectric Film** **25Mhz Central Frequency**
Transducer active surface	**45 mm²**
Transducer Resolutions	80 µm (axial) 150 µm (lateral)
Handpiece Dimension	252 x 39 x 50 mm
Handpiece display screen	**21.696 mm (W) x 10.8 mm (H)** **0.135 x 0.1356 dot pitch** **80 x RGB x 160 (TFT) Dot Matrix**
Weight	**210 grams (with battery)**
Input Voltage	**4.2V ⎓ 3A (with battery)**
Wireless Connectivity	**Wifi 2.4 GHz** **Wifi 5 GHz** **BlueTooth (BLE)**

Main Components Technical Specifications

Components Technical Specifications	
Battery Charge station	**Input: 5V ⎓ 1.3A (USB-C)** **Output: 4.2V ⎓ 3A**
Battery	**Model: 1INR18/65** **3.6 Vdc/3500 mAh**

Minimum terminal System Requirements

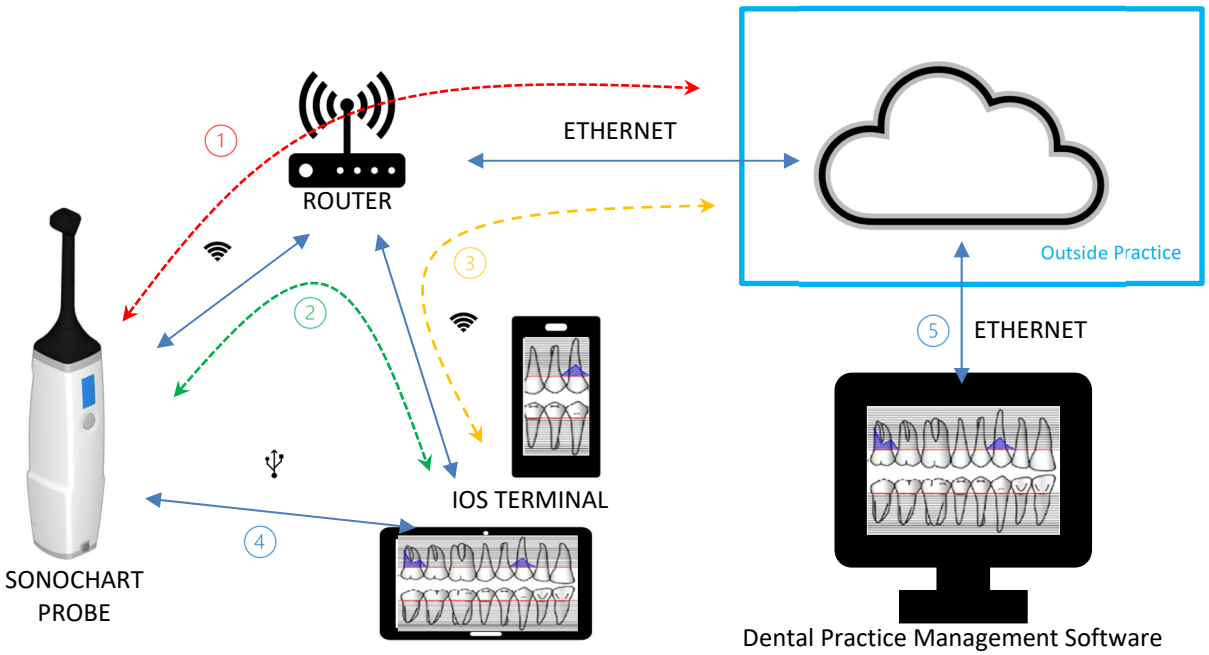
The terminal and the peripheral equipment must conform to the IEC 62368-1 standard.
A terminal can either be a smartphone or a tablet operating under iOS Operating systems.

Display and Acquisition	
CPU	ARM CPU
RAM	iOS: 2 GB
Storage Space	**100 MB for the Software-Installation** **20 GB free space recommended to use the software**
Display	734 x 1334 minimum screen resolution 32 bits color mode
Operating system	**iOS 15 or above** **Android 11 or above**
Wireless minimum connection	**Wifi 2.4 GHz, Wifi 5 GHz**
BlueTooth	Active BlueTooth capabilities with BLE support

Environmental connectivity requirements

Wireless environmental conditions requirements	
Wireless Connection	Wi-Fi 2.4 GHz, Wi-Fi 5 GHz (Recommended)
Password Encryption	WPA/WPA2 (high security level)
Wifi Network Type	Private (no public network)
Wifi Router Access	Authentication through strong password

System Configuration Diagram



Label	*Data Exchanged*
1	***Technical Data (Logs), Binaries***
2	***Probe status, Commands, Measurements***
3	***Patient Data, Technical Data (Logs), Measurements***
4	***Probe Configuration, Probe Detection***
5	***Periodontal Measurements, Exam Requests***

Figure: Sonochart System Interfaces Overview (Wifi Bluetooth)

Security Warnings

Software patches can be issued when security flaws are discovered. It is really important to stay up to date to be protected against attackers. The best option is to enable automatic updates

Only connect to private networks when possible, especially when handling sensitive information. If you do use public Wi-Fi at coffee shops, retail stores, etc. be sure not to log on to any sites containing sensitive information. Use strong passwords and biometric features, ensure you turn off your Bluetooth when not in use, don't automatically connect to any public Wi-Fi, and download with caution. The cellular data connection is generally safer than using public Wi-Fi networks.

Having a strong password is important, but it's even more imperative to have two-factor, or multi-factor, authentication. This method provides two or more layers of security measures so if a hacker can accurately guess or steal your password, there is still an additional security measure in place to ensure that your account is not breached.
Create complex passwords, protect passwords and change them regularly.
Be aware of the security implications of using personal devices for professional matters. If practicable, consider requiring staff to encrypt attachments they email if they contain a significant volume of sensitive data.

Malicious links can do damage in several different ways, so be sure to inspect links and ensure they're from trusted senders before clicking (as example, a wrong application name in the application store)

Cybersecurity attacks are often more attacks on the mind of the user, rather than on the device, to gain access to systems and information. Especially with the information publicly available online and over social media, cyber criminals come up with creative ways to dupe users.

Dot reuse passwords across multiple systems and do not share passwords with colleagues.

Note: For security reasons, we recommend removing remanent password from your internet browser once the Sonochart mobile application has been uninstalled

Imaging Performance Information

Acquisition Performances Information	
Video mode frame rate	3 images / second
Video Imaging Resolution	**150 - 200 µm**
Image Gray scale	**4096 grey levels (12 bits)**
Periodontal Measurements Accuracy	**+/- 1 mm**

Acoustic output information

Ultrasound Safety

Limits of the Thermal Index (TI) (estimates of the local temperature increase of soft tissue or bone) and the Mechanical Index (estimates of tissues damaged during the exam) are set according to the IEC 60601-2-37 (revision 2.1) standard: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.

Ultrasonic Operating mode

Probe Model	Ultrasonic Operating Mode						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Sonochart	X						

Symbols used

List of symbols used in the device acoustic outputs table.

For symbols or terms that will not be listed in the following table, you can refer to the definition section of the IEC 60601-2-37 (revision 2.1) standard: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.

Symbol	Description
MI	The Mechanical Index.
TIS	The Soft Tissue Thermal Index in an auto-scanning mode.
TIB	The Bone Thermal Index.
TIC	The Cranial Thermal Index.
Pr.α at ZMI	Attenuated peak-rarefactional acoustic pressure.
P	Output power.
P1x1	Bounded-square output power.
Zs	Depth for TIS below surface.
Zb	Depth for TIB below surface.
ZMI	Depth for MI.
Zpii,α	Depth for maximum piiα.
Fawf	Acoustic working frequency.
prr	Pulse repetition rate.
srr	Scan repetition rate.
npps	Number of Pulses Per ultrasonic Scan line.
Ipa,α at Zpii,α	Attenuated pulse average intensity.
Ispta,α at Zpii,α or Zsii,α	Attenuated spatial peak temporal average intensity.
Ispta at Zpii or Zsiin	Spatial peak temporal average intensity.
Pr at Zpii	Peak-rarefactional acoustic pressure.

Sonochart Acoustic Outputs (B-mode)

The Sonochart device complies with IEC 60601-2-37 output settings and output display safety principles. In support of that compliance, the following tables provide the global maximum acoustic output indices for the device

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0,91	0.0037		0.0037		0.0033
Index component value				0.0037	0.0037	0.0033	0.0037	
Acoustic parameters	$P_{r.\alpha}$ at Z_{MI}	(Mpa)	3.91					
	P	(mW)		0.042		0.042		0.042
	P_{1x1}	(mW)		0.042		0.042		
	Z_s	(cm)			0.48			
	Z_b	(cm)					0.48	
	Z_{MI}	(cm)	0.33					
	$Z_{pii,\alpha}$	(cm)	0.33					
	F_{awf}	(MHz)	18.3	18.3		18.3		18.3
Other information	prr	(Hz)	2048					
	srr	(Hz)	8					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$	(W/cm²)	538					
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$	(mW/cm²)	68.6					
	I_{spta} at Z_{pii} or Z_{siin}	(mW/cm²)	104					
	P_r at Z_{pii}	(MPa)	4.82					

Controlling the Image Quality

For optimum results, perform a control test of the image quality. To do this, see the User & Installation Guide.

Handpiece Environmental Requirements

Ambient Operating Conditions	
Temperatures	10 – 30 °C
Relative humidity	30 – 85%
Atmospheric pressure	700 – 1060 hpa
Altitude	Up to 3000 m

Storage Conditions	
Temperatures	-10 – 60 °C
Relative humidity	10 – 90%
Atmospheric pressure	700 – 1060 hpa

Transport Conditions	
Temperatures	-10 – 60 °C
Relative humidity	10 – 90%
Atmospheric pressure	700 – 1060 hpa

Hydrogel Accessory Environmental Requirements

Ambient Operating Conditions	
Temperatures	+10 – 35 °C
Relative humidity	10 – 90%
Atmospheric pressure	700 – 1060 hpa

Storage Conditions	
Temperatures	+10 – 35 °C
Relative humidity	10 – 90%
Atmospheric pressure	700 – 1060 hpa

Transport Conditions	
Temperatures	+10 – 35 °C
Relative humidity	10 – 90%
Atmospheric pressure	700 – 1060 hpa

Contact Information

Manufacturer's Address

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Factory

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Authorized Representatives

Authorized Representative in the European Community

EC REP

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List of Importers for European Union according to MDR 2017/745

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Hedelfinger Str. 60
70327 Stuttgart, Germany

Carestream Dental Spain
S.L.U. Paseo de la Castellana, 79
Madrid 28046, España

Carestream Dental Italy S.r.l.
Via Mario Idiojmi 3/3,
Assago 20090 (MI), Italia

List of Importers in Switzerland

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CH-8953 Dietikon
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CH-8107 Buchs
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Jordi Röntgentechnik AG
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