orascanner® 2

HARDWARE MANUAL

ORAMETRIX®

OraMetrix has its headquarters in Richardson, Texas, with offices in Berlin, Germany and Chatswood, Australia. For general information about OraMetrix, visit the OraMetrix website at www.orametrix.com.

Contact us for support

To contact us, please call one of the phone numbers listed below, or email us at customer.care@orametrix.com

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All other countries	+1 972 728 5902

DOC-500399-5

November 21, 2017

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1. Safety

1.1 Symbols Used on Product Labels

NON STERILE	**Non sterile**
	Consult instructions before use This symbol advises the reader to consult the operating instructions for information needed for the proper use of the device.
	Type B applied part (equipment intended to come into contact with the patient).
CE 0123	**Compliant with EU directive 93/42EEC**
CLASSIFIED c UL us	**UL Classified Device** AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005), CAN/CSA-C22.2 No. 60601-1 (2008), UL 60601-1 and CAN/CSA-C22.2 No. 601.1 83GF

1.2 Symbols Used in this Manual

⚠	**WARNING** Indicates a potentially hazardous situation, which, if not avoided, could result in death or serious injury**.**
⚠	**CAUTION** Indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury, product or property damage. It may also be used to alert against unsafe practices.
ℹ	**NOTICE** Indicates important information that is required to use the system properly.

1.3   Safety Precautions

The primary concern of OraMetrix is that the suresmile system equipment is operated and maintained for the safety of the patient and staff.

The orascanner 2 is classified as dental imaging equipment and must therefore be used only under the supervision of qualified dental staff.

The user bears legal responsibility for the possession, use and routine maintenance of the orascanner 2.

To ensure safe and reliable operation of the orascanner 2, the operator must read and understand this manual before attempting to operate it.

Operators must be well trained to safely and properly use the system.

Operators should strictly follow the proper cleaning instructions, as detailed in this manual, to avoid damaging the orascanner 2.

NOTICE	Caution: United States federal law restricts the use of this device to or by the order of a dentist.
	The equipment must be used in compliance with the procedures contained in the suresmile system user manuals. The equipment should never be used for purposes other than as described in the user manual.
	For additional suresmile system information, see the: • suresmile online help • SureWhite® Tooth Preparation Kit insert
	OraMetrix shall NOT be responsible for: • Any use of the suresmile equipment other than for its intended use; • Any damage to the equipment that the user causes by incorrect maintenance not in compliance with the procedures contained in the relevant user and installation manuals provided with the equipment, or by incorrect operation techniques; or • Any mechanical and/or electrical modifications made after installation.
	OraMetrix does not determine patient care. OraMetrix provides therapeutics as directed by the doctor. The best possible results from the suresmile process depend on the application of the doctor's diagnostic and clinical judgment.

1.3.1 Operational

WARNING	Patients might choke on the orascanner mirror if the mirror detaches. Do not use damaged mirrors.
	Do not use the equipment on patients with uncontrolled biting behavior.

CAUTION	Hazards related to incorrect treatment planning or archwires are possible. A trained user must control all suresmile software, data acquisition, and appliance-related functions.
	An operator might probe too deeply with the orascanner mirror and cause a gag reflex.

NOTICE	A trained operator must apply SureWhite properly so that the scanned image is of acceptable quality. For more detailed information, see the paper insert in the suresmile Tooth Preparation Kit.
	The operator will touch the patient's gums, which might result in soreness. Operators should be trained to minimize patient discomfort.
	The orascanner 2 unit is not intended for use as an operative device. It is not manufactured to be sterile.

1.3.2 Environmental

WARNING	The orascanner 2 is not designed for use in environments where oxygen-rich or explosive gasses are present. Do not locate the equipment in such an area.
	Do not use the equipment in the presence of flammable anesthetics.

2. System and Equipment

2.1 suresmile Overview

suresmile is the first end-to-end system for fixed appliances that allows an orthodontist to apply 3D diagnostic imaging and computer-aided treatment planning to unlock the power of shape memory alloy archwires through customization. This results in greater control and efficiency for orthodontic care.

suresmile is comprised of several key components:

- The **orascanner 2**, a unique patented, handheld intraoral imaging device that uses white light to capture 3D images of a patient's dentition. The orascanner 2 does not use lasers or x-rays. The orascanner 2 captures the images of teeth at chairside, allowing the operator to view the resulting models as they are being made.

    Additionally, a practice can use a **suresmile-certified CBCT or intra-oral scanner** to capture 3D images of a patient's dentition either in their practice or at an imaging facility.

- **suresmile 3D software** provides powerful visualization tools for precision diagnosis, treatment simulation, and customized appliance design. The doctor can review the digital setup with this software and use it to communicate both with patients and with the Digital Lab at OraMetrix.

- The **Digital Lab** provides scan and setup processing to produce precise robotically bent archwires.

2.2 orascanner 2 Kit

Table 1: orascanner 2 Kit

Component	Quantity	Description
orascanner 2	1	Handheld 3D scanner
USB cable	1	3m (9.84 feet) cable that connects the computer to the orascanner 2
cradle	1	Plastic cradle designed to hold the orascanner 2 when not in use
Wireless footswitch	1	USB wireless footswitch to control the orascanner 2
orascanner 2 mirrors	2	Detachable mirrors with integrated mirror heating
USB stick	1	Contains PDFs of product documentation

Table 2: Starter Kit

Component	Quantity	Description
Tooth Preparation Kit	1 box	20 bottles of SureWhite with brushes
Optical cloths	1 bag	Used for cleaning the orascanner 2 mirrors.

Table 3: Additional accessories*

Component	Description
Computer (laptop or desktop)	The computer used with the orascanner2 must meet the system requirements specified in the current version of the *suresmile Technical Requirements Guide*. In addition, one of the following three conditions must be met: **Condition 1:** Computer (laptop or desktop) must be specifically designed for use in a medical environment. **Condition 2:** Any laptop computer running solely on battery power can be used, but the laptop must be disconnected from a power cord to eliminate the direct connection between a power outlet and the patient. **Condition 3:** Any computer (laptop or desktop) can be used but it must be plugged into a medical grade isolation transformer. **Attention: Apple Mac Users** Use of the orascanner 2 and surescan under Mac OS X or in a virtualized Windows environment is not supported. Only Windows-based computers can be used. For more information, please refer to the *Systems Requirements* section of the *suresmile Technical Requirements Guide*.
Isolation Transformer	An isolation transformer is a special kind of electrical current transformer that is designed to provide protection to a medical device operator and the patient. An isolation transformer is only needed if you are scanning a patient with the orascanner 2 connected to a computer running on electrical current from a power outlet. If you are scanning a patient with the orascanner 2 connected to a computer running solely on battery power, an isolation transformer is not required. There are numerous devices commercially available. Just make sure the device you use complies with IEC 60601-1 and any local regulations.
Network Isolator	Network isolators are used in the medical industry to protect patients against leakage currents. A network isolator is only needed if you are scanning a patient with the orascanner 2 connected to a computer physically connected to your practice's network. If you are wirelessly connecting to your practice network, a network isolator is not needed. There are numerous devices commercially available. Just make sure the device you use complies with IEC 60601-1 and any local regulations.

** These **items** are not supplied by OraMetrix. The practice is responsible for procuring these items from other vendors/suppliers.*

2.2.1 orascanner 2 Performance

- Measurement uncertainty – less than 0.05 mm
- Depth of field – up to 18 mm (see Figure 3)
- Center of focus – approximate midpoint of depth of field

2.2.2 How the orascanner 2 Works

The orascanner 2 is a handheld wand with detachable mirror attached by USB cable to a computer.

Figure 1: suresmile orascanner 2

The orascanner mirror extends into the patient's mouth to maximize visibility of the dentition. The mirror is heated to 43°C/110°F to prevent fogging from the patient's breath. The orascanner mirror is detachable for disinfection after scanning.

The orascanner 2 is a 3-dimensional (3D) camera and high-precision measuring instrument. It contains a video camera coupled with a projector. Flashes of white light are reflected from the mirror at the end of the orascanner 2 onto the teeth. Between flashes of white light, a second light flashes to project a color-encoded pattern that bends across the curves of the dentition. Similar to flash photography, the image of the pattern is captured at the same time the light flashes. Each image consists of hundreds of points that connect to a 3D wireframe and form a model.

It only takes a few minutes to perform a scan of an arch. As you capture images intraorally, the model (or digital impression) is built on-screen.

NOTICE	
(i)	Do not use external spotlights while scanning.

In Figure 2 and Figure 3, notice that the focus of the orascanner 2 is directly below the mirror. The yellow (shaded) areas indicate the path of the light between the camera, the mirror, and the teeth. Be careful not to block this path with the anterior teeth or lips. Figure 2 and Figure 3 also depict the depth of field and the center of focus, indicating the correct distance to position the orascanner mirror in relation to the teeth.

CAUTION	
⚠	The operator and patients should not look directly into the flashing light.

Projection

Camera

22 mm

Figure 2: orascanner 2 Light Path

45°

z

X

projected mirror height

depth of field 18 mm

center of focus
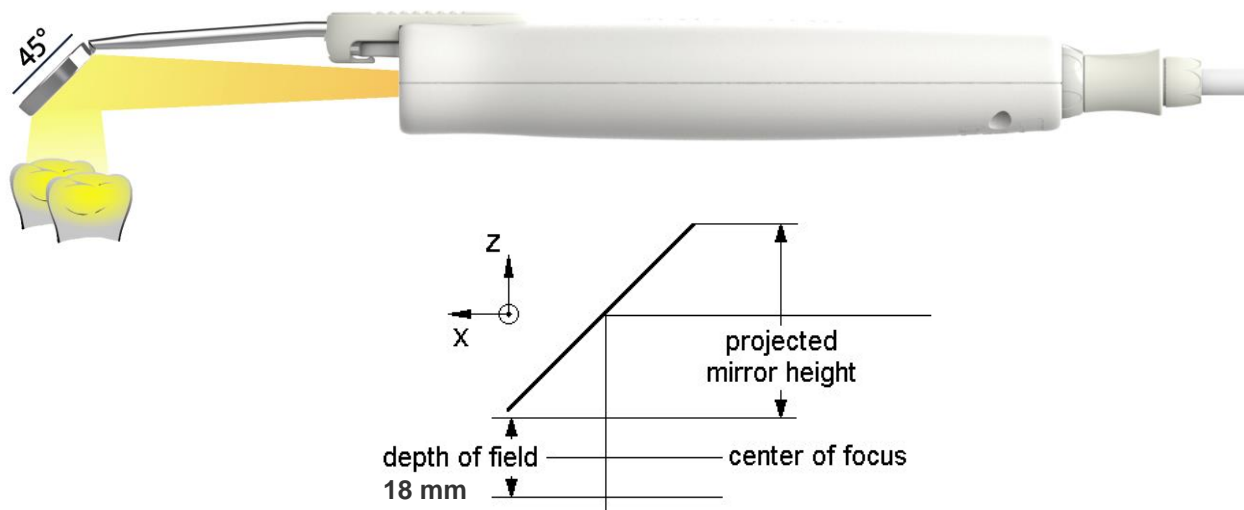
Figure 3: orascanner 2 Refraction Angle

NOTICE	Do not block the projection or camera as indicated by the shading in Figures 2 and 3.

WARNING	Do not mishandle the orascanner. Rough handling may result in failure of the unit.

2.2.3 Connections

Connect the orascanner 2 as shown.

Medical-grade isolation transformer connected to wall electrical power outlet

USB wireless footswitch receiver

Wireless footswitch

Laptop computer with wireless LAN

orascanner® 2 with USB cable in cradle

Figure 4: Configuration

2.2.3.1 Safety Precautions

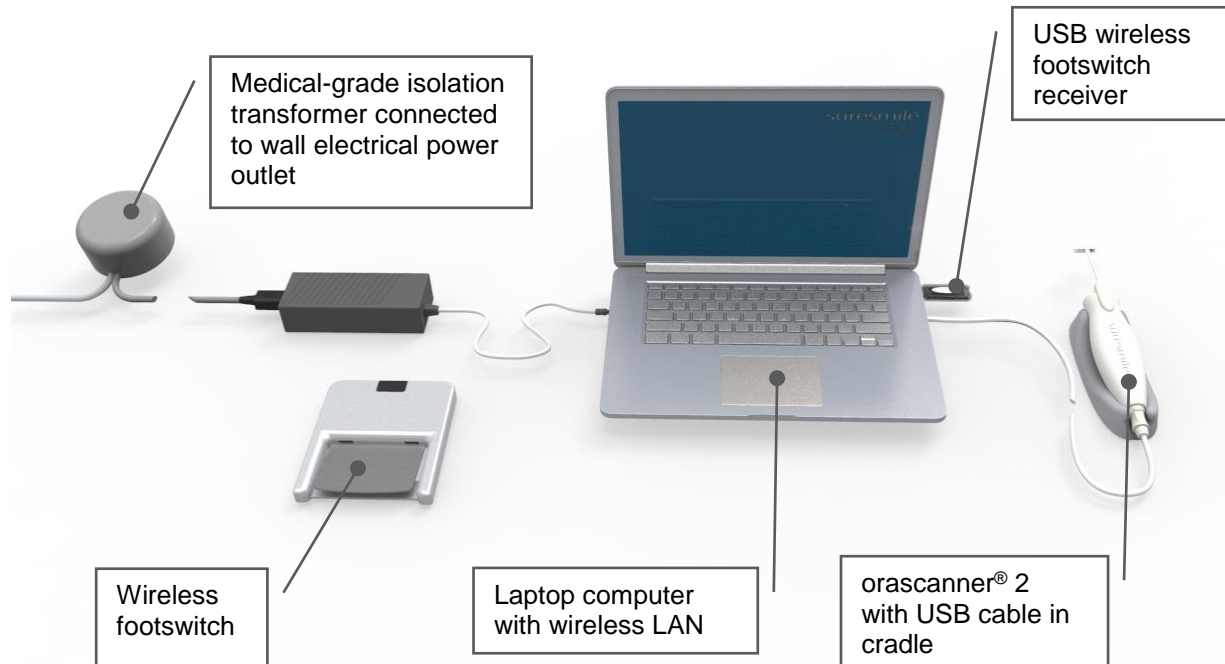| WARNING ⚠	Connect the orascanner 2 only to a medical grade laptop or desktop computer that fulfills the requirements of the current version of IEC 60601.
	The computer power supply must be connected to a medical grade isolation transformer which in turn is connected to a power source (electrical outlet) with proven earth ground (hospital-grade receptacle), or with comparable safety.
	A cable with signs of wear or damage must not be used or repaired; it must be replaced.
	Do not connect any additional device that has a separate power input (e.g., monitor, printer, external drives, hard drives, other networks) to any interface (keyboard, mouse, audio, printer, serial port, USB, FireWire, VGA or DVI) of the computer or laptop. Any additional electrical connection may disable the safety protection of the system, and may lead to harmful electrical injuries to patients or bystanders.
	Use of a wireless (i.e., WiFi) local area network (LAN) is recommended. However, if the computer is physically connected to a LAN, a network isolator must be used. See *Table 3: Additional accessories** for more information.
	Do not plug the orascanner cable into a USB connector.

CAUTION	
⚠	The orascanner 2 is a precision-measuring device and should be handled with care. Do not bend, pinch, or crimp the USB cable. Do not force the cable into the wand.

2.3 Equipment Maintenance

It is the responsibility of the operator to perform routine disinfection, storage, and maintenance in accordance with the hygienic policy of the clinic. This will also extend the useful life of the equipment.

2.3.1 Following a Maintenance Routine

OraMetrix recommends the following maintenance routines in your office. The operator should perform the following tasks.

2.3.1.1 Before Each Use

- Clean the front window and the orascanner mirror as needed with an optical cloth.
- Visually inspect the orascanner mirror for any obvious signs of wear or damage.

2.3.1.2 After Each Use

- Disinfect the orascanner mirror.
- Disinfect the orascanner 2.

2.3.1.3 Daily

- Visually inspect the orascanner mirror for any obvious signs of wear or damage.
- Clean the orascanner mirror mount area of the handheld unit as described in *Cleaning the* below.

2.3.1.4 Weekly

- For optimum software operations, reboot desktop or laptop computer weekly or after every five scans, whichever occurs first.

CAUTION	
⚠	Before using any disinfectant, read the instructions from the manufacturer.

2.3.2 Cleaning the orascanner mirror

You will be supplied with multiple orascanner mirrors. The orascanner mirror consists of a mirror and neck mounted in a base, which clips to the hand-held unit. Clean it *after each patient use.*

To clean the orascanner mirror:

1. Carefully remove the orascanner mirror by pulling it away from the orascanner 2.
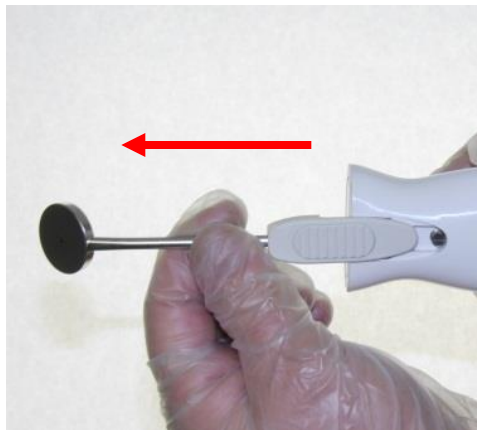

Figure 5: Removing the orascanner mirror

2. Since it is in contact with the oral mucosa, the orascanner mirror is a semicritical medical device. It is your responsibility to determine the required disinfection protocol by checking with the agency that regulates medical hygiene in your practice location.[1] At a minimum, perform a 30 minute, high-level immersion disinfection with an appropriate disinfection solution that is a final bactericidal, fungicidal and virucidal.

   You can use disinfection solutions that contain an aldehyde or a combination of hydrogen peroxide and phosphoric acid. Follow the manufacturer's instructions when using these disinfection solutions. OraMetrix recommends the following disinfection solutions:

Disinfection Solution	Manufacturer
Banicide®	Pascal International
CIDEX® OPA Instrumentendesinfektion	Johnson & Johnson
CIDEX® OPA Solution	Johnson & Johnson
CIDEX® Plus	Johnson & Johnson
DESODELTA S NEU	Desomed -Dr. Trippen GmbH
DESTAsept ID + R plus	Dr. Schumacher GmbH
PdCare®	Patterson dental
ProCide-D™	Metrex research
SPOROX II	Sultan Healthcare

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[1] Here are a few examples of agencies that regulate medical hygiene: Robert Koch-Institute – RKI (Germany); Australian Commission on Safety and Quality in Health Care; Centers for Disease Control and Prevention (USA); Public Health Agency of Canada.

CAUTION ⚠️	OraMetrix only guarantees compatibility of the mirrors with the specified disinfectant solutions.
	Avoid soaking the mirror with other instruments that may scratch or damage it.
	Do not soak the orascanner mirror in these solutions past the manufacturer's recommended time for a high-level disinfection. It is not necessary to soak the orascanner mirror to the point of sterilization. Soak times past 90 minutes may degrade the mirror, potentially causing risk to the patient.
	Do not sterilize the orascanner or an orascanner mirror in an autoclave.
	Do not place the orascanner mirror in an ultrasonic cleaning unit. Ultrasonic cleaning erodes the mirror adhesive.
NOTICE ℹ️	These high-level disinfectants are specifically produced for heat-sensitive medical devices. The method of cleaning the orascanner mirror is similar to that for cleaning other intraoral mirrors. However, the orascanner mirror is more vulnerable to scratching due to a high-tech surface coating that enables very high light reflection.

3. Rinse the orascanner mirror with water and gently dry it with an optical cloth.

NOTICE ℹ️	It is important to rinse the orascanner mirror because rinsing: • removes the chemicals for the patient's safety. • removes the disinfectant film from the mirror. This film interferes with scanning, erodes the base mount, and significantly reduces the lifespan of the orascanner mirror.

4. Place the orascanner mirror in a location where the mirror will not become contaminated or damaged.
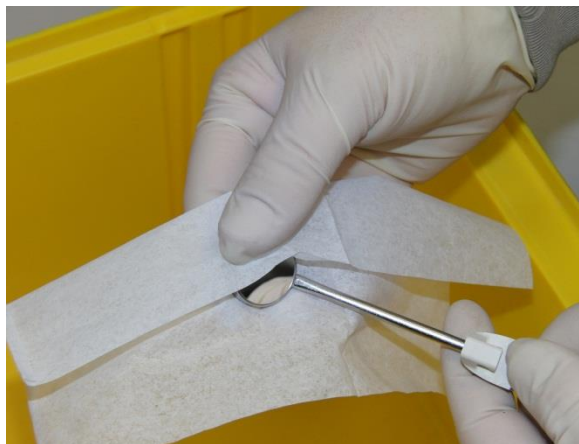
Figure 6: Cleaning the Mirror

CAUTION ⚠️	Be careful not to scratch the mirror.

2.3.3 Cleaning the orascanner 2

To clean the orascanner 2:

1. Apply a spray disinfecting solution to a paper towel according to the hygienic policy of the clinic. Wipe down the handheld portion of the orascanner 2.

2. Wipe the orascanner 2 front window with an optical cloth as shown (Figure 7).
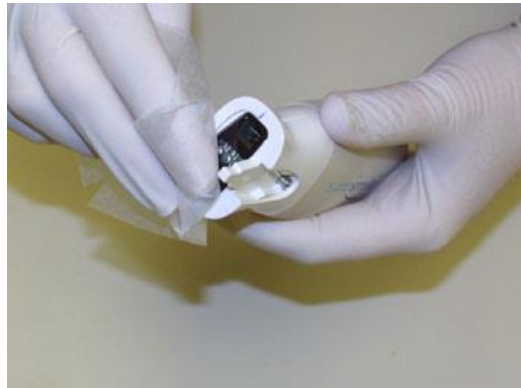
Figure 7: Cleaning the orascanner 2 Front Window

To clean the orascanner mirror mount:

1. Carefully remove the orascanner mirror from the orascanner 2.

2. Dip a cotton swab into alcohol (isopropanol or ethanol) and rub it over the area (Figure 8). Keeping the area clean extends the life of the clips connecting the orascanner mirror to the orascanner 2 hand-held unit.

Figure 8: Cleaning the orascanner mirror Mount

CAUTION	
⚠️	*Do not* apply a spray disinfecting solution directly to the orascanner 2 or its cable.

2.3.4 orascanner 2 USB cable replacement

You should replace the orascanner 2 USB cable if:

- The cable has been bent and there is a permanent kink in it.

- The cable plastic covering is cracked or torn.

- The connector to the laptop or the orascanner is loose or is becoming separated from the cable.

- You notice interruptions in scanning when you move or shake the cable.

CAUTION	Make sure to follow the steps below in the order listed. Doing otherwise may damage the orascanner.

Follow these steps to replace the orascanner 2 cable:

1. Disconnect the cable from the PC or laptop.

2. Disconnect the connector at the orascanner 2 only after it has been disconnected from the PC or laptop. Disconnect by pulling the connector in the direction of the cable (Figure 9). Do not pull on the cable.

3. Connect a new orascanner 2 USB cable to the orascanner 2 by pushing the connector in direction of the orascanner 2 until it clicks.

4. Connect the USB connector of the new cable to your PC or laptop. Do this only after the new cable has been connected to the orascanner 2.

Figure 9: Removing the USB Cable from the orascanner 2

If you remove the connector from the orascanner 2 first or connect it to the orascanner 2 after the cable is connected to the PC or laptop, the orascanner 2 may not automatically connect to suresmile. If this happens, remove the cable from the PC or laptop, wait two minutes and then reconnect it to the PC or Laptop.

If you still have problems, please contact suresmile customer care. See the inside front cover of this manual for contact information.

3.   Technical Addendum

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The orascanner 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the orascanner 2 should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF-emissions CISPR 11	Group 1	The orascanner 2 uses RF for the operation of its wireless footswitch only at the frequency 2.4 GHz. Its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF-emission CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	The orascanner 2 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.
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration - Electromagnetic Emissions			
The orascanner 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the orascanner 2 should ensure 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	± 6 kV Contact ± 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/ bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for I/O lines (input/output)	± 2 kV for Power supply lines ± 1 kV for I/O lines	Main power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Main 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 UT) for 0,5 cycle 40% U_T (60% dip in UT) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles 0% for 5000 ms	< 5% U_T (> 95% dip in UT) for 0.5 cycle 40% U_T (60% dip in UT) for 5 cycles 70% U_T (30% dip in U T) for 25 cycles 0% for 5000 ms	Main power quality should be that of a typical commercial or hospital environment. If the user of the orascanner 2 requires continued operation during power main interruption, it is recommended that the orascanner 2 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC Main voltage prior to application of the test level.			

Recommended separation distance between portable and mobile RF communications equipment and the orascanner 2

The orascanner 2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the orascanner 2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitter) and the orascanner 2 as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter (watts)	Separation distance according to frequency of transmitter power of transmitter (meters)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.4
10	3.69	3.69	7.8
100	11.67	11.67	23.34

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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: To calculate the recommended separation distance of transmitters in the frequency range at 80 MHz to 2.5 GHz, an additional factor of 10/3 was used to include the possibility of disturbances caused by the unintentional introduction of mobile or portable communication equipment into the patient area.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The orascanner 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the orascanner 2 should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the orascanner 2 (including cables) than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
			$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
		((•))	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and is the recommended separation distance in metres (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: ((•))

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/FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access 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 orascanner 2 is used exceeds the applicable RF compliance level above, the orascanner 2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the orascanner 2.

b. Field strengths should be less than $[V_1]$ V/m over the frequency range 150 kHz to 80 MHz,

3.1 Environmental and Storage Conditions

The suresmile system components are suitable for use in a standard office environment.

Environmental Parameters		
Power	Power supply orascanner 2	5V === 500mA per USB Port
Temperature	Operating	From +10° C to + 30° C or 50° F to 86° F
	Storage (non-operating)	From -15° C to +45° C or 5° F to 113° F
Humidity	Operating outside of mouth	18 – 80% RH, non-condensing
	Operating inside mouth	95% RH
	Storage (non-operating)	90% RH for 90 hours at 65°C or 149°F
Altitude	Operating	3 km or 1.86 miles
	Storage (non-operating)	4.6 km or 2.86 miles

The image acquisition process may be influenced by high levels of electromagnetic interference (EMI).

The orascanner 2 is protected against EMI generated by devices that meet the limits of FCC part 15 class A/B.

3.2   Regulatory Information

The versions of the suresmile system meet the appropriate requirements of each market region.

The orascanner 2 has been tested to meet the requirements of IEC60601-1 for safety, and the requirements of IEC60601-1-2 for Electromagnetic Compatibility and Electromagnetic Immunity.

The orascanner mirror is the only applied part in the suresmile system. It is galvanically isolated from all other system components.

The suresmile system is classified as follows:

3.2.1 USA

The suresmile system has been accepted by the FDA as a Class I medical device.

The orascanner 2 has been tested to meet the safety requirements of ANSI/AAMI ES60601-1 (2005) and UL 60601-1.

The wireless footswitch contains RF-Modules with FCC ID: OA3MRF24J40MA

3.2.2 Canada

The suresmile system has been accepted by Health Canada as a Class I medical device.

The orascanner 2 has been tested to meet the requirements of CAN/CSA-C22.2 No. 60601-1 (2008) and CAN/CSA-C22.2 No. 601.1.

 The wireless footswitch contains RF-Module with IC: 7693A-24J40MA

3.2.3 EU

According to the Medical Device Directive (MDD), the suresmile system is a Class I medical device with measuring function.

The respective components are CE marked. The declaration of conformity is available upon request.

3.2.4 Australia

The suresmile system has been accepted by the Therapeutic Goods Administration (TGA) as a Class I medical device with measuring function.

Notes

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to be sure.