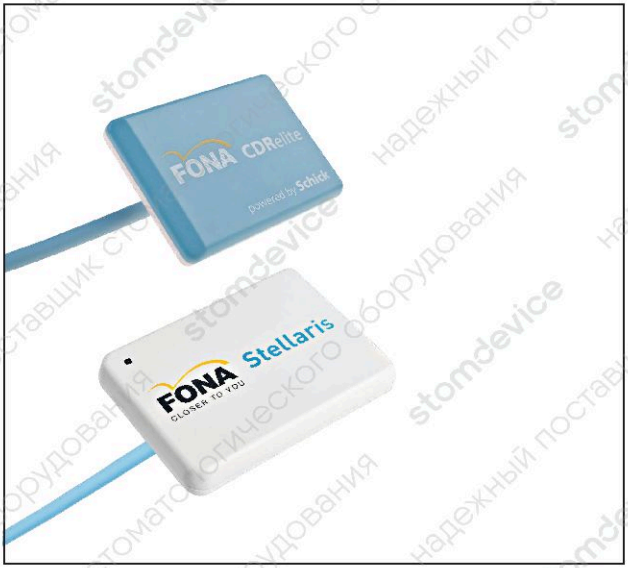
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FONA
CLOSER TO YOU

FONA Stellaris / CDRelite Sensor

Quick User Guide - Please Read This First

English



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1. Getting started

Dear Customer

Congratulations on the purchase of your FONA Stellaris / FONA CDRelite system.

FONA Stellaris combines high-resolution image acquisition and an easy-to-use design that includes in-office serviceable cables, which is also benefit of FONA CDRelite.

The FONA Stellaris/CDRelite system acquires intraoral X-ray images and transmits them by USB connection to desktop or laptop PCs. There are two main devices in the system: the *FONA Stellaris/ FONA CDRelite Sensor*, which acquires the intraoral X-ray images and the *FONA USB Stellaris / CDRelite Remote Interface* (referred to as the *USB Interface* for the remainder of this document), which sends the images by USB cable to the PC. Images can be viewed, enhanced, saved, and printed.

To install the system, please follow the steps starting on Page 3 of this Guide. For the latest updates, please check our website at www.fonadental.com.

The illustration on the next page shows the location of visual indicators and connections to your FONA Stellaris / FONA CDRelite system.

Latest information

For complete details about your FONA Stellaris system / FONA CDRelite system and the latest software, please visit our website at www.fonadental.com

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2. FONA Stellaris / CDRelite at a glance



FONA Stellaris / CDRelite connections and LED indicators

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3. Get the most out of your sensor

Have the right sensor size for every patient

FONA sensors are available in sizes 0, 1 and 2. Get the right size for every patient, big and small.



Serve multiple workplaces with one sensor

Do you have more chairs, or even treatment rooms, where you need to use your sensor? Don't carry around miles of cable! Ask about additional USB Remote modules for convenient sensor portability.



Make sure you get the best image quality

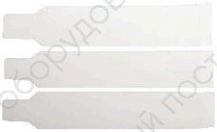
Less movement means sharper images. Positioners hold the sensor where you need it to be. Get either adhesive or grip system versions to fit all sensor sizes.



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Prevent cross-contamination

Always use the hygienic sheets with your sensor to prevent cross-contamination. Available in packs of 100 or 300 pieces.



Protect your investment and workflow

Should anything happen to the sensor cable, you can simply replace it on-site and continue your work.



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4. Installation and operation

Prepare for Installation

- Exit Image acquisition software
- Verify that the FONA Stellaris/CDRelite USB Interface is NOT connected to laptop or desktop PC. If connected, disconnect the FONA Stellaris/CDRelite USB Interface by unplugging the USB cable.

Install the FONA Stellaris / CDRelite USB Interface Driver

- Visit our website at **www.fonadental.com/support** to download and unzip the latest driver.
- Find FONA Sensor drivers and install the FONA USB Driver.
- If prompted, click Yes to install Microsoft's .NET framework.
  This may take up to 5 minutes to complete.
- Follow the on-screen instructions until installation is complete.
- If prompted, click Yes to restart the laptop or desktop PC.

Connect the USB Interface

- Connect the USB cable to the USB Interface.
- Connect the USB cable to the laptop or desktop PC.
  The amber LED on the FONA Stellaris/CDRelite USB Interface illuminates momentarily.
- Connect the FONA Stellaris / CDRelite Sensor to the FONA Stellaris/CDRelite USB Interface. The green LED on the Sensor side of the FONA Stellaris/CDRelite USB Interface illuminates.

Verify Firmware Version

- Click Windows > Start > All Programs > CDR DICOM for Windows > Upgrade Utility.
- Upgrade any Firmware / FPGA number in red by clicking the appropriate button.
- When the upgrade is complete, verify that all version numbers are green. If any version numbers remain red, please contact your service provider for FONA products.
- Click Close to exit the utility.

Start Imaging Program and Take Sample Exposures

- Start your imaging program, refer to the User Guide for instructions.
- Create a sample X-ray patient.
- Place a radio-opaque object like a coin or clip on the active side of the Sensor.
- Take several sample exposures and verify image quality.

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5. LED Indications

Normal indications

LED	Color	Indication	Description
	Green	ON	Sensor is connected, imaging software is running, and device is ready to support image acquisition.
	Green	ON	Sensor is connected, and imaging software is running.
	Amber	FLASHING	Sensor is connected, imaging software is running, and device is ready to receive, or is receiving, image from Sensor.

Error indications

LED	Indication	Sensor	Description
	FLASHING	Connected	Low current condition. Replace Sensor cable. Replace Sensor if problem persists.
	OFF	Connected	Cable short or overcurrent condition. Replace Sensor cable. Replace Sensor if problem persists.
	AMBER	Connected or not connected	Low USB voltage condition. Use FONA USB cable or try different USB port / hub.
	AMBER OR GREEN (Other LEDs Flashing)	Connected	Start the Upgrade Utility and refer to diagnostic messages for corrective action.

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6. Setup of the acquisition button in OrisWin DG Suite

Create test patient

1. Create the test patient and open the image folder.

Sensor type setup

2. To set-up the sensor, go to the settings in bottom taskbar:



Acquisition button setup

3. Select the acquisition button you want to setup.



Sensor type selection

4. Select the type of sensor from the list.

Save the settings



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7. Sensor Calibration

Calibration data for FONA Stellaris / CDRelite Sensors are programmed directly into the Sensor. A separate calibration disk is not needed.

Calibration files installation

1. Verify that all FONA Stellaris system cables are connected securely.
2. Verify that all FONA Stellaris system cables are connected securely.
3. Start OrisWin DG Suite and launch the acquisition. OrisWin DG Suite will automatically detect the Sensor and determine whether a calibration file has been installed for this Sensor previously. If the calibration file was not installed already, it will be copied from the Sensor itself.

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8. First image look in OrisWin DG Suite

OrisWin DG Suite software enables the clinician to optimize image presentation to a desired levels of visibility of various structures. These settings are applied at display time and do not affect the original image data. The original image is always available using the button Original Image.

Original image

Click on this button to get back to original image.



For further settings / presets refer to the User manual of OrisWin DG Suite software.

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9. ⚠ Safety and Compliance

Check FONA Stellaris Sensor / FONA CDRelite, USB Interface, and USB Cable before Using Them	Before each usage, check the outer surface of the FONA Stellaris / CDRelite Sensor and cable, the USB Interface, and the USB cable for any signs of physical damage or defect. FONA Stellaris / CDRelite Sensor and USB Interface surfaces should have a smooth finish, with no evidence of chipping or damage and the cables should appear undamaged. If visual defects are detected, discontinue use and contact your local distributor of FONA products for further instructions.
Do Not Touch Exposed Connectors on Non-Medical Equipment and the Patient at the Same Time	When the FONA Stellaris / CDRelite Sensor and USB Interface are in use, avoid touching exposed connectors on non-medical electrical equipment and the patient at the same time. The human body is capable of conducting electrical current and may cause a shock hazard to patients if appropriate safety practices are not observed.
Follow All Instructions to Ensure Cable Replacement Procedures are Performed Correctly	Follow all instructions to ensure the successful replacement of your FONA Stellaris cables. When performing the cable replacement procedure, it is especially important to tighten the screws that attach the cable to the Sensor by turning them at least one-quarter revolution clockwise after initial resistance or until they cannot be turned any further. An improperly attached cable may cause an intermittent connection and prevent the Sensor from operating effectively. Refer to the FONA Stellaris User Guide for complete instructions.
Use Only USB Cables Approved for the FONA Stellaris / CDRelite System	For normal operation of your FONA Stellaris system and to ensure compliance with regulatory EMC and EMI standards, use only the USB cables described and specified for your system. Refer to the FONA Stellaris User Guide for details.
Do Not Connect Items that are Not Part of the System	Only items specified for use with the FONA Stellaris / CDRelite Sensor and USB Interface are to be connected to it. The device should not be used adjacent to other equipment that is not part of the system. If, however, use with adjacent equipment is necessary, normal operation should be observed and verified in that configuration.
RF Interference Considerations	Although the FONA Stellaris / CDRelite Sensor and USB Interface are designed to provide a reasonable degree of protection from electromagnetic interference, according to IEC International regulations, they must be installed at an adequate distance from electricity transformer rooms, static continuity units, two-way amateur radios and cellular phones. To ensure proper operation, the latter (meaning, electricity transformer rooms, static continuity units, two-way amateur radios and cellular phones) can be used only at a minimum distance of 5 feet (1.5m) from any part of the FONA Stellaris / CDRelite Sensor and USB Interface. Any instrumentation or equipment for professional use located near the FONA Stellaris / CDRelite Sensor and USB Interface

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must conform to Electromagnetic Compatibility regulations, to which the EMC tables in the Appendix of the FONA Stellaris User Guide serve as guidance. Non-conforming equipment, with known poor immunity to electromagnetic fields, may not operate properly unless they are installed at a distance of at least 10 feet (3m) and supplied by a dedicated electrical line.

Apply Recommended Procedures for Cleaning the Equipment

Safe and proper operation of the equipment requires following a regular schedule of preventive maintenance. Refer to "Protective Measures" in this document for details.

Although water-resistant, the Sensor should never be soaked or submerged in disinfecting solution during any cleaning procedure. Failure to comply with this precaution may cause liquid to enter the Sensor and can prevent it from operating properly.

Installers to Ensure that FONA Stellaris / CDRelite Sensor and USB Interface Operate Optimally

Installers must ensure that the FONA Stellaris / CDRelite Sensor and USB Interface provide the user with the optimal use of the equipment. This includes, but is not limited to, ensuring that the system operates as described in this document. To avoid unintentional contact with the USB Interface by the patient, place the USB Interface in a location where accidental contact is prevented.

Installers must also ensure that the system presents no physical obstacles or hazards during operation and when not in use. To verify this requirement, installers shall confirm that the FONA Stellaris / CDRelite Sensor and USB Interface are installed as described in the FONA Stellaris User Guide and shall perform the appropriate procedures therein.

Only Dentists or Authorized Designees Are Permitted to operate the System

To ensure the correct use of the FONA Stellaris / CDRelite Sensor and USB Interface in a clinical environment, for purposes that correspond to its intended design and application, only dentists, or their designees, are authorized to operate the system.

Ensure Proper System and PC Workstation Installation and Operation

The FONA Stellaris / CDRelite Sensor and USB Interface have been determined to be in accordance with international safety standards and are deemed suitable for use within the patient area, which extends from the patient for a distance of 5 ft (1.5m). To comply with these standards, do not operate non-medical equipment (such as a PC workstation) inside the patient area.

Outside the patient area, the presence of approved non-medical grade equipment and Listed / Approved / IEC 60950-1 certified Information Technology Equipment (ITE) computer equipment is acceptable.

The host computer (PC workstation) should be CE-approved and conform to the Low Voltage [73/23/EC] and EMC Directive [89/336/ERC]. Also, to help ensure optimal performance, ensure that all software programs residing on the workstation are virus-free and have been adequately tested so they will not

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impact imaging applications after installation.

Product Manuals from FONA

The contents of this document are subject to change without prior notice. For the latest version of this guide and other information from FONA, visit our website: www.fonadental.com.

Operate the FONA Stellaris / CDRelite Sensor and USB Interface as Directed

Always use the FONA Stellaris / CDRelite Sensor and USB Interface in accordance with the directions and recommendations contained in the FONA Stellaris / CDRelite User Guide. Do not attempt to modify the FONA Stellaris / CDRelite Sensor and USB Interface or use it in system configurations not specified in the User Guide.

Protect Sensor from Potential ESD Damage

Like other electronic devices, your FONA Stellaris / CDRelite Sensor is susceptible to electrostatic discharge (ESD), particularly when the device is used in or around carpeted areas or low-humidity environments. During cable replacement, when Sensor contacts are exposed, it is especially important to protect the device from potential ESD damage.

Touching a metal surface prior to replacing the cable will reduce the risk of damaging Sensor components by accidental static discharge. Using anti-static floor mats will also help eliminate static build-up in your office.

Wait for Appropriate Prompts before Operating X-ray Source

To avoid exposing the patient to unnecessary X-rays, ensure that the OrisWin DG Suite exam window viewbox is flashing green (default color) before triggering the X-ray Source.



Always Use Sheaths with FONA Sensors

Use sheaths every time the Sensor is used. Never use a damaged sheath. Always dispose of the sheath after every patient.

Protective sheaths are single-use items and must not be reused under any circumstance. Reuse of single-use items/instruments may cause them to become contaminated, compromise their intended function, and result in patient and user infection, injury and/or illness.

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Patent Notice

Sirona Dental, Inc. products are covered by one or more US patents. For a current listing, please type Patent Notice into the Search box of the Schick by Sirona website at www.schickbysirona.com.

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We reserve the right to make any alterations which may be required due to clinical improvements

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