Generic / Preliminary

Sirona

USER MANUAL

Caution: **FEDERAL LAW RESTRICTS THIS DEVICE FOR SALE TO OR ON THE ORDER OF A PHYSICIAN.**

Carefully read all instructions prior to use. Observe all warnings and precautions noted in these directions. Failure to do so may result in patient complications.

IntriCon Datrix
340 State Place
Escondido, CA 92029

Table of Contents

Notices

Conventions Used in this Manual

 **WARNING** Warning statements describe conditions or actions that can result in personal injury or loss of life.

 **CAUTION** Caution statements describe conditions or actions that can result in damage to the equipment or loss of data.

NOTE Notes contain additional information on usage.

Manufacturer's Responsibility
IntriCon Datrix considers itself responsible for effects on safety and performance only if:

1. Readjustments, modifications or repairs to the IntriCon Datrix Holter/Event recorders are carried out only by IntriCon Datrix authorized personnel.
   AND
2. The IntriCon Datrix SIRONA is used as presented in this manual.

The warranty is only valid if you use IntriCon Datrix approved replacement parts and accessories.

User Responsibility
The user of this product is responsible for ensuring the implementation of a satisfactory maintenance schedule. Failure to do so may cause undue failure and possible health hazards.

Equipment Identification
IntriCon Datrix equipment is identified by a serial number on the back of the device. Take care not to deface these numbers.

Copyright and Trademark Notices

Other Important Information
IntriCon Datrix reserves the right to change or amend this manual at anytime without notice.

IntriCon Datrix makes no warranty of any kind with regard to this material, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. IntriCon Datrix shall not be liable for errors or omissions that may appear in this document. IntriCon Datrix makes no commitment to update or to keep current the information contained in this document.

Before using the IntriCon Datrix SIRONA Holter/Event recorder read this manual in its entirety and become thoroughly familiar with the contents.

User Safety Information

Intended Use
The SIRONA APETS recorder is a small, portable, digital Holter/Event recorder intended for use by medical professionals to acquire ECG data from a single patient in a clinical, point of care or outpatient setting. ECG data is first recorded to a Secure Digital (SD) card and then transferred to a Holter/Event analysis system for review by a physician or other qualified professional.

Explanation of Symbols


READ MANUAL FIRST


KEEP AWAY FROM MOISTURE


TYPE BF DEVICE


DC CURRENT


NON-IONIZING RADIATION


ELECTRONIC EQUIPMENT
DISPOSE OF PROPERLY


MANUFACTURER / MANUFACTURE YEAR

IP54 RESISTANT TO WATER AND DUST INGRESS
(when patient cable is attached)

Warnings

1. This device captures and presents data reflecting a patient's physiological condition that when reviewed by a trained medical professional can be useful in determining a diagnosis. However, the data should not be used as sole means for determining a patient's diagnosis.

2. Use of accessories other than those recommended by IntriCon Datrix may compromise product performance.
3. To maintain designed operator and patient safety, any peripheral equipment and accessories that can come in direct patient contact must be in compliance with IEC 60601-1.
4. Hardware is designed to meet or exceed IEC 60601-1-2, however some environmental electrical interference may cause an artifact in the ECG. The quality of ECG signals may be adversely affected by electromagnetic interference from environmental sources resulting in non-physiological waveforms with the potential for misinterpretation.
5. This device is not intended for use during an MRI.
6. Before performing defibrillation or applying any high frequency surgical equipment to a patient, remove SIRONA leads and electrodes from the chest area. Cable leads or electrodes trapped under defibrillator pads or paddles during defibrillation or electrodes in contact with high frequency electrosurgical equipment can cause patient burns.
7. Once one or more SIRONA patient leads are connected to a patient, do not allow patient leads to meet with any grounded or live parts. Contact could cause unacceptable levels of electrical current to flow to the patient.
8. The equipment is not intended for infants weighing less than 10 kgs.

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Cautions

1. Although the plastic enclosure is designed for a clinical environment and can resist moisture, neither the device nor patient cables should be subjected to autoclaving or steam cleaning.
2. Recommended cleaning procedure is to wipe the exterior surfaces with a cloth dampened with warm water and mild detergent solution and then dry with a clean soft cloth.
3. No serviceable parts are inside. The case cannot be opened without destroying it.
4. Do not pull or stretch patient cables, as this could result in mechanical and/or electrical failures. Store patient cables after use by forming them into a loose loop.
5. Align patient cable connector key and SIRONA key before plugging in patient cable. Forcing misaligned connectors can damage connector pins.
6. Avoid shock or sudden impact.

Notes:

1. Excessive patient movement could interfere with the operation of the device.
2. Proper patient preparation is important to successful application of ECG electrodes and operation of the device.
3. This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by IntriCon for compliance could void the user's authority to operate the equipment.
4. 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 wireless transmission off and on,then the user is encouraged to consult the dealer.

Section 1: Introduction

This manual is written for clinical professionals. It is assumed that the reader has a working knowledge of medical terminology and procedures as required for monitoring cardiac patients.

Purpose of the User Manual

The User Manual describes how to safely operate the SIRONA Holter/Event recorder, Smart Dock and linkStream. In the manual, the following are described:

- Preparing the device for use
- Understanding and using the keyboard
- Acquiring and storing ECG data
- Transmitting stored ECG data
- Maintenance

System Description

The SIRONA Holter/Event recorder is a portable, battery-operated ambulatory ECG recorder used by trained technicians to collect ECG data from patients in a clinical, point-of-care or outpatient setting. SIRONA provides ECG waveform analysis and automated transmission of ECG data for review by a physician or other qualified professional. ECG data is stored on an internal SD card and can be accessed through the Smart Dock interface or by transmitting the data over a telephone line. Smart Dock is an interface between a PC based application called Sirona Viewer and the SD card in Sirona. Smart Dock has two functions –

1) Charge the battery in Sirona
2) Access the data stored on the SD card in Sirona

linkStream is an accessory which provides the convenience of checking lead hook-up wirelessly.

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Section 2: Getting Started

Batteries

The Sirona uses an internal lithium polymer battery that is not accessible in the field. The battery is designed to last for the life of the product.

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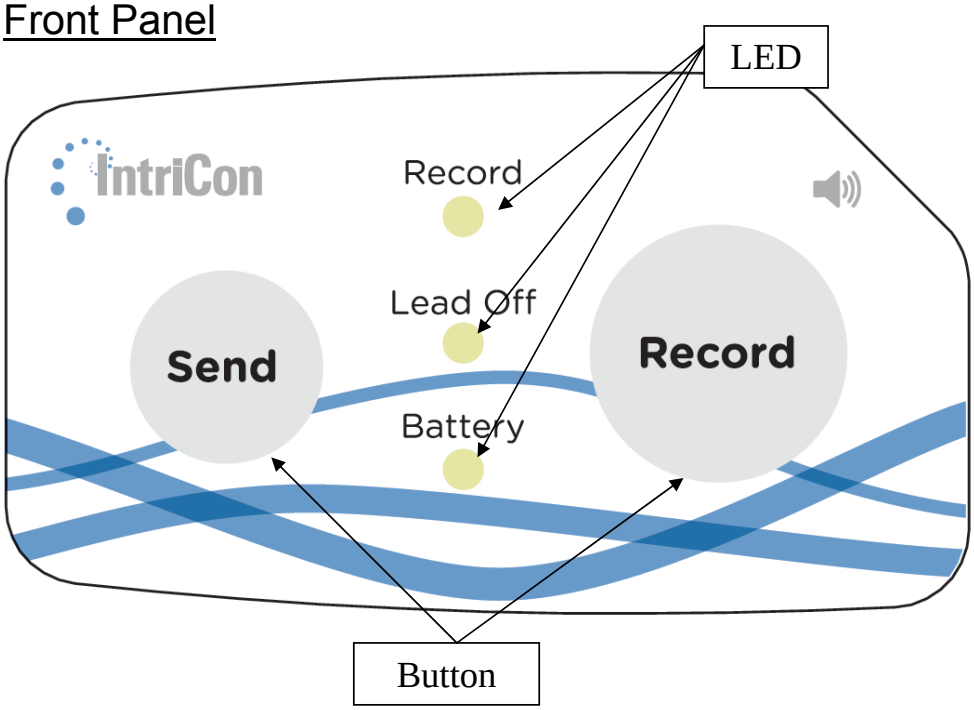
Caution: THE BATTERIES USED IN THIS DEVICE MAY PRESENT A FIRE OR CHEMICAL BURN HAZARD IF MISTREATED. DO NOT DISASSEMBLE, HEAT ABOVE 100° C (212° F) OR INCINERATE.

Caution: DISPOSE OF ALL BATTERIES IN ACCORDANCE WITH ALL APPLICABLE LOCAL REGULATIONS

KEEP AWAY FROM CHILDREN.

Front Panel



The Sirona front panel contains two buttons and five LED lights (Light Emitting Diodes) as follows:

- Record Button
- Send Button
- Record Green or Red LED
- Lead-off Red LED
- Battery Green or Red LED

Section 3: Initial Device Setup

Setting Parameters

One of the advantages of this device is that it can easily be configured to work in different modes, and with different operational parameters. In order to enable this, the device has an internal non-volatile microSD card where it will store configuration parameters. These parameters are retrieved from microSD card upon device start-up.

Device ID is set by the manufacturer . The device ID is secured from accidental modification. It is readable but not modifiable by the cardiac technician. A technician can read and modify several parameters before connecting the device to the patient. This configuration is done using the Smart Dock docking station, coupled with the Sirona Viewer PC application.

Examples of parameters which can be modified are:

- Recording length
- Pre-trigger time length
- Post-trigger time length
- Recorded Event Threshold for LED and Audible Alarm: number of recordings that will trigger LED to flash periodically to inform the patient that he should send data to the monitoring center.
- Audible Alarm Enable: Enable/disable an audible alarm to the patient when the number of recorded events reaches the preset limit.
- Tachycardia threshold
- Bradycardia threshold
- Cardiac Pause threshold

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Configuration

The device is designed to use several cables configurations as listed below in **Error! Reference source not found.**. The device detects the type of cable attached and configure itself accordingly.

Section 4: Connecting Devices

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4.1 Attaching Recorder to Patient

Patient Cable

The Patient cable connects to the Walta connector on the side of the SIRONA recorder. The cable is keyed for proper alignment. Be sure to align the key. Do not force a cable into position. Use only IntriCon Datrix cable part numbers listed in table 1.

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Patient Preparation

Note: Proper patient preparation and electrode placement are important for acquiring a high quality ECG.

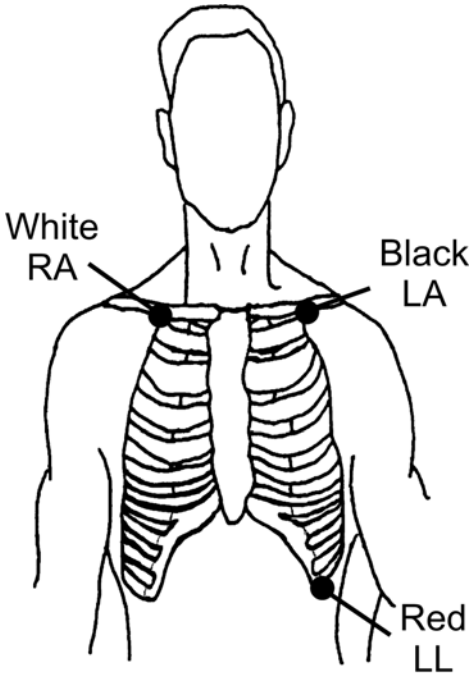
1. Prepare the electrode site by removing oils and lotion from the skin. If necessary, shave the area where electrodes will be placed.
2. Clean the skin at the placement site with an alcohol prep pad.
3. Dry the area with a lint-free cloth.
4. Use Silver Chloride disposable electrodes designed for 24 hour Holter/Event monitoring. Do not use 12-lead ECG or Stress Test Electrodes.

Patient Hookup

In order to obtain a high-quality ECG signal it is necessary to maintain good electrical contact between the electrodes, patient cables and the patient's skin. A suggested electrode placement is shown in the diagram below. However, it is up to the physician to make the final placement determination.

Deleted: The recorder's ECG display screen can be used to verify a proper patient hookup.

Warning: CONDUCTIVE PARTS OF ELECTRODES AND ASSOCIATED CONNECTORS, SHOULD NOT CONTACT OTHER CONDUCTIVE PARTS.



Black CH1+ Red Ch2+ Red Ch3+
White Ch1- White Ch2- Black Ch3-

3-Lead 1-Channel Electrode Placement

Read and follow instructions included with the electrodes.

1. Check the patient cable for damage or wear. Replace if necessary. Use Silver Chloride disposable electrodes designed for 24 hour Holter/Event monitoring.
2. Place the electrodes onto the ECG leads.
3. Remove the backing from the pre-gelled disposable electrode.
4. Firmly place an electrode on each of the prepared skin surface sites. Dispose of any electrode that does not properly adhere to the skin.

Warning: ECG REPORTS MUST BE READ BY A PHYSICIAN WHO IS TRAINED TO INTERPRET AN ECG STUDY.

4.2 Connecting Smart Dock to a PC or to a wall socket using a wall adapter

The Smart Dock is connected to a PC through a mini-USB to USB cable. The mini-USB end plugs into the Smart Dock and the USB end plugs into the PC or to a wall adapter (only when the Smart Dock is being used to charge the Sirona)

4.3 Connecting the linkStream to a PC

The linkStream is connected to a PC through a mini-USB to USB cable. The mini-USB end plugs into the linkStream and the USB end plugs into the PC

Section 5: Instructions for Use

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5.1 Instructions for Patient

Before the patient leaves the office inform the patient about:

a) Proper use of the Record button and patient diary.
b) Transmitting ECG by TTM.
c) Light message displays.

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5.2 Instructions for Technician

Before putting the Sirona on the Smart Dock make sure the Sirona is in docking mode. Sirona can be put in docking mode by pressing the Send and Record button simultaneously for 5 seconds.

Start Up

Upon the connection of a cable, the SIRONA performs a system check and briefly flashes each LED. It will then sound three tones using the speaker.

RECORD Button

The event button is the large round Record button on the device with a raised ring around it. Press the Record button to store ECG data before and after the button press to the SD card. The event time, when used in conjunction with a patient diary, provides a physician with the ability to correlate patient symptoms with the ECG data.

SEND Button

The recorder will sound an audible alert when the number of events stored is equal to or greater than the number previously set in the event threshold option. The patient must contact the call center using a traditional land line. After the technician answers, the patient will be instructed to hold the Sirona's speaker up to the phone's mouthpiece and then press and hold the Send button for 5 seconds. This will transmit the stored events to the doctor or service via Trans-Telephonic Monitoring (TTM). The unit should be held up to the phone until the sound stops. When the sound stops the patient should get back on the phone to talk to the technician. The technician will then inform the patient of a successful transmission or instruct the patient to repeat the process in the case of an incomplete transmission.

Deleted: . The Green Record LED will flash a number of times corresponding to the number of recordings saved in memory

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Heart Rate and Pause Calculation

The method used by the Sirona device to detect beats and derive heart rates for preprocessing uses digital filtering and peak detection to create event vectors. The event vectors are further processed using decision rules based on MIT/BIH database testing. Once an ECG complex has been identified, a corresponding time is logged in milliseconds. The distance between each ECG complex is used to calculate heart rate.

Pauses are classified when the interval of any beat is longer than the user specified threshold for pause and is less than 30000 milliseconds.

Smart Dock Operation

When Sirona is placed on the dock Smart Dock will charge battery. The charging status is indicated by the battery LED on Sirona. The table in charging section below explains the battery LED behavior.

To extract data from the SD card in the Sirona. Put the Sirona in "dock mode" by pressing "Send+Record" together for 5 seconds. Place the Sirona on the Smart Dock. Open the Sirona Viewer application on the PC and hit the "Save Holter Data" tab to save the data as a bin file.

linkStream Operation

After connecting the linkStream to the PC, open the Sirona Viewer application on the PC. Press "Send" button on the Sirona for more than 5 seconds to start wireless transmission mode. On the Sirona Viewer hit the "Scan for device" button. And then press Start ECG to see the signal that is being wirelessly transmitted by the Sirona.

Press "Stop ECG" button to stop wireless ECG transmission.

SIRON A Patient Interface Light Signals

There are several messages that could appear to alert you that action may be required, or simply to alert you that an error has occurred. These messages include:

LIGHT	MESSAGE	ACTION
Battery LED solid Red when device is on the Smart Dock	Battery is charging	Leave the device on the Smart Dock until the Battery light turns off
Battery LED off when device is on the Smart Dock	Battery is fully charged	Remove the device from the Smart Dock
Battery LED flashes green every 10 seconds	Device is functioning normally	None
Battery LED flashes red every 2 seconds	Low Battery	Charge the Sirona by placing it on the Smart Dock
Battery LED flashing red every 500ms when on the Smart Dock	Faulty Battery	Contact technician/service
Lead-off LED flashes red every 2 seconds	Indicated lead disconnected or poor patient connection	Check lead / electrode
Record LED lights up green for 5 seconds	Record button has been pressed	None
Record LED flashes red continuously	Recording error	Contact technician / service

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Deleted: becomes solid green

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Section 6: Device Maintenance

Inspection and Cleaning

Routine inspection will help maintain the safety and performance of your SIRONA Holter/Event recorder, Smart Dock and linkStream. Before operating the device perform a visual inspection to identify any damage or excessive wear.

The outside surfaces can be cleaned with a cloth dampened with a mild soap and water solution.

Do not dispose of the unit in trash. Dispose of as the Waste Electrical and Electronic Equipment (WEEE) regulations for your area require.

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Caution: DO NOT IMMERSE THE DEVICE IN LIQUID!

Caution: DO NOT CLEAN THE PATIENT CABLES WITH ALCOHOL. DO NOT AUTOCLAVE THEM, OR USE ULTRASONIC CLEANERS.

Caution: DO NOT USE ANY HARSH CHEMICALS SUCH AS ACETONE, AMMONIA OR IODINE TO CLEAN THE SIRONA.

Testing

The SIRONA executes a self-diagnostic check at these three times:

a. At power-up
b. At the insertion of any cable
c. Upon removing the PWM device from the Smart Dock
d.

Any errors in the unit's subsystems will be reported with an appropriate error message. If error messages persist contact your IntriCon Datrix service representative. There are no user serviceable parts in the SIRONA. The unit must be returned to IntriCon Datrix for service.

The SIRONA may also be tested by attaching the patient leads to a commercially available ECG simulator and verifying each lead has amplitude and morphology as described in the simulator's manual. Excessive artifact usually indicates the patient cable needs replacing. Use only replacement cables purchased from IntriCon Datrix.

Charging

The Sirona should only be charged with equipment supplied by Intricon Datrix (Model Number – RX 92446-0009 and Model Number – RX92598) intended for that purpose. The charging cable is attached to either a PC or a wall adapter through USB on one end and through a Walta connector to the Sirona on the other end, The Smart Dock(Model Number RX92446-0009) and Charging cable (Model Number RX92598) should only be used with the wall adapter(Model Number RX83103) when they are connected to the wall adapter through the USB cable. The lights on the Patient Worn Module will inform the user of the state of the charge of the battery as described below:

Condition	Battery LED	Meaning
PWM on the Smart Dock	Solid Red	Charging
PWM on the Smart Dock	Off	Battery is fully charged
PWM on the Smart Dock	Flashing Red	Charger is not charging
PWM attached to a patient	Green flash every 10 seconds	Normal Operation
PWM attached to a patient	Flashing Red	Battery Voltage is LOW
PWM attached to charging cable	Flashing Green	Charging
PWM attached to charging cable	Solid Green	Battery is fully charged

Deleted: Flashing Green

Deleted: Solid Green

Comment [NP2]: Only true for holter?

Storage

The Sirona, Smart Dock and linkStream should be stored between 10°C and 70°C and 10% to 95% relative humidity (non-condensing).

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Transport

The Sirona, Smart Dock and linkStream should be transported between 10°C and 70°C and 10% to 95% relative humidity (non-condensing).

Caution: **DO NOT IMMERSE IN WATER. KEEP AWAY FROM CHILDREN.**

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Sirona Accessory List	
Description	**Part Number**
3 Wire 1-Channel Event Cable 20"	RX92368-001
5 Wire 2-Channel Holter Cable 20"	RX92368-003
5 Wire 5-Channel Event Cable 20"	RX92368-004
7 Wire 3-Channel Holter Cable 20"	RX92368-005
3 Wire 1-Channel Event Cable 39"	RX92368-006
5 Wire 2-Channel Holter Cable 39"	RX92368-008
5 Wire 2-Channel Event Cable 39"	RX92368-009
7 Wire 3-Channel Holter Cable 39"	RX92368-010
5 Wire 3-Channel Holter Cable 20"	RX92368-011
5 Wire 3-Channel Holter Cable 39"	RX92368-012
2 Wire 1-Channel Event Cable 20"	RX92368-013
2 Wire 1-Channel Event Cable 39"	RX92368-014
3 Wire 2-Channel Event Cable 20"	RX92368-015
3 Wire 2-Channel Event Cable 39"	RX92368-016
Belt Clip	RX82765-000
USB Cable	RX82929-000
Wall Charger	RX83103-000
Smart Dock	RX92518-000
Charging Cable	RX92598-000

SIRONA DATASHEET

General Specifications:

Input impedance: ≥ 10 MΩ
CMRR: > 60 dB
AC signal range: ± 5mV
DC signal range: ± 300mV
Bandwidth: 0.05 –40 Hz.
Sampling rate: 250 samples/sec.
Resolution: 10 bits
Battery: Lithium-Polymer rechargeable
Memory type: Flash
Waterproof rating: IP54 and brief immersion to 6" (when patient cable attached)
Lead status: Automatic lead-off detection
User alerts: LED indicators and audible alerts.
Wireless link option: 2.4Ghz PhysioLink internal transceiver
Operating temperature range: 0 –60 °C
Operating humidity range: 10 –90% r.h. (non-condensing)
Weight: 42 gr. (1.5 Oz.) excluding cable.

Comment [NP3]: Ingress Protection Rating: IP54 and brief immersion to 6"(when patient cable attached)

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Holter Monitor Specifications:

2 or 3 channel recording depending on cable
24, 48 and 192 hour recording length
Typical battery life: 192 hours minimum between charges†
Upload to PC via smart-dock USB 2.0 accessory

Event Recorder Specifications:

1 or 2 channels depending on cable
Pre-trigger length: 30, 45, 60, 90, or 300 seconds*
Post-trigger length: 30, 60, 90, 120 and 180 seconds
Maximum number of events: 2048
Automatic arrhythmia detection: brady, tachy, pause and AF
Pacemaker pulse detection
TTM event data transmission
Typical battery life: 15 days between charges*

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The Sirona is compliant with IEC 60601-1 as a Type BF, internally powered device designed for short time operation. The equipment is not suitable for AP or APG category environments.

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The Sirona complies with Part 15 of the FCC rules.

Service/Technical Support:

IntriCon Datrix
340 State Place
Escondido, CA 92029
Tel: 760-480-8874
Fax: 760-480-9474

Warning: THE SIRONA SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT. IF ADJACENT OR STACKED USE IS NECESSARY, THE SIRONA SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION IN WHICH IT WILL BE USED.

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Guidance and manufacturer's declaration - electromagnetic emissions		
The Sirona is intended for use in the electromagnetic environment specified below. The customer or user of the Sirona should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Sirona uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Sirona is suitable for use in all establishments other than domestic 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
The Sirona is intended for use in the electromagnetic environment specified below. The customer or user of the Sirona should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 6100-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	N/A 3V/m 80 MHz to 2.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Sirona, including cables, than the recommended separation distance calculated for the equation applicable to the frequency of the transmitter. **Recommended separation distance.** $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 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 d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level on 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 and 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 Sirona is used exceeds the applicable RF compliance level above, the Sirona should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Sirona.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Guidance and manufacturer's declaration - electromagnetic immunity			
The Sirona is intended for use in the electromagnetic environment specified below. The customer or user of the Sirona 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	+/- 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/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	N/A	N/A
Surge IEC 6100-4-5	+/- 1kV line(s) to lines(s) +/- 2kV line(s) to earth	N/A	N/A
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	N/A	N/A
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic if a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Recommended separation distances between portable and mobile RF communications equipment and the Sirona

The Sirona is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Sirona can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sirona 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 $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800 MHz to 5 GHz** $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.77
1	1.17	1.17	2.33
10	3.69	3.69	7.37
100	11.67	11.67	23.3

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 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.

Record LED flashes green	Number of flashes corresponds to the number of stored recordings[NP1]	None