NOMAD™

Handheld X-ray System

for Intraoral Radiographic Imaging

Operator Manual

DEXIS

Thank you for choosing the DEXIS NOMAD Pro 3

At Dental Imaging Technologies Corporation we value your business and would like to hear from you because your feedback and suggestions are important to us. If you have comments, please email us: NOMADsupport@dexis.com

DO NOT OPERATE THIS DEVICE UNTIL YOU HAVE READ THIS MANUAL AND REVIEWED THE ACCOMPANYING MATERIALS.

Disclaimer: DEXIS NOMAD Pro 3 is sold with the understanding that the user assumes sole responsibility for radiation safety (as well as any state, provincial, or local regulatory compliance) and that Dental Imaging Technologies Corporation, its agents or representatives, do not accept responsibility for:

a) injury or danger to personnel from X-ray exposure,
b) image over/under exposure due to poor operating techniques or procedures,
c) equipment not properly serviced or maintained in accordance with instructions contained in this publication, and
d) equipment which has been damaged, modified, or tampered with in any way.

Table of Contents

DEXIS NOMAD Pro 3

NOMAD Pro 3 Handheld X-ray System is a battery powered, portable dental X-ray source designed for handheld operation. It is designed to produce diagnostic quality images utilizing either film or digital imaging techniques. The NOMAD Pro 3 Handheld X-ray System is designed for use in a dental office. It can also be used in other similar environments (orthodontic office, general practitioner's office, hospital ward, etc.) where appropriate safeguards are implemented. The device uses a rechargeable battery to allow for the use of the NOMAD Pro 3 Handheld X-ray System where transportation or use of other x-ray devices might be prohibitive due to the other device's size and/or lack of mobility.

The NOMAD Pro 3 Handheld X-ray System is an X-ray device with a DC generator. The handheld device features a main unit (tube head), rechargeable battery (handset), charger, and charger AC/DC power supply. The power is supplied by a rechargeable Lithium Ion battery core pack built into a handset. This facilitates portability of the device. A beam-limiting cone is incorporated within the device. Internal and external shielding provide sufficient radiation protection to allow the clinician to remain in the operatory with the patient.

To make the system as simple as possible for the operator, NOMAD Pro 3 Handheld Xray System uses a fixed tube voltage of 65kV and a fixed tube current of 2.5mA. The only operator-adjustable parameter is the exposure time. This adjustment can be quickly accomplished through the user-friendly control panel.

Control buttons, display, and a trigger provide the primary operator interface. Settings can be selected and displayed. Voltage (65 kV) and current (2.5 mA) are fixed with the exposure time varying based on patient type, detector type, and anatomical feature. Exposures can be completed using the trigger. The device can be used with three detector types: film, digital imaging intraoral sensors, and phosphor plates.

NOMAD Pro 3 has a beneficial effect on the dental health of the patient, and results in the meaningful (relevant to the patient) and measurable positive impacts on outcomes related to diagnosis, such as allowing a correct diagnosis to be made, providing early diagnosis of diseases or specifics of diseases, or identifying patients more likely to respond to a given treatment.

1.0 Getting Started

1.1 Indications for Use

The NOMAD Pro 3 Handheld X-ray System is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors.

1.2 Warnings and Precautions

The device is designed for use with patients of any overall health status, as solely determined by the practitioner, with the following considerations for specific circumstances:

- Pregnant women. The medical practitioner must weigh the benefits conferred by use of the device against the potential hazard to the pregnant woman and fetus resulting from radiation exposure. If use of the device is considered justified, the practitioner must take the appropriate precautions, such as use of radiation safety garments, to limit radiation exposure beyond the maxillofacial complex.
- Pediatric. The medical practitioner must weigh the benefits conferred by use of the device against the potential hazard to the child resulting from radiation exposure, considering the maturity of the child's physical development. If use of the device is considered justified, the practitioner must take the appropriate precautions, such as use of radiation safety garments, to limit radiation exposure beyond the maxillofacial complex.
- Patients with medical conditions causing involuntary movements. For patients who experience seizures or who have been diagnosed with conditions such as Parkinson's Disease which can cause difficulty in controlling physical movements, the medical practitioner must weigh the benefits conferred by use of the device against the potential hazard to the patient resulting from additional radiation exposure due to a re-scan in the event that an involuntary movement renders an image unusable for diagnostic purposes.
- Some components of the NOMAD Pro 3 may have the presence of Nickel greater than 0.1% by article weight. Contact may result in an allergic reaction due to Nickel sensitivity. Use of a sheath that covers the sensor positioning system may reduce the risk of exposure to the patient. Use of gloves while handling the alignment bar may reduce the risk of exposure.

1.3 Unpack, Check, Register and Clean NOMAD Pro 3 System

Report any damaged components to the shipping company and any missing components to your dealer within 24 hours of receiving the shipment.

❶ Unwrap individual components from the protective plastic and check for any noticeable signs of damage. The package system includes the following items:

- NOMAD Pro 3 Device
- Charging Cradle
- One or two Rechargeable Battery Handsets depending on kit type
- AC/DC Power Supply
- Universal Alignment Bar

- Short Endodonic Alignment Bar
- Short Bitewing Alignment Bar
- NEMA 1-15p USA pin Cord

See the ""Appendix - Accessories"" for information on accessories.

❷ Preliminary Checks:

Item	Check
Device Labels	Verify that the serialized device label is in place (located on lower side of unit).
Other Labels	Verify that the serial number on the product registration card matches the device serial number on the device and the device serial number on the carrying case. Verify that the handsets' label (located on the top of each handset) and the Charging Cradle label (located on the bottom of the Charging Cradle) are all in place.
Backscatter Shield	This item provides operator protection and should be inspected for shipping damage.
Trigger Switch	Should freely move in and out when depressed and released.
Device Housing	Should be free of cracks or fractures.

❸ Complete the product registration at
https://dexis.com/en-us/product-and-warranty-registration

Registering your device will activate your DEXIS Complete (the first year is free). For terms and conditions of the NOMAD Pro 3, please visit dexis.com

❹ Clean the NOMAD Pro 3. Use a CaviWipes 2.0 to wipe the exterior surfaces of the NOMAD Pro 3 & charger. Don't use cleaners intended for hard surfaces or acetone based, since chemical combinations may deteriorate the NOMAD Pro 3 plastic.

1.4 Charging the Handset

NOMAD Pro 3 charging system includes a rechargeable handset, a Charging Cradle and an AC/DC Power Supply. The AC/DC Power Supply has a removable power cord which plugs into an AC electrical outlet (universal voltage accommodated).

DEXIS NOMAD Pro 3 handsets and Charging Cradles are compatible with both DEXIS and KaVo branded Charging Cradles, Handsets and AC/DC Power Supplies.

- Handsets must be charged before initial use. Alternate handsets each week to maximize service life.
- Do not spray disinfectant or cleansers directly on to the handset.
- Do not attempt to charge below 50°F (10°C) or above 104°F (40°C).
- Charge the Handset before use & after any extended period of inactivity.
- See Section 3 for more information.

Use the supplied AC/DC power supply. Connect the power cord to the Charging Cradle, and plug into an AC outlet.

❶ The Charging Cradle flashes red and green while initializing. When ready, the three charging indicator bars will turn off. A single green circle illuminates to indicate there is adequate power to the Charging Cradle.

If the green circle does not illuminate, the Charging Cradle is not receiving adequate power and may need to be sent to a manufacturer authorized service center for repairs.

❷ Carefully slide the handset onto the Charging Cradle (do not force the handset onto the Charging Cradle or damage may result). The first bar illuminates green to indicate that the cradle and handset are communicating and begins flashing when charging starts.

Expect charge time to be less than five hours. The handset, Charging Cradle, and AC power supply may become warm to the touch while charging.

❸ The first bar turns solid green when1/3 charged, and the second bar begins flashing green. This sequence occurs until handset is fully charged. Remove the handset from the Charging Cradle once it is fully charged.

❹ If the bars illuminate or flash red, see Section 6.3 Troubleshooting.

Receiving Adequate Power and Ready

Handset 1/3 Charged

Handset 2/3 Charged

Handset Fully Charged

See Section 6.3

2.0 Safety Precautions

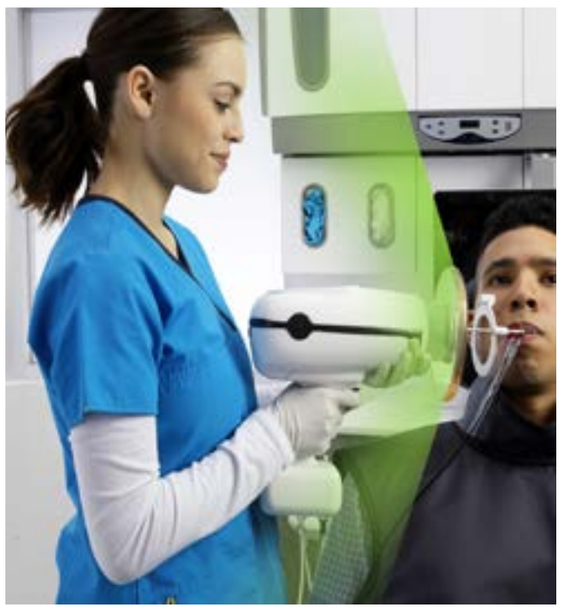
2.1 Radiation Safety

The NOMAD Pro 3 is designed to be used in clinical settings (e.g., a dental office) and controlled settings where transportation or use of other X-ray devices might be prohibitive due to the device's size and/or mobility. It is designed to be operated by trained healthcare professionals who are educated and competent in the techniques described in the Operator's Manual. Specific educational requirements are determined by state and/or national regulatory agencies. Operators are strongly urged to comply with the current recommendations of the International Commission on Radiological Protection and, in the United States, the US National Council for Radiological Protection.

The manufacturer recommends completing the training course on elableing.dexis.com.

This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions, and maintenance schedules are observed.

This X-ray unit must only be operated by trained personnel in a controlled setting. Within such a setting, ensure that only the patient is in the direct beam of the x-ray, and that any ancillary personnel are a minimum of 6 feet away from the patient. If it is necessary for any ancillary personnel to be closer than 6 feet, these personnel should stay out of the direct beam and wear personal protective equipment, such as an apron and thyroid collar.



- The NOMAD Pro 3 provides a high degree of protection from unnecessary radiation. However, no practical design can provide complete protection nor prevent operators from exposing themselves or others to unnecessary radiation. It is important to restrict use and follow all applicable government radiation protection regulations. Pregnant women should not be exposed to X-rays unless necessary. Proper safety precautions should be taken to minimize dose to the fetus.
- Operators must be fully acquainted with industry safety recommendations, established maximum permissible doses, and local jurisdiction requirements for use.
- Optimal operator protection from radiation backscatter exists when the following measures are taken:

a) backscatter shield is positioned at the outer end of the collimator cone,
b) backscatter shield is close to the patient,
c) patient tilts his or her head when needed to accommodate exposures (see Section 4.7 Exposure Techniques), and
d) operator remains within the significant zone of occupancy immediately behind the device shield.

- Do not enable the NOMAD Pro 3 until patient & operator are positioned & ready for the exposure, preventing interruption and inadvertent exposure of anyone to X-rays.
- Do not attempt an exposure if anyone other than the patient is in the direct beam. If others are assisting, then they should wear protective covering as required by local jurisdictions. An apron and thyroid collar are recommended for ancillary personnel who are closer than 6 feet to the patient.
- When selecting and using sensors, preference should be given to models that allow the backscatter shield to remain at the outer end of the collimator cone for maximum operator protection.
- An exposure can be terminated for any reason by prematurely releasing the depressed trigger (for more information, see Section 4.0 Operation).
- As shown in graphics, maximum protection (green area) from backscatter radiation (red area) exists when the NOMAD Pro 3 is positioned near the patient, is perpendicular to the operator (with the patient's head tilted if needed), and the backscatter shield is fully extended toward the patient and parallel to the operator.

Stay in the ZONE				
				
	Proper Position	Held Back	Shield Slid Back	Non-perpendicular
Protection:	Maximum	Minimized		

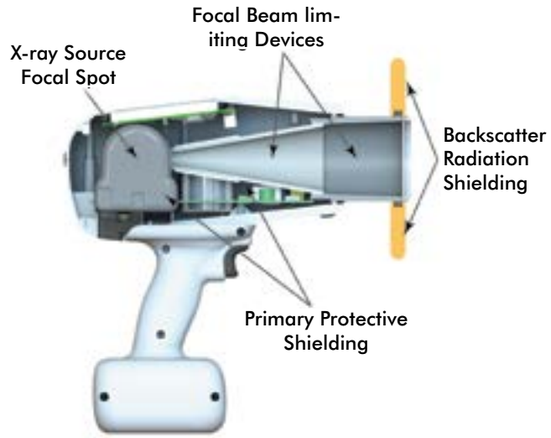
- Operation outside the protection zone (or with a diminished protection zone) requires proper precautions such as the use of an apron and thyroid collar, according to requirements of local jurisdictions.
- Do not operate if the backscatter shield or collimator cone is broken.
- For further information on the tests performed to ensure NOMAD Pro 3 safety as a handheld device, please see Section 2.2 Studies and Data on Leakage and Scatter.

In implementing a radiation protection program, consult all applicable regulations governing radiation protection and the use of X-ray equipment, and ensure full compliance with any such regulations.

2.2 Studies and Data on Leakage and Scatter

Besides direct beam, potential exposure from X-ray devices has only two other possibilities:

1) leakage radiation and
2) scatter radiation from the patient/ subject in the direct beam.

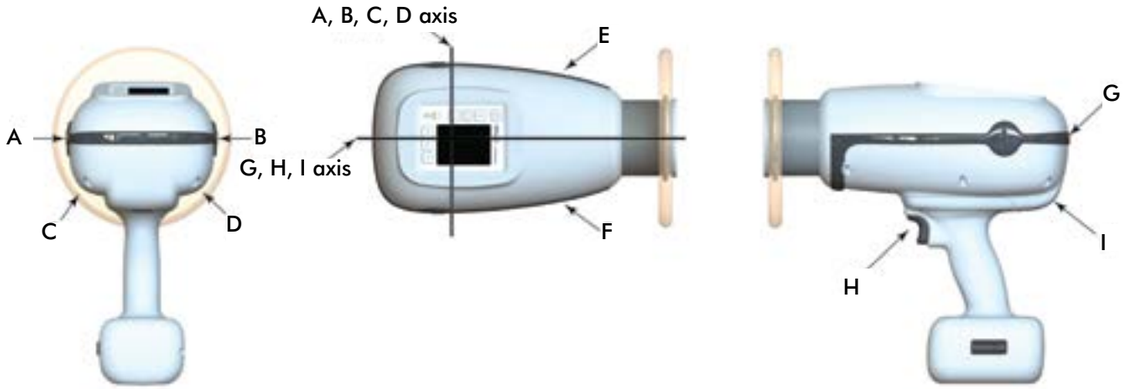


Leakage

Unique internal shielding of Pro 3 encases the X-ray tube, practically eliminating leakage radiation. This makes it safe to use Pro 3 as a handheld device during exposures.

FDA regulations specify that leakage radiation from X-ray devices not exceed 0.88 milligray (mGy)/hr at 1 meter, while IEC regulations stipulate that devices stay below 0.05 mGy/hr, an even tighter limit. In response to these regulations, Dental Imaging Technologies Corporation will only ship product that tests below 0.88mGy/hr (at 1 meter), 0.25mGy/hr (at 1 meter), 0.02mGy/hr (at 5 cm) for leakage.

In order to verify compliance with this leakage requirement, each individual device is tested with a calibrated survey meter at 12 points on the device housing, as shown in the following diagram. The highest measurement out of these 12 points is reported on the device Certificate of Conformance (which is shipped with every device) and must be lower than 0.02mGy/hr in order for the device to successfully pass product release testing.



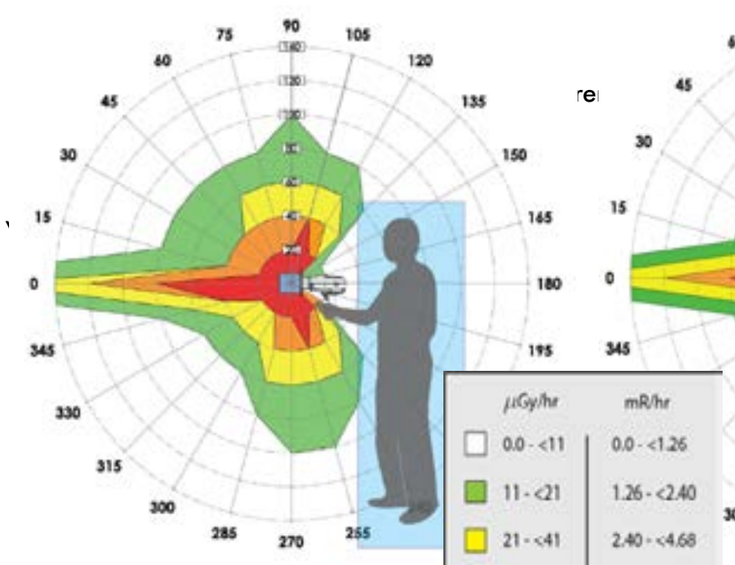
Test points for product release testing

Scatter

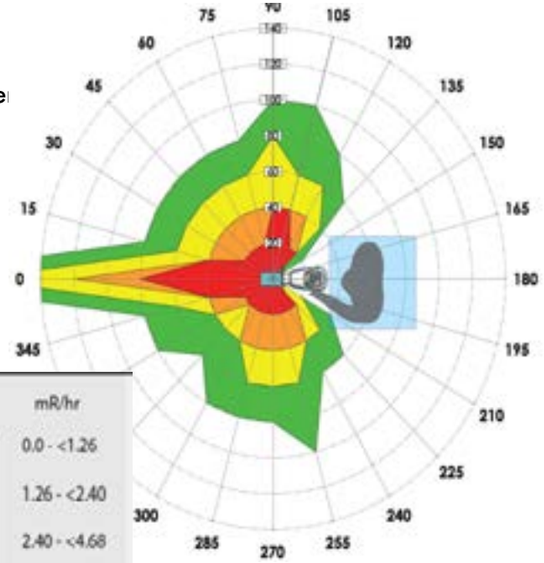
As discussed in Section 2.1 Radiation Safety, the transparent shield on the NOMAD Pro 3 collimator, when properly oriented, acts as a barrier against backscatter radiation, making it safe for the operator to stay in the room. The NOMAD Pro 3 backscatter shield may contain lead dependent on its date of manufacture.

The significant zone of occupancy for operators has been further verified by internal testing. A NOMAD Pro 3 device was remotely fired into a water phantom repeatedly, with an ion chamber recording radiation readings at 336 points in the room, first to establish the vertical significant zone of occupancy and then to establish the horizontal significant zone of occupancy for each unit located 100 cm above the floor. Each exposure was taken at 1.00 seconds in order to simulate "worse case scenario" results. The vertical significant zone of occupancy measures 60 cm X 200 cm, while the horizontal significant zone of occupancy is 60 cm X 60 cm. A calibrated survey dosimeter can be used in order to confirm scatter radiation data shown in the following diagrams. For further information on these tests, please contact Dental Imaging Technologies Corporation.

Scatter plots were created by taking measurements with bismuth(Bi) and lead(Pb) backscatter shields. The higher of the measured values from each shield was included on the plots for a given radius and angle.



Verticlel Plane, Significant Zone of Occupancy: 60 cm x 60 cm



Horizontal Plane, Significant Zone of Occupancy: 60 cm x 200 cm

2.3 Usage and Duty Cycle

As a safety feature, the NOMAD Pro 3 will not emit X-rays with insufficient voltage (low battery).

The NOMAD Pro 3 is also designed to avoid damage from overheating. The minimum duty cycle rating for maximum exposure (the relationship between duration and frequency of exposures taken during a rolling 60 second period) is 1:60. This duty cycle is programmed into your NOMAD Pro 3.

The NOMAD Pro 3 is a reusable device, but depending on usage patterns, handling, and maintenance, service life may vary. If any of the conditions below are observed, the device should be immediately removed from service. In this case, it may be possible for the device to be factory repaired and returned to service for the remainder of its design life. Contact Customer Service for details.

- Reduction in performance
- Cracks on the housing, collimator cone, and/or backscatter shield
- System dropped
- Subject to moisture (wetting, immersing, or soaking)
- Exposed to heat or fire
- Housing opened

The NOMAD Pro 3 Handset is considered a consumable with a 2 year service life depending on usage patterns. The handset should be replaced when it no longer powers the device for 3 days of typical use without re-charging. The device has an Expected Service Life of 7 years.

Do not operate the NOMAD Pro 3, the handset, Charging Cradle, or AC power supply if equipment was subjected to moisture (wetting, immersing, or soaking). Return to manufacturer or authorized service center for service.

- Do not open the housings. Doing so will void the warranty. There are no user serviceable parts inside the NOMAD Pro 3, handset, Charging Cradle, or AC power supply.
- The NOMAD Pro 3 should not be used in environments where flammable cleaning agents are present.
- Locate the Charging Cradle away from the normal patient environment.
- Connect only items that are specified as part of the system or that are specified as being compatible with the system.

2.4 Cleaning

❶ Leave the handset connected to the tube head.

❷ Wipe all surfaces of the device components (i.e., tube head, handset and charging cradle) thoroughly for one (1) minute, using Metrex CaviWipes™ 2.0 Disinfecting Wipes. Pay close attention to any seams, recessed surfaces or crevices. If wipes become visibly soiled, use additional wipes.

Note: Only exceed one (1) minute if soil is not visibly removed.

❸ If necessary, use a standard cotton tipped applicator to thoroughly clean seams and any other crevasses that a saturated disinfectant wipe cannot reach such as screw heads and screw cavities.

❹ Use low-linting wipes to dry all surfaces.

❺ Visually inspect each device for absense or presence of remaining soil in a well lit area.

NOTE: Use a CaviWipes 2.0 to wipe the exterior surfaces of the NOMAD Pro 3 & charger. Don't use cleaners intended for hard surfaces or acetone based, since chemical combinations may deteriorate the NOMAD Pro 3 plastic.

NOTE: The NOMAD Pro 3, the handsets, the Charging Cradle, and the AC power supply are not designed to be subjected to any kind of sterilization procedure.

Alignment Bars

It is recommended to follow facility established cleaning and disinfection procedures. If the infection control guidelines in your country permit, the alignment bars can be disinfected using appropriate cleaning agents. Refer to cleaning agent manufacturer instructions.

Do not spray disinfectant or cleaners directly on the NOMAD Pro 3, handsets, Charging Cradle, or AC power supply. The connecting areas are open to ingress and damage to your device may result.

2.5 Disinfecting

❶ For all steps below, ensure that all surfaces stay "wet" for the recommended time according to the manufacturer's label directions for the disinfection solution [i.e., two (2) minutes]. Additional applications of the solution may be required to meet the required "wet" time.

❷ Wipe and wet the device components (i.e., tube head, handset and charging cradle) using Metrex CaviWipes™ 2.0.

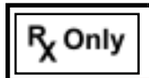
❸ If necessary, use a saturated cotton tipped applicator to thoroughly disinfect seams and any other crevasses that a saturated disinfectant wipe cannot reach such as screw heads and screw cavities.

2.6 Security, Storage, and Transportation

- Do not store the NOMAD Pro 3, handsets, Charging Cradle, or AC power supply in extreme conditions: below -4°F (–20°C) or above 122°F (+50°C), or 5% to 90% relative humidity (non-condensing). The optimal storage location is cool, dry, and away from direct sunlight.
- DITC recommends that the NOMAD Pro 3 (like all electronic equipment) be allowed to acclimate before use when switching between temperature extremes (i.e., cold storage area to a warm use area or hot storage area to a cool use area).
- When finished for the day with the NOMAD Pro 3, detach the handset.
- The X-ray Lock and Unlock (Section 4.2) serves as the device security key to prevent unauthorized use. In addition, it is recommended that the device be locked away when not in use. For a further level of security, securely store handsets in a separate location.
- Take steps to ensure the NOMAD Pro 3 will not be knocked to the ground when not in use by laying it on its side. The device will automatically go into Standby mode after a period of inactivity (approximately three minutes). Remove the handset from the battery to fully power off when done using the device.
- Some battery charge may be lost during extended inactivity (leading to fewer exposures between handset charging cycles).

- The NOMAD Pro 3 should not be operated if it has been dropped or if performance degrades; it should be returned to the manufacturer or an authorized service center for an evaluation.
- When finished for the day with the NOMAD Pro 3, detach the handset.
- Handset should be at least 2/3 charged for long term storage. Do not store haphazardly or in contact with metal objects. Store in a cool, dry place.

2.7 Product Symbols

	Caution: U.S. Federal law restricts this device to sale by or on the order of a physician or other licensed practitioner.
	Type BF Equipment (providing a degree of protection against electric shock, pertaining particularly to allowable leakage currents) complying with IEC 60601-1
	Warning of ionizing radiation
	CAUTION: X-RAYS
	The positive and negative connections (the polarity) of a d.c. power supply.
	Filtration value
	X-ray source assembly
	Focal Spot
	Marking indicating that product is compliant with certain United States safety standards
	Standby Switch
	General warning
	Caution
	Recycling instructions
	Used Electrical and electronic products should not be mixed with general household waste
	Manufacturer
	Date of manufacture
REF	Model/Catalog number
SN	Serial number
	Follow Operating Instructions for Use

	Refer to Instruction Manual
	Dangerous Voltage: Electrical Shock Hazard
	The maximum and minimum temperature limits at which the item shall be stored transported or used
	Kept away from rain and in dry conditions
	To indicate that the content of the transport package are fragile and the package shall be handled with care
	Audible signal, indicating audible cues emitted by device during operation
	The acceptable upper and lower limits of relative humidity for transport and storage

2.8 Location of Device Labels

The DEXIS Handheld X-ray System and Charger have identification labels that specify the model number and applicable product approval listings.

	Complies with FDA radiation performance standards 21 CFR, subchapter J. Location: Bottom of the NOMAD handheld device.
	Standard Trigger Handset Refer to Instructions for Use for compatible Charging Cradle Contains Li-ion Battery Location: Top of device handset (visible when detached from device).
	Standard Trigger Handset (2 Handsets) Refer to Instructions for Use for compatible Charging Cradle Contains Li-ion Battery Location: Top of device handset (visible when detached from device).
	Charging Cradle Use only with compatible handset and AC/DC Power Supply. Refer to Instructions for Use. Max Input Max Output Location: Bottom surface of Charging Cradle

3.0 Setup and Power Check

Carefully follow setup, assembly and alignment procedures defined in this manual, to ensure quality image captures of defined areas of the patient's anatomy.

3.1 The Backscatter Shield

In addition to the radiation shielded cone, the backscatter shield provides additional protection to the operator & can be adjusted to permit exposures made at various angles.

❶ The shield should remain fully extended to the outer edge of the cone, as close to the patient as possible during each image taken (see Section 2.1 Radiation Safety).

❷ To keep the shield securely on the cone, a cap is permanently attached at the outer cone end. Do not attempt to remove this cap or to remove the backscatter shield. Attempting to do so will result in damage to your device and will void the warranty.

3.2 Attaching a Charged Handset

❶ With the NOMAD Pro 3 placed bottom up on a secure surface, properly orient and carefully slide the charged handset onto the base of the NOMAD Pro 3. (A properly oriented handset should click into place with firm pressure.)

❷ The clicking sound ensures the locking mechanism has secured the NOMAD Pro 3 to the handset. To verify this lock, apply slight pressure in the release direction.

There are electric voltages present at the handset terminals. Protect the handset from damage; do not probe with fingers or conductive objects.

3.3 Checking for Power

❶ After locking a handset in place, press the Standby ⏻ button.

❷ The display panel will activate with a battery power level icon in the upper right corner. Four bars is an indication of a fully charged handset.

❸ If the battery charge is too low, the NOMAD Pro 3 will not emit an X-ray and the Recharge Handset alarm will display.

❹ When a battery is depleted to the single bar level ▯, it is recommended the handset be recharged. Remove the handset from the charging cradle once it is fully charged.

❺ Replace the handset when fully charge. It is recommended that you keep a second handset fully charged at all times to ensure continuous operation.

3.4 Charging Over Discharged Handset

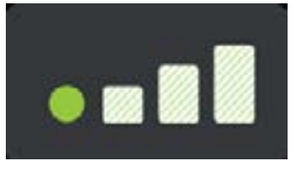
Occasionally, a Handset may enter Over Discharge Protection (ODP) mode and disable itself. This feature is designed to extend the useful life of the battery by preventing over discharge of battery cells. ODP mode may be invoked after the Handset has not been used for an extended period or when stored attached to the Device.

To check if your handset is in ODP, remove Handset from the Charging Cradle or Device and wait five seconds. Looking at the top of the Handset, pull and hold the trigger. Watch the red window for a small light flashing one or more times. If no light is seen, the Handset is in ODP. To enable the Handset, simply put the Handset on the Charging Cradle.

If the Charging Cradle is already plugged in and Ready, the Handset will Initialize and begin Pre-Charging. While Pre-Charging, all three green charging bars will blink simultaneously.

Ready

Initializing



Pre-Charging

If the Charging Cradle is plugged in with the Handset attached, the Power Good indication will be followed by the red blink of the Ready sequence before Initializing and Pre-Charging. While Pre-Charging, all three green charging bars will blink simultaneously.

Power Good ***Ready*** ***Initializiing*** ***Pre-Charging***

See Section 6.2 for complete descriptions of the Charging Cradle indications.

Charging a Handset from ODP may take up to five hours. To prevent an immediate return to ODP, do not remove the Handset until the first green bar is blinking with the second and third bars off.

To avoid ODP in the future, store the Handset detached from the Device and fully charge every two months.

3.5 Optional Checks

The NOMAD Pro 3 is factory calibrated and tested prior to release (see your Certificate of Conformance). A self-diagnostic is completed each time an exposure is taken. However, the optional checks listed below may be performed periodically as desired. Some locations may require initial and periodic checks as a condition of use.

The NOMAD Pro 3 has an X-ray disable feature that allows the X-rays to be disabled for training purposes. Test firing this X-ray unit may otherwise be dangerous to the testing technician or bystanders. See Section 4.2 for more information.

- Power On/Off: Attach a fully charged handset to the NOMAD Pro 3 device. Press the Standby button and verify that the device in Standby mode. The Nomad Pro 3 is still drawing power in Standby mode. The device is only truly powered off when the handset is removed from the device.
- Increase/Decrease Exposure Time: With the device on, select the patient size, the image receptor type, and the tooth type. The exposure time corresponding to the selections will display on-screen. Press the Increase and the Decrease buttons, and verify that the exposure time changes appropriately. When the Increase or Decrease buttons are pressed and held, the rate at which the displayed time setting changes on screen accelerates.
- Triggering: With the device on and an exposure time selected, press and release the trigger once. This will ready the device, and the display will indicate the Ready state. To end the Ready state, press any button on the user interface panel or wait approximately 15 seconds for the timeout.
- Automatic Shut-down: With the device on, allow approximately three minutes of inactivity to pass for the system to automatically shut down.

The NOMAD Pro 3 should not be operated if it has been dropped or if performance degrades; it should be returned to the manufacturer or an authorized service center for an evaluation.

(See Section 6.1 Alarms and Alerts for more information.)

4.0 Operation

4.1 Powering Up

NOTE: The manufacturer's recommendation is for the operator to wear nitrile or other gloves during basic operation of the NOMAD Pro 3.

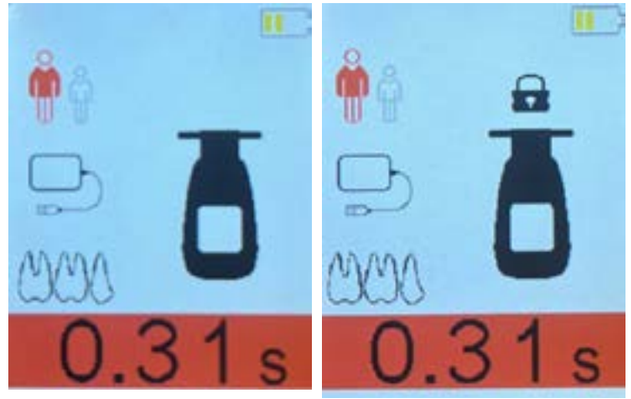
Press and release the Standby button to turn on the NOMAD Pro 3. An audible double tone and an active display panel indicate the device has power.

NOTE: The Nomad Pro 3 is still drawing power in Standby mode. The device is only truly powered off when the handset is removed from the device.

Technique factors are redisplayed according to what was displayed when the device was turned off, along with the last saved time setting.

4.2 Lock/Unlock the X-ray

The X-ray lock and unlock functionality can be activated to prevent unauthorized use when the NOMAD Pro 3 is idle or stored. This functionality may also be used for training purposes.



X-ray unlocked ***X-ray locked***

To lock the X-ray, press the Settings button. The screen will change from at-rest state to the Settings Menu.

Using the Decrease button, scroll down to the Lock symbol. The yellow highlight indicates that the Lock symbol is selected. Once the icon is selected, then press the Settings button to change the red with a green check. The device is now in lock mode.

Using the Increase button, scroll back up to the Return symbol. Press the Settings button to return to the at-rest state.

Upon returning to at-rest state, the Lock icon will appear above the X-ray tubehead, indicating that, while routine functions of the device may be performed, no X-rays will be fired.

4.3 Ensuring the Right Exposure Time is Set

When the device is in Standby mode (via the Standby button or timeout), the most recent setting for the exposure time is stored in the memory and redisplays when re-activated. However, if the battery is replaced, the display is reset to the default value.

To change exposure settings press each of the buttons to toggle through the choices:

1) Patient Size (adult or child)

2) Image Receptor (sensor, film, or phosphor plate)

3) Tooth Group (anterior, posterior, or bitewing)

Examples from factory default settings:

Child, Sensor, and Anterior = 0.16sec

Adult, Film, and Posterior = 0.70sec

When necessary, use the Increase or Decrease buttons to adjust the time in 0.01 second increments. Adjusted exposure settings may be saved, replacing factory settings (see Section 4.9 Technique Factors Settings and Adjustments).

4.4 Ready the Device

To prevent accidental radiation exposure, properly position the patient and operator before readying the NOMAD Pro 3.

Press and release the trigger once to ready the device. A green trefoil will briefly appear above the X-ray tubehead, which is the Enabling X-rays alert. Once the device has shifted to the Ready state, the inside of the tubehead, the time display, and the LED will also turn green. The visual Ready alert and a double tone alert confirm that NOMAD Pro 3 is prepared to fire X-rays.

The Ready state continues until an exposure is initiated or time-out occurs after 15 seconds of inactivity (and a double tone and the return of normal operations).

Ready Alert

The illuminated green LED square displays on the panel, and a double tone alert confirm that NOMAD Pro 3 is prepared to fire X-rays. The Ready state continues until either an exposure is initiated or timeout occurs after 15 seconds of inactivity (accompanied by a double tone and the return to the at-rest state).

While the device is in the Ready state, any changes to the settings (pressing any user interface panel button) will end the state.

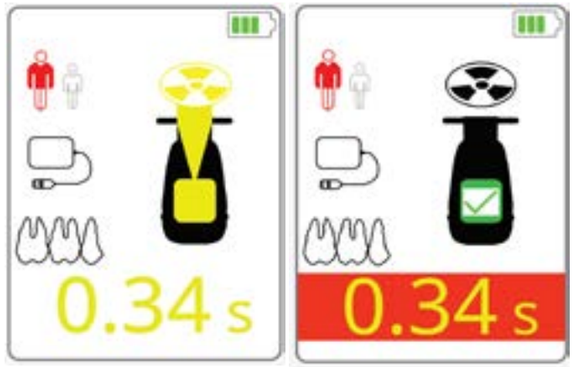
Note: As a safety precaution, if the trigger is held longer than one second or pulled a second time while still displaying the Enabling X-rays alert, the device will not transition to the Ready state. (This is to prevent an accidental activation of the device by unintended triggering.)

4.5 Initiating and Completing an X-ray Exposure

To begin the exposure, press and hold the trigger. The Ready alert is replaced with the X-rays On alert, the green LED is replaced with a yellow LED, and there is an alert tone for the duration of the exposure.

To ensure complete exposure, keep the trigger depressed until the audible tone is complete, the yellow LED off, and the X-ray Complete alert briefly displays. The device then returns to the at-rest state.

NOTE: An exposure can be terminated for any reason by prematurely releasing the depressed trigger or Remote Exposure Switch.



X-rays On Alert ***X-ray Complete Alert***

4.6 Powering Off

Press and release the Standby ⏻ button to turn the NOMAD Pro 3 off.

The NOMAD Pro 3 also automatically shuts off after approximately three minutes of inactivity.

The NOMAD Pro 3 display darkens, accompanied by a tone to indicate shut-down.

⚠ In the event of a malfunction or a noticeable change in image quality, it is recommended to immediately cease the use of the device on the patient and call Technical Support at 1-888-883-3947

⚠ Any serious incident that has occurred in relation to the use of the NOMAD Pro 3 should be reported to Technical Support at 1-888-883-3947.

4.7 Exposure Techniques

As an intra-oral dental X-ray system, the NOMAD Pro 3 can be easily positioned. This high degree of flexibility makes it easy to take exposures while the patient is reclined, lying completely on their back, or sitting upright. Ensure the patient is protected by using an apron.

❶ When taking images, operators may hold the NOMAD Pro 3 by having both hands on the handset grip, or, for increased stability and patient safety, by placing one on the grip and the other on the underside of the housing.

❷ Position the NOMAD Pro 3 relative to the imaging system to minimize cone-cutting. (If your practice uses film holding kits or aiming devices, check compatibility in advance.)

❸ Exposure times increase proportionally when the imaging angles vary away from 90° (or perpendicular) to the film or sensor. To maintain low patient X-ray doses and to keep the operator within the protection zone, have the head of the patient slightly tilted, and/or raise or lower the chin as needed. (See Section 2.1 Radiation Safety.)

❹ When the device must be angled and the operator cannot be completely within the protection zone, ensure operator protection through the use of proper safety measures, such as the use of a lead or lead equivelant apron. (See Section 2.1 Radiation Safety.)

❺ Avoid touching the patient with the cone or backscatter shield; disposable plastic coverings can be used to prevent cross-contamination.

❻ Determine what NOMAD Pro 3 exposure time settings deliver optimal results for the type of imaging (digital or film-based) that is used on a regular basis.

NOTE: Both digital imaging sensors and film and phosphor plate speeds can vary somewhat in their characteristics and could require different exposure settings to meet density preference. (See Section 4.10 Settings Menu for more information.)

4.8 Ensuring Image Quality

The following NOMAD Pro 3 features contribute to high image quality:

- DC voltage X-ray generation is efficient in delivering energy at the level optimized for diagnostics, with shorter exposure times required.
- The smaller the focal spot, the better the resolution. The NOMAD Pro 3 has a small 0.4mm focal spot.

- Absorption of scatter by the NOMAD Pro 3 backscatter shield reduces incidence of noise for the image receptor, which tends to increase image contrast.

Motion during Exposures

As with the suspended tubehead of a conventional wall-mounted X-ray system, some motion of the tubehead during actual exposures is possible. Use both hands to hold the NOMAD Pro 3 during the exposure and keep steady. The pistol-grip style is ideal for keeping hands behind the backscatter shield, positioning and aiming (with line of sight through the clear shield) so as to achieve a quality image and avoid cone-cutting or retakes.

Time Settings, Sensors, and Complete Exposures

To ensure image quality, use correct time settings. The NOMAD Pro 3 comes with pre-sets to give you a starting point. However, these time settings can be adjusted to achieve the desired image quality and then saved for future use. See Section 4.10 Settings Menu for further help.

The NOMAD Pro 3 works with the fastest sensor technologies in the market to assure that exposure times are as short as possible, also limiting any effects of motion.

Make sure you are as close to the patient's cheek as possible without touching. If your sensor holder prevents you from getting close enough, you may want to use the Short Alignment Bars, enabling the NOMAD Pro 3 to be placed directly against the positioning ring.

Always double-check for the Incomplete Exposure alarm on the NOMAD Pro 3 display. The Incomplete Exposure alarm indicates that the trigger was released prematurely, resulting in an incomplete exposure. To achieve complete exposures, do the following: quickly press and release the trigger to enable the X-ray and wait for the device to shift to the Ready state; press and hold the trigger until the audible tones and the display indicate the X-ray Complete alert.

4.9 Technique Factors Settings and Adjustments

The factory settings in this chart are intended as a reference starting point only and are based upon average preferences and use with the cone perpendicular to the image receptor. Individual results may vary based upon a number of factors including image density preferences, the various imaging sensors or available film speeds and brands, patient size, practitioner techniques, and preferences.

Pediatric Considerations

Use of equipment and exposure settings designed for an average-sized adult can result in excessive radiation exposure for a smaller patient, especially pediatric. Pediatric patients may be more radio-sensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher), and so unnecessary radiation exposure is of particular concern for pediatric patients. Please use caution when configuring the NOMAD Pro 3 by considering the patient's age, size, body habitus, and clinical indication when verifying exposure time settings.

The following links to US FDA and Image Gently websites are useful resources for pediatric imaging guidelines and information:

https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/default.htm

http://www.imagegently.org/Procedures/Dental#35771809-guidelines-and-resources

Pre-set Technique Factors Chart

2.5 mA 65 kV

		Posterior	Anterior	Bitewings
Digital Sensor	Adult	0.31	0.20	0.25
	Child	0.25	0.16	0.20
Film	Adult	0.70	0.45	0.56
	Child	0.56	0.36	0.45
Phosphor Plate	Adult	0.38	0.24	0.30
	Child	0.30	0.19	0.24`

Technique Factor time settings can be adjusted by the operator. This is done from the main display screen by following these steps:

❶ Press the Increase ∧ or Decrease ∨ buttons until the desired time setting is selected.

NOTE: When the Increase ∧ or Decrease ∨ buttons are pressed and held, the rate at which the displayed time setting changes on screen accelerates.

❷ Press and release the Settings button to activate the Settings Menu.

❸ The Save icon will be highlighted. Press the button to replace the red ✗ with a green check ✓.

❹ Return the Settings Menu to save the new settings.

❺ Once saved, this change will be maintained in memory until overwritten or until the factory defaults are restored through the Reset Defaults menu item.

4.10 Settings Menu

The NOMAD Pro 3 menus allow the operator to customize settings according to individual preferences. To access the Settings Menu, press the Settings button for three seconds. When the Settings Menu appears, the operator can access the desired menu item(s) by pressing the Increase ∧ and Decrease ∨ buttons to scroll up or down. A menu item is selected when it is highlighted in yellow.

When the operator exits the Settings Menu by using the Return menu item, any settings that have been modified will be saved.

Following is a table discussing the various menu items and the options and functionality associated with each.

Menu Item	Icon	Options
Return		Allows the operator to leave the Settings Menu and return to normal operation. (Powering off and then on also exits the menu but changed settings will not be saved.)
Lock/Unlock X-rays		Can be activated to prevent unauthorised use when the NOMAD Pro 3 is idle or stored. This functionality may also be used for training purposes. The red ✗ indicates that the X-ray is unlocked. In order to lock the X-ray, the operator presses the Settings button. The red ✗ will change to a green check ✓, indicating that the X-ray is now locked. The X-ray can be unlocked by pressing the Settings button again, replacing the green check ✓ with the red ✗.
Audible Sound		Allows the operator to adjust the volume. The range is from zero (softest), up to five (loudest). The Settings button is used to cycle through the different volume options. The system emits a tone as each volume is selected so the operator can determine the choice. Once the desired option is displayed, the operator may scroll either up or down to change other settings; the selected volume will remain. The operator may return to the audible sound menu item to make further adjustments during the current Settings Menu session. However, once the operator exits the Settings Menu, the volume choice will be saved and can only be changed by re-entering the Settings Menu.
Trip Counter	0005 0000	May be used to track the number of X-rays taken during a given period of time. In order to reset the trip counter, press the Settings button to toggle between the current X-ray count (which will be displayed in red) and the reset count (zero, which will be displayed in green). Once the desired option is displayed, the operator may scroll either up or down to change other settings; the selected Trip Counter option will remain. The operator may return to the Trip Counter and change from a reset count to a previous count at any time during the current Settings Menu session. However, once the operator exits the Settings Menu, the previous trip count may not be recovered after it has been reset.

Menu Item	Icon	Options
Reset Defaults		Allows the operator to restore the factory default settings with which the device was shipped. These defaults are: • X-rays will be unlocked; • Audible sound will be set at full volume; • Trip counter will be reset to zero; • All factory timer settings/technique factor combinations will be reset to factory defaults, overriding any custom settings the operator may have input. In order to reset, press the Settings button, replacing the red ✕ with a green check ✓. The operator may return to Reset Defaults and determine to not reset at any time during the current Settings Menu session. However, once the operator exits the Settings Menu, the device will be reset to factory defaults and any custom settings previously saved by the operator may not be recovered.
Save Settings		Allows the operator to save customised timer settings and technique factors. In order to ensure that settings are saved, press the Settings button, replacing the red ✕ with a green check ✓. The operator may return to Save Settings and determine to not save at any time during the current Settings Menu session. However, once the operator exits the Settings Menu, the timer settings and technique factors displayed on the user interface will be saved over any previous settings, whether they are factory defaults or another customised setting. If an operator wants to restore factory defaults, this can be done through the Reset Defaults menu item.

5.0 Handset Replacement and Care

- Handsets must be charged before initial use. Alternate handsets each week to maximize service life. Handset should be at least 2/3 charged for long term storage.
- After daily use, it is recommended to disconnect the Handset from the device housing for overnight storage.
- Do not spray disinfectant or cleansers directly on to the handsets.

A Recharge Handset alarm on the display panel indicates the need for a recharged handset. The NOMAD Pro 3 cannot emit X-rays with a low, depleted battery (insufficient voltage). Follow these steps to clear the Recharge Handset alarm.

❶ Press and release the Standby button on the control panel to turn off the NOMAD Pro 3.

❷ Place the NOMAD Pro 3 bottom up on a stable surface and depress the release button on the housing, just behind the handset, to release it from the housing.

❸ Slide the handset forward toward the backscatter shield and the collimator cone.

❹ Carefully align a newly charged handset and, while avoiding possible pinch points between the housing and the handset, slide it into place. A properly oriented handset should snap into place without force. A clicking sound ensures that the handset is fastened. Make sure the handset is secure by pushing it toward the cone.

IMPORTANT HANDSET CARE NOTES:

- If you have a second handset, rotate the handsets each week to maximize service life.
- Routinely change discharged handset with a fully charged handset (sold separately).
- Remove the handset from the Charging Cradle once is fully charged.
- Battery life is expected to be at least 2 years with proper care and maintenance.
- Batteries and Handsets may only be replaced with NOMAD Pro 3 Batteries and Handsets. NOMAD 2 batteries are compatible with the NOMAD Pro 3 Handset.
- Battery charge will diminish during extended inactivity. Fully recharge handsets every three months during inactivity. Never place a low charged battery into long-term storage.
- To quickly check the charge level of a handset when it is not attached to the tube head or charger, pull the trigger and watch the dark red window. A blinking light will indicate the charge level from 1 (low) to 5 (high).

- Do not attempt to charge a handset with damaged batteries. Damage can occur if handset experiences liquid ingress, if it has been dropped or punctured, or exposed to heat or fire. Replace handset immediately if there are any signs of deterioration or if batteries do not retain a charge during normal operation.
- Risk of fire or explosion exists if batteries inside the handset are replaced by unauthorized service personnel; do not use batteries from other sources.
- Properly dispose of spent or damaged handsets; return to the manufacturer or an authorized distributor for replacement and recycling. Do not place in municipal waste stream.

5.1 Locating the Software revision version

To locate the current version of the firmware:

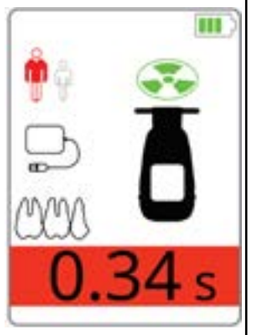
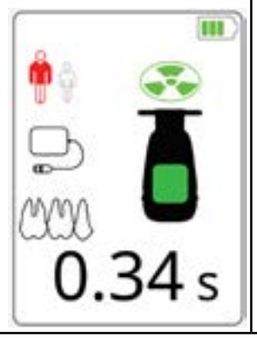
1. Attach the handset to the device.
2. Press and release the Standby ⏻ button.
3. View the Firmware ID String on the Splash Screen.
   Example: FGD_2.2.2 is firmware version 2.2.2.

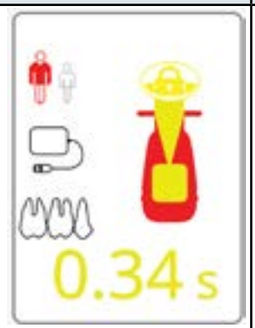
6.0 DEXIS NOMAD Pro 3 Care and Upkeep

6.1 Alarms and Alerts

The visualan audible alarms signal a programmed action designed to prevent harm to operators, patients, and/or the NOMAD Pro 3. The visual/audible alerts confirm normal conditions or draw the operator's attention to a required action.

NOTE: All audible signals except X-ray termination and completion may be turned down with the Audible Sound option. See Section 4.10 Settings Menu.

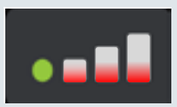
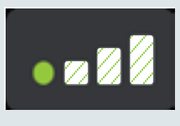
Alerts & Alarms: Visual and Audible Indicators		Function/Resolution
Visual	Audible	
Enabling Alert 	None	This alert is initiated by a single pull and release of the trigger, within one second. If no further action is taken, the device will shift into the Ready state. If the trigger is pulled again before the Ready state is indicated, the second pull is disregarded.
Ready Alert 	Double ascending tone	At the conclusion of the Enabling X-Rays alert, the device will shift into the Ready state. The Ready state will last for 15 seconds, or until one of the buttons on the user interface panel is pressed, or until the exposure is initiated by a second pull of the trigger.

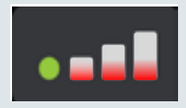
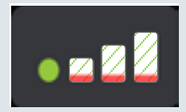
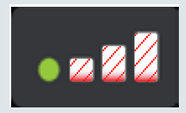
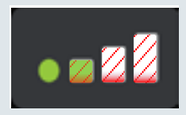
Alerts & Alarms: Visual and Audible Indicators		Function/Resolution
Visual	**Audible**	
X-ray Exposure Alert 	Single tone for duration of exposure (X-ray exposure alert)	At the end of the successful exposure the yellow LED turns off, and the panel briefly displays X-ray Complete alert and the screen returns to the at-rest state.
X-ray Complete Alert 		
X-ray Lock Alert 	Tones will be the same as the actual operation tones	When the device is put in lock mode, the trefoil symbol is displayed on the at-rest screen is replaced with a lock symbol. All other operation remains the same, although no X-rays will be fired. For instructions on how to lock/unlock the device, see Section 4.2.
Duty Cycle Enforcement Alert 	Double tone at the start and end of the delay cycle	If the operator presses the trigger to activate the Ready alert before the duty cycle time has elapsed, the device will display the alert, and a countdown timer will be displayed showing the duty cycle time remaining. This will lock the device and the alert will be displayed until the duty cycle is complete. The device will then return to the at-rest state.

Alerts & Alarms: Visual and Audible Indicators		Function/Resolution
Visual	**Audible**	
Recharge Handset Alarm (Flashing Display) 	6 audible tones	The Recharge Handset alarm terminates after five seconds and goes into auto shutdown. Replace the current handset with a freshly charged handset. NOTE: If the battery voltage is lower than required for the X-ray exposure, the device will not allow the exposure.
Incomplete Exposure Alarm 	A warning tone	Activates if the trigger is released before the timed X-ray exposure finishes. This condition is cleared by pressing any button on the user interface panel, by turning the power off then on, or by pressing the trigger. To avoid this error, depress the trigger for the duration of the exposure time.
System Failure Alarm (Flashing Display) 	7 audible tones followed by descending tone	See Section 6.3 Troubleshooting or a manufacturer authorized service center.
Handset Failure Alarm (Flashing Display) 	7 audible tones followed by descending tone	See Section 6.3 Troubleshooting or a manufacturer authorized service center.

The NOMAD Pro 3 should not be operated if it has been dropped or if performance degrades; it should be returned to the manufacturer for an evaluation.

6.2 Charging Cradle Indications

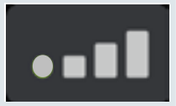
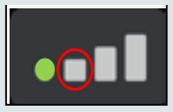
Indication	Name	Notes
	Power Bad	While the AC/DC Power Supply is connected, the round indicator should be lit green.
	Power Good	When AC/DC Power Supply is connected, the round indicator should light green immediately. After a short pause (~2s), the Lamp Test should commence.
   	Lamp Test	If a Handset is already engaged, the Lamp Test will be skipped. If a handset is engaged during the Lamp Test, it is terminated early. The Lamp Test alternates between lighting red and green (as shown) providing time (~4s) to verify that all the LEDs are functional. After Lamp Test, the Ready indication will be displayed.
 	Ready	The Ready indication is a red blink (~1s) followed by all bars off. The bars will remain off until a connection is detected. If a Handset is already engaged, the transition to Initializing may be so quick that the off portion may be hard to see. This sequence occurs at the end of Lamp Test and after a Handset has been removed to indicate that the Charging Cradle is Ready to initiate a charge cycle.
	Initializing	When a connection has been detected, the first green bar is lit while the Charging Cradle verifies the Handset. If the Handset is compatible, one of the following charge indications will be displayed. If the Handset is not compatible or does not respond, the Not Charging indication will be displayed.
	Pre-Charging	While the Handset is in an Over Discharge Protection mode, the Pre-Charging indication will be displayed; all three charging bars blinking green simultaneously. When the protection mode is cleared (usually 3 minutes or less), normal charging begins.

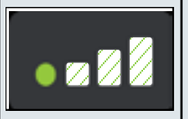
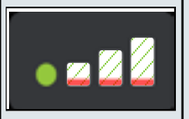
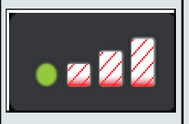
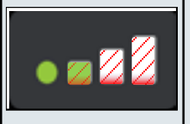
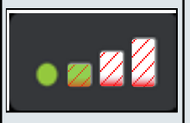
Indication	Name	Notes
	Charging (Level < 33%)	While the first charging bar is blinking green, the Handset is charging. The Level has not yet reached 33% of Fully Charged. Charging to the 33% level will take longer than usual for a Handset that has been in Over Discharge Protection mode.
	Charging (Level < 66%)	While the first green charging bar is on and the second bar is blinking green, the Handset is charging. The Level has reached 33% but not yet reached 66% of Fully Charged.
	Charging (Level < 100%)	While the first two green charging bars are on and the third bar is blinking, the Handset is charging. The Level has reached 66% but not yet reached Fully Charged.
	Fully Charged	When charging is complete, blinking will stop, and all three green charging bars will be on. If the Handset is removed before charging is complete, blinking will stop, current Level will be displayed briefly (~2s), the Charging Cradle will prepare to start a new cycle, and the Ready indication will be displayed. If the Handset is left on the Charing Cradle, it remains enabled and the Charging Cradle continues monitoring status. If the Level drops below the Fully Charged range, a top-off charge cycle will be initiated; third bar will begin blinking.
	Not Charging	If the Charging Cradle cannot charge the attached device, the steady red Not Charging indication is displayed. The Charging Cradle is not communicating with the device and its removal will not be detected as quickly as normal. The charge controller is re-enabled periodically (~10s) to detect device removal.
	Pre-Charging Timeout	After Pre-Charging for ten minutes, charging will stop and the Pre-Charging Timeout indication will be displayed. All three green bars will continue to flash along with the solid red (Not Charging) indication.
	Temperature Holdoff	If the Handset reports a status that prevents charging, a blinking red indication is displayed. Temperature outside the allowed range results in the Temperature Holdoff indication - blinking red with all of the green bars off. The Handset status is monitored, and if the condition clears, normal operation will resume.
	Handset Error	If the Handset reports a status that prevents charging, a blinking red indication is displayed. An error results in the Handset Error indication - blinking red with the first green bar on. This indication is also used if communication with the Handset fails (e.g., when attaching/detaching Handset). The Handset status is monitored, and if the condition clears, normal operation will resume.

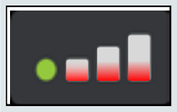
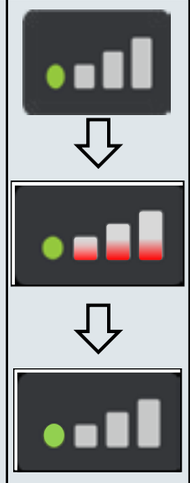
6.3 Troubleshooting

If you encounter results and/or errors in the operation of the NOMAD Pro 3 that are not explained in the previous sections, check the following table on user troubleshooting to determine the need for authorized service. If you have additional questions or require help, contact the manufacturer: NOMADsupport@dexis.com

Device Symptom	Potential Problem	Corrective Action
6.3.1 The handset did not seem to be working when the trigger was pulled.	The trigger is not communicating with the device.	If this condition persists, authorized service is required. See Maintenance and Repair for more information.
6.3.2 Device does not turn on.	If pressing *Power* multiple times does not cause the display to illuminate, the attached handset may be the cause.	Ensure handset is securely attached.
		Remove handset, and check charge status by looking at the top red window adjacent to the unit label then pulling and holding the trigger. If fewer than two flashes are seen, recharge the handset.
		Re-try with the second handset.
		If this condition persists, authorized service is required. See Section 7.0 Maintenance and Repair.
6.3.3 Incomplete Exposure alarm displayed on-screen.	Incomplete exposure: the depressed trigger is released before the timed exposure is able to complete.	Clear this message by pressing and releasing the trigger or by pressing any button on the user interface panel. Be sure to depress the trigger for the full duration of the timed exposure.
6.3.4 Device does not shift to the *Enabling X-rays* alert or *Ready* alert.	The trigger is pulled for longer than one second.	Pull and release the trigger within one second and wait for the Ready alert.
	The device may be above the maximum operating temperature of 104°F (+40°C).	Allow the device to return to the operating range as stated in Section 8.
6.3.5 Image from X-ray exposure does not have sufficient contrast.	Underexposure (too light).	Increase the exposure time setting; or see "Incomplete Exposure" below.
	Overexposure (too dark).	Decrease the exposure time setting. Also check film expiration date (old film can produce dark, grainy/foggy images).
	Chemical developer (for film-based imaging).	Ensure chemical freshness and proper temperature.
6.3.6 Image from X-ray exposure is blurred.	Combined movements of operator and patient during exposure produced too much distortion.	Check the exposure time setting and re-enable when operator and patient are again properly situated.
6.3.7 *System Failure* alarm displayed on-screen.	Self-diagnostics, which automatically run during X-ray firing, detects a potential issue.	This warning alarm can be cleared by powering off, then on. If the alarm redisplays, the NOMAD Pro 3 will require authorized service; see Section 7.0 Maintenance and Repair.
6.3.8 *Handset Failure* alarm displayed on screen.	The handset, in general, is not communicating with the device.	Ensure handset is securely attached.
	The batteries are impaired or at the end of their life cycle.	Replace with a newly charged handset in order to continue. Use the Charging Cradle to determine the handset status. See Section 7.0 Maintenance and Repair.
	A different problem exists if all handsets appear fully charged.	If this condition persists, authorized service is required. See Section 7.0 Maintenance and Repair.
6.3.9 NOMAD Pro 3 automatically shuts down.	NOMAD Pro 3 times out after about three minutes of inactivity.	Manually turn on NOMAD Pro 3 when you are ready to use the device.
	A different problem exists if shut-down occurred during regular activity.	If this condition persists, authorized service is required. See Section 7.0 Maintenance and Repair.
6.3.10 *Ready* state terminated before an exposure started.	The *Ready* state expires because the X-ray exposure is not initiated within 15 seconds of the start of the *Ready* state.	Double-check the exposure time setting and re-enable when operator and patient are again properly situated.
6.3.11 Device unresponsive. Keypad input indicator (dot in the top right corner of Time Display).	Button on keypad is stuck.	Press and release each button to see if stuck button will release. If this condition persists, authorized service is required. See Section 7.0 Maintenance and Repair.
6.3.12 Device unresponsive. Trigger input indication (dot in bottom right corner of Time Display).	Handset trigger is stuck.	Press and release trigger to see if the trigger will release. Swap handsets and see if the second handset has the same issue. If this condition persists on either handset, authorized service is required. See Section 7.0 Maintenance and Repair.

Symptom	Display	Cause/Problem	Action
Charging Cradle Power Good indication does not come on.		Faulty LED(s)	Check for any working LEDs: 1) Remove Handset 2) Unplug power cord from rear of Charging Cradle 3) Wait 5 seconds and re-connect 4) Round indicator should light immediately 5) Press various spots on indicator label for seven seconds (through Lamp Test period) 6) Watch for any LED to light If any light is seen, AC/DC Adapter is good; return Charging Cradle.
		Faulty AC/DC Adapter	Try another AC/DC Adapter; if Charging Cradle works, return adapter.
		Faulty circuit board	Try AC/DC Adapter in another Charging Cradle; if works, return cradle.
During power on Lamp Test, some Charging Cradle LEDs do not come on or stay on when they should go off. [Three red alternating with all green (one green in first bar, two green in second bar, three green in third bar)]	Examples:   	Faulty LED(s) or circuit board	Return Charging Cradle
When Handset is attached to Charging Cradle, the first green bar does not turn on solid (Initializing indication)		Handset is in an undetectable state	Verify Charging Cradle is functional by trying another Handset. (Check Handset charge level using trigger. Check charge level by connecting to Device. If Handset has charge, use normally, and see if problem repeats next charge cycle.)
		Charging Cradle is not detecting properly (faulty circuit board)	Verify Charging Cradle is NOT functional by trying another Handset. Return Charging Cradle.

Symptom	Display	Cause/Problem	Action
When Handset is attached to Charging Cradle, first green bar on solid (Initializing indication) is followed by red on solid (Not Charging indication)		Handset is not compatible	DEXIS NOMAD Handsets and DEXIS NOMAD Charging Cradles are compatible with both DEXIS and KaVo branded Charging Cradles, Handsets and AC/DC Adapters.
		Communication path is block or distorted	Clean communication path windows on Charging Cradle and Handset. Check for severe scratches that may be preventing communication. Verify Charging Cradle is functional by trying another Handset. If it works, return Handset or return Charging Cradle if it does not work.
		Handset is not communicating (faulty Handset)	Verify Charging Cradle is functional by trying another Handset. Return Handset.
		Charging Cradle is not communicating (faulty circuit board)	Verify Charging Cradle is NOT functional by trying another Handset. Return Charging Cradle.
All three green bars are blinking (Pre-Charging indication)		Handset is recovering from an over discharged condition	No action. The Charging Cradle should begin to indicate normal charging within ten minutes. After experiencing an over discharge, the time to reach 33% (first green bar solid) will be longer than normal.
All three green bars are blinking (Pre-Charging indication) and red is on solid (Not Charging indication) - Pre-Charging Timeout indication		Unchargeable Handset	Remove Handset and wait for Charging Cradle Ready indication. Re-engage Handset. If problem persists, return Handset.
After Initializing or while Charging, red starts blinking (green bars are off) - Temperature Holdoff indication		Handset reported internal temperature outside the allowable range	The Charging Cradle has halted charging and will resume if temperature returns to normal range. Try relocating Charging Cradle to cooler/warmer location as appropriate. If condition persists, return Handset (after verifying Charging Cradle is functional using another Handset).
After Initializing or while Charging, red starts blinking and first green bar is on solid - Handset Error indication		Handset reported status prevents charging	The Charging Cradle has halted charging and will resume when Handset status returns to normal. If indication does not clear, disconnect Handset, wait for Ready indication (red blink then all bars off), reconnect Handset. If condition persists, return Handset.
When connecting or disconnecting Handset from Charging Cradle, red starts blinking and first green bar is on solid - Handset Error indication		User action caused communication error	The indication should clear without action. If indication does not clear, disconnect Handset, wait for Ready indication (red blink then all bars off), reconnect Handset.

Symptom	Display	Cause/Problem	Action
While Charging, green bar stops blinking, but all three green bars are not on solid (no Fully Charged indication)	Example: 	Handset charge monitoring algorithm is out of sync with the battery	Use Handset until recharge is required. Charging has stopped and the Level indicated is the level reported by the Handset while the Charging Cradle detected fully charged conditions. Usually a result of over discharge or a long storage period, this should correct itself after a discharge-charge cycle. If condition persists, return Handset.
		Charging Cradle is terminating charge incorrectly (faulty circuit board)	Use another discharged Handset to verify that Charging Cradle will complete a charge cycle correctly. If condition persists, return Charging Cradle.
Third green bar starts blinking after Handset has been fully charged		Handset stored on Charging Cradle	No Action. The Charging Cradle monitors the fully charged Handset until it is disconnected. If it is not removed, the Handset cannot enter its low power mode, and the charge Level will eventually drop below 94%. When this happens, a top-off charge cycle is initiated guaranteeing that the Handset will be between 93% and 100% at all times.
Not Charging indication does not clear after Handset has been removed from Charging Cradle		Handset removal not detected or faulty LEDs	Wait 15 seconds after Handset is removed from Charging Cradle. If indication does not clear, unplug power cord from rear of Charging Cradle, wait 5 seconds, and re-connect. If condition persists, return Charging Cradle.
Without Handset connected, Charging Cradle blinks red		Detection of stray IR input	No Action. Charging Cradle has reinitialized the Ready state.

7.0 Maintenance and Repair

Incorrect operation or failure to maintain the device in accordance with the maintenance schedule relieves the manufacturer or their agent from all the responsibilities for subsequent non-compliance, damage, injury, defect and/or other malfunction. It is strongly recommended that only authorized service representatives, trained specifically on the NOMAD Pro 3 device, maintain and service the device.

Modifications and additions to the device (including replacement of power cords and exposure switches) must be carried out only by personnel or third parties that are expressly authorized by the manufacturer, and must comply with the applicable legal requirements.

7.1 Maintenance Schedule

The following quality checks and maintenance items can be performed by any trained personnel. Log sheets for tracking pertinent maintenance information (e.g., what tests were performed by who on what date) can be found in Section 7.3 Maintenance Log Sheets.

On-going Maintenance: Observe the following steps for on-going maintenance of the NOMAD Pro 3.

1. The NOMAD Pro 3 may be sent to the manufacturer for maintenance and inspections as required by local regulatory authority.
2. Review Section 1.1 Indications for Use and product labeling periodically in order to verify understanding of indications for use for the NOMAD Pro 3.
3. A routine wipe-down of the NOMAD Pro 3 between patients per instructions listed in Section 2.4 and 2.5 is recommended, along with a quarterly visual inspection for damage. Make sure the power is off while cleaning. It is recommended for the handset to be attached during cleaning of the device. Use a CaviWipe 2.0 to wipe the exterior surfaces of the device and Charging Cradle. Don't use cleaners intended for hard surfaces or acetone based, since certain chemical combinations may deteriorate the NOMAD Pro 3 plastic prematurely. Also do not use cleaners that leave any sort of residue or sticky build-up on the device surface. Such cleaners can eventually interfere with properly connecting and disconnecting the handset.
4. See Section 5.0 Handset Replacement and Care for more information related to Handset maintenance.
5. Periodically assess operator familiarity with the NOMAD Pro 3 in order to determine whether refresher training/certification (per local, national, and jurisdictional requirements) is needed.
6. Periodically review Section 4.9 Technique Factors Settings and Adjustments for comprehension and to assess whether or not chart information is being incorporated into daily use.

7. Periodically review Section 2.1 Radiation Safety and Section 2.2 Studies and Data on Leakage and Scatter in order to become reacquainted with safety precautions, which include designating a Significant Zone of Occupancy and understanding exposure information near the unit.

Annual Maintenance: Observe the following steps for annual maintenance of the NOMAD Pro 3.

1. Verify that the Standby button is working properly. When the device is powered on, the display should illuminate and an indicator alarm should sound.
2. Verify that the device is in lock mode when the Settings and Patient buttons are pressed simultaneously. Repeat the process to unlock the device. Verify that the device is unlocked.
3. Verify that, when left on for a period of approximately three minutes without pressing any buttons, the device automatically shuts off.
4. With the device powered on and unlocked, verify that a time selection value displays on the user interface panel. Also check the function of the Increase ∧ and Decrease ∨ buttons. Pressing the buttons should cause the time setting to adjust accordingly.
5. Verify that the trigger moves freely in and out when depressed and released.
6. Verify that a single pull and release of the trigger enables the X-rays and the device moves into the Ready state.
7. Verify that the backscatter shield is firmly attached to the collimator cone and that it is not cracked or broken.
8. Select an exposure of 1.00 second using the time exposure buttons. Initiate an exposure, but release the exposure switch after a brief period of time before the timer terminates the exposure. Verify that the exposure terminates immediately upon release of the trigger.
9. While taking the exposure, verify that the X-Rays On LED illuminates and the audible signal is heard.
10. Ensure that the operator of the system has received a copy of the operator manual.

- The NOMAD Pro 3 should not be operated if it has been dropped, if housing is broken, if performance degrades, or if the backscatter shield has been broken or compromised in any way; it should be returned to the manufacturer for an evaluation.
- For long-term storage, it is recommended to charge batteries at least 2/3 every 3 months.

The NOMAD Pro 3, the handsets, and the Charging Cradle are NOT designed to be user-serviceable. There are dangerous voltages inside. Do not open the device, handset, or charger housing. Doing so, will void the warranty.

7.2 Calibration Checks

The NOMAD Pro 3 is factory calibrated and tested prior to release (see your Certificate of Conformance) and there are no adjustment options.

Prior to checking the NOMAD Pro 3 calibration performance, please review the information provided below.

The following is a detail of the testing equipment, used at the factory, to check conformance of the NOMAD Pro 3. Using other test instruments may yield differing results. Please contact Customer Care for additional testing guidelines.

Measurement Method: Final performance measurements are made using a Piranha model 255 X-ray meter from RTI Group or a Nero mAx model 8000 X-ray meter from Victoreen. Tube current (mA) is sensed across a series connected resistor with an accuracy of ±1% and measured using a digital multimeter, prior to encapsulation; the NOMAD Pro 3 has no provision for external measurement of beam current after final manufacture. Exposure time is measured during the entire exposure, referenced to 75% rise/fall. Accelerating voltage (kV) is measured at both peak (kVp) conditions and effective conditions (kVeff), which is the equivalent kV as if the kV were constant through the whole exposure time. Linearity is calculated per IEC 60601-2-65, 203.6.3.1.101.

This X-ray unit may be dangerous to the testing technician and any bystanders unless safe test exposure factors, such as placing the test detector in a lead lined box or using a protective lead apron and thyroid collar, are observed.

Enable the NOMAD Pro 3 and, with the cone perpendicular to the test detector, make exposures into the test detector and capture the resulting data.

Compare the results with the factory release parameters (indicated in the chart below). For results outside these parameters, discontinue use and contact your manufacturer.

Test Description	Acceptance Limits			
		400 ms	600 ms	1000 ms
kVp (eff) Accuracy	65kV ±10%	58.5 to 71.5	58.5 to 71.5	58.5 to 71.5
Timer Accuracy	Setpoint ±10%, +1ms	359 to 441	539 to 661	899 to 1101

A duty cycle of 1:60 is required after each X-ray discharge to prevent over-heating damage to the X-ray tube.

7.3 Maintenance Log Sheets

Maintenance Test	Year 1	Year 2*	Year 3	Year 4*	Year 5	Year 6
	Date/ Initial	Date/ Initial	Date/ Initial	Date/ Initial	Date/ Initial	
1. Standby Button						Schedule Five-Year Maintenance Inspection at Manufacturer
2. Lock-out Mode						
3. Automatic Shut-Off						
4. Time Selection Buttons						
5. Trigger						
6. Enable/Ready State						
7. Backscatter Shield						
8. Exposure Termination						
9. X-Rays On LED and Audible Signal						
10. Operator Manual						
11. Calibration Checks (Optional)						

Maintenance Test	Year 1	Year 2*	Year 3	Year 4*	Year 5	Year 6
	Date/ Initial	Date/ Initial	Date/ Initial	Date/ Initial	Date/ Initial	
1. Standby Button						Schedule Five-Year Maintenance Inspection at Manufacturer
2. Lock-out Mode						
3. Automatic Shut-Off						
4. Time Selection Buttons						
5. Trigger						
6. Enable/Ready State						
7. Backscatter Shield						
8. Exposure Termination						
9. X-Rays On LED and Audible Signal						
10. Operator Manual						
11. Calibration Checks (Optional)						

*It is recommended to replace handsets after years 2 and 4. Contact manufacturer for more information on covering battery replacement through DEXIS Complete.

7.4 Repair

There are no parts designated as repairable in the field by the owner/user of the device, including fuses. Contact Technical Support at 1-888-883-3947 if repairs are needed.

Only manufacturer supplied components may be used. Substituting manufacturer parts may cause incorrect operation or failure to the device.

See Applendix - Accessories for user replaceable components.

Damaged or faulty NOMAD Pro 3 materials and components must be properly disposed of according to local requirements, or returned to an authorized distributor or Dental Imaging Technologies Corporation (DITC). Please protect the environment, and do not improperly dispose of any part of the NOMAD Pro 3 system, the handsets, the Charging Cradle, or the AC power supply. At end of life, return these items to DITC for replacement, and proper disposal or recycling.

- Do not dispose of any parts of this product with industrial or domestic waste. Incorrect disposal of any of these materials may lead to serious environmental pollution.
- Properly dispose of spent or damaged handsets; return to DITC or an authorized distributor for replacement and recycling. Do not place in municipal waste stream.

If product return is required, contact Technical Support for a Return Material Authorization (RMA) number and shipping instructions to return the product to an authorized service center. You will be required to provide the serial number from the label affixed on the underside of the NOMAD Pro 3.

Be sure to include the RMA number on the package you are returning. Products without an RMA number cannot be serviced or given credit consideration.

DITC will not assume responsibility for shipping damages; however, it will help you file a claim with the freight carrier.

To avoid any potential hazard or danger to Operators and Patients, contact Technical Support at 1-888-883-3947 immediately if you experience any unusual operation, non-recoverable faults, or equipment malfunctions or failures.

Do not operate the device with any covers open or removed. Operating the device with open or removed covers could expose mechanical operating systems that could cause serious or fatal personal injury to you or the Patient. Only qualified and authorized service personnel should remove covers from the device.

8.0 Technical Description

8.1 Basic Technical Specifications

Maximum deviation from fixed factors: ±5% (unless otherwise noted)
Total weight: 6.3 pounds (2.8kg)

Environmental	
Operation	
Temperature	50°C (10°C) to 104°F (40°C)
Relative humidity	30% to 80%, non-condensing
Storage and transportation	
Temperature	–4°F (–20°C) to 50°F (10°C)
Relative humidity	5% to 90%, non-condensing

Do not use the NOMAD Pro 3 outside of the temperature and relative humidity ranges specified.

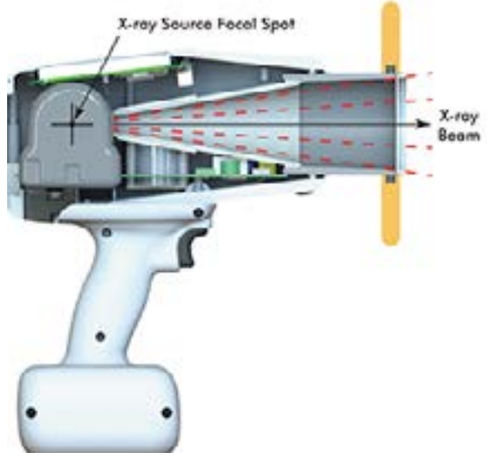
Classification / Specification Compliance	
Conforms to AAMI ES60601-1, IEC STDS. 60601-1-3, 60601-1-6, 62366, 60601-2-65	
Complies with FDA radiation performance standards 21CFR, Subchapter J	Internally Powered, Type BF
MDD (93/42/EEC): Annex IX	Class IIb
IPX specification	IPX0; do not operate under wet conditions
Mode of operation	Intermittent operation
Applied part (non-detachable)	Collimator Cap

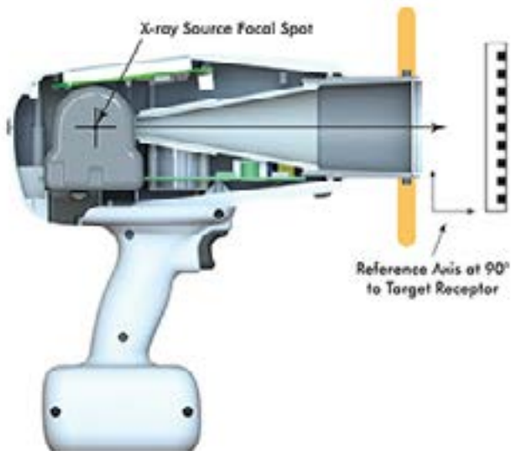
X-ray Controls and Generator	
Exposure time range	0.04 – 1.00 sec. (in 0.01 second increments)
Duty cycle	1:60 (one 1 second exposure every 60 seconds)
Inherent filtration	>1.5mmAl (Typical 2.0mm Al equivalent)
Output power	162.5W nominal at 65kV, 2.5mA
Generator rating	2.5mA (±5%) at 65kVp (±10%) direct current (DC) output
Leakage technique factors	65kV, 2.5mA, 1.00 sec.
Maximum air kerma at handgrips and control panel	<0.02mGy in 1 hour

Measurement Base of Technique Factors
Final output dose measurements are made using a Piranha model 255 X-ray meter from RTI Group. Tube current (mA) is sensed across a series connected resistor with an accuracy of ± 1% and measured using a digital multimeter, prior to encapsulation; the NOMAD Pro 3 has no provision for external measurement of beam current after final manufacture. Exposure time is measured during the entire exposure, referencing 50% rise/fall, using the Piranha model 255 X-ray meter.

Collimator Cone	
Minimum source to skin distance	21cm from focal spot to cone tip
Nominal dose output at cone tip (20cm)	3.41mGy/sec.
X-ray field size and configuration	6cm diameter circle

Backscatter Shield	
Dimensions	Ø158mm x 12mm thick
Attenuation	≥0,5 mm Pb equivalent at 65 kV





Retangular Collimator

NOTE: The Rectangular Collimator Cone Adapter dimensions are contained entirely within the 6 cm circular exit field diameter. This collimator can rotate freely, 360 degrees. Use rectangular Collimator with rectangular film and sensors to reduce the dose by 57% versus using the 6cm diameter circular cone. Use with rectangular film and sensors to reduce dose useful for imaging by 57% for the 6cm diameter circular cone.

Area of rectangular collimator is 3cm x 4cm = $12cm^2$

Circular collimator area is π x $(6cm/2)^2 = 28.27cm^2$

Dose Area Product (DAP)

Data display at kV65, 2.5mA

Age	Sensor	Tooth	Exposure Time (s)	Exposure ((μGy)	Dose Area Product ($mGy*cm^2$)
Adult	Digital	Posterior	0.31	1063	33.6
		Anterior	0.20	688	21.7
		Bitewing	0.25	858	27.1
Adult	Film	Posterior	0.70	2393	75.6
		Anterior	0.45	1540	48.7
		Bitewing	0.56	1915	60.5
Adult	Phosphor Plate	Posterior	0.38	1301	41.1
		Anterior	0.24	824	26.0
		Bitewing	0.30	1029	32.5
Child	Digital	Posterior	0.25	858	27.1
		Anterior	0.16	554	17.4
		Bitewing	0.20	688	21.7
Child	Film	Posterior	0.56	1915	60.6
		Anterior	0.36	1233	39.0
		Bitewing	0.45	1540	48.9
Child	Phospher Plate	Posterior	0.30	1029	32.6
		Anterior	0.19	655	20.6
		Bitewing	0.24	824	26.1

Air Kerma at other distances from the focal spot can be determined by the following formula; Air Kerma (at distance of X cm from focal spot)=Air Kerma (at 20 cm from focal spot)*[$(20cm/X)^2$].

For exposure times between table values, Air Kerma and DAP is proportional to time.

Overall deviation of the air kerma from the values shown does not exceed 40%. The exit field size at the end of the circular collimator cone (20 cm from the focal spot) is 6 cm. The exit field size of the rectangular cone is 3cm x 4cm.

Therefore,

DAP = mGy x $28.27cm^2$

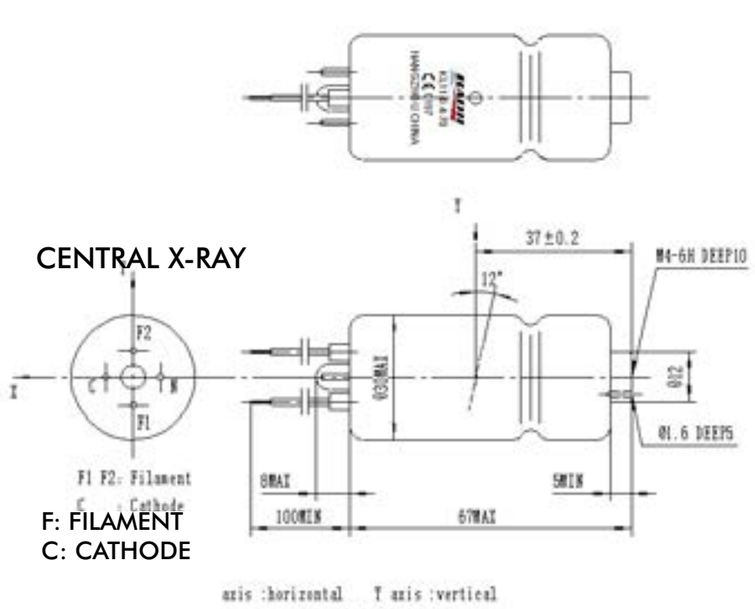
Compliance with Applicable Standards

Standard	Title	Edition
IEC 60601-2-65	Complies with X-ray equipment for dental intra-oral radiography IEC 60601-2-65:2012Ed. 1+A1	1.2 (2021)

8.2 X-ray Tube Specifications and Characteristics

The KL 11-0.4-70 is designed for intra-oral dental imaging by an X-ray unit and is available for nominal tube voltage with self-rectified or constant potential circuit – manufactured by Kailong.

Nominal tube voltage	70kV
Nominal focal spot (IEC 60336:1993)	0.4mm
Maximum anode heat content	4500J
Maximum current continuous service	1.5mA x 70kV
Maximum anode cooling rate	100W
Nominal anode input Power	430W
Target material	Tungsten
Minimum target angle	12°
Filament characteristics	2.2 – 3.0A, 2.0 – 3.5V
Minimum permanent filtration (IEC 60522:1999)	0.8mm Al/50kV
X-ray source assembly maximum heat content	6500J
X-ray source assembly	PS454

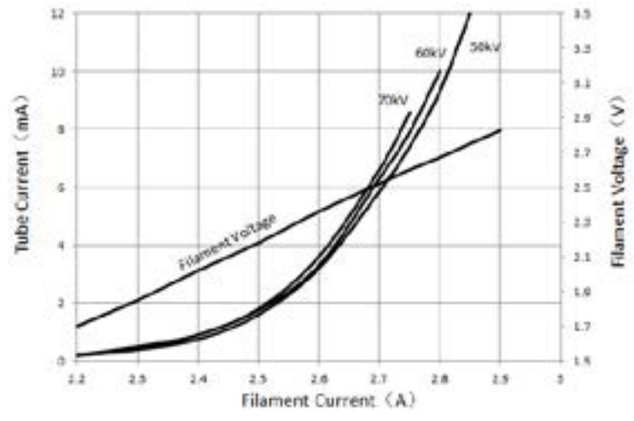


F: FILAMENT
C: CATHODE

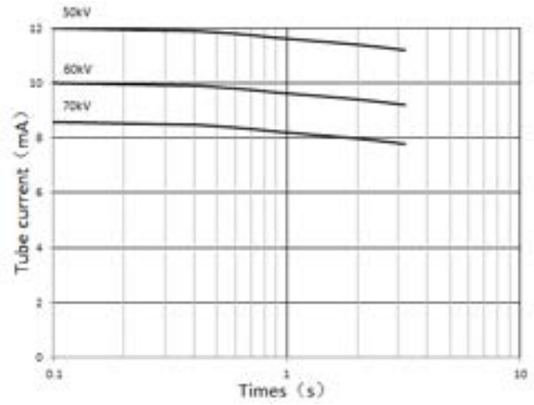
X axis: horizontal y axis: vertical

OUTLINE DRAWING

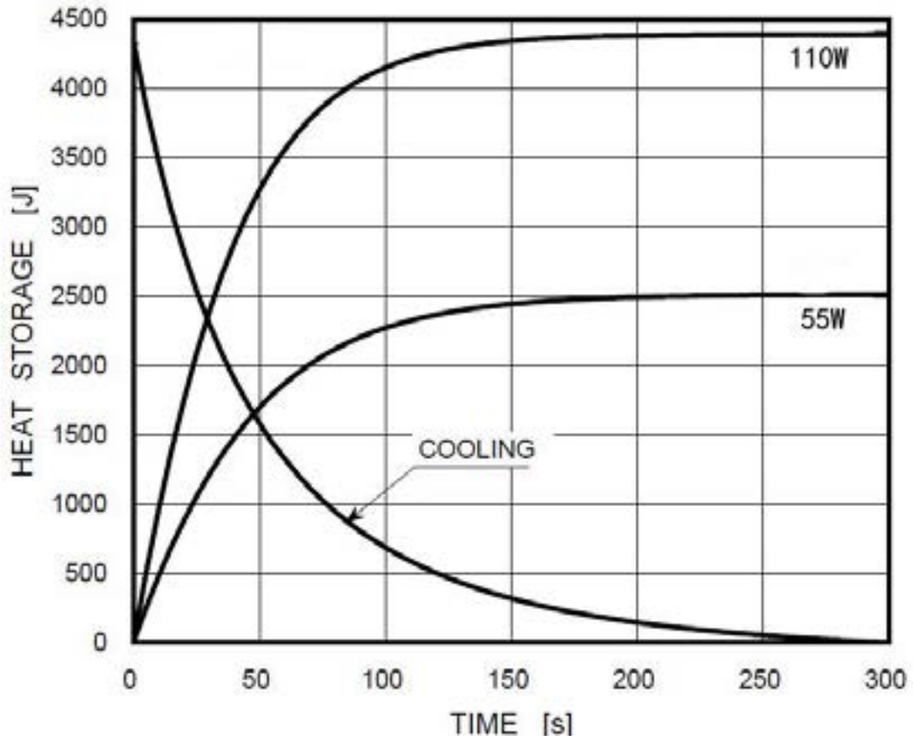
Cathode Emission/Filament Characteristics Chart



Rating Chart



Thermal Characteristics Chart



8.3 Manufacturer's Declaration

The NOMAD Pro 3 Dental X-ray System has been tested and found to comply with the limits of electromagnetic compatibility standards for medical devices, which provide reasonable protection against harmful interference in a typical medical/dental setting. The NOMAD Pro 3 may generate and radiate radio frequency energy that causes interference to other devices in the vicinity, if not used in accordance with the instructions (though there is no guarantee that interference will not occur in a particular instance). If interference occurs, the user is encouraged to try the following corrective measures: reorient or relocate the receiving device; increase the separation between the equipment; consult the device manufacturer or field service technician for help.

The NOMAD Pro 3 is intended for use in the electromagnetic environment as specified. The following tables describe the tests performed and the status of the testing. The NOMAD Pro 3 uses RF energy only for its internal function. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

The test results show that the NOMAD Pro 3 is suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage Power supply networks that supply buildings used for domestic purposes.

The NOMAD Pro 3, classified as Medical Electrical Equipment, needs special precautions regarding EMC and must be installed and put into service according to the EMC information provided in the accompanying product documentation. Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.

Electromagnetic disturbances may affect the equipment's ability to generate X-rays at controlled technical factors. Accuracy of loading factors and reproducibility of radiation output may be affected.

The NOMAD Pro 3 is suitable for use in hospitals except for near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbance is high.

The NOMAD Pro 3 device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Portable RF communications equipment (including peripheral such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NOMAD Pro 3, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The NOMAD Pro 3 Intraoral X-ray System is intended for use in the electromagnetic environment specified below. The customer or user of the NOMAD Pro 3 Intraoral X-ray System should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The NOMAD Pro 3 Intraoral X-ray System 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.

Immunity Test Summary

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The NOMAD Pro 3 Intraoral X-ray System is intended for use in the electromagnetic environment specified below. The customer or user of the NOMAD Pro 3 Intraoral X-ray System 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	+/-8 kV contact +/-15kV air	+/-2, 4, 6 & 8kV contact +/-2, 4, 8, & 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h 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	+/-0.5, 1 & 2 kV for Power supply lines +/-0.5 & 1 kV for input/output lines	Mains Power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/-1 kV differential mode +/-2 kV common mode	+/-0.5 & 1 kV differential mode +/-0.5, 1 & 2 kV	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	100 % Dip; for 0,5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 60% Dip for 1 Cycle 30% Dip for 25 Cycles 100% Dip for 5 Seconds	100 % Dip for 0,5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 60% Dip for 1 Cycle 30% Dip for 25 Cycles 100% Dip for 5 Seconds	Mains Power quality should be that of a typical commercial or hospital environment. If the user of the NOMAD Pro 3 Intraoral X-ray System requires continued operation during Power mains interruptions, it is recommended that the NOMAD Pro 3 Intraoral X-ray System be Powered from an uninterruptible Power supply or battery.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The NOMAD Pro 3 Intraoral X-ray System is intended for use in the electromagnetic environment specified below. The customer or user of the NOMAD Pro 3 Intraoral X-ray System should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	3 & 30A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The NOMAD Pro 3 Intraoral X-ray System is intended for use in the electromagnetic environment specified below. The customer or user of the NOMAD Pro 3 Intraoral X-ray System should ensure 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	3 Vrms 150 kHz to 80 MHz 6Vrms in ISM Bands between 0,15 MHz and 80 MHz	(V1)=3Vrms	Portable and mobile communications equipment should be separated from the NOMAD Pro 3 Intraoral X-ray System by no less than the distances calculated/listed below: D=(3.5/V1)(Sqrt P) 150 kHz to 80MHz D=(3.5/E1)(Sqrt P) 80 to 800 MHz
Radiated RF IEC 61000-4-3	3 Vrms 80 kHz to 2,7 GHz	(E1)=6Vrms in ISM bands (E1)=3Vrms	D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz where P is the max Power in watts and D is the recommened separation distance in meters. Field strenghts from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1) Interference may occur in the vicinity of equipment containing a transmitter. 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).

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The NOMAD Pro 3 Intraoral X-ray System is intended for use in the electromagnetic environment specified below. The customer or user of the NOMAD Pro 3 Intraoral X-ray System should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
			Field strenghts from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. 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.

Field strenghts 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, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 005 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 005.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

The ISM (scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 Mz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2.0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 15 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21.0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 to 54,0 MHz

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the NOMAD Pro 3 device			
The NOMAD Pro 3 Intraoral X-ray System is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the NOMAD Pro 3 Intraoral X-ray System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the NOMAD Pro 3 Intraoral X-ray Systems recommended below, according to the maximum output power of the communications equipment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Rated Maximum Output Power (Watts)	Separation Distance According to Frequency of Transmitter m		
	Separation (m) 150kHz to 80MHz D=(3.5/V1)(Sqrt P)	Separation (m) 80 to 800MHz D=(3.5/E1)(Sqrt P)	Separation (m) 800MHz to 2.5GHz D=(7/E1)(Sqrt P)
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined 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 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.			

8.4 Cables

The following table lists cables used with the device. No support equipment is used with the device.

Always use supplied cables. The use of an accessory, transducer, or cable with the system other than those specified may result in increased emissions or decreased immunity of the system.

Cables				
Description	Length (m)	Shielding	Ferrites	Termination
No cables for NOMAD Pro 3	n/a	n/a	n/a	n/a
AC Charger PS, line cord	2	none	none	AC PS
AC Charger PS, 12VDC cable	1.5	none	2	Charger

Appendix - Accessories

The section lists available NOMAD Pro 3 accessories, oher devices and other products that are not devices.

Accessories, Other Devices, Other Products that are not Devices			
Part Number	Part Name	Part Image	Part Description
0.850.0061	NOMAD Rect. Collimator Adapter		Component, Controls size of X-ray beam
1.011.1451	Bar, Alignment, Universal, Short		Universal Alignment bar included in 1.010.8482 Kit
1.011.1571	Bar, Alignment, Endodontic, Short		Endodontic Alignment bar included in 1.010.8482 Kit
1.011.1450	Bar, Alignment, Bitewing, Short		Bitewing Alignment bar included in 1.010.8482 Kit
1.013.1887	Handset, DEXIS NOMAD, White		Component, Replacement handset
1.013.2534	Charger, AC Adapter Kit, DEXIS White, US		Component, Replacement charger with power supply and cord set
1.013.8612	NOMAD Adjustable Stand		Component, Floor Stand See the NOMAD Portable Stand Guide for more information
1.013.9695	NOMAD Remote Exposure Switch		Component, Replacement Remote Exposure Switch

LIMITED WARRANTY

COVERAGE. Dental Imaging Technology Corporation (DITC) warrants its medical and dental X-ray equipment and accessories purchased from the manufacturer or an authorized reseller to be free from any defects in material or workmanship for a period of one (1) year from the date of purchase.

The liability of DITC is limited to repair or replacement of any parts that DEXIS or its authorized resellers determine to be defective. Contact DITC for a Return Material Authorization (RMA) number and shipping instructions. Parts proving defective shall be repaired or replaced free of charge (labor and shipping included) if defective equipment is returned freight collect to manufacturer Quakertown, PA, USA) or the location of the authorized service center. Equipment repaired or replaced under warranty shall continue to be warranted for the balance of the original warranty term. All warranty claims must be made not later than ten (10) business days following the expiration of the applicable warranty period.

LIMITATIONS OF COVERAGE. This warranty does not apply to equipment that is or has been abused, misused, or altered (including opening enclosure or tampering), improperly maintained, subjected to use beyond rated conditions, and/or damaged as a result of any carelessness or accidents. This warranty does not apply to equipment purchased, leased, or otherwise obtained from including, but not limited to, persons, resellers, and Internet resellers that are not authorized resellers. This warranty does not cover ordinary wear and tear or maintenance. To verify the authorization status of an authorized reseller, please call 1-888-88-DEXIS.

LIMITATIONS OF LIABILITY. The manufacturer makes no other warranty, either expressed or implied, with respect to any equipment purchased from the manufacturer or an authorized reseller, including without limitation any implied warranties of merchantability or fitness for a particular purpose, whether or not the manufacturer may have been informed of the actual uses to which any of such equipment may be put. The manufacturer shall not under any circumstance be liable for incidental, indirect, consequential, punitive, or exemplary damages, including without limitation damages for delay or lost profits, and in no event shall liability of the manufacturer arising from the purchase, sale or use of the equipment, or breach of any warranty made above, exceed in the aggregate the purchase price paid therefore.

Dental Imaging Technologies Corporation
450 Commerce Drive
Quakertown, PA 18951, USA
Phone: +1-888-88-DEXIS (1-888-883-3947)
Email: NOMADsupport@dexis.com
http://www.dexis.com

 8.000.4880 US Rev 00 2026-03-24