NOMAD™

Portable X-ray System

for Intraoral Radiographic Imaging

Operator Manual

DEXIS™

Thank you for choosing the NOMAD Pro 2

At Dental Imaging Technologies Corporation we value your business and we 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: NOMAD Pro 2 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

NOMAD Pro 2

NOMAD Pro 2 Portable X-ray System is a battery-powered, portable dental X-ray source designed for Portable operation. It is designed to produce diagnostic quality images utilizing either film or digital imaging techniques. The NOMAD Pro 2 Portable 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 2 Portable 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 2 Portable X-ray System is an X-ray device with a DC generator. The Portable device features a main unit (tube head), rechargeable battery (handset), Portable X-Ray Stand, Remote Exposure Switch, Remote Exposure 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 2 Portable X-ray System uses a fixed tube voltage of 60kV 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 (60 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 2 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 2 Portable 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.

The NOMAD Pro 2 shall be operated with the provided stand and remote switch and the operator should stand off at minimum of 2 meters or appropriate distance in accordance with local Provincial regulations. Use as a portable (handheld) X-ray system shall be in exceptional circumstances only. Exceptional circumstances include scenarios where the operator must stay with the patient (when a caregiver is unable to do so) to ensure appropriate imaging, or in a mobile care unit or the operating room or intensive care unit where a portable or compact portable X-ray unit cannot be set up appropriately.

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 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 to the operator.

1.3 Unpack, Check, Register, and Clean NOMAD Pro 2 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 2 Device
- Charging Cradle
- Two Rechargeable Battery Handsets
- AC/DC Power Supply
- Universal Alignment Bar
- Short Endodonic Alignment Bar
- Short Bitewing Alignment Bar
- NEMA 1-15p USA pin Cord
- Portable X-Ray Stand Kit
- Certificate of Conformance and Getting Started Guide

❷ Preliminary Checks:

Item	Check
Device Labels	Verify that the serialised device label is in place (located on lower side of unit).
Other Labels	Verify that the serial number on the warranty/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.
Collimator Cone and Backscatter Shield	These two items provide 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 card 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 NOMAD Pro 2, please visit www.dexis.com.

❹ Clean the NOMAD Pro 2 and X-Ray Stand. Use a non-acetone based disinfectant wipe or a cloth to wipe the exterior surfaces of the NOMAD Pro 2, charger and X-Ray Stand. Do not use cleaners intended for hard surfaces, since certain chemical combinations may deteriorate the NOMAD Pro 2 plastic prematurely.

1.4 Charging the Handsets

NOMAD Pro 2 charging system includes rechargeable handsets, 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 handsets and DEXIS NOMAD charging cradles are compatible with both DEXIS and KaVo branded Charging Cradles, Handsets and AC/DC Adapters.

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

Use only the supplied AC/DC power supply. Connect the electrical outlet.

Receiving Adequate Power and Ready

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.

Handset 1/3 Charged

Handset 2/3 Charged

Handset Fully Charged

❹ If the bars illuminate or flash red, see the troubleshooting guide section 6.2.

See Section 6.2

2.0 Safety Precautions

2.1 Radiation Safety

The NOMAD Pro 2 shall be operated with the provided stand and remote switch and the operator should stand off at minimum of 2 meters or appropriate distance in accordance with local Provincial regulations. Use as a portable (handheld) X-ray system shall be in exceptional circumstances only. Exceptional circumstances include scenarios where the operator must stay with the patient (when a caregiver is unable to do so) to ensure appropriate imaging, or in a mobile care unit or the operating room or intensive care unit where a portable or compact portable X-ray unit cannot be set up appropriately.

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 2 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 radiation backscatter protection exists when the following measures are taken:

a) the backscatter shield is positioned at the outer end of the collimator cone,

b) the backscatter shield is close to the patient,

c) the patient tilts his or her head when needed to accommodate exposures.

d) the operator is positioned directly behind NOMAD device, as shown.

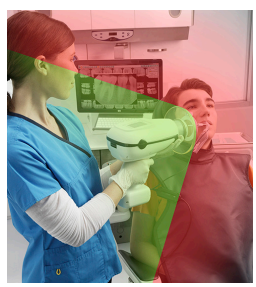
e) operator must stand at lease 2 meters behind the X-Ray device and must not extend cord more than 3 meters behind the X-Ray device.

- Do not enable the NOMAD Pro 2 until patient and operator are positioned and 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.
- 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).
- 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 2 safety as a Portable 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.

Handheld Option

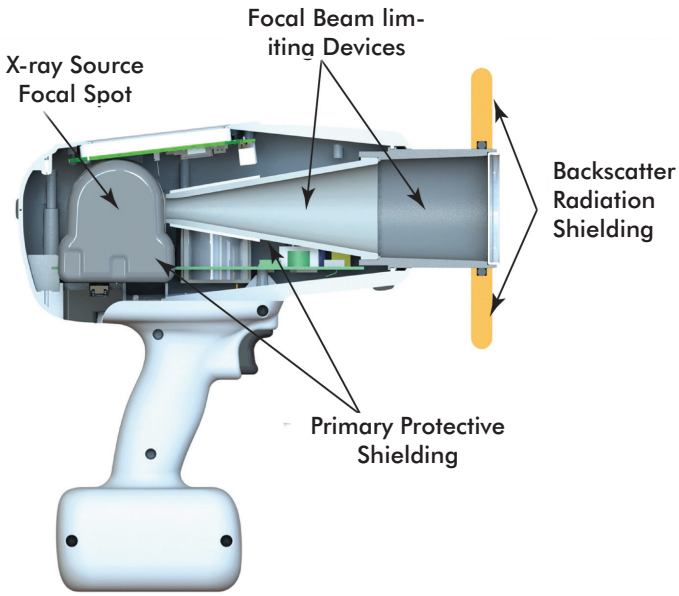
- As shown in graphic representations, maximum protection (green area) from backscatter radiation (red area) exists when the NOMAD Pro 2 is positioned near the patient, is perpendicular to the operator (with the patient's head tilted if needed), and the backscatter shield is fully extended toward the patient and parallel to the operator.

Stay in the ZONE				
				
	Proper Position	Held Back	Shield slid back	Non-perpendicular
PROTECTION:	MAXIMUM	MINIMIZED		

2.2 Studies and Data on Leakag 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.

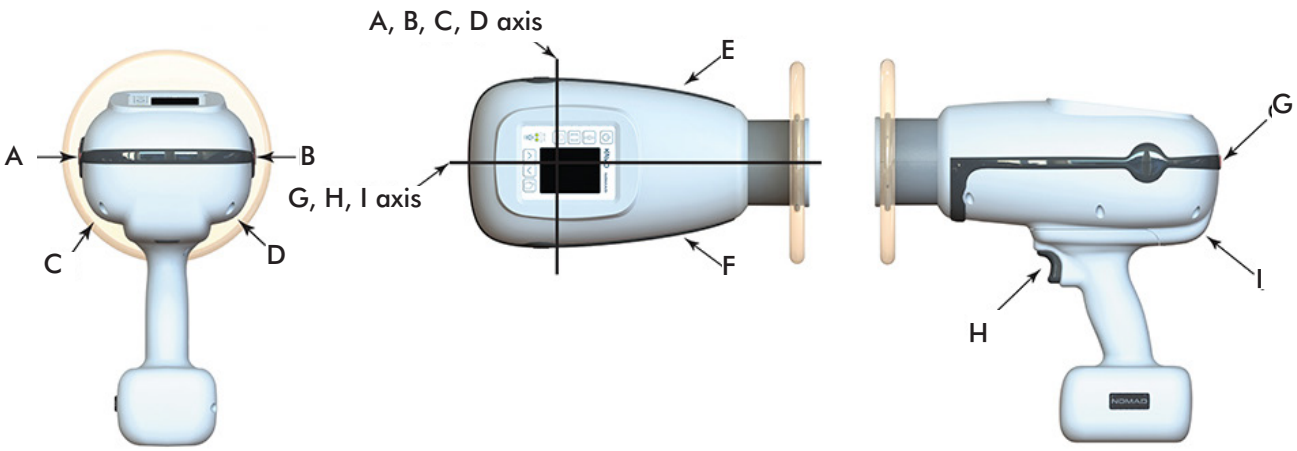


Leakage

Unique internal shielding of NOMAD Pro 2 encases the X-ray tube, practically eliminating leakage radiation. This makes it safe to use Pro 2 as a Portable device during exposures.

FDA regulations specify that leakage radiation from X-ray devices not exceed 0.88mGy/hr, while IEC regulations stipulate that devices stay below 0.25mGy/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

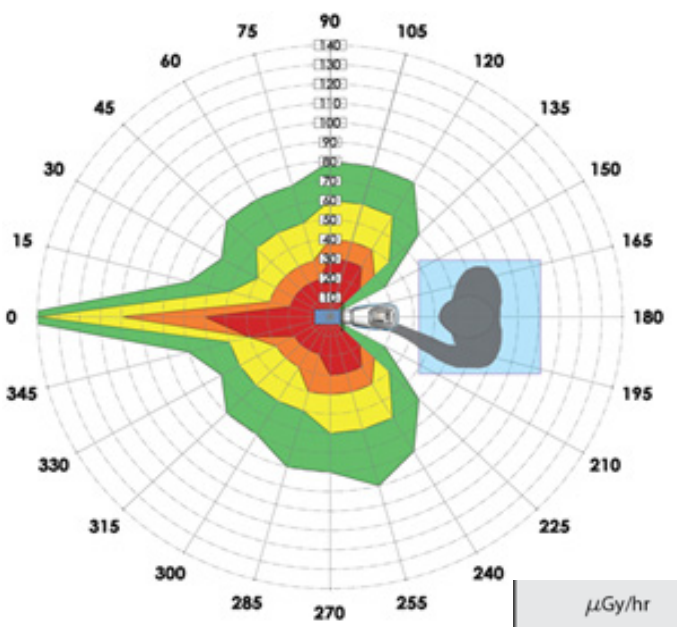
Scatter

As discussed in Section 2.1 Radiation Safety, the transparent shield on the NOMAD Pro 2 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 2 backscatter shield may contain lead dependent on its date of manufacture to attenuate scatter radiation.

The significant zone of occupancy for operators has been further verified by internal testing. A NOMAD Pro 2 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 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 radiation data shown in the following diagrams.

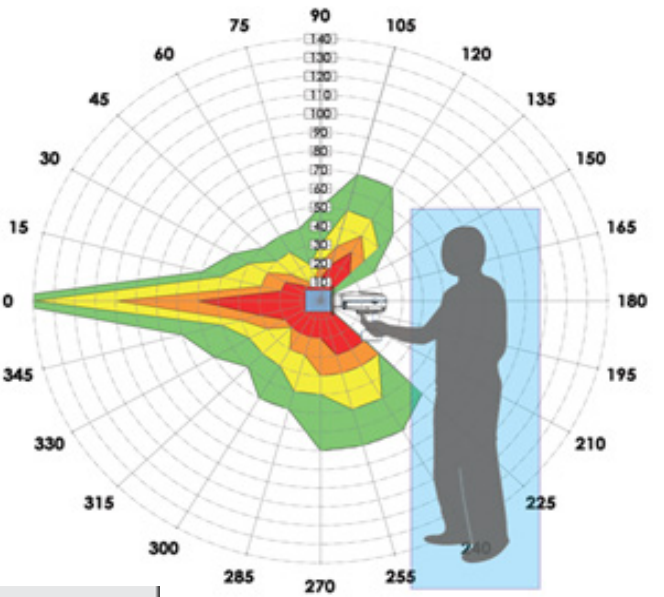
For further information on these tests, please contact Dental Imaging Technologies Corporation

Scatter Results using Lead-Free Shield



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

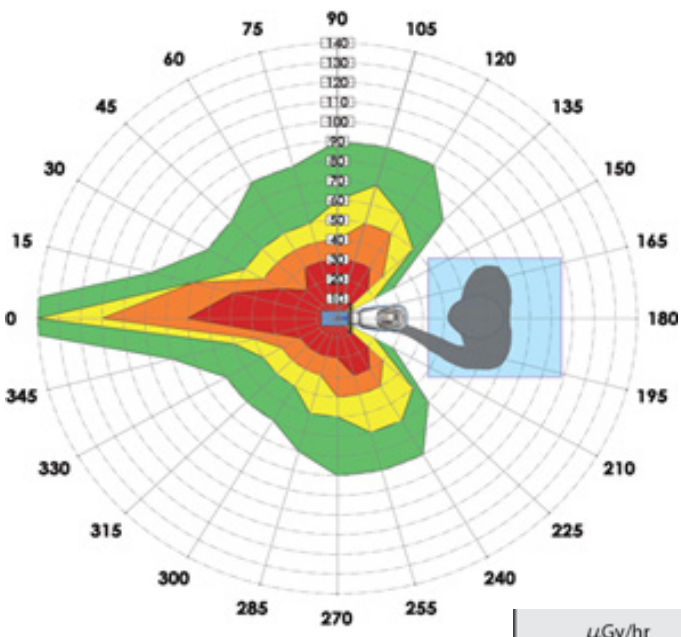
	µGy/hr	mR/hr
	0.0 - <11	0.0 - <1.26
	11 - <21	1.26 - <2.40
	21 - <41	2.40 - <4.68
	41 - <81	4.68 - <9.24
	>81	>2.40

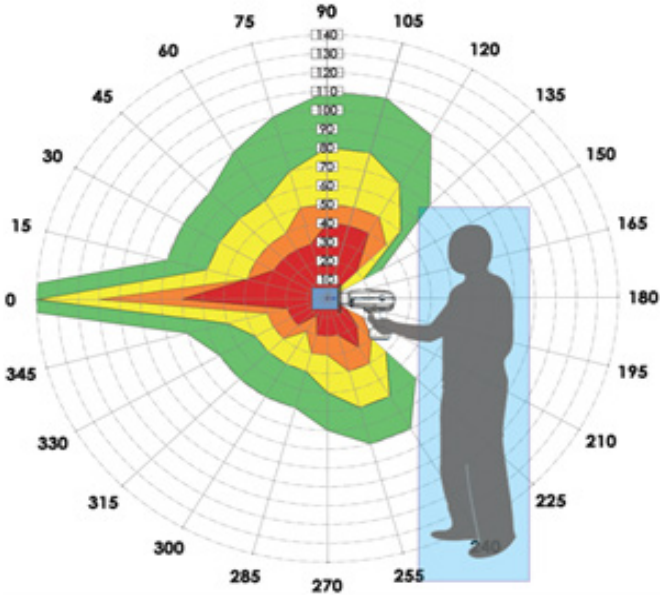


Vertical Plane,
Significant Zone of Occupancy: 60
cm x 200 cm

NOTE: Depictions of the user are for reference only.

Scatter Results using Lead Shield





	µGy/hr	mR/hr
	0.0 - <11	0.0 - <1.26
	11 - <21	1.26 - <2.40
	21 - <41	2.40 - <4.68
	41 - <81	4.68 - <9.24
	>81	>2.40

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

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

2.3 Usage and Duty Cycle

As a safety feature, the NOMAD Pro 2 will not emit X-rays with insufficient voltage (low battery).

The NOMAD Pro 2 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 2.

The NOMAD Pro 2 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 2 Handset is considered a consumable with a 1-2 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.

Do not operate the NOMAD Pro 2, the handset, charging cradle, or AC power supply if equipment was subjected to moisture (wetting, immersing, or soaking). Return to DEXIS or authorised service centre for service.

- Do not open the housings. Doing so will void the warranty. There are no user serviceable parts inside the NOMAD Pro 2, handset, charging cradle, or AC power supply.
- The NOMAD Pro 2 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 Use a non-acetone based disinfectant wipe or a cloth to wipe the exterior surfaces of the NOMAD Pro 2, charger and Portable X-Ray Stand. Do not use cleaners intended for hard surfaces, since certain chemical combinations may deteriorate the NOMAD Pro 2 plastic prematurely.

❷ Leave the handset connected to the NOMAD Pro 2 and wipe down all surfaces of the device.

❸ Unplug the charging cradle before cleaning.

NOTE: The NOMAD Pro 2, the handsets, the charging cradle, and the AC power supply are not designed to be subjected to any kind of sterilisation 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.

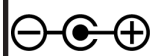
Do not spray disinfectant or cleaners directly on the NOMAD Pro 2, handsets, charging cradle, or AC power supply. The connecting areas are open to ingress and damage to your device may result.

2.5 Security, Storage, and Transportation

- Do not store the NOMAD Pro 2, handsets, charging cradle, or AC power supply in extreme conditions: below –20°C or above +50°C, or beyond 90% relative humidity (non-condensing). The optimal storage location is cool, dry, and away from direct sunlight.
- DITC recommends that the NOMAD Pro 2 (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 2, detach the handset.
- The X-ray Lock and Unlock (Section 4.2) serves as the device security key to prevent unauthorised 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 2 will not be knocked to the ground when not in use. Lay it on its top, side, or in the accessory tabletop stand. Power will automatically shut off after a period of inactivity (approximately three minutes).
- Some battery charge may be lost during extended inactivity (leading to fewer exposures between handset charging cycles).

- The NOMAD Pro 2 should not be operated if it has been dropped or if performance degrades; it should be returned to the manufacturer or an authorised service centre for an evaluation.
- When finished for the day with the NOMAD Pro 2, 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.

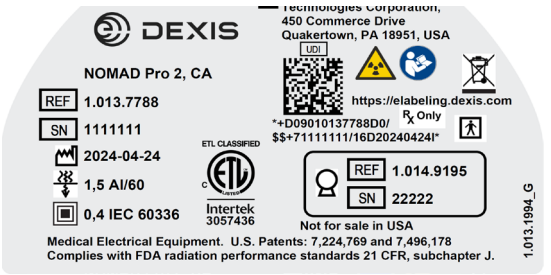
2.6 Product Symbols

Rx Only	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 North American safety standards
	Power 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/Catalogue 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
MD	Medical Device

2.7 Location of Device Labels

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

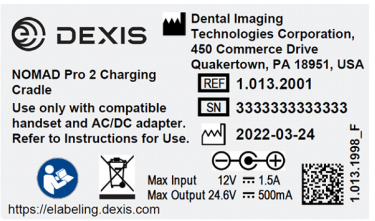
<table>
<tr>
<td> 
</td>
<td>Not for sale in U.S.

Complies with FDA radiation performance standards 21 CFR, subchapter J.

Location: Bottom surface of the NOMAD Portable device.</td>
</tr>
<tr>
<td> 
</td>
<td>Standard Trigger Handset

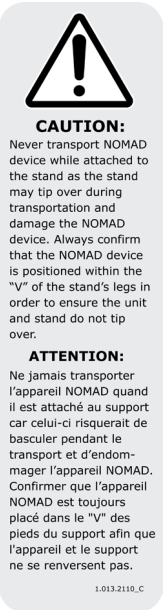
Refer to Instructions for Use for compatible Charging Cradle

Contains Li-ion Battery

Location: Top of device handset (visible when detached from device).</td>
</tr>
<tr>
<td> 
</td>
<td>Charging Cradle

Use only with compatible handset and AC/DC adapter. Refer to Instructions for Use

Max Input
Max Output

Location: Bottom surface of Charging Cradle</td>
</tr>
<tr>
<td> 
</td>
<td>CAUTION:

Never transport NOMAD device while attached to the stand as the stand may tip over during transportation and damage the NOMAD device. Always confirm that the NOMAD device is positioned within the"V" of the stand's legs in order to ensure the unit and stand do not tip over.

Location: Bottom Tube of X-Ray Stand</td>
</tr>
</table>

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 and can be adjusted to permit exposures made at various angles.

❶ You may find that the backscatter shield needs to be adjusted to accommodate sensors or angled exposures. If adjustments are needed, gently glide the shield up or down along the cone using equal pressure to maintain a perpendicular alignment and to avoid binding.

❸ 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 2 placed bottom up on a secure surface, properly orient and carefully slide the charged handset onto the base of the NOMAD Pro 2. (A properly oriented handset should click into place with firm pressure.)

❷ The clicking sound ensures the locking mechanism has secured the NOMAD Pro 2 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

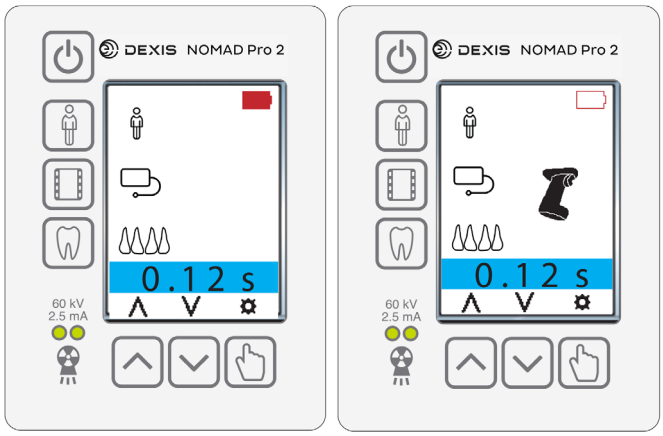
❶ After locking a handset in place press the Power ⏻ button.

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

❸ If the battery charge is too low, the NOMAD Pro 2 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 a low charge handset with the secondary handset (which should be charged in advance). It is recommended that you keep one handset fully charged at all times to ensure continuous operation.



The Recharge Handset Alarm consists of the user interface alternately flashing the two screen shown above.

3.4 Checking for Handset in Sleep Mode

Occasionally, a Handset may enter sleep mode and disable itself. This feature is designed to extend the useful life of the battery. Sleep mode occurs when the Handset is not used for an extended period of time or when stored while attached to the device.

To check if your handset is in sleep mode, remove handset from the Charging Cradle or device and wait 5 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 sleep mode. To enable the Handset, follow the three steps below.

❶ Remove Handset from Charging Cradle. Unplug cord from Charging Cradle.

❷ Wait 5 seconds, then put the Handset on the Charging Cradle. Plug cord back in.

❸ Indicator bars will flash red and green. Once initialized, watch for the first indicator bar to flash green.

To prevent an immediate return to sleep mode, do not remove until second bar starts flashing.

To avoid sleep mode in the future, store handset detached from device and fully charge every two months.

Note: Charging a handset from the sleep mode may take up to 5 hours. If initialization ends without the first bar flashing green, repeat the process described above. If the process described above fails to enable the Handset after 3 attempts, authorized service may be required.

(See Section 6.2 for Troubleshooting.)

3.5 Optional Checks

The NOMAD Pro 2 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 2 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 2 device. Press the Power ⏻ button and verify that the device correctly powers on and off.
- 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 time-out.
- 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 2 should not be operated if it has been dropped or if performance degrades; it should be returned to the manufacturer or an authorised service centre for an evaluation.

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

3.6 Portable X-Ray Stand

This X-Ray stand features a telescoping frame and an adjustable, rotating mounting clamp. The X-Ray stand is designed to prevent motion of the tubehead during actual exposures. This mobile stand sets up in only a minute.

The standard stand package system (1.013.7787) includes the following items:

❶ NOMAD Portable X-Ray Stand (1.013.8612)

❷ Remote Exposure Switch (1.013.9695)

❸ Handset with Female Connector (1.013.6642)

❹ Setup Instructions (not shown)(1.013.6494)

❺ Soft-Padded Carrying Case (not shown)
(not sold separately)

Setup X-RAY Stand

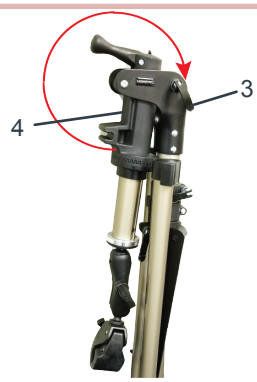
❶ Swing open the Bottom Tube Collar Locking Lever and unfold base legs until the bottom collar touches frame stop. Swing close the Locking Lever when legs are fully opened.

❷ Swing open the Upper Tube Locking Lever 180 degrees from the closed to open position and raise the Upper Sliding Tube. Swing the Locking lever back 180 degrees ensuring that the lever is tightly in place against the tube collar.

Beware of pinch points. When folding or unfolding the base, keep hand and fingers clear of moving parts.

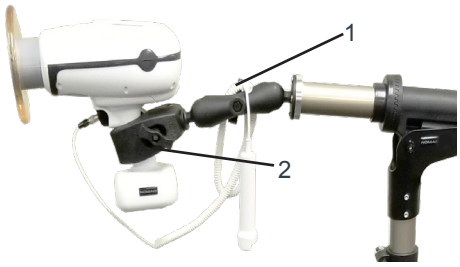
❸ Loosen Top Arm Locking Lever.

❹ Rotate the Top Arm up past vertical and back down to horizontal on the opposite side of the Upper Tube. Tighten the Top Arm Locking Lever.



Open/Close Clamp

Loosen the Clamp Handle to spread open the Clamp to accept the handle on the NOMAD device.

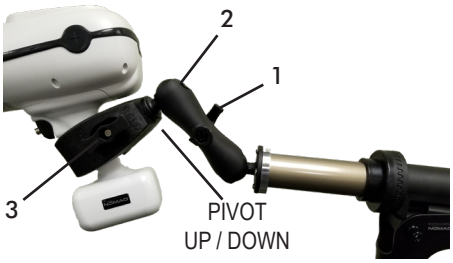


Mount NOMAD to Stand

❶ Before mounting the NOMAD device, make sure that the Pivot Arm Handle is tightened so that the device does not suddenly drop out of position.

❷ Loosen Clamp Handle to spread open Clamp to fit device handle.
Hold device in place with one hand while tightening Clamp Handle. Ensure that the device is secure and does not wiggle.

⚠ Always confirm that the device is positioned within the "V" of the stand's legs to prevent the stand from tipping over.

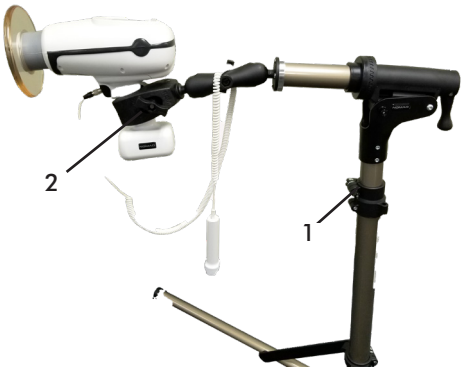


Adjust Pivoting Clamp Up/Down

❶ Loosen Pivot Arm Handle.

❷ Pivot unit into position, then tighten Pivot Arm Handle when finished.

❸ You may also rotate the device Clamp after loosening the Pivot Arm Handle.



Positioning and Setup

❶ With the base legs extended, raise the Upper Tube to the approximate desired height.

❷ Mount the NOMAD device in the stand Clamp.

Using two hands, move the stand into position next to the patient chair or patient stool. Ensuring the Upper Locking Lever is closed, move the stand into position with one hand on the Upper Tube and one hand on the Lower Tube. Adjust the Pivot Bracket to move the NOMAD device into position on the patient.

Ensure that the NOMAD device is properly in position with the patient.

Attach Remote Switch

Plug the Remote Exposure Switch into the NOMAD handle. Rotate the plug to properly align with the connector. An audible click should be heard when fully seated.

NOTE: To disconnect, pull connector sleeve away from handset and remove plug.

Operating Position

Maximum protection from backscatter radiation exists when the operator is positioned directly behind NOMAD device, as shown

Operator must stand at least 2 meters behind the X-Ray device and must not extend cord more than 3 meters behind the X-Ray device.

⚠ Before pressing the expose switch, ensure that the NOMAD device did not move out of position..

4.0 Operation

4.1 Powering Up

NOTE: Manufacturer's recommendation is for the operator to wear nitrile or other gloves during basic operation of the NOMAD Pro 2.

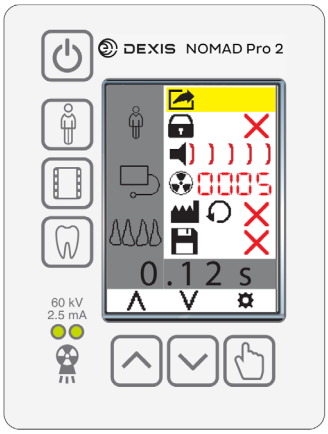
Press and release the Power ⏻ button to turn on the NOMAD Pro 2. An audible double tone and an active display panel indicate the device has power.

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

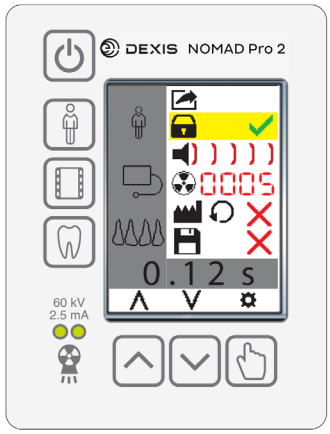
4.2 Lock/Unlock the X-ray

The X-ray lock and unlock functionality can be activated to prevent unauthorised use when the NOMAD Pro 2 is idle or stored. This functionality may also be used for training purposes.

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



Settings Menu:
X-ray Unlocked

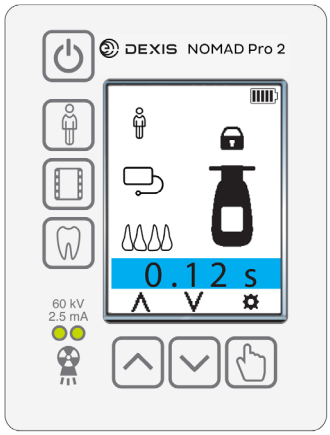


Settings Menu:
X-ray Locked

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 Select button to change the red "x" ✗ with a green check ✓. The device is now in lock mode.

Using the Increase ﹀ button, scroll back up to the Exit symbol. Press the Select 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.



X-ray Locked

4.3 Ensuring the Right Exposure Time is Set

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

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

1) the Patient Size (adult or child)

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

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

Examples from factory default settings:

Child, Sensor, and Anterior = 0.09sec

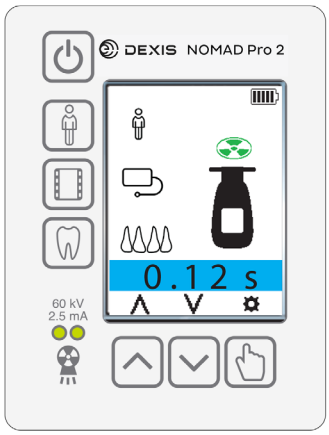
Adult, Film, and Posterior = 0.38sec

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).

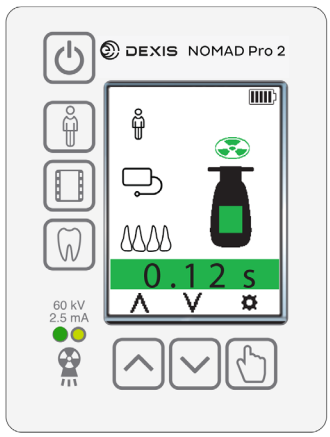
4.4 Ready the Device

Properly position patient and operator before readying the NOMAD Pro 2.

Press and release the trigger once to ready the device. A green trefoil will briefly appear on screen 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 2 is prepared to fire X-rays.



Enabling X-rays Alert



Ready State

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

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

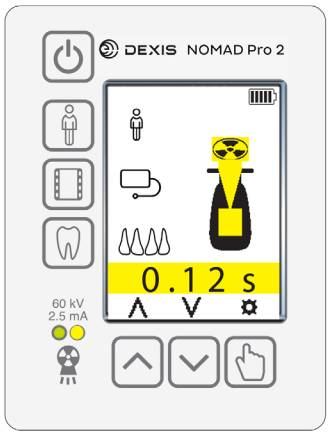
NOTE: As a safety precaution, if the trigger is held longer than one second or pulled a second time while still displaying the Enabling X-rays alert, the device will not transition to the Ready state. (This is to prevent an accidental activation of the device by unintended triggering.)

4.5 Initiating and Completing an X-ray Exposure

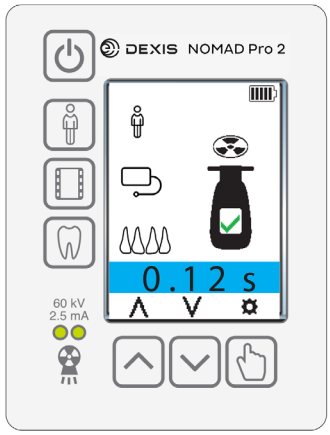
To begin the exposure, press and hold the trigger. The Ready alert is replaced with the X-rays On alert, the green LED is replaced with a yellow LED, and there is an alert tone for the duration of the exposure.

To ensure complete exposure, keep the trigger depressed until the audible tone is complete, the yellow LED is 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 Power ⏻ button to turn the NOMAD Pro 2 off.

The NOMAD Pro 2 also automatically shuts off after approximately three minutes of inactivity.

The NOMAD Pro 2 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 1-888-88-DEXIS.

⚠ Any serious incident that has occurred in relation to the use of the NOMAD Pro2 should be reported to Technical Support at 1-888-88-DEXIS.

4.7 Exposure Techniques

As an intra-oral dental X-ray system, the NOMAD Pro 2 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, properly position the Portable X-Ray Stand to acquire desired NOMAD Pro 2 position.
As an option, operators may hold the NOMAD Pro 2 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 2 relative to the imaging system to minimise 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 an 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 2 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 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 2 features contribute to high image quality:

- DC voltage X-ray generation is efficient in delivering energy at the level optimised for diagnostics, with shorter exposure times required.
- The smaller the focal spot, the better the resolution. The NOMAD Pro 2 has a small 0.4mm focal spot.
- Absorption of scatter by the NOMAD Pro 2 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 X-Ray Stand to hold the NOMAD Pro 2 during the exposure and keep steady.

If using the handheld technique, use both hands to hold the NOMAD Pro 2 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 2 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 2 works with fast sensor technologies 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 2 to be placed directly against the positioning ring.

Always double-check for the Incomplete Exposure alarm on the NOMAD Pro 2 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 paediatric. Paediatric patients may be more radio-sensitive than adults (i.e., the cancer risk per unit dose of ionising radiation is higher), and so unnecessary radiation exposure is of particular concern for paediatric patients. Please use caution when configuring the NOMAD Pro 2 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 60 kV

		Anterior	Posterior	Bitewings
Digital Sensor	Adult	0.12	0.16	0.17
	Child	0.09	0.13	0.14
Film	Adult	0.30	0.38	0.40
	Child	0.18	0.30	0.32
Phosphor Plate (P)	Adult	0.16	0.19	0.20
	Child	0.09	0.15	0.16

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

❶ Press the Increase ^ or Decrease v buttons until the desired time setting is selected.

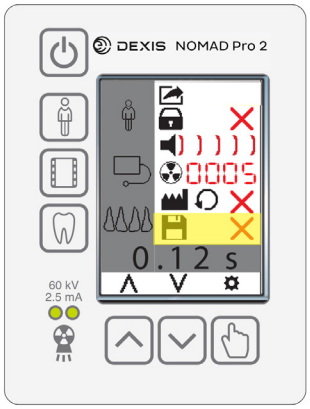
NOTE: When the Increase ^ or Decrease v buttons are pressed AND held, the rate at which the displayed time setting changes on screen accelerates.

❷ Press the Select button to activate the Settings Menu.

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

❹ Exit 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.



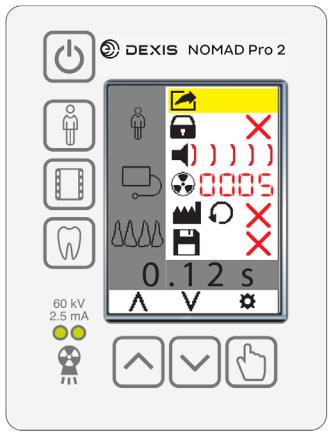
The Settings Menu: Save selected

4.10 Settings Menu

The NOMAD Pro 2 Settings Menu allows the operator to customise settings according to individual preferences. To access the Settings Menu, press the Select button. When the Settings Menu appears, the operator can access the desired menu item(s) by pressing the Increase ^ and Decrease v buttons to scroll up or down. A menu item is selected when it is highlighted in yellow.

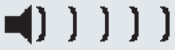
When the operator exits the Settings Menu by using the Exit menu item, any settings that have been modified will be saved.

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



The Settings Menu: with Exit selected

Menu Item	Icon	Options
Exit		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.)

Menu Item	Icon	Options
Lock/Unlock X-rays		Can be activated to prevent unauthorised use when the NOMAD Pro 2 is idle or stored. This functionality may also be used for training purposes. The red "x" ✗ indicates that the X-ray is unlocked. In order to lock the X-ray, the operator presses the Select button. The red "x" ✗ will change to a green check ✓, indicating that the X-ray is now locked. The X-ray can be unlocked by pressing the Select button again, replacing the green check ✓ with the red "x" ✗.
Audible Sound		Allows the operator to adjust the volume. The range is from zero (softest), up to five (loudest). The Select 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.

Menu Item	Icon	Options
Trip Counter		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 Select 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.
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 Select button, replacing the red "x" 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.

Menu Item	Icon	Options
Save Settings		Allows the operator to save customised timer settings and technique factors. In order to ensure that settings are saved, press the Select button, replacing the red "x" 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 maximise 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 2 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 Power ⏻ button on the control panel to turn off the NOMAD Pro 2.

❷ Place the NOMAD Pro 2 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:

- Alternate handsets each week to maximize service life.
- Routinely change discharged handset with fully charged one as needed.
- Remove the handsets from the charging cradle once they are 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 2 Handsets.
- 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).

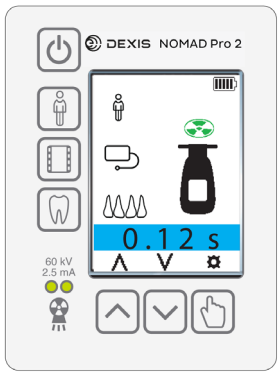
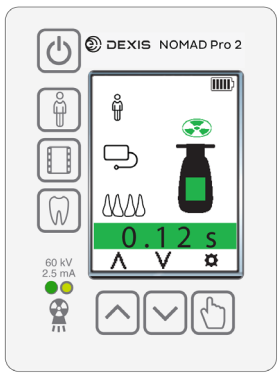
- Do not attempt to charge a handset with damaged batteries. Damage can occur if handset experiences liquid ingress, if it has been dropped or punctured , or exposed to heat or fire. Replace battery immediately if there are any signs of deterioration or if batteries do not retain a charge during normal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

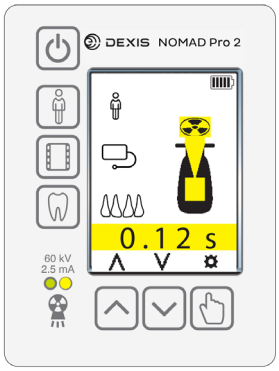
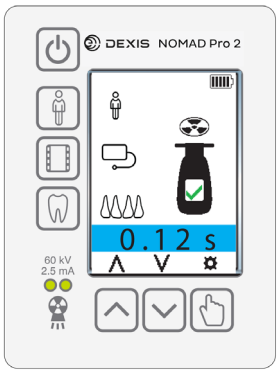
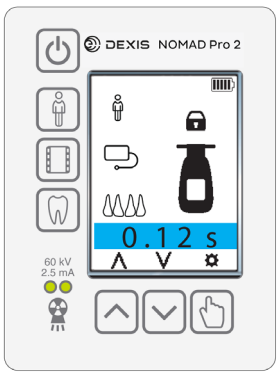
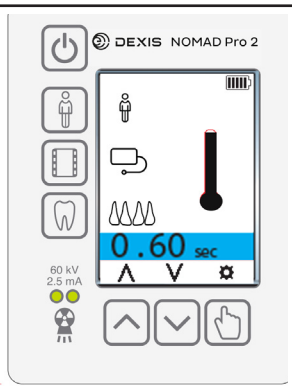
6.0 NOMAD Pro 2 Care and Upkeep

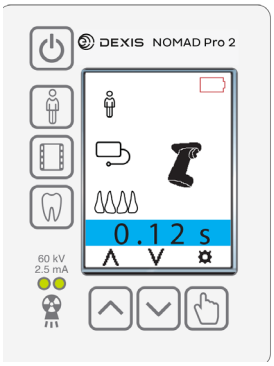
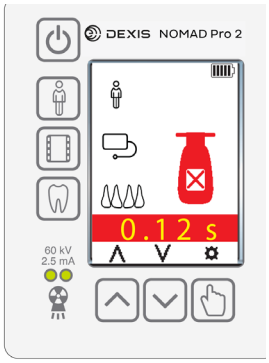
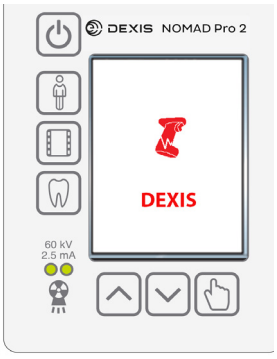
6.1 Alarms and Alerts

The visual and audible alarms signal a programmed action designed to prevent harm to operators, patients, and/or the NOMAD Pro 2. 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-rays On Alert 	Single tone for duration of exposure (X-rays On 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 shut-down. 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	Consult Section 6.2 Troubleshooting (6.2.8) or a manufacturer authorised service centre.
Handset Failure Alarm (Flashing Display) 	7 audible tones followed by descending tone	Consult Section 6.2 Troubleshooting (6.2.12) or a manufacturer authorised service centre.

The NOMAD Pro 2 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 Troubleshooting

If you encounter results and/or errors in the operation of the NOMAD Pro 2 that are not explained in the previous sections, check the following table on user troubleshooting to determine the need for authorised service. If you have additional questions or require help, contact the manufacturer: NOMAD support@dexis.com

Device Symptom	Potential Problem	Corrective Action
6.2.1 The handset did not seem to be working when the trigger was pulled.	Le déclencheur ne communique pas avec l'appareil.	Si cette condition persiste, un service autorisé est requis. See Section 7.0 Maintenance and Repair.
6.2.2 Handset does not begin to charge (no flashing green bars).	If the green power circle is illuminated, the handset may be in over-discharge sleep mode and require a wakeup procedure.	Leave the handset on the charger, unplug the power cord from the rear of the charging cradle, wait 5 seconds, and re-connect. All Charger LEDs should flash several times and finish with a single flashing green bar. Repeat this process up to 3 times for heavily discharged handsets. The handset may take up to 5 hours to fully charge.
	If the green power circle is illuminated and the above wakeup procedure does not help, an older charger may be incompatible with the newer KaVo or DEXIS Handset.	DEXIS NOMAD Handsets and DEXIS NOMAD Charging Cradles are compatible with both DEXIS and KaVo branded Charging Cradles, Handsets and AC/DC Adapters.
		If this condition persists, authorized service is required. See Section 7.0 Maintenance and Repair.
6.2.3 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 there is no red flash, follow the steps for Handset wakeup in 6.2.2. If 2 or fewer flashes are seen, recharge the handset.
		Re-try with the 2nd handset.
		If this condition persists, authorized service is required. See Section 7.0 Maintenance and Repair.
6.2.4 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.

Device Symptom	Potential Problem	Corrective Action
6.2.5 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.
6.2.6 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.
6.2.7 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.
6.2.8 Charging Cradle shows Red LEDs.	Alternate Red and Green LEDs are shown on the charger when first plugged in.	This is the standard startup process to test the display. There is no problem with the charger.
	If the LEDs are solid red with no attached Handset, there may be Infra Red (IR) communication interference.	Unplug the power from the charging cradle, wait 5 seconds, and re-connect. If the problem persists, relocate the charging cradle as the cause may be environmental (Fluorescent lights, computer monitors, etc.)
	If the LEDs are solid red with a handset attached, there may be an intermittent interference.	Remove the handset, wait 5 seconds, and replace. If the issue persists, attempt to relocate the Charger as described above.
	If the LEDs are flashing red, the handset has been stored above it's operating temperature.	Remove the handset from the charger and allow to cool. Once cooled, the handset can be charged. Evaluate storage processes and temperatures.
	If the LEDs are solid red the charger may be incompatible	Refer to 6.2.2 information regarding incompatible components.
		If this condition persists, authorized service is required. See Section 7.0 Maintenance and Repair.
6.2.9 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 2 will require authorized service; see Section 7.0 Maintenance and Repair.

Device Symptom	Potential Problem	Corrective Action
6.2.10 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. If the charging bars illuminate solid red or if no illumination occurs, the handset will require authorized service. 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.
6.2.11 NOMAD Pro 2 automatically shuts down.	NOMAD Pro 2 times out after about three minutes of inactivity.	Manually turn on NOMAD Pro 2 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.
6.2.12 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.
6.2.13 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.
6.2.14 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.

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 2 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 , 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 2.

1. In order to ensure device functionality, schedule the NOMAD Pro 2 for a maintenance inspection at the manufacturer every five years.

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 2.

3. A routine wipe-down of the NOMAD Pro 2 and Portable X-Ray Stand with a disinfectant cloth or wipe-down between patients 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 non-acetone based disinfectant wipe or a cloth to wipe the exterior surfaces of the NOMAD Pro 2 and charging cradle. Do not use cleaners intended for hard surfaces, since certain chemical combinations may deteriorate the NOMAD Pro 2 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 also Section 5.0 Handset Replacement and Care for more information related to Handset maintenance.

5. Periodically assess operator familiarity with the NOMAD Pro 2 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 2.

1. Verify that the Power 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 Select 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 2 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 2, 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 2 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 2 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 2. 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 2 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 2 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	Timer Settings and Corresponding Acceptable Ranges				
		20 ms	40 ms	400 ms	600 ms	1000 ms
kVp (eff) Accuracy	60kV ±10%	54 to 66	54 to 66	54 to 66	54 to 66	54 to 66
Timer Accuracy	Setpoint ±10%, +1ms	17 to 23	35 to 45	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. Power 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. Power 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 1-888-88-DEXIS if repairs are needed.

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

The following are user replaceable components:

- Replacement handset
- Replacement charger kit (includes charger, AC/DC power supply, and cord)
- Remote Exposure Kit (Includes Adjustable stand, Remote Exposure Handset, Remote Exposure Switch, and Carrying Case)
- Rectangular Collimator
- Universal Alignment Bar, short
- Endodontic Alignment Bar, short
- Bitewing Alignment Bar, short
- Adjustable Stand
- Remote Exposure Handset
- Remote Exposure Switch
- Wall Hook
- Hard-Shell Carrying Case
- Countertop Stand

Damaged or faulty NOMAD Pro 2 materials and components must be properly disposed of according to local requirements, or returned to an authorized distributor or Dental Imaging Technologies Corporation (DITC), Inc. Please protect the environment, and do not improperly dispose of any part of the NOMAD Pro 2 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 centre. You will be required to provide the serial number from the label affixed on the underside of the NOMAD Pro 2.

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 1-888-88-DEXIS 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 pounds (2.7kg)

Environmental	
Operation	
Temperature	50°F (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 2 outside of the temperature and relative humidity ranges specified.

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

Electrical	
Rechargeable lithium batteries	21.6V nominal; 24.6V maximum, 1.7A hr
Battery current at 2.5mA, 60kVp output	12.5A
Charging Power Supply	Input: 100-240V~50-60Hz Output: 12V direct current (DC) 1.5A

X-ray Controls and Generator	
Exposure time range	0.02 – 1.00 sec. (in 0.01 second increments)
Duty cycle	1:60 (one 1 second exposure every 60 seconds)
Minimum permanent filtration	≥1.5mm Al (0.8mm glass, 0.5mm Al, 0.2mm plastic cap)
Output power	150W nominal at 60kV, 2.5mA
Generator rating	2.5mA (±5%) at 60kVp (±10%) direct current (DC) output
Leakage technique factors	60kV, 2.5mA, 1.00 sec.
Maximum air kerma at handgrips and control panel	<0.08mGy in 1 hour

Measurement Base of Technique Factors

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 2 has no provision for external measurement of beam current after final manufacture. Exposure time is measured during the entire exposure, references to 75% rise/fall, using the 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 ekvivalentti 60 kV jännitteellä

Dose Area Product (DAP)

kV	mA	Exposure Time (milliseconds)	Air Kerma (mGy)	Dose Area Product (mGy*cm^2)
60	2.5	20	0.07	2
		40	0.14	4
		400	1.36	39
		600	2.05	58
		1,000	3.41	96

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

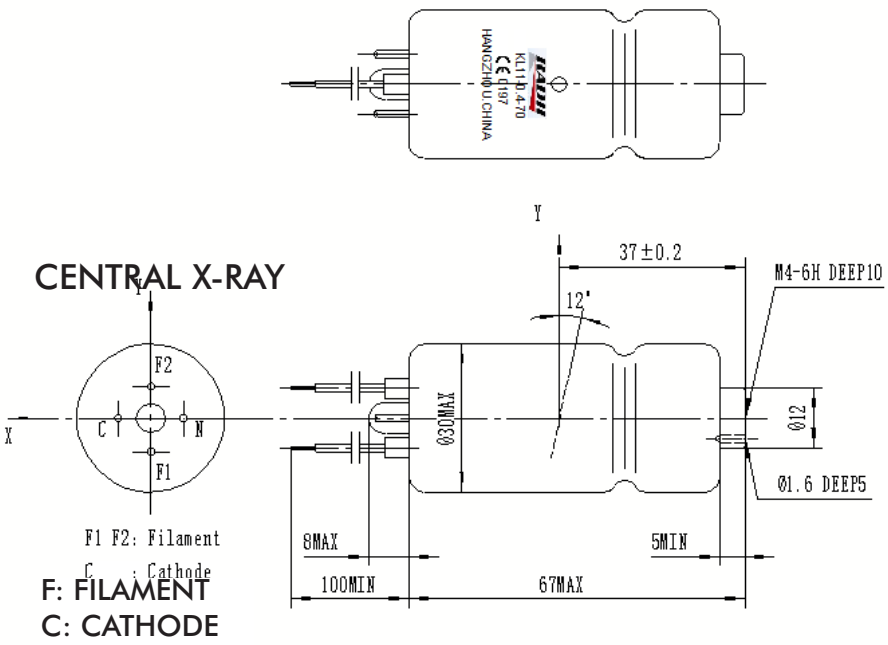
Compliance with Applicable Standards

Standard	Title	Edition
IEC 60601-2-65	Complies with X-ray equipment for dental intra-oral radiography IEC 60601-2-65:2012, NOMAD Pro 2.	2012

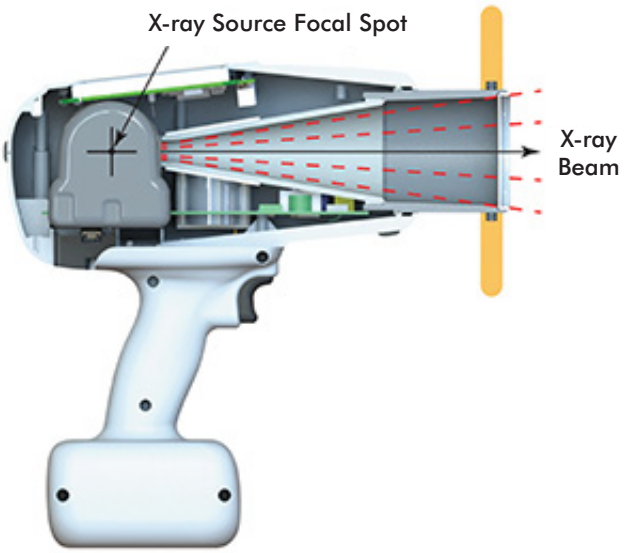
8.2 X-ray Tube Specifications and Characteristics

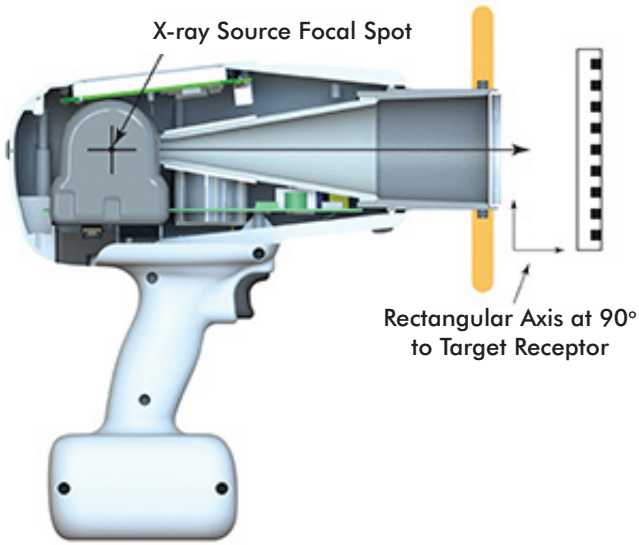
The KL 11-0.4-70 is designed for intra-oral dental imaging by an X-ray unit and is available for nominal tube voltage with self-rectified or constant potential circuit – manufactured by Kailong.

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

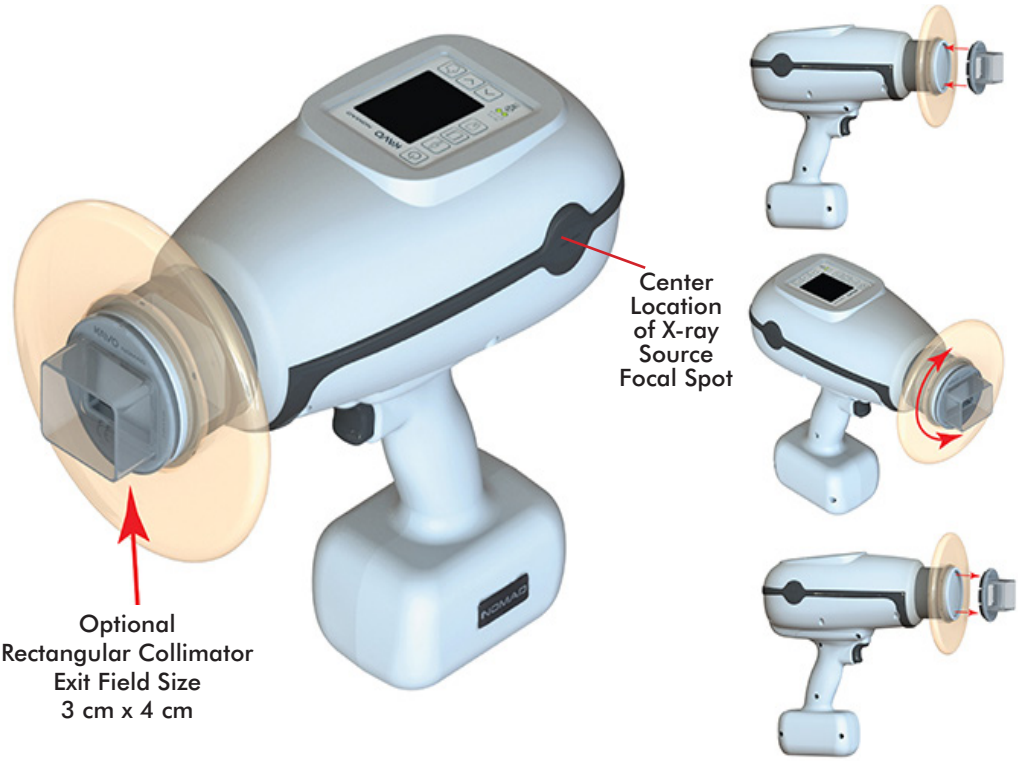


OUTLINE DRAWING





Rectangular Collimator

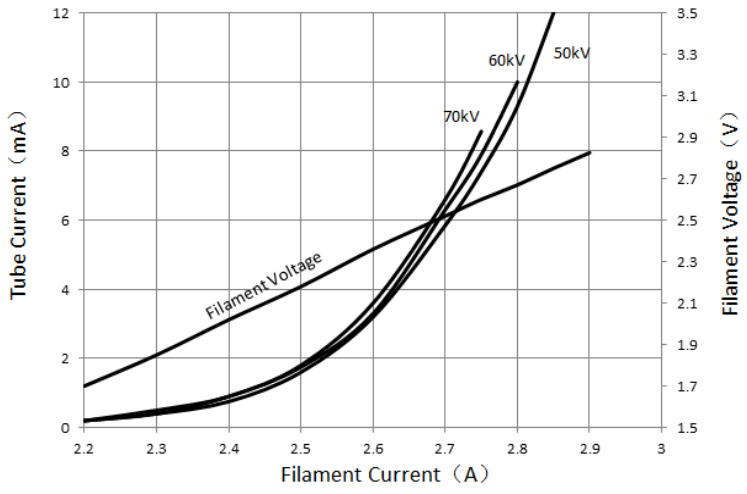


NOTE: The Rectangular Collimator Cone Adapter dimensions are contained entirely within the 6 cm circular exit field diameter. This collimator can rotate freely, 360 degrees. Use rectangular Collimator with rectangular film and sensors to reduce the dose by 57% versus using the 6cm diameter circular cone.

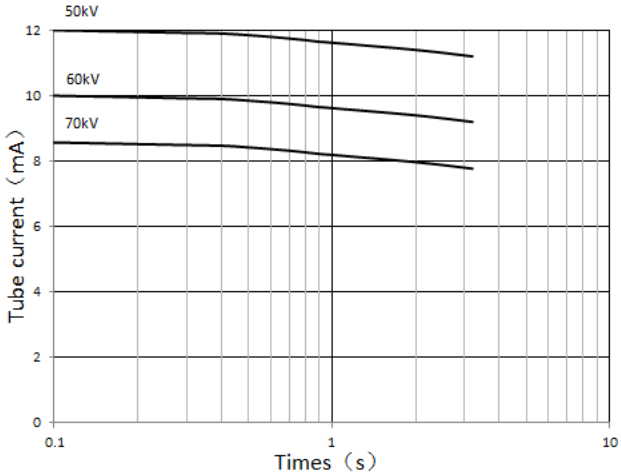
Area of rectangular collimator is 3cm x 4cm = $12cm^2$

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

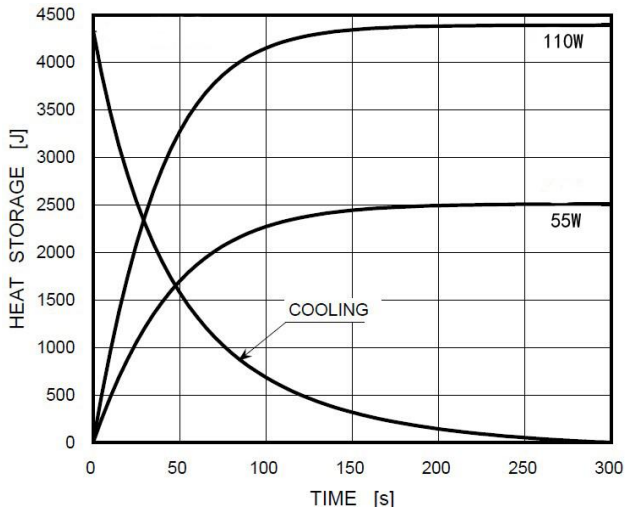
Cathode Emission/Filament Characteristics Chart



Rating Chart



Thermal Characteristics Chart



8.3 Manufacturer's Declaration

The NOMAD Pro 2 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 2 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 2 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 2 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 2 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 2, 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 2 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 2 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 2, 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 2 Intraoral X-ray System is intended for use in the electromagnetic environment specified below. The customer or user of the NOMAD Pro 2 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 2 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.
RF emissions CISPR 11	Class B	The NOMAD Pro 2 Intraoral X-ray System is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Immunity Test Summary

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The NOMAD Pro 2 Intraoral X-ray System is intended for use in the electromagnetic environment specified below. The customer or user of the NOMAD Pro 2 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 2 Intraoral X-ray System requires continued operation during power mains interruptions, it is recommended that the NOMAD Pro 2 Intraoral X-ray System be powered from an uninterruptible power supply or battery.
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 2 Intraoral X-ray System is intended for use in the electromagnetic environment specified below. The customer or user of the NOMAD Pro 2 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	(V1)=3Vrms	Portable and mobile communications equipment should be separated from the NOMAD Pro 2 Intraoral X-ray System by no less than the distances calculated/listed below:
	6Vrms in ISM bands between 0,15 MHz and 80 MHz	(E1)= 6Vrms in ISM bands	D=(3.5/V1)(Sqrt P) 150kHz to 80MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz	(E1)=3V/m	D=(3.5/E1)(Sqrt P) 80 to 800 MHz D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths 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 2 Intraoral X-ray System is intended for use in the electromagnetic environment specified below. The customer or user of the NOMAD Pro 2 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 strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a 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 strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 005 is used exceeds the applicable RF compliance level above, 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 (industrial, scientific and medical) bands between 0,15 MHz 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. 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, 14 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 MHz to 54,0 MHz.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the NOMAD Pro 2 device			
The NOMAD Pro 2 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 2 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 2 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 2	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

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) 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
Email: NOMADsupport@dexis.com
http://www.dexis.com

 1.013.9884 EN-CA Rev 06 2025-04-01