

ARIBEX™

NOMAD DENTAL™



***Portable X-ray System for
Intraoral Radiographic Imaging***

USER MANUAL

Disclaimer: NOMAD Dental 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 Aribex, Inc., its agents or representatives, do not accept responsibility for:

- a) injury or danger to personnel from x-ray exposure,
- b) image overexposure 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 modified or tampered with in any way.

DO NOT OPERATE THIS DEVICE UNTIL YOU HAVE READ THIS MANUAL and reviewed the accompanying materials.

See the *Certificate of Conformance* accompanying your device. NOMAD Dental is also cleared by the US Food and Drug Administration (FDA) as a medical device and complies with DHHS Radiation Performance Standard, 21 CFR Subchapter J.

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The symbols used in this publication and used to mark the equipment have the following meanings:



Caution or Attention, review documentation



Ionizing Radiation



Electrical Shock Hazard



Instructions for handling product at end of life



Type BF Equipment (providing a degree of protection against electric shock, pertaining particularly to allowable leakage currents)



USER MANUAL

NOMAD® Dental

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Thank you for choosing the Aribex NOMAD® as your x-ray solution!

At Aribex we value your business and we would like to hear from you, because your feedback or suggestions are important to us. If you have comments, please email us: NOMAD@aribex.com

NOMAD Dental Features

- **Performance** – battery power source delivers dependable high voltage (60kV, true DC) and direct current (2.3mA).
- **Consistent Emission Radiation** – high-frequency, constant-potential x-ray generator provides high quality images, with a lower radiation dosage to the patient than standard AC x-ray systems.
- **Radiation Protection** – operator shielded from source and backscatter radiation.
- **Simple Operation** – exposure time is the only setting requiring operator input, digitally displayed on the user-friendly control panel along with indicators for machine and battery status.
- **Lightweight and Ergonomic** – design provides complete flexibility and convenience, enabling exposures without moving the patients.
- **Exposure Safety Feature** – cannot emit x-rays with insufficient voltage (low battery).
- **Engineered for Compatibility** – works with both film and digital imaging systems.
- **Authorized Service** – complete support and maintenance from Aribex and our authorized distributors.

1.0 Getting Started

1.1 Intended Use

The NOMAD Dental X-ray System is designed to be used for both adult and pediatric patients by trained dentists and dental technicians for producing diagnostic x-ray images.

1.2 Unpack, Check, and Register NOMAD

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

- NOMAD Device with a Backscatter Shield attached
- 2 Charged Batteries
- Battery Charger (the charger should be appropriate for local AC line voltage)
- Certificate of Conformance, Getting Started guide and Battery Charger manual, Warranty Card, and NOMAD Operator Training CD



2 Preliminary Checks:

Item	Check
Device Labels	Verify that the device labels (Serial Number Label on lower side of unit in front of the handle and Warning Label on the lower side behind the handle) are legible and in place.
Other Labels	Verify that the serial number on the Warranty/Registration card matches the device serial number and the device carrying case serial number.
Collimator Cone	Inspect for damage. The lead lining must cover the entire interior surface.
Control Panel	Should be smooth and free of nicks, scratches, or damage.
Trigger Switch	Should move freely in when depressed and out when released.
Device Housing	Should be free of cracks or fractures.

- 3 Complete the product Warranty/Registration card and mail it with proper postage to Aribex today. Completing the card fulfills a condition of warranty coverage (see the inside back cover of this manual) and enables you to receive valuable product news and updates.

1.3 Charging the Battery

NOTE: Batteries are charged at the factory, and should be fully recharged before the initial use of the NOMAD. If the system has been in long-term storage prior to initial use, batteries will definitely require a proper charge first. In fact, it is recommended to fully recharge batteries every 3 months for long-term storage to avoid damage to any low battery.

- 1 Unwrap the power cord of the battery charger and connect it to an AC electrical outlet (110/120V or 220/240V, dictated by the country/region).

Position the battery charger away from the normal patient environment. A plug adapter may be used as needed; use only the supplied battery charger (for manufacturer and model info, see section 6.3, *Repair and Maintenance*).



- 2 Invert one of the batteries and carefully plug it into the charger (do not force the battery into the charger or damage to the battery may result). The red indicator light  on the top of the charger will flash at a steady rate while the battery is charging. The required charge time varies (normally between 30 to 45 minutes). Battery and charger may become warm to the touch while charging, which is a normal condition.

- 3 When the battery is fully charged and ready to use, the indicator light  will stop flashing and remain on continuously. Remove the charged battery and charge the second battery for future use.
- 4 Optimal battery life and performance occurs when the NiCad battery is fully discharged prior to recharging. (For more information review the accompanying battery charger Instruction Manual, also see section 5.0, *Battery Replacement*.)

2.0 Safety Precautions

2.1 Radiation Safety

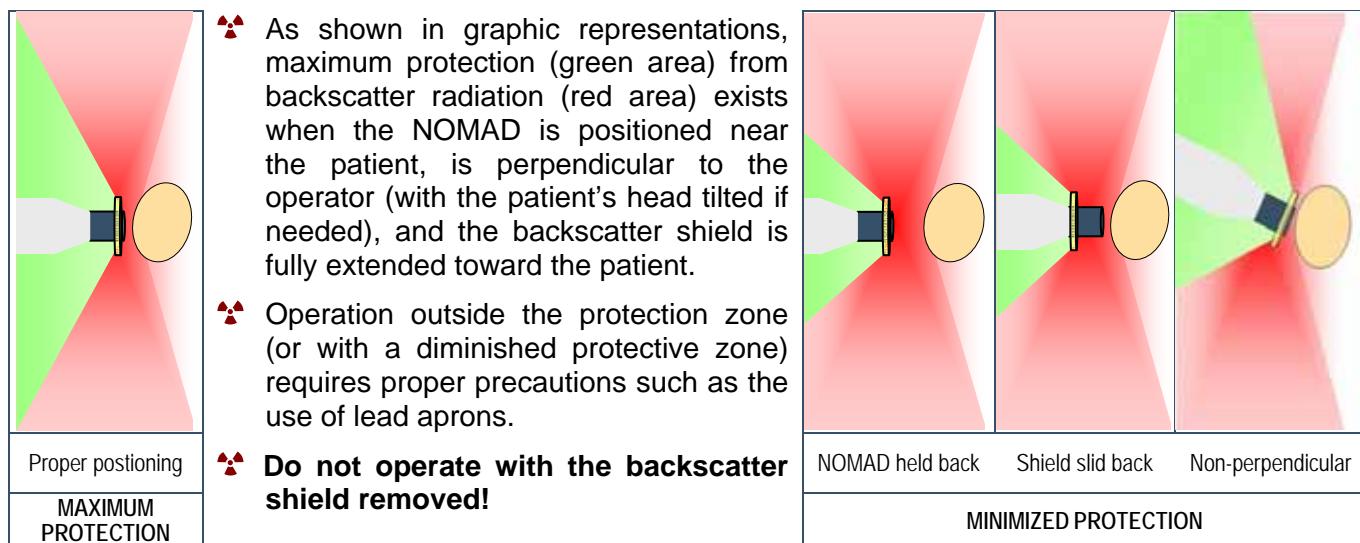
 This x-ray unit may be dangerous to operator and bystander unless safe exposure factors and operating instructions are observed.



- ❖ Operators must follow all guidelines dictated by applicable regulations and in-house radiation protection program in regard to patients and operators who are pregnant or expect to become pregnant.
- ❖ Operators must be fully acquainted with safety recommendations and established maximum permissible doses.
- ❖ Optimal operator radiation backscatter protection exists when:
 - a) the operator remains within the cone-shaped backscatter protection zone immediately behind the backscatter shield,
 - b) the backscatter shield is positioned at the outer end of the collimator cone,
 - c) the patient tilts their head when needed to accommodate exposures (see section 4.7), and
 - d) the backscatter shield is close to the patient.
- ❖ Do not enable NOMAD until patient and operator are positioned and ready for the exposure, diminishing the likelihood of interruption and preventing inadvertent exposure of anyone to x-rays.
- ❖ Do not attempt an exposure if anyone else is in the same room unless it is necessary that the patient be accompanied by another person. That person must then stay out of the direct beam and wear protective clothing.
- ❖ When selecting and using Position Indicating Devices (PIDs), 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.

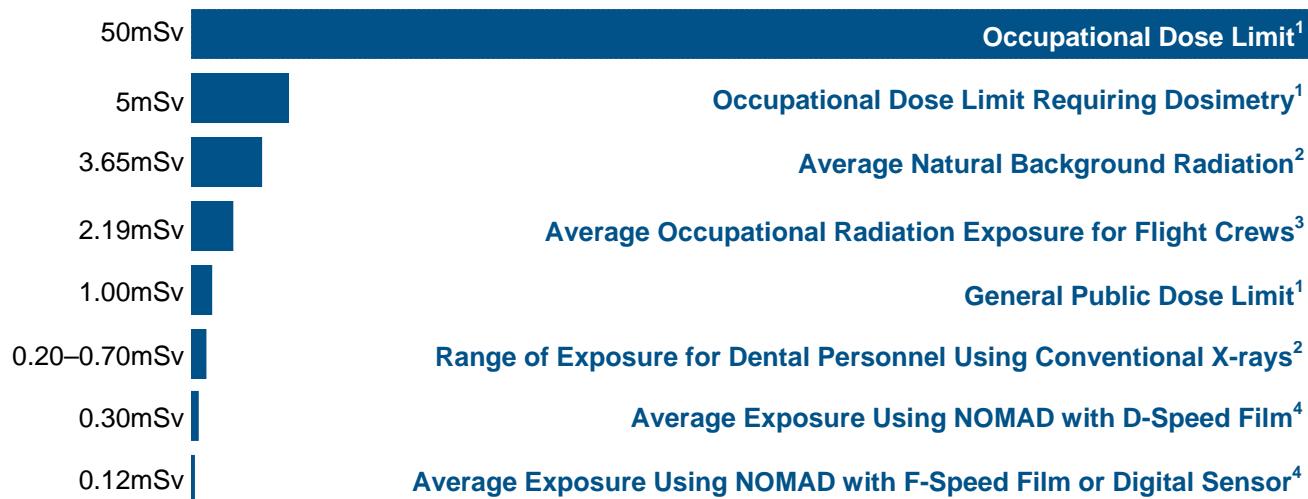
NOMAD

- ☢ An exposure can be terminated for any reason by abruptly releasing the depressed trigger (for more information see section 4.0, *Operation*).



NOTE: In implementing a radiation protection program, please consult all applicable (state, provincial, and local) regulations governing radiation protection and the use of x-ray equipment, and ensure full compliance with any such regulations.

Comparative Data for Whole Body Exposure (Annual)



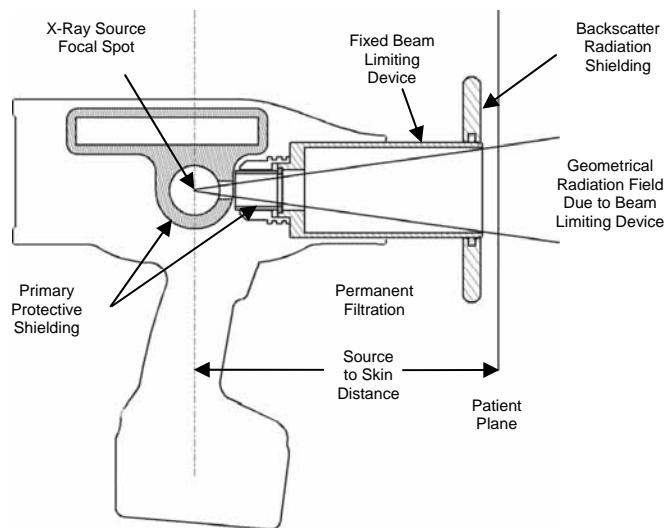
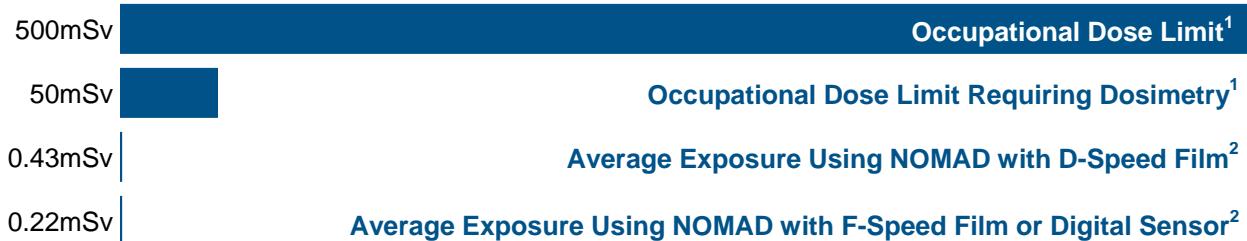
1) Standards for Protection Against Radiation, 10 CFR 20 (US Federal Standards), 1994 (see also *NCRP Report No. 116*)

2) *NCRP Report No. 145* (National Council on Radiation Protection and Measurements), p7-9

3) "Estimated Cosmic Radiation Doses for Flight Personnel", Feng YJ et al, *Space Medicine and Medical Engineering*, 15(4) 2002, p265-9

4) Normalized average assumes 7,200 exposures per year, and the average length of exposure for D-speed = 0.50 seconds, F-speed = 0.25 seconds, digital sensor = 0.20 seconds

Comparative Data for Hand and Extremity Exposure (Annual)



1) Standards for Protection against Radiation, 10 CFR 20 (US Federal Standards), 1994 (see also *NCRP Report No. 116*)

2) "Radiation Exposure with the NOMAD Portable X-ray System", Goren AD et al, Dentomaxillofacial Radiology, 37 (2008), p109-12; normalized average (includes leakage and backscatter radiation) assumes 7,200 exposures per year, and the average length of exposure for D-speed = 0.50 seconds, F-speed = 0.25 seconds, digital sensor = 0.20 seconds

2.2 Usage

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

The NOMAD is also designed to avoid damage from overheating. The minimum duty cycle rating (the relationship between duration and frequency of exposures) is 1:60. Examples of optimal use:

Duration	0.25s	0.46s	0.50s	0.99s
Cycle	Every 15 sec	Every 28 sec	Every 30 sec	Every 60 sec



Do not operate NOMAD or the battery charger if either was immersed in liquid or subjected to an undue amount of moisture.

NOMAD



- There are no user serviceable parts inside the NOMAD.
- Do not open the device housing. Doing so will void the warranty.
- NOMAD should not be used in environments where flammable cleaning agents are present.
- Locate the battery charger away from the normal patient environment (see section 5.0, *Battery Replacement*).

2.3 Cleaning

- 1 Turn off the power and detach the battery before cleaning. Ensure the battery charger is unplugged before attempting to clean it.
- 2 Use a **non-acetone** based disinfectant wipe or a cloth to wipe the exterior surfaces of the NOMAD and charger.

NOTE: NOMAD and the accompanying battery charger are not designed to be subjected to any kind of sterilization procedure.

2.4 Security, Storage, and Transportation

- **NOMAD must be kept in a secure location**, such as a locked cabinet, when not in use to prevent unauthorized access.
- **The battery serves as the device security key**. When finished with NOMAD for the day, detach the battery and lock it away in a separate location to prevent unauthorized use.
- Make sure NOMAD will not be knocked to the ground when not in use. Lay it on its side if necessary. Power will automatically shut off after a period of inactivity (approximately 2.5 minutes).
- Do not store or carry batteries so that metal objects can contact exposed battery terminals.
- Do not store the NOMAD, battery charger, or batteries in extreme conditions: below -20°C (-4°F) or above +40°C (+104°F), or beyond 95% relative humidity (non-condensing). This storage location should be cool, dry, and away from direct sunlight. For more info about storage and operational temperature limits, see section 7.1, *Basic Technical Specifications*.

- Some battery charge may be lost during extended inactivity (leading to fewer exposures between charging).



- For long-term storage, it is recommended to fully recharge batteries every 3 months.

3.0 Setup and Check

3.1 The Backscatter Shield

In addition to the lead-lined cone, the backscatter shield provides additional protection to you, the operator, and features an adjustable position to permit exposures made at various angles.

1 Ideally, the shield should remain fully extended to the outer edge of the cone, as close to the patient as possible for each image taken (see 2.1, *Radiation Safety*).



2 You may find that the backscatter shield needs to be adjusted to accommodate position indicating devices or angled exposures. If adjustments are needed, stand the NOMAD on-end on a stable surface and, while holding the backscatter shield perpendicular to the collimator cone (tube-shaped cone), gently glide the shield up or down along the cone using equal pressure to maintain a perpendicular alignment and avoid binding.

3 To keep the shield securely on the cone a retainer o-ring is permanently attached in the groove at the outer cone end. Do not attempt to remove this o-ring or to remove the backscatter shield, attempting to do so will result in damage to your device.

3.2 Attaching a Charged Battery

- 1** Properly orient and carefully insert the newly charged battery into the base of the NOMAD handle, (a properly oriented battery should click into place without force, forcing the battery into position may damage the battery and/or the NOMAD). The clicking sound ensures the snaps on both sides of the handle bottom are fastened.
- 2** Make sure the battery is secure by giving it a tug. NOMAD can be placed into service after the check for power (section 3.3).
- 3** Read the battery charger instruction manual for complete information on how to achieve the longest life and best performance from your batteries.



3.3 Checking for Power and Adequate Charge



- 1** After inserting a fully charged battery, press and release the POWER button. The numeric (LED) display should illuminate, accompanied by a single, long audible signal ➤.
- 2** NOMAD measures whether sufficient battery charge exists prior to a timed exposure, when ENABLE is pressed to ready the device.
- 3** If the battery is too low, the yellow LOW BATTERY indicator ⚡ at the lower right of the control panel will flash (accompanied by an intermittent audible signal ➤).

- 4 Once a battery is depleted, indicated by the LOW BATTERY alert, it **must** be recharged before use.
- 5 For continued use, insert the secondary, replacement battery (which should be charged in advance).

NOTE: See section 5.0, *Battery Replacement*, for more information.

3.4 Optional Checks

The NOMAD is factory calibrated and tested prior to release (see your *Certificate of Conformance*), there are no adjustment options. However, the optional checks listed below may be performed by a qualified technician as desired.



Test firing this x-ray unit may be dangerous to the testing technician or bystanders unless safe test exposure techniques are used such as the use a lead lined cap to cover the end of collimator or test firing in a protected area.

ON/OFF Switch: Install fully charged battery to NOMAD device. Press the POWER button and verify the ON and OFF conditions.

Increase/Decrease Switch (Up and Down Arrows): With the device turned ON, press each of the Increase then Decrease buttons and verify that the exposure times as displayed on the LED display change appropriately.

Enable Switch: With the device turned ON and the LED display set at 50 (500ms), press the ENABLE button and verify functional conditions. Wait approximately 30 seconds, at which point the enabled condition should expire.

Automatic Shut-Off: Press the POWER button to turn the device ON and wait for it to automatically shut off after approximately 2.5 minutes of inactivity.

See section 6.1, *Alarms and Alerts*, for more information.

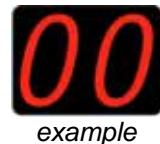
4.0 Operation

4.1 Powering Up



Press and release POWER button to turn NOMAD on (after approximately 2.5 half minutes of inactivity, NOMAD shuts off automatically).

When the power is turned on a single, long audible signal ➤ and an illuminated numeric (LED) display indicate the unit has power.



example

4.2 Ensuring Battery Charge Is Adequate

If the LOW BATTERY indicator ☀️ flashes, accompanied by an intermittent audible signal ➤, see sections 3.3, *Checking for Power and Adequate Charge* and 5.0, *Battery Replacement*.



For other error conditions, please see sections 6.1, *Alarms and Alerts* or 6.2, *Troubleshooting*.

4.3 Ensuring the Right Exposure Time Is Set



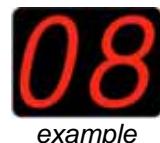
increase



decrease

When power is turned off, the most recent setting for exposure time is stored in memory and redisperses when power is turned back on. (However, if the battery is replaced, the display is reset to the 00 default value.)

To change exposure settings press the increase or decrease buttons (by tenths / hundredths of a second). A single, short audible signal ➤ confirms input when a button is pressed/released. (For example, **08** LED setting = 0.08 seconds; **35** LED setting = 0.35 seconds.)



example

4.4 Situating the Patient and Enabling the Device

Properly position the patient and yourself before enabling NOMAD (to prevent accidental exposure).



Press and release ENABLE to ready the device; be sure to re-enable NOMAD if any subsequent changes are made to the time setting prior to exposure.



The flashing, green ENABLED indicator ☀ and audible signal ➡ (intermittent, double beep) confirm that NOMAD is enabled. This continues for 30 seconds or until an exposure is initiated.

4.5 Initiating and Completing an X-ray Exposure

NOTE: An exposure can be prematurely terminated for any reason by abruptly releasing the depressed trigger.



To begin the exposure, squeeze the handle trigger (or press and hold START). The ENABLED indicator ☀ stops flashing, and the green START and yellow X-RAYS ON indicators ☀ illuminate.



To ensure complete exposure, keep the trigger or START button depressed until the audible, continuous-tone signal ➡ ends and both indicators ☀ are off.

4.6 Powering Down



Press and release POWER to turn NOMAD off. (NOMAD automatically shuts off after approximately 2.5 minutes of inactivity.)



4.7 Exposure Techniques

NOMAD provides a high degree of flexibility, making it possible for exposures to be produced while the patient is reclined, lying on their back, or sitting upright.

- 1** When taking images, hold the NOMAD using two hands; one on the handle and the other under the battery for increased stability and patient safety.
- 2** To minimize cone-cutting, NOMAD must be properly positioned relative to the imaging system. (Check compatibility with film holding kits or aiming devices in advance. See comments pertaining to PIDs in section 2.1, *Radiation Safety*.)
- 3** Exposure times increase proportionally when the imaging angles vary from 90° or perpendicular to the film or sensor. To maintain low patient x-ray doses and keep the operator within the protection zone, request that the patient slightly tilt their head, and/or raise or lower their chin as needed. (Also see section 2.1, *Radiation Safety*.)
- 4** When angled shots are required and the operator cannot be completely within the protection zone, ensure operator protection through the use of proper safety measures such as the use of a lead apron. (Also see section 2.1, *Radiation Safety*.)
- 5** Avoid touching the patient with the cone or backscatter shield; and/or use disposable plastic coverings.
- 6** Determine what NOMAD time settings deliver optimal results for the type of digital or film-based imaging that is done on a regular basis. Note that digital imaging sensors and film speeds can vary somewhat in their characteristics and could require different exposure settings than the suggested nominal exposure times in the *Technique Factor Chart*. Adjust as needed to meet density preference.
- 7** For an explanation of the relationship between shot duration and rest cycle between exposures (duty cycle), see section 2.2, *Usage*.



Technique Factor Chart

2.3mA 60kV

Recommended exposure settings (X 1/100 second) with cone perpendicular to film/sensor.

			Incisors	Premolars & Canines	Molars	Bitewings
Digital Sensor	Schick Sensor	Adult	Maxilla (upper)	09	12	12
		Sensor #1 & #2	Mandible (lower)	07	10	10
	Air Techniques Accent Sensor	Child	Maxilla (upper)	08	09	10
		Sensor #1	Mandible (lower)	07	08	8
Planmeca DIXI 3	Air Techniques Accent Sensor	Adult	Maxilla (upper)	15	15	20
		Sensor #1 & #2	Mandible (lower)	12	12	18
	Planmeca DIXI 3	Child	Maxilla (upper)	10	15	16
		Sensor #1	Mandible (lower)	08	10	14
Phosphor Plate	Air Techniques ScanX PSP	Adult	Maxilla (upper)	15	15	20
		Sensor #1 & #2	Mandible (lower)	12	12	18
	Air Techniques ScanX PSP	Child	Maxilla (upper)	10	15	16
		Sensor #1	Mandible (lower)	08	10	14
Film	Kodak Insight	Adult	Maxilla (upper)	18	18	20
			Mandible (lower)	13	13	18
	Kodak Ultraspeed	Child	Maxilla (upper)	10	15	16
			Mandible (lower)	8	10	14
Film	Kodak Insight	Adult	Maxilla (upper)	35	35	40
			Mandible (lower)	25	25	35
	Kodak Ultraspeed	Child	Maxilla (upper)	20	30	32
			Mandible (lower)	15	20	28
Film	Kodak Ultraspeed	Adult	Maxilla (upper)	48	60	70
			Mandible (lower)	40	49	58
	Kodak Ultraspeed	Child	Maxilla (upper)	32	40	50
			Mandible (lower)	28	32	40

The settings in this chart are based upon an independent university study and are intended as a reference point only. Individual results may vary based upon a number of factors including the various imaging sensors and film speeds and brands available, patient mass, and the technician techniques.

5.0 Battery Replacement

A flashing, yellow LOW BATTERY indicator ☀ (control panel) and intermittent audible signal ➤ indicate the need for a freshly charged battery. NOMAD cannot emit X-rays with a low, depleted battery (insufficient voltage). Follow these steps to clear the LOW BATTERY alert.

- 1 Press and release POWER on the control panel in order to turn NOMAD off.



- 2 Grasp and depress the buttons on both sides of the battery to release it from the handle. You may have to put pressure at the very top of the buttons (nearest the handle). Then pull the battery away from the handle.

- 3 Carefully insert a newly charged battery into the base of the NOMAD handle (a properly oriented battery should click into place without force, forcing the battery into position may damage the battery and/or the NOMAD). A clicking sound ensures that the snaps on both sides of the handle bottom are fastened. Make sure the battery is secure by giving it a tug. When a battery is detached, any stored exposure time is erased from memory and has to be reset when the unit is turned on again.

- 4 After the initial 1-hour recharge, the charger will switch to Tune-Up Mode, which continues 8 hours as cells in the battery are equalized. The battery is ready for use and can be removed at any time during this mode. Always unplug the charger from the power supply when it is not in service. For additional info, specifically about the charger, see the accompanying instruction manual for the battery charger.

- 5 Battery charge will diminish during extended inactivity – **fully recharge batteries every 3 months during inactivity.** Never place a low battery into long-term storage.

- 6 Each battery can go through the discharge/charge cycle approximately 200 times. When the battery charger senses a bad battery, it is spent and must be taken out of service. Do not attempt to charge damaged batteries. An authorized distributor, Aribex, and your local recycling center will accept spent or damaged batteries. Order new 14.4V batteries from Aribex or your authorized distributor. Do not use batteries from other sources, which invalidates the warranty.



Risk of Shock – There is high electrical current present at the battery charger terminals. Do not probe with fingers or conductive objects.

6.0 Keeping NOMAD Up and Running

6.1 Alarms and Alerts

The visual/audible alarm signals a programmed action designed to prevent harm to operator, patients, and/or NOMAD.

The visual/audible alerts confirm normal conditions or draw the operator's attention to a required action.

Condition	Visual Indicator ☀	Audible Signal ⏪	Function / Resolution
Overheating <i>Alarm</i>	LED display begins flashing 	Series of long beeps	Operation suspends if the device overheats; after cooling for approximately 5 minutes (or longer depending upon room temperature), power on (see Duty Cycle in section 2.2, Usage)
Low Battery <i>Alert</i>	Yellow LOW BATTERY indicator flashes 	Slow series of short beeps	Replace the battery and reset exposure time (for information see section 5.0, Battery Replacement)
X-ray Exposure <i>Alert</i>	Green START and yellow X-RAYS ON indicators illuminate 	Continuous tone (for the duration of the timed exposure)	At the end of the successful exposure, audible signal and indicators stop
Incomplete Exposure <i>Alert</i>	Green START and yellow X-RAYS ON indicators flash 	Series of long beeps	Activates if trigger is released before the timed x-ray exposure finishes and ends automatically after 15 seconds or if power is manually turned off/on
System Readiness <i>Alert</i>	Green ENABLED indicator flashes 	Slow series of short, double beeps	Activates when ENABLE is pressed/released; ends automatically after 30 seconds or when an exposure starts (trigger is depressed or START is pressed)

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Condition	Visual Indicator ☀	Audible Signal ➡	Function / Resolution
Invalid Input Error <i>Alert</i>	N/A	Two short beeps	Invalid input (for example, triggering prior to enabling) activates alert, which then ends automatically
Valid Input <i>Alert</i>	For numeric LED display, time setting increments or decrements	Single short beep	Valid when panel button is pressed/released
System Alert <i>Alert</i>	LED display turns off	Two short beeps	X-ray emissions are not detected during timed exposure but the battery is OK
	Followed by a system shutdown		
Power OFF <i>Alert</i>	LED display turns off	Two short beeps	POWER button is pressed and released (while power is on)
	Followed by a system shutdown		
Power ON <i>Alert</i>	LED display lights up	Single long beep	POWER button is pressed and released (while power is off)

6.2 Troubleshooting

If you encounter results and/or errors in the operation of NOMAD that are not explained in the previous sections, check the following table on user troubleshooting to determine the need for authorized service.

Device Symptom	Potential Problem	Corrective Action
6.2.1 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.
6.2.2 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.
6.2.3 Green ENABLED indicator stops flashing (and corresponding, short double beeps end) before an exposure is started	NOMAD is no longer enabled. If an x-ray exposure is not initiated within 30 seconds of enabling, the System Ready condition will terminate.	Double-check the exposure time setting and re-enable when operator and patient are again properly situated.
6.2.4 Green START and yellow X-RAYS ON indicators flash (with corresponding series of long beeps)	Incomplete exposure – the depressed trigger was released before the timed exposure was able to complete.	This condition is cleared automatically within 15 seconds or by manually turning NOMAD off and back on. The exposure will likely need to be repeated.

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Device Symptom	Potential Problem	Corrective Action
6.2.5 Yellow X-RAYS ON indicator does not illuminate	No exposure – a subsequent Low Battery alert will signal whether a low battery is the source of the problem.	Follow proper procedures for replacing the battery; see section 5.0, <i>Battery Replacement</i> .
	If within a few seconds, two short beeps are emitted and the system automatically shuts down, a different problem exists (see section 6.1, <i>Alarms and Alerts</i>).	NOMAD will require authorized service; see section 6.3, <i>Repair and Maintenance</i> .
6.2.6 NOMAD automatically shuts down	After about 2.5 minutes of inactivity, NOMAD emits two short beeps and shuts off automatically – the system has timed out.	Manually turn on NOMAD when you are ready to use the device.
	However, if while attempting an x-ray exposure two short beeps were emitted and shutdown occurred, a different problem exists (see section 6.1, <i>Alarms and Alerts</i>).	If this condition persists, NOMAD will require authorized service; see section 6.3, <i>Repair and Maintenance</i> .
6.2.7 There is no power to the NOMAD control panel	If pressing POWER several times does not cause the numeric (LED) display to illuminate, the attached battery is the likely problem.	Ensure battery is securely attached.
	However, if while attempting an x-ray exposure two short beeps were emitted and shutdown occurred, a different problem exists (see section 6.1, <i>Alarms and Alerts</i>).	Replace with a newly charged battery before continuing. Use the battery charger to determine if the first battery is spent and must be taken out of service, or if it can be recharged.
		NOMAD will require authorized service; see section 6.3, <i>Repair and Maintenance</i> .

If you have additional questions or require help contact: support@aribex.com

6.3 Repair and Maintenance

NOMAD is a maintenance-free product, except for routine cleaning. Make sure the power is off while cleaning, detach the battery. It is unnecessary to detach anything else in order to clean the unit. Use a **non-acetone** based disinfectant wipe or a cloth to wipe the exterior surfaces of the NOMAD and charger.



The NOMAD and the battery charger are NOT designed to be user serviceable. Do not open the device housing, doing so will void the warranty.

Repairs can only be undertaken by trained service personnel. Direct all questions to an authorized distributor.

The following are factory serviceable parts and components:

- NOMAD Dental, main apparatus assembly – item AP-0001
- Retainer o-rings – item CP-0046
- Backscatter shield / inner o-ring assembly – item AP-0012
- Batteries – item CP-0001
- 110/120V AC battery charger w/ manual (DeWalt, model DW9116 or DC9310) – item CP-0002
- 220/240V AC battery charger w/ manual (DeWalt, model DE9116 or DE9135) – item CP-0045
- Hard-shell carrying case (accessory) – item MP-0018



Instructions for handling product at end of life – Please, protect the environment and do not improperly dispose of any part of the NOMAD system, battery, or charger; contact an authorized distributor or Aribex, Inc. regarding assistance in returning the product for proper disposal.

If product return is required, contact Aribex for a Return Material Authorization (RMA) number and shipping instructions to return the product to the proper facility. If the product is under warranty, you will be required to provide the serial number from the label affixed on the underside of the NOMAD.

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

Aribex will not assume responsibility for shipping damages; however, it will help you file a claim with the freight carrier. Please see warranty information at the end of this manual.

7.0 Technical Description

7.1 Basic Technical Specifications

Maximum deviation from fixed factors	±5% (unless otherwise noted)
Total weight	4kg

Environmental

Operation	
Temperature	–5°C to +40°C (+23°F to +104°F)
Relative humidity	+4°C to +40°C (+39°F to +104°F) charging 10% to 80%, non-condensing
Storage and transportation	
Temperature	–20°C to +60°C (–4°F to +140°F) NOMAD –20°C to +40°C (–4°F to +104°F) battery
Relative humidity	95%, non-condensing

Classification / Specification Compliance

IEC 60601-1 (Amnd 1 & 2), 60601-1-3, 60601-2-7; 21 CFR 1020.30 & 1020.31	Class II, Type BF
MDD (93/42/EEC): Annex IX	Class IIb
IPX specification	IP0; do not operate under wet conditions
Mode of operation	Intermittent operation
Conductive connection to patient	No conductivity with the applied part

For use in environments where no flammable anesthetics and/or flammable cleaning agents are present; **non-acetone** based disinfectant wipes or cloths.

Electrical

Rechargeable NiCd battery	14.4V, 2A/hr
Low battery alert set point	11.6V
Battery current at 2.3mA, 60kVp output	16A

X-ray Controls and Generator

Exposure time range	0.01–0.99 sec. (certified for 0.02–0.99 sec.)
Maximum duty cycle	1:60 (one 0.25 sec. exposure / 15 sec.)
Minimum inherent filtration	1.5mm Al
Maximum output power	140W nominal at 60kV, 2.3mA
Generator rating	2.3mA at 60kVp ±10%
Leakage technique factors	60kV, 2.3mA, 0.99 sec.

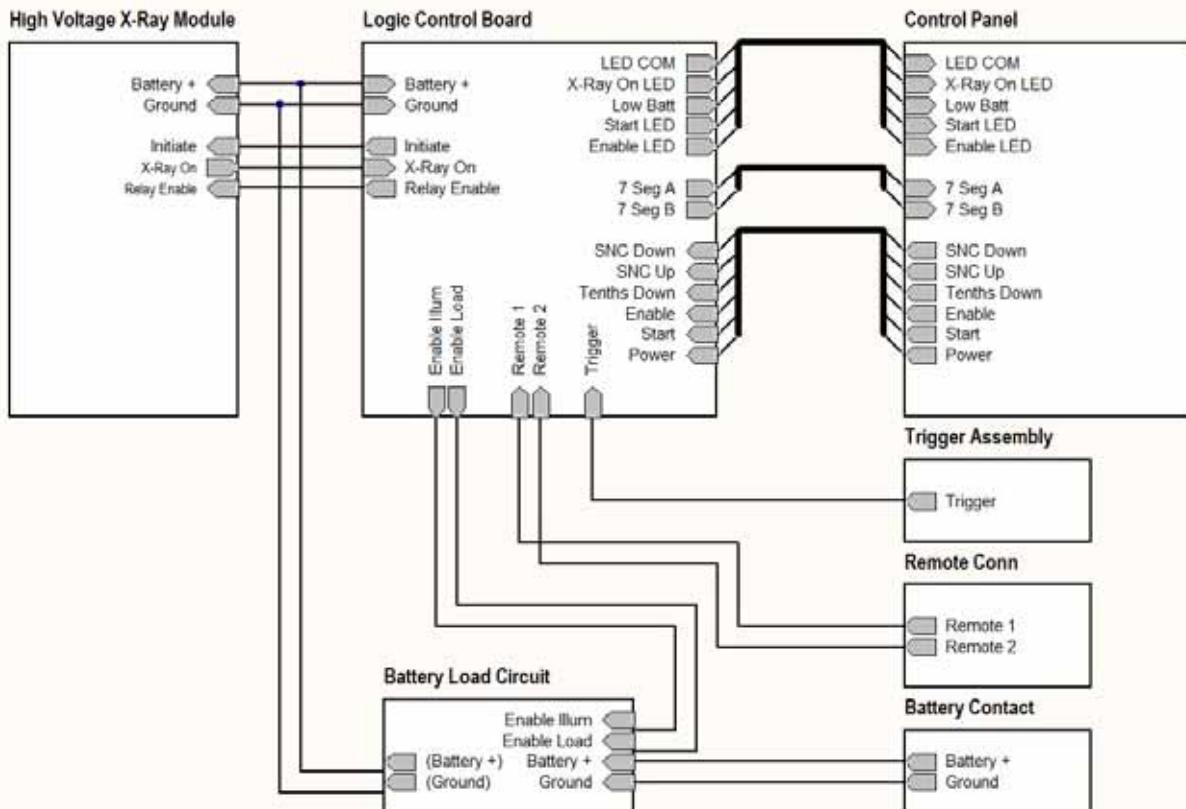
Measurement Base of Technique Factors

The kV is measured during pre-pot testing using a calibrated high voltage divider with a guaranteed accuracy of $\pm 2\%$. Final performance measurements are made using a NERO mAx, model 8000 x-ray meter from Victoreen. Tube current (mA) is sensed across a series connected resistor with an accuracy of $\pm 1\%$ and measured using a digital multimeter, prior to encapsulation; NOMAD Dental has no provision for external measurement of beam current after final manufacture. Exposure time is measured from the moment x-rays are detected until they are no longer detected (which means "zero-crossing mode" is selected with no timer delay) using the NERO mAx 8000 x-ray meter.

Collimator Cone

Minimum source to skin distance	20cm (from focal spot to cone tip)
Nominal dose output at cone tip (20cm)	3.28mGy / sec.
X-ray field size and configuration	6cm diameter circle
Shielding	Lead-lined
Backscatter radiation shielding	0.5mm Pb-equivalent

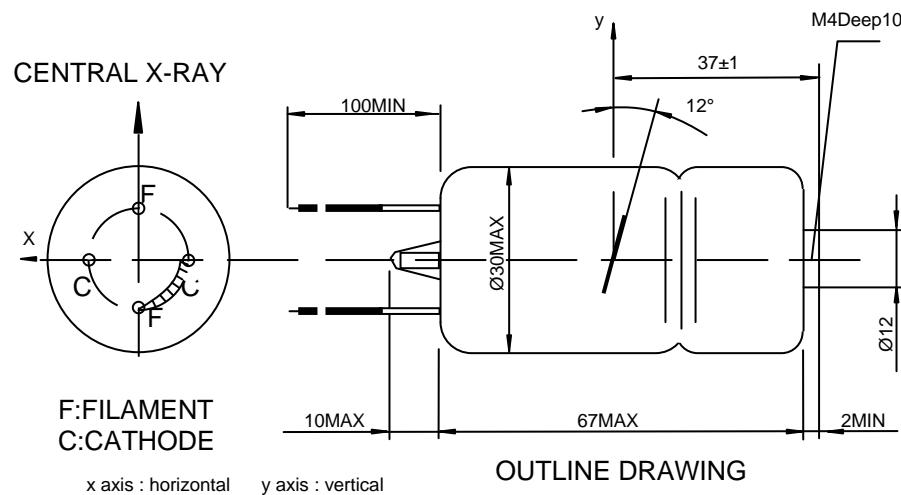
7.2 Functional Diagram

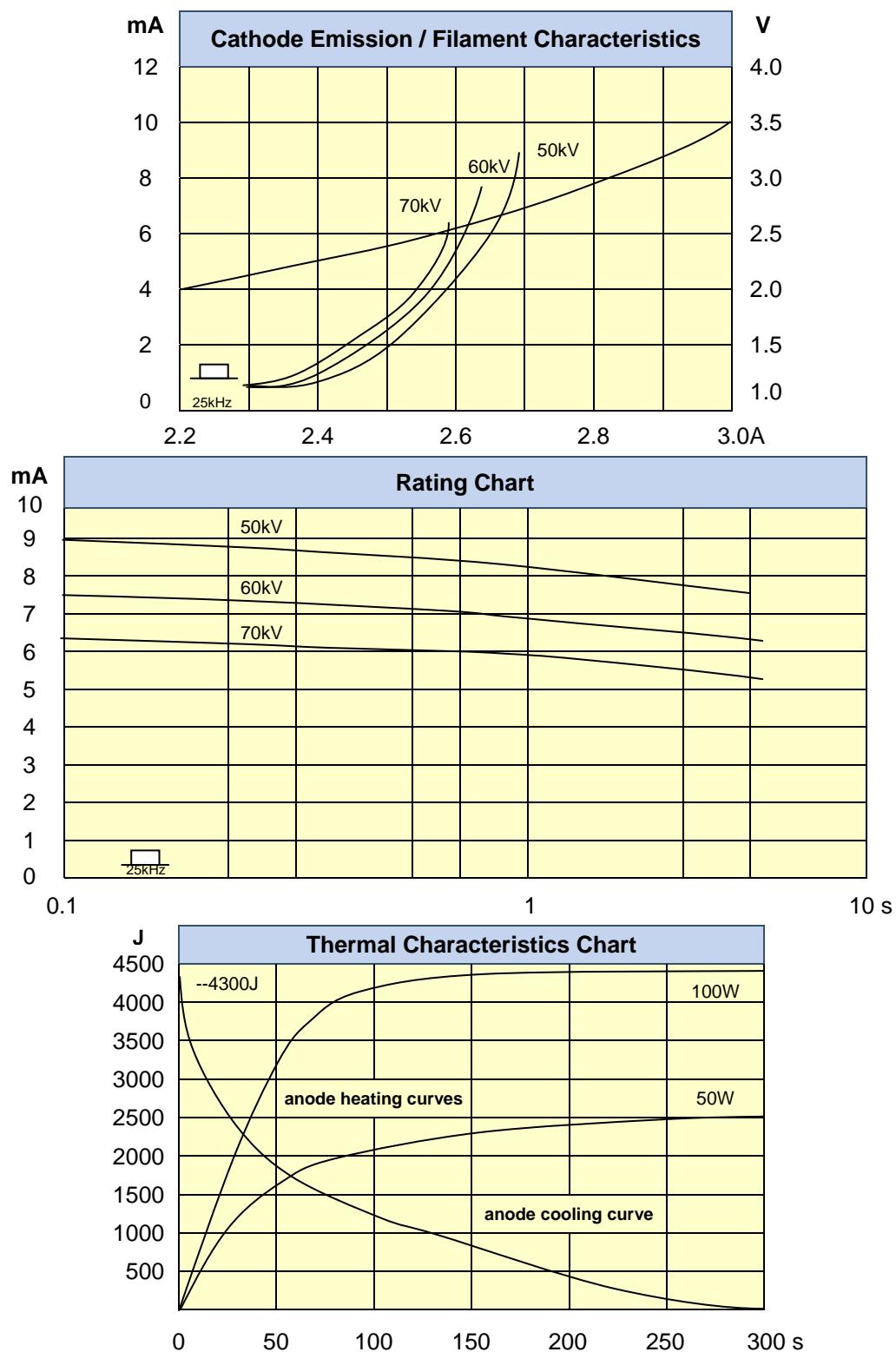


7.3 X-ray Tube Specifications and Characteristics

The VTD70/0.4/12CP is designed for intraoral dental imaging by an x-ray unit, and is available for nominal tube voltage with self-rectified or constant potential circuit – manufactured by Kailong; distributed in the U.S.A. by Vista Technology.

Nominal tube voltage	50–70kV
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
Target angle	12°
Filament characteristics	2.2–3.0A, 2.0–3.5V
Minimum permanent filtration (IEC 60522:1999)	0.8mm Al / 50kV





7.4 EMC Data

Independent laboratory testing for electromagnetic compatibility for conformity to the Sub-clause 5.10 requirements of ISO/IEC 17025 "General Criteria for the Competence of Testing and Calibration Laboratories" was conducted by:

Nemko USA, Inc.
11696 Sorrento Valley Rd, Suite F
San Diego, CA 92121-1024
USA

The NOMAD Dental X-ray System 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 uses RF energy only for its internal function. In addition, the housing includes conductive shielding; therefore, 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 is suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply network that supplies buildings used for domestic purposes.

Test Specifications

Radio Frequency Emissions and Electromagnetic Immunity tests in accordance with requirements of EN 60601-1-2 as follows:

Test Type	In Accordance with Document	Document Title
Conducted and Radiated Emissions	EN 55011 (1998), A1 Class "B"	Limits and Methods of Measurement of Radio Disturbance Characteristics of Information Technology Equipment
Electrostatic Discharge Immunity	IEC 61000-4-2 (1995), A1 (1998), A2 (2000)	Electromagnetic Compatibility for Industrial Process Measurement and Control Equipment Electrostatic Discharge Requirements
Radio Frequency Immunity	IEC 61000-4-3 (2000), A1 (2002)	Electromagnetic Compatibility, Basic Immunity Standard, Radiated Radio Frequency Electromagnetic Field, Immunity Test
Power Frequency Magnetic Field Immunity	IEC 61000-4-8 (1993), A1 (2000)	Electromagnetic Compatibility, Testing and Measurement Techniques for Power Frequency Magnetic Field, Immunity Test

NOTE: The tests documented in the table above are the only tests required for this product as it is a battery operated device and has no I/O cables. IEC 61000-4-4, 4-5, 4-6 and 4-11 are not applicable.

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Emissions Test Summary

Specification	Frequency Range	Compliance Status
EN 55011 (1991), Group 1, Class "B" Conducted Emissions	0.15 MHz – 30.00 MHz	N/A for a battery powered device
EN 55011 (1991), Group 1, Class "B" Radiated Emissions	30.0 MHz – 1000 MHz	PASS
EN 55014 (1993) – Discontinuous Disturbance Test	N/A	N/A for a battery powered device
EN 61000-3-2 (2000) – Power Line Harmonics	Up to the 40th Harmonic	N/A for a battery powered device
EN 61000-3-3 (1995), A1 (2001) – Power Line Flicker	≤4% Maximum Relative Voltage Change; Value of D(T) ≤3% for more than 200ms	N/A for a battery powered device

Immunity Test Summary

Specification	Minimum Test Level Required per EN 60601-1-2	Test Level Completed	Compliance Status
IEC 61000-4-2 (1995), A1 (1998), A2 (2000) – Electrostatic Discharge Immunity	Criterion B Air discharge up to ±8kV; contact discharge up to ±6kV	Criterion B Air discharge up to ±8kV; contact discharge up to ±6kV	PASS
IEC 61000-4-3 (2000), A1 (2002) – RF Radiated Fields Immunity	Criterion A Radiation field strength of 3V/m from 80 – 2500MHz (80% amplitude modulated @ 1 kHz)	Criterion A Radiation field strength of 3V/m from 80 – 2500MHz (80% amplitude modulated @ 1 kHz)	PASS
IEC 61000-4-4 (1995), A1 (2000), A2 (2001) – Electrical Fast Transient Immunity	Criterion B Power line pulses of ±2kV direct; I/O line pulses of ±1kV	Criterion B Power line pulses of ±2kV direct; I/O line pulses of ±1kV	N/A for a battery powered device
IEC 61000-4-5 (2001) – Lightning Surge Immunity	Criterion B Power line surges of ±2kV common, ±1kV differential mode	Criterion B Power line surges of ±2kV common, ±1kV differential mode	N/A for a battery powered device
IEC 61000-4-6 (1996), A1 (2000) – RF Common Mode Immunity	Criterion A 150 kHz – 80 MHz at 3 Vrms (80% amplitude modulated @ 1 kHz)	Criterion A 150 kHz – 80 MHz at 3 Vrms (80% amplitude modulated @ 1 kHz)	N/A for a battery powered device
IEC 61000-4-8 (1993), A1 (2000) – Power Frequency Magnetic Field Immunity	Criterion A Helmholtz coil at 50 Hz, to 3 amps (rms) per meter	Criterion A Helmholtz coil at 50 Hz, to 3 amps (rms) per meter	PASS
IEC 61000-4-11 (2001) – Voltage Dips and Short Interruptions	Criterion B and C Voltage Dips of >95%, 30% and >60%; Interruptions of >95%	Criterion B and C Voltage Dips of >95%, 30% and >60%; Interruptions of >95%	N/A for a battery powered device

7.5 Optional Calibration Checks

The NOMAD is factory calibrated and tested prior to release (see your *Certificate of Conformance*) and there are no adjustment options. However, the **optional** checks listed below may be performed by a qualified technician as desired.

Setup a calibrated Performance Meter (such as the Victoreen NERO™ mAx model 8000) according to manufacturer's specifications to detect and report the following: X-ray Tube Voltage [kV Effective Mode], Radiation Time [ms Effective Mode], and Dose [mR Average Mode]. The filter card for the Test Detector should be in the 50–100kVp position.

Measurement Method: Final performance measurements are made using a NERO mAx, model 8000 x-ray meter from Victoreen. Tube current (mA) is sensed across a series connected resistor with an accuracy of $\pm 1\%$ and measured using a digital multimeter, prior to encapsulation; NOMAD has no provision for external measurement of beam current after final manufacture. Exposure time is measured from the moment x-rays are detected until they are no longer detected (which means "zero-crossing mode" is selected with no timer delay) using the NERO mAx 8000 x-ray meter. 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 IEC60601-2-7, 50.102.2a.



This x-ray unit may be dangerous to testing technician and any bystanders unless safe test exposure factors, such as placing the Test Detector in a lead lined box or the use of a protective lead apron are observed.

Enable the NOMAD and with the cone perpendicular to the Test Detector, make exposures into the Test Detector and capture the resulting data.

Compare the result with the factory release parameters (indicated in the chart below). For results outside these parameters, discontinue use and contact your dealer/distributor or Aribex.

Test Description	Acceptance Limits	Timer Settings and Corresponding Acceptable Ranges				
		20ms	40ms	400ms	600ms	990ms
kVp (eff) Accuracy	60kV $\pm 10\%$	54 to 66	54 to 66	54 to 66	54 to 66	54 to 66
Timer Accuracy	Setpoint $\pm 10\%$, +1ms	17 to 23	35 to 45	359 to 441	539 to 661	890 to 1090



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

LIMITED WARRANTY

COVERAGE. Aribex, Inc. warrants its medical and dental x-ray equipment to be free from any defects in material or workmanship for a period of one (1) year from the date of purchase. Aribex, Inc. also warrants any accessories purchased from Aribex to be free from any defects in material or workmanship for the period of one (1) year from the date of purchase.

The liability of Aribex, Inc. is limited to repair or replacement of any parts that Aribex or its authorized resellers determine to be defective. Contact Aribex for a Return Material Authorization (RMA) number and shipping instructions. Parts proving defective shall be repaired or replaced free of charge (labor and domestic shipping included), if defective equipment is returned freight collect to Aribex (Utah, 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, or damaged as a result of any carelessness or accidents. This warranty does not cover ordinary wear and tear or maintenance.

LIMITATIONS OF LIABILITY. Aribex, Inc. makes no other warranty, either expressed or implied, with respect to any equipment purchased from Aribex, including without limitation any implied warranties of merchantability or fitness for a particular purpose, whether or not Aribex may have been informed of the actual uses to which any of such equipment may be put. Aribex, Inc. 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 Aribex 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.



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English is the original draft language for this manual.

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EC **REP**

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MP-0013, Rev G