# NOMAD™

## *Handheld X-ray System*

*for Intraoral Radiographic Imaging*

## *Operator Manual*


KAVO

Dental Excellence

# Thank you for choosing the KaVo NOMAD Pro 2

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

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

**Disclaimer:** KaVo 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 KaVo Dental Technologies, LLC, 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.

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# KaVo NOMAD Pro 2

KaVo NOMAD Pro 2 Handheld X-ray System is a battery-operated, portable dental X-ray source designed for handheld operation. It is designed to produce diagnostic quality X-rays images utilizing either film or digital imaging techniques. The KaVo NOMAD Pro 2 Handheld X-ray System is designed for use in a dental office. It can also be used in other similar environments (orthodontic office, general practitioner's office, hospital ward, etc.) where appropriate safeguards are implemented. The device uses a rechargeable battery to allow for the use of the KaVo NOMAD Pro 2 Handheld X-ray System where transportation or use of other x-ray devices might be prohibitive due to the other device's size and/or lack of mobility.

The KaVo NOMAD Pro 2 Handheld X-ray System is an X-ray device with a DC generator. The handheld device features a main unit (tube head), rechargeable battery (handset), charger, and charger AC/DC power supply. The power is supplied by a rechargeable Lithium Ion battery core pack built into a handset. This facilitates portability of the device. A beam-limiting cone is incorporated within the device. Internal and external shielding provide sufficient radiation protection to allow the clinician to remain in the operatory with the patient.

To make the system as simple as possible for the operator, KaVo NOMAD Pro 2 Handheld Xray 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. Exposures 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.

Accessories supplied with the finished device include:

- Alignment bars* (Class I, Exempt, EHA, 21 CFR 872.1820)

Optional accessories:

- Rectangular collimator – rectangular and smaller exposure area
- Tabletop stand – tabletop storage
- Wall hook – storage and display
- Hard shell carrying case – protection during transportation and storage

*Alignment bars are a device for positioning image receptors and are provided as a convenience and are not required to be used with the device.

# 1.0 Getting Started

## 1.1 Indications for Use

The KaVo NOMAD Pro 2 Handheld X-ray System is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors.

## 1.2 Warnings and Precautions

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

• Pregnant women. The medical practitioner must weigh the benefits conferred by use of the device against the potential hazard to the pregnant woman and fetus resulting from radiation exposure. If use of the device is considered justified, the practitioner must take the appropriate precautions, such as use of radiation safety garments, to limit radiation exposure beyond the maxillofacial complex.

• Pediatric. The medical practitioner must weigh the benefits conferred by use of the device against the potential hazard to the child resulting from radiation exposure, considering the maturity of the child's physical development. If use of the device is considered justified, the practitioner must take the appropriate precautions, such as use of radiation safety garments, to limit radiation exposure beyond the maxillofacial complex.

• Patients with medical conditions causing involuntary movements. For patients who experience seizures or who have been diagnosed with conditions such as Parkinson's Disease which can cause difficulty in controlling physical movements, the medical practitioner must weigh the benefits conferred by use of the device against the potential hazard to the patient resulting from additional radiation exposure due to a re-scan in the event that an involuntary movement renders an image unusable for diagnostic purposes.

## 1.3 Unpack, Check, Register and Clean KaVo NOMAD Pro 2 System

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

- KaVo NOMAD Pro 2 Devices
- Charging Cradle
- Two Rechargeable Battery Handsets
- AC/DC Power Supply
- Alignment Bars
- Certificate of Conformance, Getting Started Guide, Product Registration Card, and KaVo NOMAD Pro 2 Operator Training CD

❷ Preliminary Checks:

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

❸ Complete the product registration card and mail it with proper postage to KaVo today, or go on-line at kavo.com/portable-x-ray-machine/warranty-registration. Registering your device will activate your KaVo Complete (the first year is free). For terms and conditions of the KaVo NOMAD Pro 2, please visit kavo.com

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

## 1.4 Charging the Handsets

KaVo 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).

- Handsets must be charged before initial use. Alternate handsets each week to maximize service life.
- Do not spray disinfectant or cleansers directly on to the 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.

❶ Use only the supplied AC/DC power supply. Unwrap the power cord of the power supply and connect it to the charging cradle, then to an AC electrical outlet (universal voltage accommodated). The charger will flash red lights as it initiates, followed by a single green circle that will illuminate 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 an KaVo authorized service center for repairs.

***Receiving Adequate Power***

Position the charging cradle away from the normal patient environment. A plug adapter may be needed to accommodate the local AC configuration.

❷ Invert one of the handsets and carefully slide it onto the charging cradle (do not force the handset onto the charging cradle or damage may result). 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 When the handset is first slid onto the charging cradle, the first bar will illuminate green for approximately two seconds to indicate that the cradle and handset are communicating. If the bars illuminate or flash red, see the troubleshooting guide section 6.2.10. Authorized service will also be required if no illumination occurs upon sliding the handset onto the charging cradle.

***Contact KaVo for Service***

❹ After illuminating green, the first bar will begin flashing to indicate that charging has begun. When the first bar turns solid green, the handset is 1/3 charged, and the second bar will begin flashing green. When the second bar turns solid green, the handset is 2/3 charged, and the third bar will begin flashing green. Once the third bar turns solid green, the handset is fully charged. **Remove the handset from the charging cradle once it is fully charged and store carefully.**

***Handset 1/3 Charged***

***Handset 2/3 Charged***

***Handset Fully Charged***

# 2.0 Safety Precautions

## 2.1 Radiation Safety

The KaVo NOMAD Pro 2 was designed to be used in clinical settings (e.g., a dental office) and controlled settings where transportation or use of other X-ray devices might be prohibitive due to the device's size and/or mobility.

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 KaVo 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 protection from radiation backscatter 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 (see Section 4.7 Exposure Techniques), and
**d)** the operator remains within the significant zone of occupancy immediately behind the device shield.

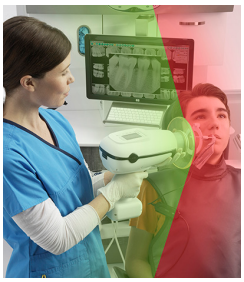
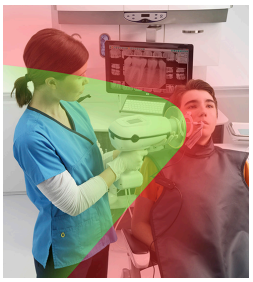
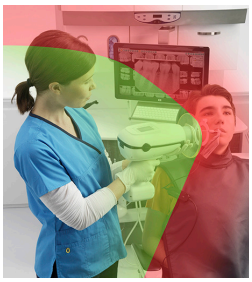
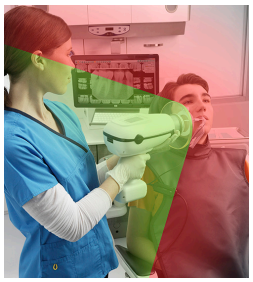
- Do not enable the KaVo NOMAD Pro 2 until patient and operator are positioned and ready for the exposure, preventing interruption and inadvertent exposure of anyone to X-rays.

- 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. An apron and thyroid collar are recommended for ancillary personnel who are closer than 6 feet to the patient.

- When selecting and using sensors, preference should be given to models that allow the backscatter shield to remain at the outer end of the collimator cone for maximum operator protection.

- An exposure can be terminated for any reason by prematurely releasing the depressed trigger (for more information, see Section 4.0 Operation).

- As shown in graphic representations, maximum protection (green area) from backscatter radiation (red area) exists when the KaVo 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** | | |

- 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.**

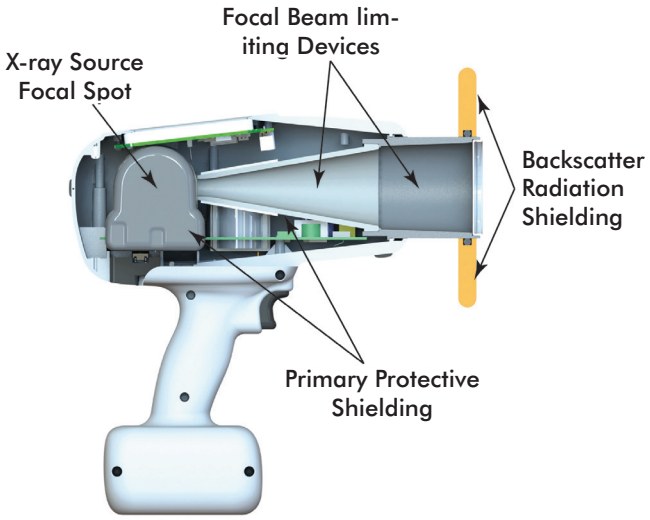
- For further information on the tests performed to ensure KaVo NOMAD Pro 2 safety as a handheld device, please see Section 2.2 Studies and Data on Leakage and Scatter.

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

## 2.2 Studies and Data on Leakage and Scatter

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

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

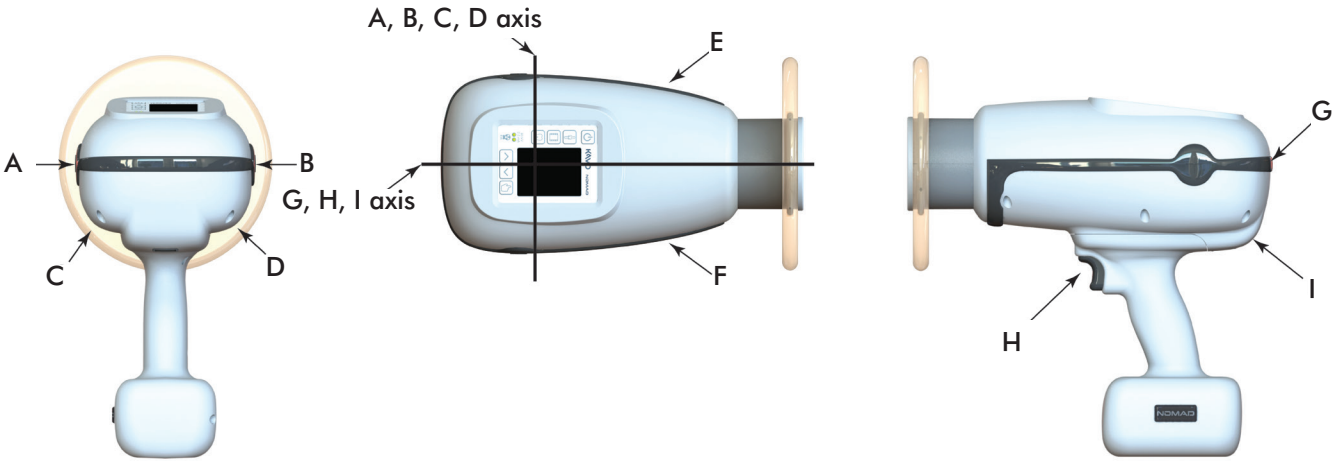



**Leakage**

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



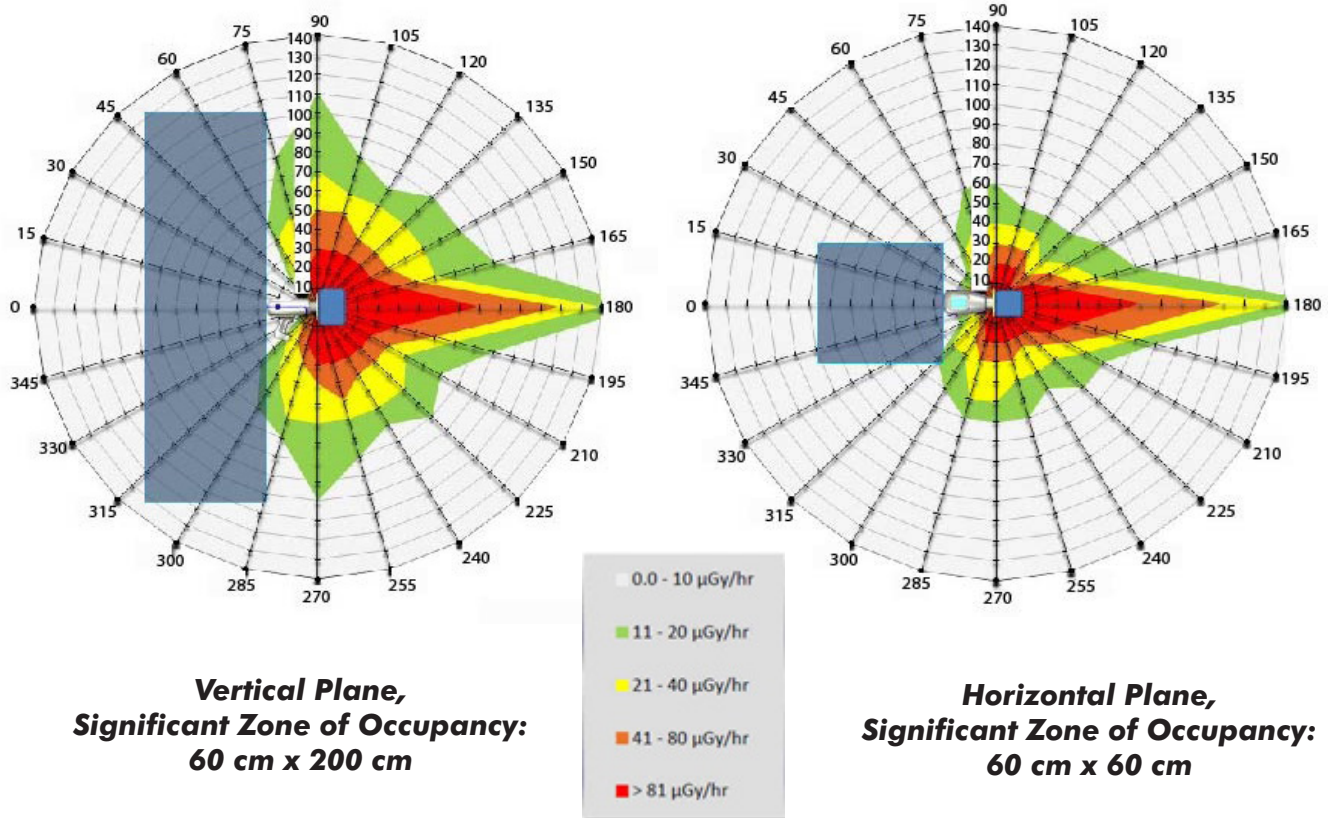

***Test points for product release testing***

**Scatter**

As discussed in Section 2.1 Radiation Safety, the transparent shield on the KaVo 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 significant zone of occupancy for operators has been further verified by internal testing. A KaVo 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 each unit located 100 cm above the floor. Each exposure was taken at 1.00 seconds in order to simulate "worse case scenario" results. The vertical significant zone of occupancy measures 60 cm X 200 cm, while the horizontal significant zone of occupancy is 60 cm X 60 cm. A calibrated survey dosemeter can be used in order to confirm scatter radiation data shown in the following diagrams.

For further information on these tests, please contact KaVo.




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

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

## 2.3 Usage and Duty Cycle

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

The KaVo 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 KaVo NOMAD Pro 2.

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

- Do not open the housings. Doing so will void the warranty. There are no user serviceable parts inside the KaVo NOMAD Pro 2, handset, charging cradle, or AC power supply.
- The KaVo 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 KaVo NOMAD Pro 2 and charger. Do not use cleaners intended for hard surfaces, since certain chemical combinations may deteriorate the KaVo NOMAD Pro 2 plastic prematurely.

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

❸ Unplug the charging cradle before cleaning.

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

### Alignment Bars

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

Do not spray disinfectant or cleaners directly on the KaVo 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 KaVo NOMAD Pro 2, handsets, charging cradle, or AC power supply in extreme conditions: below -4°F (–20°C) or above 122°F (+50°C), or beyond 90% relative humidity (non-condensing). The optimal storage location is cool, dry, and away from direct sunlight.
- KaVo recommends that the KaVo 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 KaVo NOMAD Pro 2, detach the handset.
- The **X-ray Lock** and **Unlock** (Section 4.2) serves as the device security key to prevent unauthorized use. In addition, it is recommended that the device be locked away when not in use. For a further level of security, securely store handsets in a separate location.
- Take steps to ensure the KaVo NOMAD Pro 2 will not be knocked to the ground when not in use by laying it on its side. 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 KaVo NOMAD Pro 2 should not be operated if it has been dropped or if performance degrades; it should be returned to KaVo or an authorized service center for an evaluation.
- When finished for the day with the KaVo 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 United States safety standards |
|  | Power Switch |
|  | The product meets all the legal requirements for CE markings and can be sold throughout the European Economic Area |
|  | General warning |
|  | Caution |
|  | Recycling instructions |
|  | Used Electrical and electronic products should not be mixed with general household waste |
|  | Manufacturer |

| | |
|---|---|
|  | Date of manufacture |
| REF | Model/Catalog number |
| SN | Serial number |
|  | Follow Operating Instructions for Use |
| EC REP | The name and address of the Authorized Representative in the European Community |
|  | 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 KaVo Handheld X-ray System and Charger have identification labels that specify the model number and applicable product approval listings.

| | |
|---|---|
|  | Medical Electronic Equipment. U.S. Patents: 7,224,769 and 7,496,178.<br>Complies with FDA radiation performance standards 21 CFR, subchapter J.<br>Location: Top surface of the NOMAD handheld device. |
|  | Standard Trigger Handset<br>Use only with KaVo branded charging cradle<br>Contains Li-ion Battery<br>Location: Top of device handset<br>(visible when detached from device). |
|  | Charging Cradle<br>Use only with KaVo branded handset and<br>KaVo supplied AC/DC adapter<br>Max Input<br>Max Output<br>Location: Bottom surface of Charging Cradle |

# 3.0 Setup and Power Check

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

❷ 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.

## 3.2 Attaching a Charged Handset

❶ With the KaVo NOMAD Pro 2 placed bottom up on a secure surface, properly orient and carefully slide the charged handset onto the base of the KaVo 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 KaVo 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 KaVo 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.

## 3.4 Optional Checks

The KaVo 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 KaVo 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 KaVo 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 timeout.
- **Automatic Shut-down:** With the device on, allow approximately three minutes of inactivity to pass for the system to automatically shut down.

The KaVo NOMAD Pro 2 should not be operated if it has been dropped or if performance degrades; it should be returned to KaVo or an authorized service center for an evaluation.

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

# 4.0 Operation

## 4.1 Powering Up

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

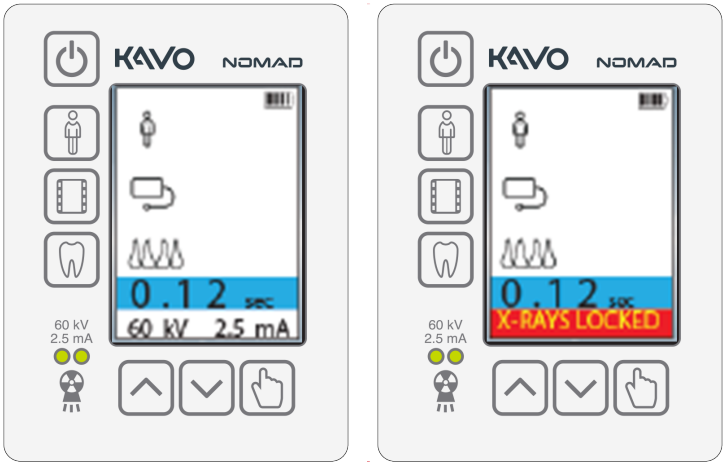
Press and release the **Power** ⏻ button to turn on KaVo NOMAD Pro 2. An audible double tone and an active display panel indicate the device has power.

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 unauthorized use when the KaVo NOMAD Pro 2 is idle or stored. This functionality may also be used for training purposes.

To lock the X-ray, first press and hold the **Select** button while pressing the **Patient** button. The device shifts into an **X-rays Locked** state, and the buttons can be released. Repeat the process to unlock the X-ray device.




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

NOTE: If the **Select** button is held down for longer than 3 seconds before the **Patient** button is pressed, the Menu mode will activate; if the **Select** button is pressed and released before the **Patient** button is pressed, the Save menu is displayed.

## 4.3 Ensuring the Right Exposure Time is Set

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

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

1) 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

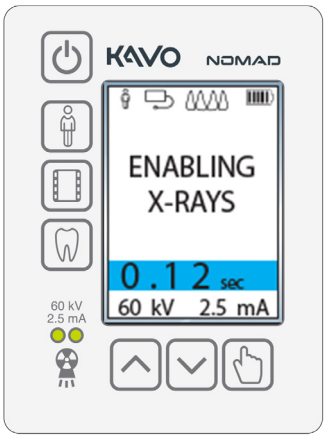
To prevent accidental radiation exposure, properly position the patient and operator before readying the KaVo NOMAD Pro 2.

Press and release the trigger once to ready the device. The device will briefly display an **Enabling X-rays** message before indicating **Ready**.

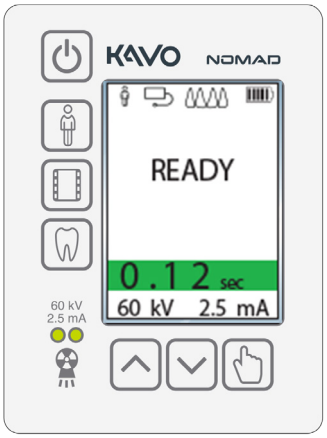
NOTE: As a safety precaution, if the trigger is held longer than one second or pulled a second time while still in the **Enabling X-rays** state, the device will not transition to the **Ready** state. (This is to prevent an accidental activation of the device by unintended triggering.)

The illuminated green LED, the message **Ready** on the display panel, and a double tone alert confirm that KaVo NOMAD Pro 2 is prepared to fire X-rays. The **Ready** state continues until either an exposure is initiated or timeout occurs after 15 seconds of inactivity (accompanied by a double tone and the return to the at-rest state).

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




***Enabling X-rays Alert***



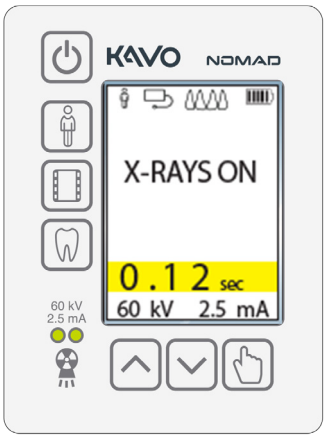

***Ready Alert***

## 4.5 Initiating and Completing an X-ray Exposure

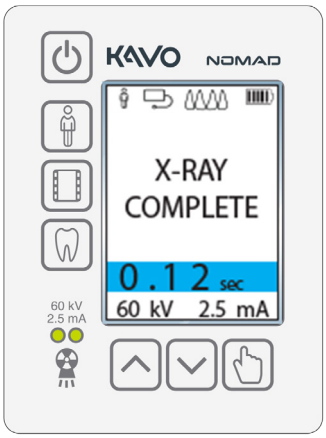
To begin the exposure, press and hold the trigger. The **Ready** alert is replaced with the **X-rays On** alert, the green LED is replaced with a yellow LED, and there is an alert tone for the duration of the exposure.

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.




***Enabling X-rays Alert***




***Ready Alert***

## 4.6 Powering Off

Press and release the **Power** ⏻ button to turn KaVo NOMAD Pro 2 off.

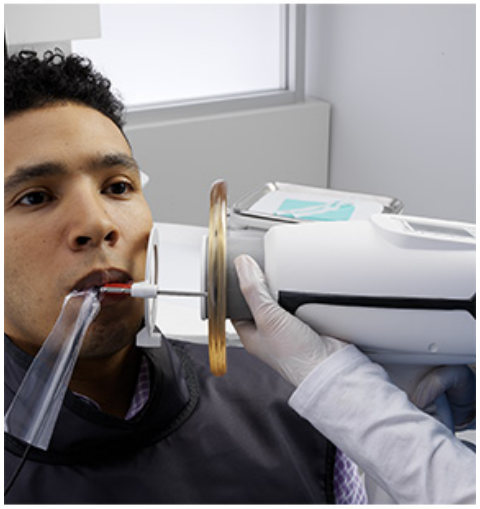
The KaVo NOMAD Pro 2 also automatically shuts off after approximately three minutes of inactivity.

The KaVo NOMAD Pro 2 display darkens, accompanied by a tone to indicate shut-down.

## 4.7 Exposure Techniques

As an intra-oral dental X-ray system, the KaVo 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, operators may hold the KaVo 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 (but not on the collimator cone).



❷ Position the KaVo NOMAD Pro 2 relative to the imaging system to minimize cone-cutting. (If your practice uses film holding kits or aiming devices, check compatibility in advance.)

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

❹ When the device must be angled and the operator cannot be completely within the protection zone, ensure operator protection through the use of proper safety measures, such as the use of 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 KaVo 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 and phosphor plate speeds can vary somewhat in their characteristics and could require different exposure settings to meet density preference. (See Section 4.10 Settings Menu for more information.)

## 4.8 Ensuring Image Quality

The following KaVo NOMAD Pro 2 features contribute to high image quality:

- DC voltage X-ray generation is efficient in delivering energy at the level optimized for diagnostics, with shorter exposure times required.
- The smaller the focal spot, the better the resolution. The KaVo NOMAD Pro 2 has a small 0.4mm focal spot.
- Absorption of scatter by the KaVo 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 both hands to hold the KaVo 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.

Image degradation or blurriness does not result due to motion of the handheld X-ray source.

**Time Settings, Sensors, and Complete Exposures**

To ensure image quality, use correct time settings. The KaVo 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 KaVo NOMAD Pro 2 works with the fastest sensor technologies in the market to assure that exposure times are as short as possible, also limiting any effects of motion.

Make sure you are as close to the patient's cheek as possible without touching. If your sensor holder prevents you from getting close enough, you may want to use the Short Alignment Bars, enabling the KaVo NOMAD Pro 2 to be placed directly against the positioning ring.

Always double-check for the **Incomplete Exposure** alarm on the KaVo 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 pediatric. Pediatric patients may be more radio-sensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher), and so unnecessary radiation exposure is of particular concern for pediatric patients. Please use caution when configuring the KaVo 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 | Adult | 0.16 | 0.19 | 0.20 |
| | Child | 0.09 | 0.15 | 0.16 |

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

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

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

❷ Press and release the **Select** button to activate the **Save Menu**.

❸ Select **Yes** by pressing the **Increase** ∧ button.

❹ Press the **Select** button to select **OK**.

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

## 4.10 Settings Menu

The KaVo NOMAD Pro 2 menus allow the operator to customize settings according to individual preferences. To access the **Main Menu**, press and hold down the **Select** button for three seconds. When the **Main Menu** appears, the operator can access the desired menu item(s) by pressing the **Increase** ∧ and ∨ **Decrease** buttons to scroll up or down. When the desired menu item is highlighted, press the **Select** button to access the menu item.

Within the menu items there are options (such as **Yes** and **No**) which are selected using either the **Increase** ∧ or **Decrease** ∨ buttons. Once a selection is made, pressing the **Select** button confirms the choice.

To exit the **Main Menu**, highlight **Exit** at the bottom of the list and then press the **Select** button, or power the device off and then on.

| Menu Item | Function |
|---|---|
| **System Info** | When system information is selected from the settings menu, the device software version information will be displayed on-screen. Pressing the **Select** button will return the operator to the settings menu. |
| **Audible Sound** | The volume may be adjusted by the operator. The range is from one (softest), up to five (loudest). The **Increase** ∧ and **Decrease** ∨ buttons are used to adjust the volume, and the system emits a tone as each volume is selected so the operator can determine the choice. Once the desired volume is determined, pressing the **Select** button saves the volume setting. |

| Menu Item | Function |
|---|---|
| **X-ray Counter** | The device will display two counters. One is the **Overall History Counter,** which displays the total lifetime X-ray shots for the device. The other, **Trip Counter**, can at any time be reset to zero by the operator.<br><br>When **Reset** is selected and the **Select** button is pressed, the user will be prompted with the message **Reset Trip Counter**?<br><br>When **Yes** is selected and the **Select** button is pressed, the **Trip Counter** is reset to zero and the device is returned to the counter display.<br><br>When **No** is selected and the **Select** button is pressed, the device is returned to the counter display with no change.<br><br>When **Back** is selected and the **Select** button is pressed, the device returns to the **Main Menu**.<br><br>NOTE: **Reset Defaults** also resets the **Trip Counter** to zero. |
| **Reset Defaults**<br>[Technique Factors and Trip Counter] | Allows the operator to restore the factory default settings with which the device was shipped. These defaults are:<br><br>• X-rays will be unlocked;<br>• Audible sound will be set at full volume;<br>• Trip counter will be reset to zero;<br>• All factory timer settings/technique factor combinations will be reset to factory defaults, overriding any custom settings the operator may have input.<br><br>The operator can use the **Increase** ∧ and **Decrease** ∨ buttons to toggle between **Yes** and **No** in response to the menu prompt **Reset Exposure Time To Factory Settings?**<br><br>If **Yes** is selected, the system will confirm the selection by displaying **All Custom Settings Will Be Erased. Are You Sure?**<br><br>Selecting **Yes** and then the **Select** button reverts any customized exposure settings to the factory defaults and returns the device to the Main Menu.<br><br>If ever **No** is selected and then the **Select** button pressed, the customized settings will not be changed and the system returns to the **Main Menu**. |
| **Exit** | Allows the user to leave the **Main Menu** and return to normal operation. (Powering off and then on also exits the menu.) |

# 5.0 Handset Replacement and Care

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

A **Recharge Handset** alarm on the display panel indicates the need for a recharged handset. The KaVo 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 KaVo NOMAD Pro 2.

❷ Place the KaVo 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 KaVo 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).

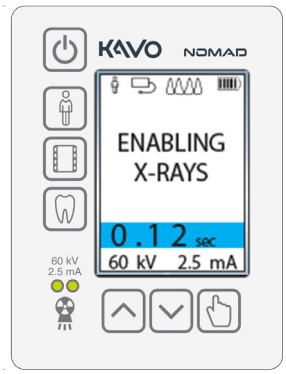
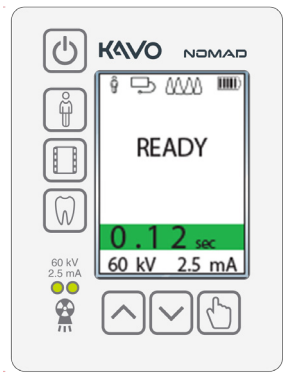
- Do not attempt to charge a handset with damaged batteries. Damage can occur if handset experiences liquid ingress, if it has been dropped or punctured, or exposed to heat or fire. Replace handset immediately if there are any signs of deterioration or if batteries do not retain a charge during normal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

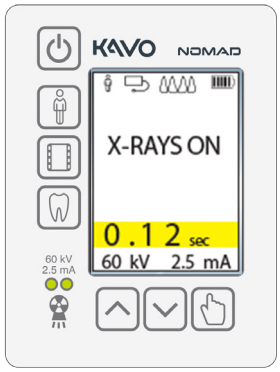
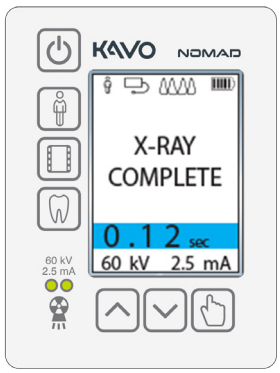
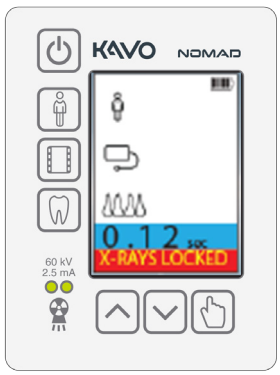
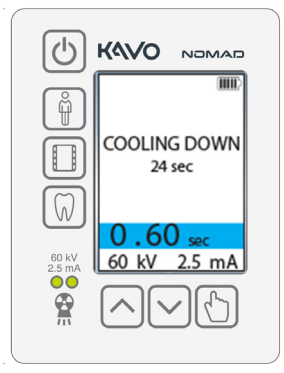
# 6.0 KaVo NOMAD Pro 2 Care and Upkeep

## 6.1 Alarms and Alerts

The visual and audible **alarms** signal a programmed action designed to prevent harm to operators, patients, and/or the KaVo 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 or off in the **Audible Sounds** menu. See Section 4.10 Settings Menu.

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

| Alerts & Alarms: Visual and Audible Indicators | | Function/Resolution |
|---|---|---|
| **Visual** | **Audible** | |
| **X-ray Exposure Alert**<br>  | Single tone for duration of exposure (X-ray exposure alert) | At the end of the successful exposure the yellow LED turns off, and the panel briefly displays **X-ray Complete** alert and the screen returns to the at-rest state. |
| **X-ray Complete Alert**<br>  | | |
| **X-ray Lock Alert**<br>  | Tones will be the same as the actual operation tones | When the trigger is activated while the device is in the X-rays locked mode and operation is attempted, various alert messages will be displayed. For example: **X-rays Locked**, **Simulation Only**, **Simulation Complete**. Toggle between **Locked** and **Unlocked** by pressing and holding down the **Select** button and then press the **Patient** button. |
| **Duty Cycle Exceeded Alarm**<br>  | Double tone at the start and end of the cool down cycle | If the operator presses the trigger to activate the **Ready** alert before the duty cycle time has elapsed, the device will display the warning 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** | |
| **Low Battery Alarm**   | 5 audible tones | The **Recharge Handset** alarm terminates after five seconds and goes into auto shutdown. Replace the current handset with a freshly charged handset. NOTE: If the battery voltage is lower than required for the X-ray exposure, the device will not allow the exposure. |
| **Incomplete Exposure Alarm**   | A warning tone | This alarm 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. To avoid this error, depress the trigger for the duration of the exposure time. |
| **System Failure Alarm**   | Descending tone | See Section 6.2 Troubleshooting (6.2.8) or an KaVo authorized service center. |
| **Handset Failure Alarm**   | 5 audible tones | See Section 6.2 Troubleshooting (6.2.12) or an KaVo authorized service center. |

The KaVo NOMAD Pro 2 should not be operated if it has been dropped or if performance degrades; it should be returned to KaVo for an evaluation.

## 6.2 Troubleshooting

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

| 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 Enabling X-rays** alert stays on. | Double triggering. | Release the trigger and wait for the **Ready** alert. |
| **6.2.4** Device does not shift to the **Enabling X-rays** alert or **Ready** alert. | The trigger is pulled for longer than one second. | Pull and release the trigger within one second and wait for the **Ready** alert. |
| | The device may be above the maximum operating temperature of 104°F (+40°C). | Allow the device to return to the operating range as stated in Section 8. |
| **6.2.5 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. |
| **6.2.6 Incomplete Exposure** alarm displayed on-screen. | Incomplete exposure: the depressed trigger is released before the timed exposure is able to complete. | This condition automatically clears within 15 seconds 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 |
|---|---|---|
| **6.2.7** KaVo NOMAD Pro 2 automatically shuts down. | KaVo NOMAD Pro 2 times out after about three minutes of inactivity. | Manually turn on KaVo 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, KaVo NOMAD Pro 2 will require authorized service. See Section 7.0 Maintenance and Repair. |
| **6.2.8 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 KaVo NOMAD Pro 2 will require authorized service; see Section 7.0 Maintenance and Repair. |
| **6.2.9** There was no power to KaVo NOMAD Pro 2 control panel. | If pressing **Power** several times does not cause the display to illuminate, the attached handset is the likely problem. | Ensure handset is securely attached. |
| | | Replace with a newly charged handset in order to continue. Use the charging cradle to determine if the first handset battery can be recharged or is impaired and must be taken out of service. |
| | A different problem exists if all handsets appear fully charged. | KaVo NOMAD Pro 2 will require authorized service; see Section 7.0 Maintenance and Repair. |
| **6.2.10** When placing handset on the charging cradle, indicator lights illuminate solid or flashing red. | If the indicator lights are solid red, there is an issue with either the handset or charger. | Ensure that the compatible components are being used by checking the labels of both the handset and charger and verifying that the correct part numbers are being used. |
| | | If correct components are being used, the handset and charger will require authorized service; see Section 7.0 Maintenance and Repair. |
| | If the indicator light blinks red, the handset is outside of the operating temperature range. | Remove the handset from the charger. Allow the handset to equilibrate to room temperature. Place the handset on the charger. If the error persists, the handset will require authorized service: see Section 7.0 Maintenance and Repair. |
| **6.2.11** The handset did not seem to be working when the trigger was pulled. | The trigger is not communicating with the device. | KaVo NOMAD Pro 2 may require authorized service; see Section 7.0 Maintenance and Repair. |

| Device Symptom | Potential Problem | Corrective Action |
|---|---|---|
| **6.2.12 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. | KaVo NOMAD Pro 2 will require authorized service; see Section 7.0 Maintenance and Repair. |
| **6.2.13 Handset does not completely charge after 5 hours.** | If the green power indicator is illuminated but the handset fails to charge, there may be an issue with compatibility of components. | Ensure that compatible components are being used by checking the labels of both the handset and charger and verifying that the correct part numbers are being used. |
| | If the green power indicator is illuminated but the correct components fail to charge, the handset may be in sleep mode. | Plug in the charger. Place the handset on the charger. Leaving the handset on the charger, unplug the charger by unplugging the power supply from either the cradle or the wall. Plug in the charger to reset the handset and begin charging. Charging a handset from the sleep mode may take slightly longer than normal. |
| | | If the process described above fails to recover the 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 his 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 KaVo 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 KaVo, and must comply with the applicable legal requirements as well as with the generally accepted technical regulations.

## 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 KaVo NOMAD Pro 2.

1. The KaVo NOMAD Pro 2 may be sent to KaVo for a maintenance and inspections as required by local regulatory authority.

2. Review Section 1.1 Indications for Use and product labeling periodically in order to verify understanding of indications for use for the KaVo NOMAD Pro 2.

3. A routine wipe-down of the KaVo NOMAD Pro 2 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 device and charging cradle. Do not use cleaners intended for hard surfaces, since certain chemical combinations may deteriorate the KaVo 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 KaVo 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 KaVo 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 **Patient** and **Select** 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 KaVo 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 KaVo for an evaluation.
- For long-term storage, it is recommended to charge batteries at least 2/3 every 3 months.

The KaVo 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 KaVo 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 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 KaVo 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 KaVo 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 60601-2-7, 50.102.2a.

Keep the Box: 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 and thyroid collar, are observed.

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 KaVo 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 dealer/distributor or KaVo.

| 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 | Schedule Five-Year Maintenance Inspection at KaVo |
| 1. Power Button | | | | | | |
| 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 | Schedule Five-Year Maintenance Inspection at KaVo |
| 1. Power Button | | | | | | |
| 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 KaVo for more information on covering battery replacement throug KaVo Complete.

## 7.4 Repair

There are no parts designated as repairable in the field by the owner/user of the device, including fuses. Contact your KaVo Service Representative if repairs are needed.

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

The following are user replaceable components:

- Optional Rectangular Collimator Cone Adapter
- Handsets
- Charging Cradle
- Charging Cradle with AC/DC Power Supply Kit
- Optional Hard-Shell Carrying Case, plastic
- Alignment Bars: Universal, Endodontic, Bitewing

Damaged or faulty KaVo NOMAD Pro 2 materials and components must be properly disposed of according to local requirements, or returned to an authorized distributor or KaVo, Inc. Please protect the environment, and do not improperly dispose of any part of the KaVo NOMAD Pro 2 system, the handsets, the charging cradle, or the AC power supply. At end of life, return these items to KaVo 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 KaVo or an authorized distributor for replacement and recycling. Do not place in municipal waste stream.

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

KaVo 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 your authorized Service Representative 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: 2.7kg

| **Environmental** | |
|---|---|
| Operation | |
| Temperature | +10°C to +40°C |
| Relative humidity | 30% to 80%, non-condensing |
| Storage and transportation | |
| Temperature | –20°C to +50°C |
| Relative humidity | <90%, non-condensing |

Do not use the KaVo 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  |
| MDD (93/42/EEC): Annex IX | Class IIb |
| IPX specification | IPX0; do not operate under wet conditions |
| Mode of operation | Intermittent operation |
| Applied part (non-detachable) | Collimator Cap |

| **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<br>Output: 12VDC 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 |

| X-ray Controls and Generator | |
|---|---|
| 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

The kV is measured during pre-pot testing using a calibrated high voltage divider with a guaranteed accuracy of ±2%. 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 KaVo 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 Piranha model 255 X-ray meter.

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

## Dose Area Product (DAP)

| kV | mA | Exposure Time (milliseconds) | Air Kerma (mGy) | Dose Area Product (mGy*cm²) |
|---|---|---|---|---|
| 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 28.27$cm^2$

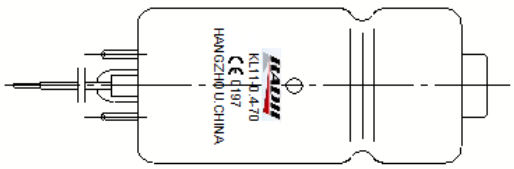
**Compliance with Applicable Standards**

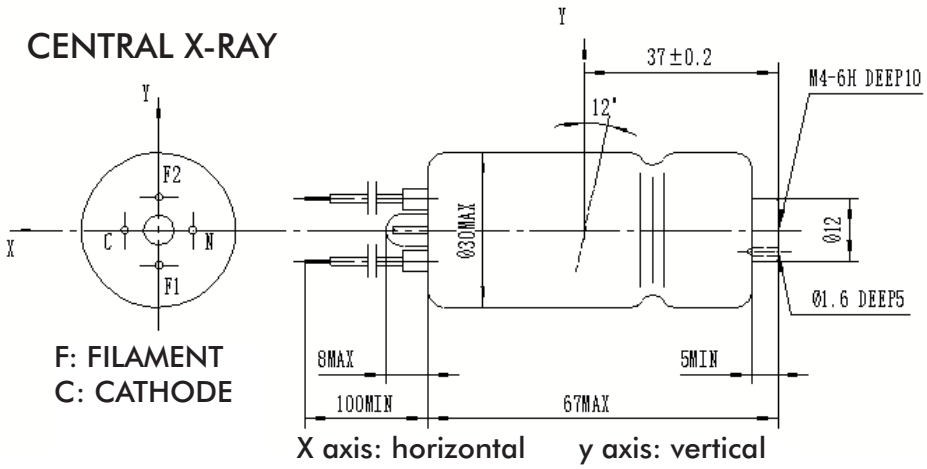
| Standard | Title | Edition |
|---|---|---|
| IEC 60601-2-65 | Complies with X-ray equipment for dental intra-oral radiography IEC 60601-2-65:2012, KaVo NOMAD Pro 2. | 2012 |

## 8.2 X-ray Tube Specifications and Characteristics

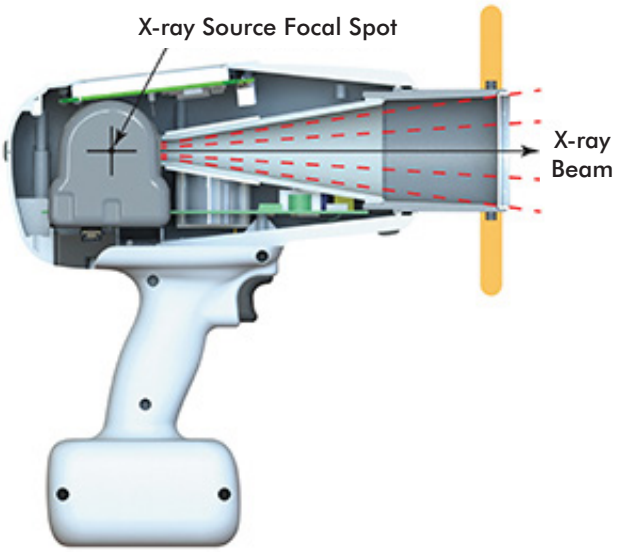
The KL 11-0.4-70 is designed for intra-oral dental imaging by an X-ray unit and is available for nominal tube voltage with self-rectified or constant potential circuit – manufactured by Kailong.

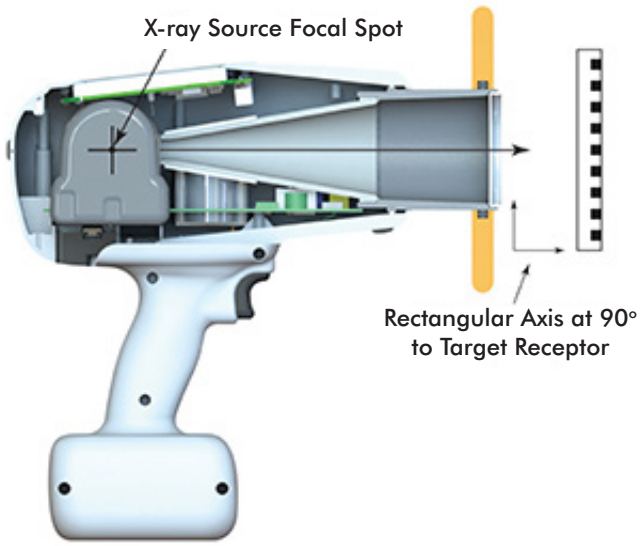
| | |
|---|---|
| Nominal tube voltage | 70kV |
| Nominal focal spot (IEC 60336:1993) | 0.4mm |
| Maximum anode heat content | 4500J |
| Maximum current continuous service | 1.5mA x 70kV |
| Maximum anode cooling rate | 100W |
| Nominal anode input power | 430W |
| Target material | Tungsten |
| Minimum 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 |



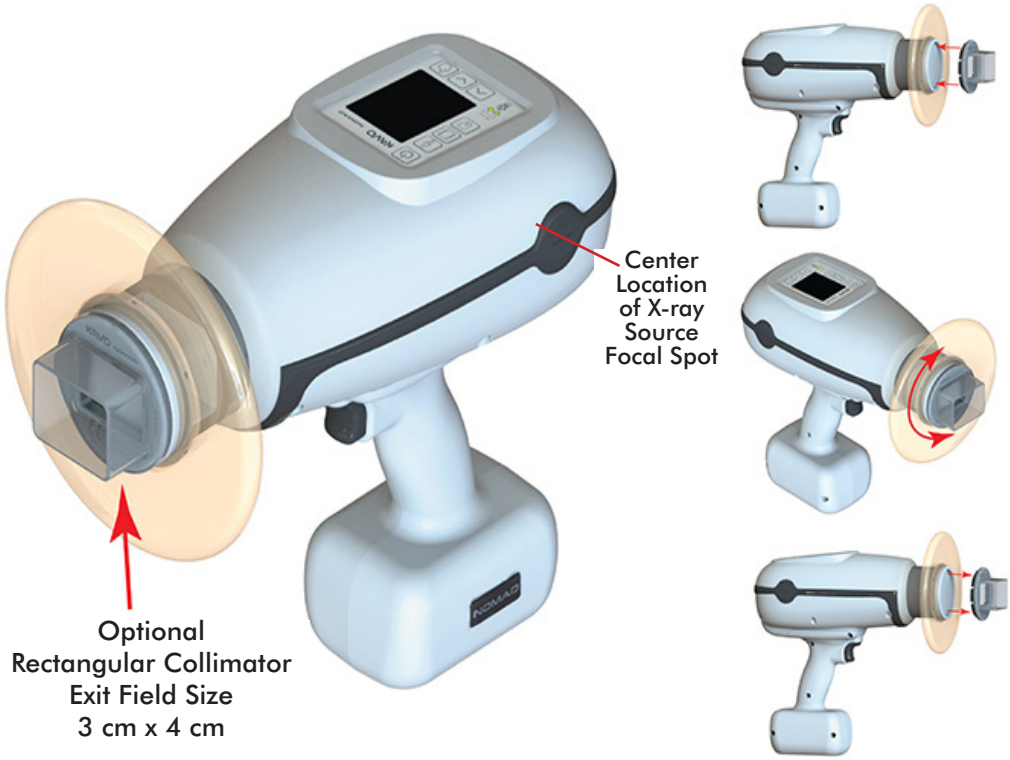




OUTLINE DRAWING




## Rectangular Collimator

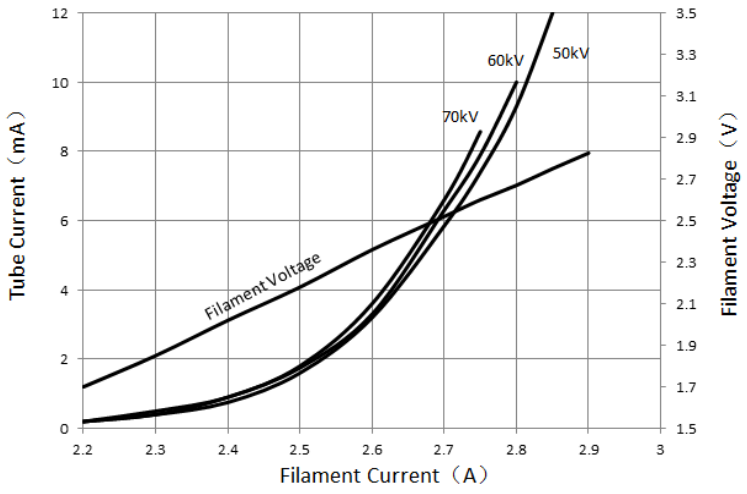



NOTE: The Rectangular Collimator Cone Adapter dimensions are contained entirely within the 6 cm circular exit field diameter. This collimator can rotate freely, 360 degrees. Use rectangular Collimator with rectangular film and sensors to reduce the dose by 57% versus using the 6cm diameter circular cone.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

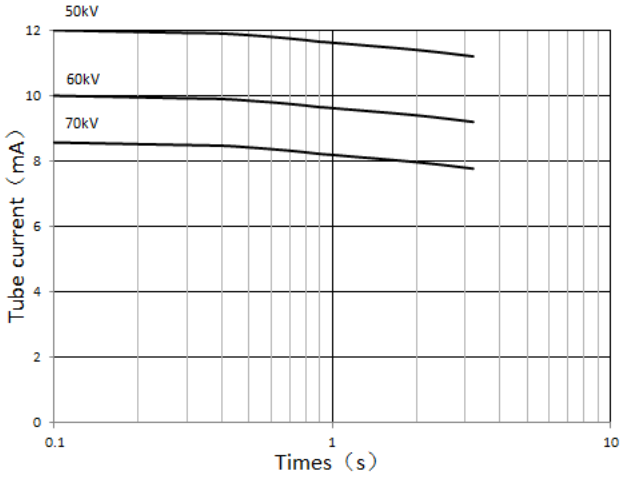
Area of rectangular collimator is 3cm x 4cm = $12cm^2$

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

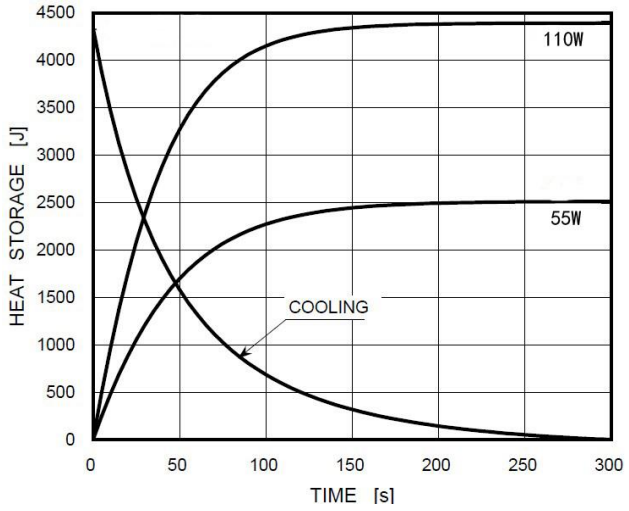
## Cathode Emission/Filament Characteristics Chart




## Rating Chart




## Thermal Characteristics Chart



## 8.3 Manufacturer's Declaration

The KaVo 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 KaVo 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 KaVo 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 KaVo 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 KaVo 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 KaVo 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 KaVo 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 KaVo 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 KaVo 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 KaVo NOMAD Pro 2 Intraoral X-ray System is intended for use in the electromagnetic environment specified below. The customer or user of the KaVo 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<br>CISPR 11 | Group 1 | The KaVo 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<br>CISPR 11 | Class B | The KaVo 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<br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3 | Complies | |

## Immunity Test Summary

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity | | | |
|---|---|---|---|
| The KaVo NOMAD Pro 2 Intraoral X-ray System is intended for use in the electromagnetic environment specified below. The customer or user of the KaVo 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)<br>IEC 61000-4-2 | +/-8 kV contact<br>+/-15kV air | +/-2, 4, 6 & 8kV contact<br>+/-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<br>IEC 61000-4-4 | +/-2 kV for power supply lines<br>+/-1 kV for input/ output lines | +/-0.5, 1 & 2 kV for power supply lines<br>+/-0.5 & 1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | +/-1 kV differential mode<br>+/-2 kV common mode | +/-0.5 & 1 kV differential mode<br>+/-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<br>IEC 61000-4-11 | 100 % Dip; for 0,5 cycles<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>60% Dip for 1 Cycle<br>30% Dip for 25 Cycles<br>100% Dip for 5 Seconds | 100 % Dip for 0,5 cycles<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>60% Dip for 1 Cycle<br>30% Dip for 25 Cycles<br>100% Dip for 5 Seconds | Mains power quality should be that of a typical commercial or hospital environment. If the user of the KaVo NOMAD Pro 2 Intraoral X-ray System requires continued operation during power mains interruptions, it is recommended that the KaVo NOMAD Pro 2 Intraoral X-ray System be powered from an uninterruptible power supply or battery. |
| Power frequency (50/60 Hz) magnetic field<br>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 KaVo NOMAD Pro 2 Intraoral X-ray System is intended for use in the electromagnetic environment specified below. The customer or user of the KaVo 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<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | (V1)=3Vrms | Portable and mobile communications equipment should be separated from the KaVo 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)<br>150kHz to 80MHz |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 2,7 GHz | (E1)=3V/m | D=(3.5/E1)(Sqrt P)<br>80 to 800 MHz<br><br>D=(7/E1)(Sqrt P)<br>800 MHz to 2.5 GHz<br><br>where P is the max power in watts and D is the recommended separation distance in meters.<br><br>Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1).<br><br>Interference may occur in the vicinity of equipment containing a transmitter.<br><br>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 KaVo NOMAD Pro 2 Intraoral X-ray System is intended for use in the electromagnetic environment specified below. The customer or user of the KaVo 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.<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>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 KaVo NOMAD Pro 2 device**

The KaVo 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 KaVo 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 KaVo 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 KaVo 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. KaVo warrants its medical and dental X-ray equipment to be free from any defects in material or workmanship for a period of two (2) years from the date of purchase. KaVo also warrants any accessories purchased from an authorized reseller. KaVo also warrants any defects in material or workmanship for the period of two (2) years from the date of purchase.

The liability of KaVo is limited to repair or replacement of any parts that KaVo or its authorized resellers determine to be defective. Contact KaVo 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 KaVo (North Carolina, 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 KaVo authorized resellers. This warranty does not cover ordinary wear and tear or maintenance. To verify the authorization status of a KaVo reseller, please contact KaVo at 1-888-ASK-KAVO.

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