

Peak VN Neonatal Video Laryngoscope kit

- PRODUCT DESCRIPTION

The Peak VN monitor MO-2, in conjunction with reusable VNScope handles and single-use video laryngoscopes blades VNBlade, is designed to deliver clear airway views and enable rapid intubation. Low-profile designs and innovative construction make these blades streamlined and lightweight, offering improved maneuverability and working space for routine and difficult airways. With more scope options, including NOX insufflation attachment and NOX-S insufflation attachment with guiding tube, clinicians can choose their preferred tools for a wide range of patients and clinical settings.

- INTENDED USE

The monitor with cameras/handles and blades is intended to work for laryngoscopy within the airway of neonates from preemies with very low birth weight to newborns with normal weight. The blades are of 4 sizes MILLER type from as small as 000 to 1

The shape blades and dimensions of the blades comply with Common Specification of such type of the blades There for the intubations could be performed even with no image on the monitor.

- CONTRAINDICATIONS

No contraindications relating directly to the product are currently known. The use of the Peak VN video laryngoscope is contraindicated if, in the opinion of a responsible physician, the health of the patient is endangered through its use, for example, due to the patient's general condition, or if laryngoscopy as such is contraindicated.

- Peak VN kit PARTS & ACCESSORIES

#	Catalog reference number	Qty units	Commercial name	Generic Device Term	Description	GMDN code	Remark
<u>1</u>	VNS G1	1	VNScope 1	Laryngoscope handle	Laryngoscope handle for endotracheal intubation	<u>46830</u>	-----
<u>2</u>	VNS G0	1	VNScope 0	Laryngoscope handle	Laryngoscope handle for endotracheal intubation	<u>46830</u>	-----
<u>3</u>	VNS G00	1	VNScope 00	Laryngoscope handle	Laryngoscope handle for endotracheal intubation	<u>46830</u>	-----
<u>4</u>	VNS G000	1	VNScope 000	Laryngoscope handle	Laryngoscope handle for endotracheal intubation	<u>46830</u>	-----
<u>5</u>	MO-2	1	Monitor MO2	Monitor	Monitor LCD 5"	-----	-----
<u>6</u>	VNB 1	-	VNBlade 1	Laryngoscope blade	Laryngoscope blade for endotracheal intubation	<u>46828</u>	Not included Purchased separately
<u>7</u>	VNB 0	-	VNBlade 0	Laryngoscope blade	Laryngoscope blade for endotracheal intubation	<u>46828</u>	Not included Purchased separately
<u>8</u>	VNB 00	-	VNBlade 00	Laryngoscope blade	Laryngoscope blade for endotracheal intubation	<u>46828</u>	Not included Purchased separately
<u>9</u>	VNB 000	-	VNBlade 000	Laryngoscope blade	Laryngoscope blade for endotracheal intubation	<u>46828</u>	Not included Purchased separately
<u>10</u>	NOX	-	NOX	Attachment	Laryngoscope handle for insufflation	<u>46828</u>	Not included Purchased separately
<u>11</u>	NOX-S	-	NOX-S	Attachment	Laryngoscope handle for insufflation with guide	<u>46828</u>	Not included Purchased separately
<u>12</u>	DNS 100	1	DNScope	Laryngoscope handle	Laryngoscope handle for endotracheal intubation	<u>47806</u>	-----
<u>13</u>	Cab.	<u>1</u>	<u>Cable</u>	Cable	Cable USB-A to Mini USB-B	-----	-----
<u>14</u>	Adapter	-	Adapter	Adapter	Adapter for charging ; Output 5VDC:1.5-2.0A Output Socket USB-A Medical Grade; IEC 60601-1 approved	-----	Not included Purchased separately by a user. FRIWO FOX6-XM-USB or similar
<u>15</u>	EN-1	1	Enclosure	Enclosure	Transparent enclosure for monitor	-----	-----



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Instruction for Use







Warnings and Cautions

- It is the user's responsibility to read and understand these instructions prior to the application of Peak Medical laryngoscopes.
- Tracheal intubation requires specialized training. Only personnel who have received training should be authorized to use video laryngoscopes.
- Don't use if the package of disposable products is opened or damaged
- Do not attempt to use any laryngoscope unless pre-use checks as described below have been carried out successfully.
- Store in dry clean condition away from heat and light.
- In the vicinity of patients and in the treatment area use the monitor only closed into the protective enclosure.
- Avoid penetration of liquids into the monitor
- Charge the monitor battery after each application, if it not in use charge at least once a week. **Don't charge the battery during intubation**
- Don't perform Charge of the battery, Set up of the monitor and File management in the vicinity of patients and in the treatment area.
- **Except battery charging and visual inspection of all components, regular technical service is not required.**

Pre-use checks and preparations prior to commencing an intubation procedure:

- Put monitor into the protective enclosure and lock it properly (latch clicked into place)
- Choose VNScope and blade size in accordance with the weight of newborn (make sure that sizes and color-coding are similar for both)
- Remove protective caps
- Check VNScope handle and blade for sharp edges or flaws that may have resulted from mechanical damage.
- Ensure that the blade is securely and correctly clicked into place on the handle.
- Connect VNScope cable securely to "Av-In" socket of the monitor (**before switch it On**)
- Switch On monitor by a short press on  button of the monitor, **wait for 10-15 sec** and check the quality of the image on the screen and battery charge level.
- Don't use the monitor if the battery is not fully charged according to the bar indicator or image is not acceptable.
- Switch Off the monitor by press on  button of the monitor for **3 secs**.
- If insufflation or guidance is required, insert the connecting pin of NOX/NOX-S in the corresponding hole of VNScope handle, direct orifice along the blade and secure it.
- Connect NOX/NOX-S with blender and adjust blender to desired oxygen concentration and flow. Check gas flow at the distant end of blade
- Open support and install the monitor steadily in the best position for intubation.
- Make sure that a view angle during intubation will be in a range of 30Deg.

Operating Instruction

- Switch On monitor by press  button of the monitor and **wait for 10-15 sec**.
- Open gas flow (if applied)
- If a recording is required, press on  button to open information screen, press on  button again to start recording, to stop recording press on  button to open information screen, press on  button again to stop recording. **SD memory card should be inserted prior to switching On the monitor**
- Intubate by applying technique recommended for video laryngoscopy
- After intubation Switch Off the monitor by press on  button of the monitor for **3 secs**.
- Discard the blade and the attachment after use and dispose them according to standard hospital procedure. Don't sterilize.
- Close the camera and the plug of the VNScope with protective caps.
- Take out the monitor from protective the enclosure for cleaning and disinfection of the enclosure, battery charge and file management.
- For management of the recorded files and set up of the monitor see **MO 2 User Guide**

Routine care and maintenance


- Video laryngoscope handles should always be cleaned and thoroughly dried before storing in a dry place.
- Keep lens always protected with cap and avoid contact with sharp and abrasive objects and materials and contamination.
- In case of contamination of the optical surface, clean it according to the procedure recommended for optical systems.
- Battery of the monitor should be recharge after each application.


Cleaning, disinfection and sterilization








- Always comply with local health&safety regulations
- Clean and disinfect handle according to standard hospital procedure for similar devices.
- When using disinfectant or sterilizing solution, always observe manufacturer's recommendation.
- Do not use chemical sterilants or disinfectants that are not approved by Peak Medical Ltd.
- Immediately after use, the VNScope should be rinsed in clean tap water to remove any residue. (**be sure that the plug and the camera are properly protected by caps**).
- External surfaces should be gently scrubbed in soapy water with a soft brush to prevent encrusted deposits. Do not use abrasive materials such as steel wool.
- VNScope may be immersed in solution (**be sure that the plug and the camera are properly protected by caps**).
- After exposure to the solution, rinse the VNScope handle with warm sterile water and dry thoroughly.
- The blades and the attachments are supplied not sterile, if required, blades could be sterilized in original packaging by EtO only. **Don't use other sterilization or**

disinfection procedures

- Ultrasonic cleaning and autoclaving are not recommended and will void warranty.

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 **Manufacturer name and address**
  **Product non sterile**
  **Special operation instructions**
  **Date by which device should be used in safety**
  **Device is for single use**
  **Batch number**
  **US representative name and address**