

Peak VN Neonatal Video Laryngoscope kit (REF. PVN100-MO3)

- PRODUCT DESCRIPTION

The Peak VN monitor MO-3, 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 U1	1	VNScope 1	Laryngoscope handle	Laryngoscope handle for endotracheal intubation	<u>46830</u>	-----
<u>2</u>	VNS U0	1	VNScope 0	Laryngoscope handle	Laryngoscope handle for endotracheal intubation	<u>46830</u>	-----
<u>3</u>	VNS U00	1	VNScope 00	Laryngoscope handle	Laryngoscope handle for endotracheal intubation	<u>46830</u>	-----
<u>4</u>	VNS U000	1	VNScope 000	Laryngoscope handle	Laryngoscope handle for endotracheal intubation	<u>46830</u>	-----
<u>5</u>	MO-3	1	Monitor MO3	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 attachment for insufflation	<u>46828</u>	Not included Purchased separately
<u>11</u>	NOX-S	-	NOX-S	Attachment	Laryngoscope handle attachment 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.	1	Cable	Cable	Data cable USB-A to USB-C	-----	-----
<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-2	1	Enclosure	Enclosure	Transparent enclosure for monitor	-----	-----

Peak VN Neonatal Video Laryngoscope kit (REF PVN100-MO3)

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.
- Use the monitor only closed into the protective enclosure near patients and in the treatment area.
- Avoid penetration of liquids into the monitor and C-connector of the VNScope.
- 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.
- Disconnect the monitor from the adapter and adapter from the mains when charging is finished (ON-OFF LED stops blinking)

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

- Choose VNScope and blade size in accordance with the weight of newborn (make sure that sizes and color-coding are similar for both)
- Carefully remove protective caps (do not apply to camera excessive force, it would break its angular setting).
- 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 "Camera" socket of the monitor and insert SD card if recording supposed (**before switching on the monitor**)
- Press ON-OFF button for 3 sec to Switch On the monitor, 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.
- Press again ON-OFF button to Switch Off the monitor.
- Put monitor into the protective enclosure and lock it properly (latch clicked into place)
- 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 of the enclosure and install the monitor steadily in the best position for intubation.

Operating Instruction (for additional information see User Guide)

- Switch On the monitor by ON-OFF button of the enclosure.
- Open gas flow (if applied)
- If a recording is required, chose desired mode of recording **PHOTO** or **FILM** (default mode is PHOTO) and then close the enclosure, press on **REC** button once to take a picture or to start recording, to stop recording press again on **REC** button . **SD memory card should be inserted prior** to Switching On the monitor.
- Intubate by applying technique recommended for video laryngoscopy.
- After intubation press on ON-OFF button to Switch Off the monitor.
- 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 3 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. Disconnect the monitor from the adapter and adapter from the mains when charging is finished (ON-OFF LED stops blinking)

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. (see attached list of approved disinfectants and cleaners) .
- 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 camera is properly protected by caps**) .
- Do not immerse C-connector of the VNScope covered by protective cap in any liquid.
- 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.

Manufactured by: Peak Medical Ltd.10 Giborey Israel Str. P.O.B. 4044 Netanya 4210401, Israel, 2022

US REP International Biomedical, 8206 Cross Park Drive Austin, Texas Tel: +1.512.873. 0033, Fax: +1.512.873.9090, e-mail: sales@int-bio.com