

AIRWAY SCOPE AWS-S200NK

AWS-S200




General

This instrument must be used in combination with the PBLADE (required accessory - sold separately).

The AWS-S200 in combination with the PBLADE, is a Video Rigid Laryngoscope system used to examine and visualize a patient's upper airway and aid placement of an endotracheal tube.

It projects images during tracheal intubation on the monitor screen attached to this instrument, to support smooth and accurate operation.

Safety Information

- | | |
|--|---|
|  DANGER | A danger alerts the user to a hazardous situation which causes death or serious injury. |
|  WARNING | A warning alerts the user to possible injury or death associated with the use or misuse of the instrument. |
|  CAUTION | A caution alerts the user to possible injury or problems with the instrument associated with its use or misuse such as instrument malfunction, instrument failure, damage to the instrument, or damage to other property. |

Pay attention to all safety information in the Operator's Manual or Installation Guide.

DANGER:

- Avoid using this instrument in a combustible atmosphere, such as an environment with high oxygen concentration, and avoid using with high-frequency or laser treatment equipment.

WARNING:

- This instrument should only be used on patients by qualified personnel.
- Remove any dirt before and after using this product by cleaning it or wiping it with a gauze soaked in ethanol. Otherwise, cross-infection may occur.
- Note that this product is not disinfected or sterilized prior to shipment.
- If lubricant is used when performing tracheal intubation, make sure that the trachea and tubes are not blocked by the lubricant. Otherwise, the ventilation of the patient will be obstructed.
- Do not use this product if scratches, dirt or damage is found on the imaging pickup section or light source of the scope tip.
- The PBLADE can only be used once.

WARNING:

- The PBLADE can only be used once.
- Do not allow the area around the scope window of the PBLADE to make contact with a patient for longer than one minute. This area becomes hot and may cause burns.

WARNING:

- The PBLADE is sterilized when packaged. Take particular care to not touch the tip that enters the larynx with your hands.
- The PBLADE can only be used once.

WARNING:

- This device is ETO gas sterile. Do not use this device if there is any evidence of damage to the sterile package.
- Handle this product with sterilized gloves.

WARNING:

- Before using this product, make sure that the PBLADE is connected to the product in the correct direction and that it is securely fixed. Tracheal intubation is only possible when the PBLADE is connected in the correct direction. If the PBLADE is not securely fixed, it may fall over or be damaged during operation.

WARNING:

- The terminals of this product only can connect with IEC 60601-1 approval product.

WARNING:

- Remove any dirt before and after using this product by cleaning it or wiping it with a gauze soaked in ethanol. Otherwise, cross-infection may occur. Note that this product is not disinfected or sterilized prior to shipment.
- This equipment is designed to be cleaned and disinfected via immersion. When this equipment is extremely dirty or there is suspicion of infection, refer to DOCUMENT 1.

CAUTION:

- Do not use this product on the following patients, because there is a risk of injuring the palatal wall or performing incorrect intubation.
 - Patients who have surgical wounds or damage on their palatal wall
 - Patients for whom oral access is difficult due to external wounds or other reasons
 - Patients who require long-term artificial respiration
- Before using this product, make sure that the light source of the scope tip is turned on, the image is displayed on the monitor screen, and the battery exhaustion caution or warning icon is not flashing.
- Do not look directly at the light from the light source on the scope tip.
- Do not connect any device other than the designated PBLADE to this product.
- Before using this product, make sure that the PBLADE is connected to the product in the correct direction and that it is securely fixed. Tracheal intubation is only possible when the PBLADE is connected in the correct direction. If the PBLADE is not securely fixed, it may fall over or be damaged during operation.

- If the scope section does not enter smoothly when attaching the PBLADE to the product, apply a water-soluble lubricant whose suitability for use on humans has been confirmed (in principle, K-Y jelly or olive oil) to the metal surface of the scope tip. At this time, take care not to get lubricant onto the light source or imaging pickup section of the scope tip. Otherwise, the field of view will be obstructed.
- When setting the endotracheal tube in the PBLADE, do not rub the endotracheal tube cuff on the end section of the PBLADE endotracheal tube-guiding groove any more than is necessary. Otherwise, the cuff may be torn.
- Before performing tracheal intubation, make sure that the endotracheal tube is completely fixed onto the hooks of the PBLADE.
- When performing tracheal intubation, first visually confirm that the epiglottis lifting blade of the PBLADE has been inserted beyond the teeth into the mouth, and then proceed with intubation while confirming the insertion status of the product on the monitor screen. Otherwise, the teeth, lips, tongue, palatal wall, pharynx or epiglottis of the patient may be injured.
- When using a demulcent or topical anesthetic to facilitate the insertion of the endotracheal tube or suction catheter, in principle, use Xylocaine Jelly.
- When disconnecting the PBLADE from the product, do not pull it out roughly. Otherwise, the PBLADE attachment areas may be damaged. Further, the scope tip may get caught, which may break the cord and cause failure.
- The scope tip may be hot immediately after using the product. Do not touch this area.
- If you notice any abnormality while using this product, disconnect the product from the patient while making sure it is safe to do so.
- If you determine that tracheal intubation with this product will be difficult, or in an unexpected situation such as when product failure occurs, disconnect the product safely without placing any undue burdens on the patient and promptly stop performing the tracheal intubation. In this case, promptly change to an alternative method of tracheal intubation that you have prepared in advance.
- Do not use the product if it is dropped or subjected to any other strong impact, because the internal parts may be damaged.
- Only use the specified batteries.
- Disassembly, modification or repair of this product must only be performed by service providers designated by Nihon Kohden.
- If there are scratches or damage on the packing, O-ring or other areas of the battery cover or terminal covers, the waterproofing performance cannot be guaranteed. If scratches or damage is found, contact the service provider designated by Nihon Kohden for repair. In addition, receive a periodic inspection once a year.
- This equipment has been tested and found to comply with the limits emissions and immunity for electro-medical equipment found in IEC 60601-1-2:2014. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause or receive detectable interference with another device, the user is encouraged to limit the interference by one or more of the following measures:
 - reorient or relocate the receiving (affected) device
 - increase the separation between equipment
 - connect the equipment into a mains outlet on a different circuit to the device(s) causing the interference
 - consult the manufacturer or field technician for help

⚠ CAUTION:

- The type of the designated battery is AA/MIGNON ALKALINE (LR6) BATTERY.
- Nickel batteries, nickel manganese batteries, and nickel hydride batteries can be used. However, due to the characteristics of these batteries, the battery exhaustion warning icon or battery exhaustion caution icon may not be displayed appropriately when these batteries are used.
- Manganese batteries CANNOT be used.
- Battery life: Approximately 60 minutes for continuous usage (using alkaline battery: under the in-house test condition)
- Timing of battery replacement: When the batteries are running low, the battery exhaustion caution icon is displayed on the monitor screen. When the batteries run even lower, the battery exhaustion warning icon starts flickering (Site "C" indicated on the monitor screen on Page 9).
If this occurs, the operation should be stopped immediately to replace the batteries.
- Set the batteries with the correct polarities (positive [+] and negative [-]).
- Promptly replace the exhausted batteries with new ones.
- The lock lever must be securely locked in the direction of the arrow to ensure the waterproof property.

⚠ CAUTION:

- The power will turn off if you press and hold the power button for an extended period of time (1 second or more).

⚠ CAUTION:

- If there is any black dot or fog over the image, lightly wipe the image pickup section on the scope tip with dry fabric, etc.
- If no image is displayed, check the remaining capacity of the batteries or the polarity of the batteries.

⚠ CAUTION:

- Confirm that the PBLADE is free of sharp edges, burs and other features which can cause trauma to the patient.
- Read the instruction manual of the PBLADE as well.

⚠ CAUTION:

- If the PBLADE is attached in the wrong direction, tracheal intubation cannot be performed. If it is not securely fixed, it may fall over or be damaged during operation.
- If the lock ring does not rotate, it means that the PBLADE is not connected properly. Perform the connection process of the PBLADE again.
- Check whether the scope tip has been inserted correctly.
If there is a space between the scope tip and the scope window or the scope is inserted at an angle, a precise image will not be obtained.

⚠ CAUTION:

- When disconnecting the PBLADE from the product, do not pull it out roughly. Otherwise, the PBLADE attachment areas may be damaged. Further, the scope tip may get caught, which may break the cord and cause failure.

⚠ CAUTION:

- Use endotracheal tubes of the corresponding size.
- Use after deaeration from the endotracheal tube cuff.
- Read the instruction manual of endotracheal tubes as well.

⚠ CAUTION:

- Take care not to get lubricant onto the scope window.
- When setting the endotracheal tube in the PBLADE, do not rub the endotracheal tube cuff on the end section of the PBLADE endotracheal tube-guiding groove any more than is necessary. Otherwise, the cuff may be torn.

⚠ CAUTION:

- Before performing tracheal intubation, make sure that the endotracheal tube is completely fixed onto the hooks of the PBLADE.

⚠ CAUTION:

- Visually confirm that the epiglottis lifting blade of the PBLADE is inserted beyond the teeth into the mouth. Otherwise, the teeth, lips, tongue, palatal wall, pharynx or epiglottis of the patient may be injured.

⚠ CAUTION:

- If the view is obstructed by the presence of secretions, blood, etc., remove them using a suction catheter. (ITL-SL only)

⚠ CAUTION:

- The scope tip may be hot immediately after using the product. Do not touch this area.

⚠ CAUTION:

- Use a suction catheter of the corresponding size.
- Use a lubricant to facilitate the insertion of the suction catheter.
- When using a suction catheter, it is recommended to check, before use, whether the suction catheter is insertable.
- Read the instruction manual of Suction catheter as well.

⚠ CAUTION:

- If the cover is pulled unduly, the strap may be torn off. Do not handle the cover roughly.
- Loss of the cover ruins the waterproof property, making the product unavailable for cleaning and disinfection.

⚠ CAUTION:

- Parts such as the USB cable are not waterproof. Do not allow them to become wet.
- Ultrasonic cleaning cannot be performed on this product.
- Parts such as the USB cable cannot be sterilized.
- When cleaning or disinfecting this product, make sure that the battery has been removed and that the terminal covers and battery cover have been securely shut.
- After cleaning or disinfecting this product, allow sufficient time for it to dry naturally.

⚠ CAUTION:

- Dispose of this equipment according to your local regulations for waste disposal.

⚠ CAUTION:

- If there are scratches or damage on the packing, O-ring or other areas of the battery cover or terminal covers, the waterproofing performance cannot be guaranteed. If scratches or damage is found, contact the service provider designated by Nihon Kohden for repair. In addition, receive a periodic inspection once a year.

This Safety and Performance Information is an extract from the general and safety information sections of the most recent edition of Operator's Manual or Installation Guide. Therefore, the contents of your Operator's Manual or Installation Guide may differ from those of this Safety and Performance Information. For detailed operating procedures, follow the instructions of your Operator's Manual or Installation Guide.

 Manufacturer
NIHON KOHDEN CORPORATION
1-31-4 Nishiochiai, Shinjuku-ku,
Tokyo 161-8560, Japan
Phone +81 3-5996-8041
<https://www.nihonkohden.com/>

EC REP European Representative
NIHON KOHDEN EUROPE GmbH
Raiffisenstrasse 10, 61191 Rosbach, Germany
Phone +49 6003-827-0 Fax +49 6003-827-599

1st Edition: 18 Apr 2019
2nd Edition: 7 Jul 2022

