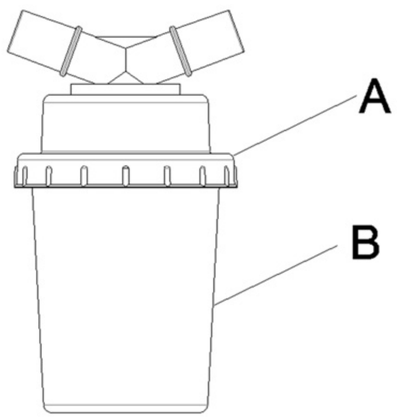
Water Trap Infant

Product code：2603

Symbol Definitions：

CE	CE Marking	REF	Catalogue number	UDI	Unique device identifier
MD	Medical device		Do not re-use		Use-by date
LOT	Batch code		Manufacturer		Date of manufacture
	Temperature limits		Humidity limitation	7	7 Days maximum use
NON STERILE	Non-sterile		Keep dry		Caution
EC REP	Eurpoean Union authorised representative		Keep away from sunlight		Do not use if package is damaged
	Consult instruction for use or consult electronic intructions for use				Importer



A	**Trap Cap**	**B**	**Trap Body**

Intended use：

This device, Water Trap Infant, is a device used to drain water collected by the breathing circuit during respiratory therapy and prevent the increase in respiratory resistance.
Intended user: healthcare professionals and trained care provider.

Instruction for Use：

1. Ensure the integrity of package prior to use.
   DO NOT use the product if package is not intact or the product is damaged.
2. Perform circuit test using a test lung prior to attaching system on patient.
3. Auto-filling humidification chamber:
   - First, unwind the IV-set tubing to detach it from the dust-cover.
   - Remove the dust-cover by pulling up the finger ring.
   - Spike the IV-set to the distilled water and open the vent on the IV-set.
   - The water level in the humidification chamber should never rise above Max mark.
   - Install the humidifier chamber onto the humidifier and ensure it is stable.
   - Follow the instruction of the humidifier to achieve the intended humidification and temperature.
4. Attach inspiratory limb to the humidification chamber and chamber limb from humidification chamber to the ventilator.
5. Attach the humidifier power supply cable to the inspiratory limb chamber connector.
6. Attach the temperature probe (T type) to the temperature port by aligning the locating tooth to the red mark at the chamber end of the circuit.
7. Attach the temperature probe (L type) to the temperature port available at the patient end of the circuit.
8. Connect the expiratory limb to ventilator.
9. Additional elbow and straight connectors are available for use with different ventilators.
10. Ensure that device alarm systems, ventilators and humidifiers, are active all the time prior to use.
11. Ensure that breathing circuit set are connected properly prior to use against air leaking.

Indications：

The water trap is applicable to be used with non-heated limb of breathing circuit with 10 mm ID in respiratory, anesthesia, and humidification system.

Contraindications：

There is no specified contraindication claimed on clinics

⚠ Warning：

1. DO NOT touch the heated base of the humidification chamber during the humidifier operation or when removing the heated chamber from the humidifier.
2. BE AWARE OF aluminum edge of the chamber base for the sharp edge covering a housing might cause injury.
3. DO NOT mount the humidification chamber on a humidifier at an angle of over 10° degrees against spillage.
4. Always Keep the humidifier lower than patients.
5. Water supply shall not be added over the maximum level printed on the chamber housing for extra water might spill onto breathing circuits.
6. The water supply must be higher than the chamber.
7. DO NOT fill the chamber with water in excess of 37 °C.
8. The product must be used with distilled water.
9. Must conduct a circuit check with ventilator and its device by following the required instructions prior to use the product and only operate while the result is pass.
10. The responsible organization MUST EUSURE the COMPATIBILITY of the product, humidifier, ventilator, and breathing circuit system, prior to use.
11. The product is for single patient use. The recommended period of using for this product is 7 DAYS.
    Any adjustment, processing, cleaning, or sterilization may lead to device failure or malfunction, and increase the risk of cross-infection.
12. Always keep monitoring patient's medical sign, e.g. blood oxygen concentration, while users operate the product. Negligence might lead to the risk of injury or death.
13. DO NOT cover the circuit with materials such as blankets, towels, clothing or anything else while using.
14. DO NOT pull or squeeze the pipeline while using the product to avoid deformation and affect its functionality.
15. STOP using the product if discomfort occurs. Consult your physician all the time.
16. Follow the local waste disposal act against cross infections or environmental contamination.
17. Always keep the water trap lower than the breathing circuit.
18. DO NOT fill the product with any other substance.
19. DO NOT USE the product if there are sharp edge on products because users might be hurt.
20. Ensure that the heater wire is evenly distributed along the circuit and not twisted prior to use.
21. AVOID prolonged contact of breathing circuit with patient's skin.
22. Always be aware of the condensation in the breathing circuit while operating and empty it if necessary.
23. Dispose of product according to the responsible organization protocol. User may be exposed to respiratory substances during disposal.
24. The user (e.g. healthcare professionals, trained care provider) and/or patient should report any serious incident related to the use of this device to the Manufacturer as well as the Competent Authority of the Member State (i.e. applicable local regulator) where the incident occurred.

Specification：

1. Wye connector of water trap：10mmOD, meet ISO 5356-1
2. Water trap Volume：55ml
3. Operating temperature：18-26°C
4. Operating environmental humidity：30-60%
5. Compliance with requirements of EN ISO 5356-1; EN ISO 10993-1& EN ISO 10993-5&EN ISO 10993-10&EN ISO 10993-17& EN ISO 10993-18&EN ISO 10993-23; EN ISO 18562-1& EN ISO 18562-2&EN ISO 18562-3&EN ISO 18562-4

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