



## INSTRUCTIONS FOR USE – Manual Suction (Manual Vacuum Pump)

### 1. Intended Purpose

Manual Suction is a hand-operated medical device intended to generate negative pressure for the temporary removal of fluids and secretions from the airway in emergency and clinical situations.

The device is not intended for continuous or long-term suction.

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### 2. Intended Users

Healthcare professionals and trained emergency or rescue personnel.

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### 3. Patient Population

Adults and children, according to applicable clinical protocols.

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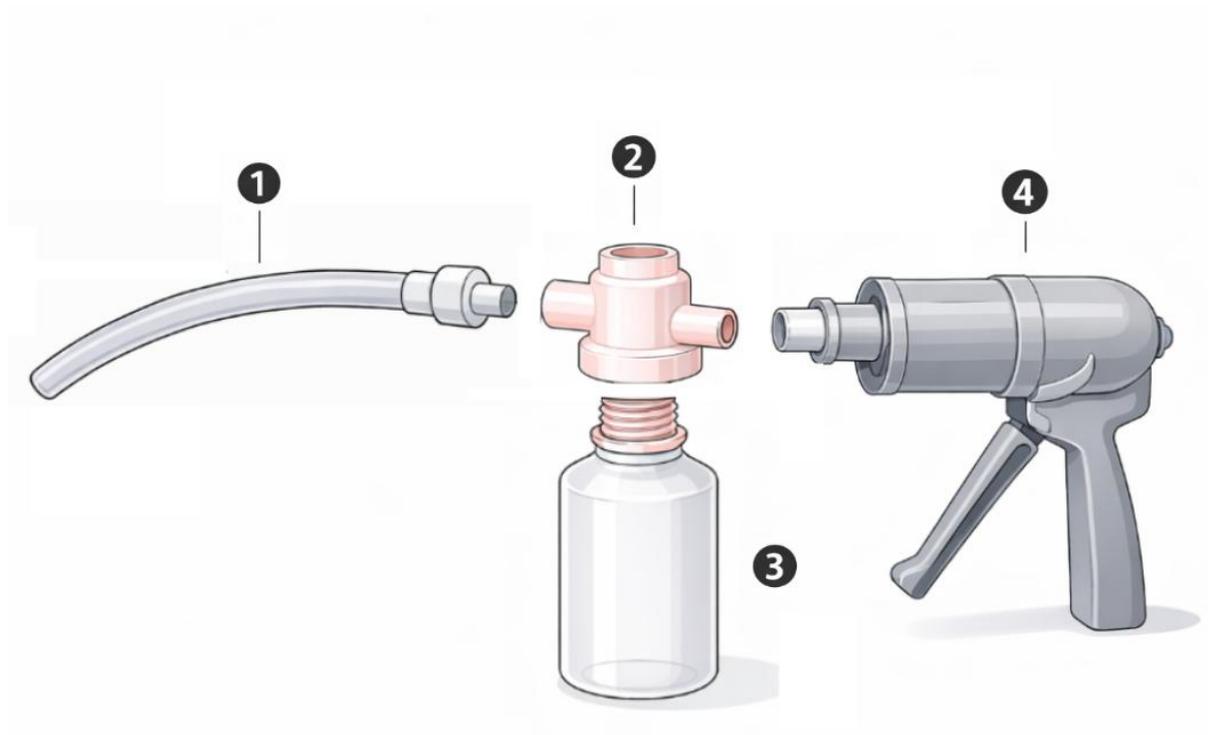
### 4. Device Description

Manual Suction is a lightweight, portable, hand-powered suction device designed for single-hand operation.

The device consists of four main components:

1. Suction tube
2. Middle component (valve housing)
3. Collection container (300 ml, single-use)
4. Pump handle (reusable vacuum chamber)

The device generates vacuum manually by pumping the handle. Vacuum level is adjustable between 50 % and 100 % stroke.



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## 5. Contraindications

Do not use the device if:

- any component is damaged, missing or contaminated
- the pump handle is cracked or broken

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## 6. Warnings

- Do not use the device upside down
- Do not autoclave any components
- Do not immerse the pump handle in liquid
- Use only by trained personnel

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## 7. Precautions

- Ensure all components are correctly assembled and firmly seated before use
- Always perform a functional vacuum test before clinical use
- If resistance increases or the handle becomes difficult to pump, stop use and check for blockage

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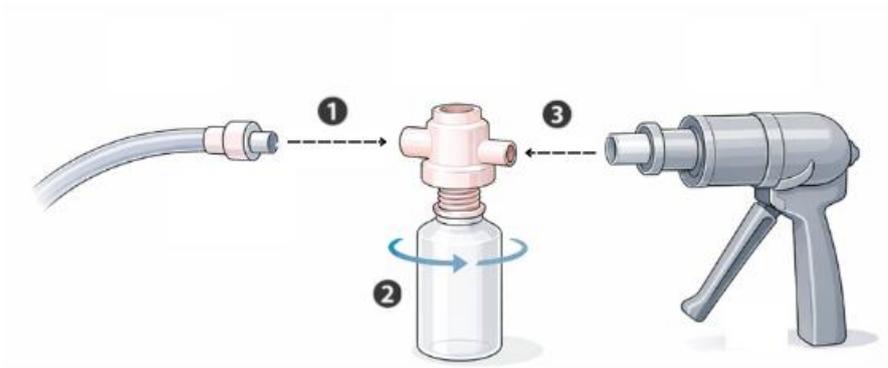
## 8. Assembly Instructions

The hand suction unit consists of four components and must be assembled in the correct order.

Assembly steps:

1. **Connect the suction tube to the middle component**  
Ensure the connection is fully seated.
2. **Attach the collection container**  
Attach the collection container by screwing it firmly into the middle component.
3. **Mount the pump handle**  
Ensure the handle is correctly aligned and fully secured.

All components must be assembled correctly before use.



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## 9. Functional Check Before Use

A functional vacuum test must be performed after assembly and before clinical use.

### Vacuum test procedure:

1. Place a finger over the end of the suction tube, ensuring the opening is completely sealed
2. Pump the handle **5–6 times**
3. Release the finger

An **audible vacuum sound** indicates correct function.

After successful testing, the device is ready for use.

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## 10. Directions for Use

1. Select the appropriate catheter size according to patient needs
2. Insert the catheter carefully into the airway
3. Operate the pump handle to generate vacuum
4. Remove fluids as required
5. Remove the catheter slowly after use
6. Dispose of all single-use components according to local protocols

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## 11. Stop Valve Function and Handling Considerations

The device is equipped with an **internal stop valve** located in the middle component.

### Purpose of the valve

The stop valve is designed to **prevent fluids from entering the pump handle**, which contains the vacuum chamber.

### Handling considerations

If the device is:

- held horizontally
- held upside down
- shaken while fluid is present in the collection container
- placed on the ground in a non-upright position

the valve may temporarily move into a position that **blocks airflow**.

This may cause the pump handle to feel **hard or difficult to operate**.

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## 12. Restoring Normal Function

If increased resistance or blockage is experienced:

- Tap the device on a firm surface to allow the valve to return to its normal position,  
**or**
- Release the vacuum by removing the pump handle and reattaching it

Normal function will then be restored.

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### 13. Performance

- Vacuum at 20 kPa (1 min):  $\geq 15$  kPa
- Maximum vacuum:  $\geq 39.9$  kPa
- Container volume: 300 ml

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### 14. Technical Data

- Operating temperature:  $-20$  °C to  $+50$  °C
- Storage temperature:  $-40$  °C to  $+60$  °C
- Net weight: 230 g

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### 15. Cleaning

Clean reusable parts with warm water and mild detergent.

Do not autoclave any components.

Do not immerse the pump handle in liquid.

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### 16. Storage

Store the device dry and protected from damage.

Observe temperature limits.

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### 17. Symbols

Symbols comply with **ISO 15223-1**.

Refer to the device label for symbol explanations.

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### 18. UDI

UDI is provided on the device label and packaging.

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### 19. Manufacturer

Zhangjiagang Xiehe Medical Apparatus & Instruments Co., Ltd.

No. 7th, Middle Xinzha Road,

Zhashang Industrial Zone, Yangshe Town,  
Zhangjiagang City, Jiangsu 215600, China

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## **20. EU Authorized Representative**

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Fascinatio Boulevard 522, Unit 1.7  
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## **21. Distributor**

Heimdall Rescue  
Innlaget 25, 3185 Skoppum, Norway

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## **22. Regulatory Compliance**

This medical device complies with **Regulation (EU) 2017/745**.

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## **23. Document Control**

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