Be sure to read the Operator's Manual before using the product

Hand-held Hi-Lo Cuff Pressure Gauge

CPM-A

User Manual

Wuxi Conglay Medical Technology Co., Ltd.

Table of Contents

I. Introduction

Statement

- Certain parts, appearances or functions mentioned in this Operator's Manual may be copyrighted. Without the written permission of Wuxi Conglay Medical Technology Co., Ltd, this document shall not be photocopied, copied or translated into other languages.
- Our company has the right to revise the contents of this document without further notice.
- Some of the pictures in this Operator's Manual are sketches for reference only. If the pictures do not match the material object, the latter shall prevail.
- Our company is not responsible for the damage caused by other equipment or by connecting other equipment without authorization.

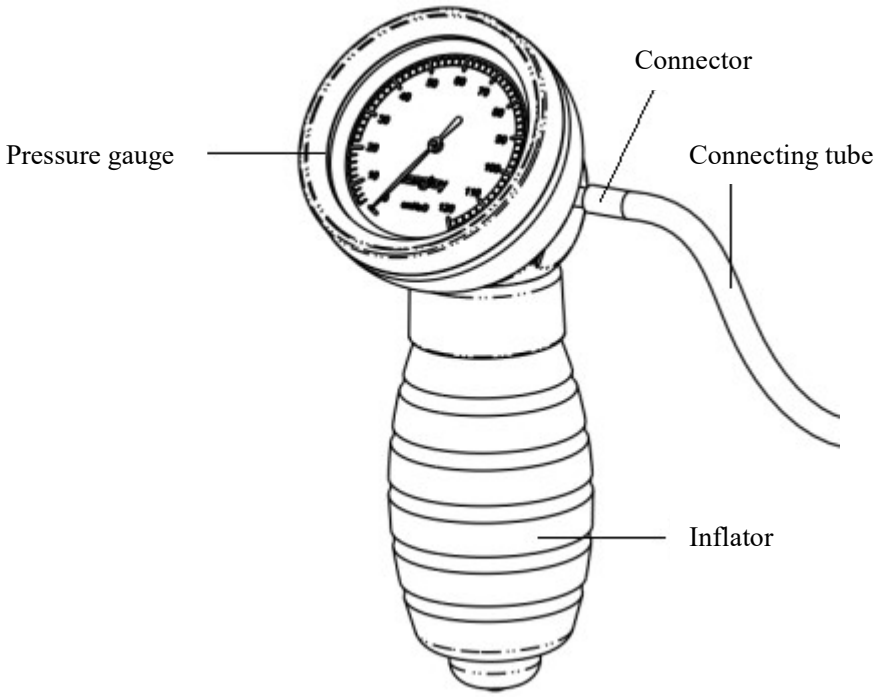
CE 0123

II. Product overview:

The Hand-held Hi-Lo Cuff Pressure Gauge is used for inflation, deflation and pressure control of tracheal tubes with high volume low pressure cuffs.

III. Product composition:

The balloon inflation device is composed of injection system, pressure gauge and connecting tubes. Non-sterile. The specific structure is as follows:



IV. Product accessories

No.	Accessory name	Quantity	Note
1	Operator's Manual	1	Packaging box
2	Certificate of conformity	1	Packaging box
3	Connecting tubes	1	Paper plastic bag

V. Application

The Hand-held Hi-Lo Cuff Pressure Gauge is used for inflation, deflation and pressure control of tracheal tubes with high volume low pressure cuffs.

VI. Description of symbols and graphs:

⚠	Be careful! Refer to the attached documents		Refer to the Operator's Manual
REF	Catalog number	LOT	Batch No.

	Keep dry		Importer
	Production date		Manufacturer
	No direct sunlight		Made in China
	Medical device		Non-sterile product
	EC Representative		CE conformity mark

VII. Cautions

- Do not immerse the product in liquid.
- Do not clean or sterilize the product automatically or manually.
- Don't use aggressive detergent to clean glass (plastic).
- Please read and follow the instructions carefully before using this product.
- Only trained medical personnel can use this product.
- Before use, it is necessary to visually check whether the product is damaged (cracked, broken, etc.) and conduct functional check (see the section “Functional Check”).
- Hand-held Hi-Lo Cuff Pressure Gauge is not suitable for MRI!
- If the Hand-held Hi-Lo Cuff Pressure Gauge is used for monitoring and it is kept on the inflation tube, the user must check the pressure regularly every 15 minutes. If the pressure increases, press the pressure relief valve button to adjust; if the pressure drops, press the balloon to adjust. The inflation device is a manual system, and cannot keep the cuff pressure constant for a long time.
- When the inflation device is disconnected from the inflation tubes, it must be disconnected with the connecting tube simultaneously, otherwise it will cause air leak.
- The connecting tube is disposable and cannot be treated repeatedly, otherwise function of the connecting tube will be impaired. Reuse may lead to potential risk of cross contamination.
- If the user / patient is aware of any serious event related to the device, he / she should report it to the competent authorities and manufacturers of the member country of the user and / or patient.

VIII. Instructions

Before use, please check the low pressure cuff for leakage. Before intubation or extubation, all gases should be extracted from the cuff by syringe or vacuum valve. Connect the Hand-held

Hi-Lo Cuff Pressure Gauge to the inflation line of the air tube (it is connected by connecting tube finally). Inflate the cuff to 60-90cmH_2O (pressure) to ensure that the cuff is in close contact with the tracheal wall. Press the pressure relief valve button until the pointer points to the green area, and the pressure will be released immediately. Keep inspecting and monitoring cuff pressure. Adjust the pressure relief valve button to reduce the pressure, and inflate the balloon to increase the pressure. It is recommended that the internal pressure of the cuff should not be less than 22cmH_2O (risk of expiration or pneumonia) and not higher than 32cmH_2O (risk of ischemia of tracheal mucosa) (Please refer to *Respiratory Care*, published by J. Stauffer in July, 1999)

Before extubation, connect the indicator balloon to the vacuum valve and squeeze the inflatable balloon until it cannot return to its original position. Connect the indicator balloon to the Luer taper nozzle of the device to check whether the air has been completely deflated. The pointer of the device will rotate counterclockwise to a negative pressure index position. Only when the cuff is completely deflated, the air tube in the patient can be pulled out.

Combined application device: airbag monitoring tube model: KL-ICG-03

IX. Functional check

Functional check

Test the Hand-held Hi-Lo Cuff Pressure Gauge according to the following steps:

1a) Close the Luer nozzle with your finger (Fig. 1).

Fig. 1

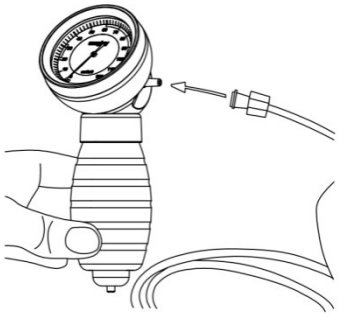
1b) Inflate to 40cmH_2O with a balloon; keep the value constant for 2-3 seconds; if the pressure drops, the device must be returned to the manufacturer for repair.

If a connecting tube is used, the system consisting of the airbag manometer and the connecting tube must be checked according to the following steps (supplement to step 1):

2a) Connect the connecting tube to the Luer nozzle of the Hand-held Hi-Lo Cuff Pressure

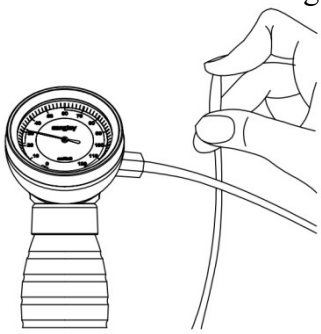
Gauge (Fig. 2).

Fig. 2



2b) Seal the end of the connecting tube with your finger (Fig. 3).

Fig. 3



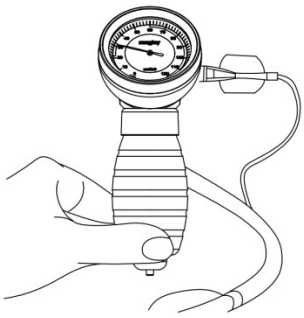
2c) Inflate to 40cmH_2O with a manual balloon; keep the value constant for 2-3 seconds; if the pressure drops, the connecting tube will leak and must be replaced. Check again with a new connecting tube (repeat steps 2a-2c).

Do not bend the Luer taper of the device during the connection and disconnection of the connecting tube to prevent damage. In addition, be sure to secure the connecting tube to the connector (not to any fitting).

The following test shall be performed before the use of vacuum valve (if to be used):

3a) Inflate the low pressure cuff of air tube to 40cmH_2O by using the Hand-held Hi-Lo Cuff Pressure Gauge (Fig. 4).

Fig. 4



3b) Connect the inflation tube to the Luer nozzle of vacuum valve (Fig. 5 and Fig. 6).

Fig. 5

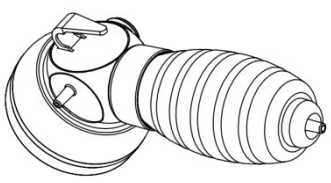
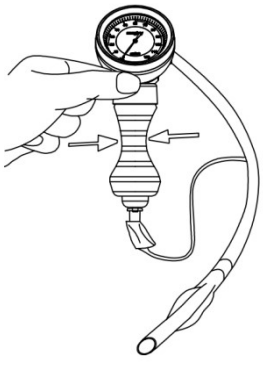


Fig. 6

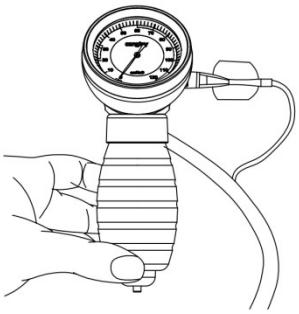


3c) Press the balloon for several times; the low pressure cuff must be deflated.

3d) Press the balloon until it will not return to its original position; then remove air from the low pressure cuff thoroughly (Fig. 6).

3e) Disconnect the inflation tube from the vacuum valve. Connect the inflation tube to the Luer nozzle of the Hand-held Hi-Lo Cuff Pressure Gauge. Negative pressure can be indicated on the inflation device via counterclockwise movement of its pointer (Fig. 7).

Fig. 7



X. Expected clinical benefits

1) Reduce the medical risk of airway tissue damage due to excessive pressure.

2) Reduce the incidence of ventilator-associated pneumonia.

XI. Maintenance and repair

Maintenance: wiping and disinfection

The device shall be wiped and disinfected with medical alcohol. When choosing disinfection products, disinfectants with corresponding effects must be used, including bactericide, yeast-like disinfectant, tuberculosis bacteria disinfectant and virus disinfectant. The device must be checked for any visible contamination after wiping and disinfection. Where necessary, the device shall be wiped and disinfected repeatedly. After wiping and disinfection, the device must be checked in accordance with the requirements of the section “Functional Check”. An appropriate amount of alcohol shall be used for wiping the device, for excessive alcohol may penetrate into the device and hence affect its accuracy.

Where necessary, it’s possible to wipe and clean this device with clean cloth dipped in mild soapy water. The device shall not be immersed in liquid. To avoid infection, the device can be externally disinfected with alcohol, and shall not be reprocessed or mechanically sterilized.

Repair

This medical product can only be repaired by personnel who master required repair

methods. After repair of this medical product, it's necessary to check the basic construction and functional characteristics of this product in terms of safety and functionality, because such basic construction and functional characteristics may be affected by the repair process.

To facilitate the repair of the medical product, a detailed description of defects shall be attached to the returned product.

XII. Transport and storage

The shelf life of the Hand-held Hi-Lo Cuff Pressure Gauge is 6 years.

The shelf life of the connecting tube is 2 years.

· The equipment shall be used in an environment with specialized medical facilities.

· Keep the product away from heat sources and store it in a dry place.

· Keep the product away from sunlight and light sources.

· Use the original package when storing and transporting the product.

· This product is a precision instrument. Do not drop it.

· In accordance with effective regulatory requirements, the used or damaged product must be sterilized before disposal.

XIII. Metering inspection

The accuracy of the Hand-held Hi-Lo Cuff Pressure Gauge is ±2cmH_2O and must be checked every 24 months. If the required measuring equipment is not available, the manufacturer shall conduct metering control. In this case, the inflation device must be sent to the manufacturer.

If there are indications that the measurement accuracy of the inflation device cannot be maintained within 24 months, or that the measurement characteristics of the inflation device are affected, the metering control must be carried out immediately. The metering control can only be performed by personnel who meet the requirements of metering control. The control results, measurement values and measurement procedures must be recorded.

After the successful completion of metering control, mark the year of next inspection and the person performing the metering control on the Hand-held Hi-Lo Cuff Pressure Gauge (in a clear

and traceable way).

In order to check the correctness of values, the Luer nozzle of the inflation device must be connected to the calibrated pressure gauge (the maximum measuring error is ± 0.6cmH_2O).

Then, inflate it to 30cmH_2O, 60cmH_2O and 90cmH_2O through inflatable ball and record the values. The values must be within the specified tolerance range. It not, the device shall be returned to the manufacturer. If values are within the tolerance range, the device can continue to be used.

Precautions for converting cmH_2O to Pascal, the international unit: 1cmH_2O = 0,98067Pa

EC-REP Name: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany

Registrant/Manufacturing Enterprise/After-sales Service Unit: Wuxi Conglay Medical Technology Co., Ltd.

Residence/Production Address: 4th Floor, 1719-12 Huishan Main Road, Huishan Economic Development Zone, Wuxi City

Contact/After-sales Service Telephone: 0510-83593959 18112353959

E-mail: wxkl@conglaymed.com

Operator's Manual Version: A/0

Revision date: July 2020

Explanation for compilation of Operator's Manual:

1. Date of first compilation: July 2020; version: A/0; effective date: July 20, 2020.