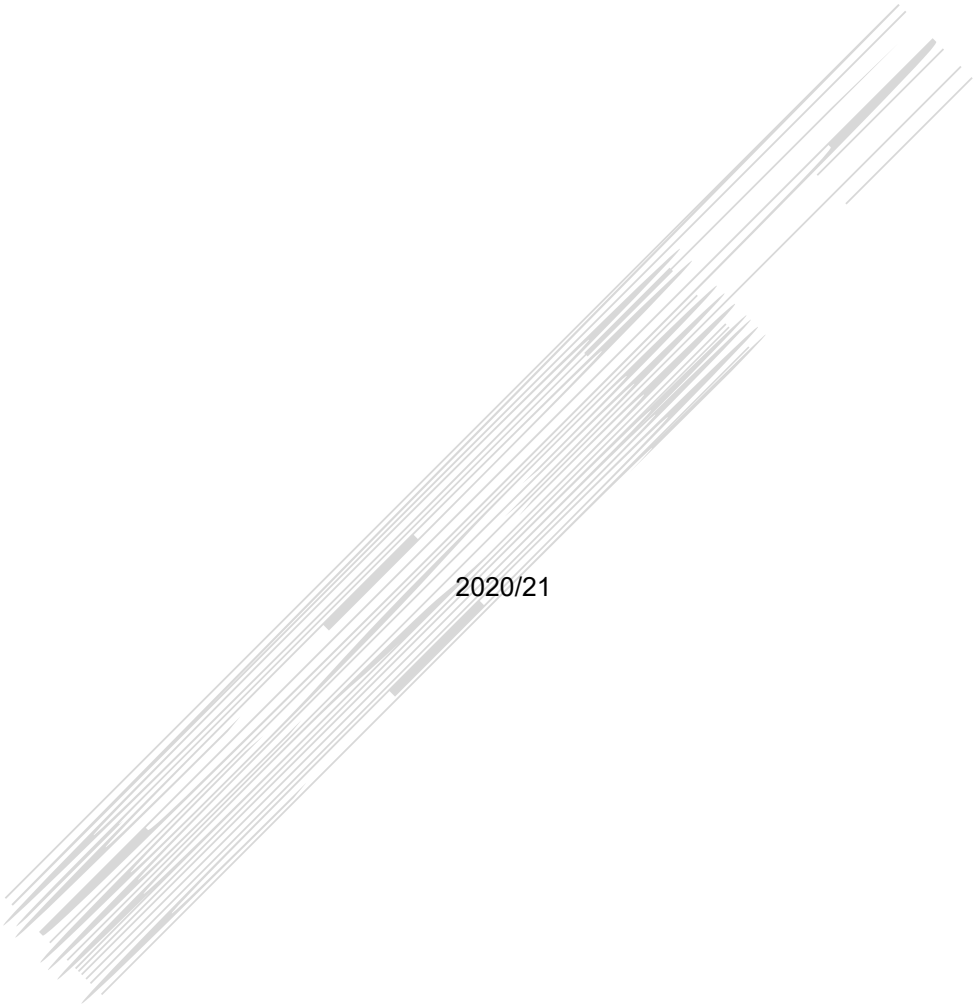
TaBea
Semi-automated resuscitator

Extract from the short summary of an internal ad hoc project of the Physikalisch-Technische Bundesanstalt



2020/21

Contents

(Photo: S. Rubrecht)

1. Disclaimer

The concept of an auxiliary resuscitator in disaster management (semi-automated resuscitator/ bag valve mask, TaBea) developed at the Physikalisch-Technische Bundesanstalt (PTB) with the aid of a prototype, includes the presentation of the prototype structure, its functional principle as well as possible areas of application in the field of disaster management, and is intended solely for the purpose of information and technical discussions.
The prototype is not intended or suitable for medical use and it is not a medical device as defined by the German Medical Devices Act (MPG). A future medical use could only take place after independent testing and certification by a competent body and approval by the responsible body.
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2. Overview

Formally, the semi-automated resuscitator is a volume and variable pressure-limited auxiliary device for use on adult patients, for example in situations where manual ventilation with the aid of a ventilation bag have to be performed alternatively over longer periods of time.

It offers adjustment possibilities to vary the stroke volume, the upper limit of the ventilation pressure, the positive end-expiratory pressure (PEEP) and the ventilation frequency. A

suitable PEEP valve is used on the inspiratory side for pressure limitation of the inspiratory pressure. Since too high ventilation pressures can permanently damage the patient's lung tissue, it is recommended to install a quantitative control display of the ventilation pressure; to avoid contamination transfer it is recommended to integrate suitable viral/bacterial filters.

3. Design of the device

The guiding principles of the presented concept are – in addition to a transparent mode of operation – robustness and simplicity as well as scalability of the manufacturing and a secure availability by extensively using certified components from emergency and rescue medicine that are not manufacturer-specific[1].

The inlet of an approved ventilation bag to which an oxygen reservoir can be connected, for example, forms the starting point of the airflow for ventilation.
The ventilation bag is fixed on a stainless steel base and is compressed and balanced by a combination of an arm with a roll and a rotating cam disk (see also technical drawings or figures below/attached). The shape of the cam disk has been chosen in such a way that the pressure history is achieved as smoothly as possible without pressure peaks and the inspiratory/expiratory ratio does not fall below 1:2. The cam disk and/or its rotating axis are driven by a DC motor. A commercially available windscreen wiper motor with a supply voltage of 12 V has been used for the prototype.
The stroke volume can be varied via mechanical adjustment of the compression depth (adjustment of the arm). The compression arm is designed in such a way that it compresses the ventilation bag as material-friendly as possible.
The ventilation frequency is adjusted via the rotational speed of the DC motor. This adjustment is currently made in the prototype by means of a commercial pulse width modulator circuit.

The ventilation bag including the compression mechanism and electronics is located in a stackable casing in Eurobox format (400 mm x 300 mm x 320 mm, LxWxH) with an integrated viewing window on the inside. The viewing window serves to make the functioning and condition of the device transparent for the user (no "black box"). The casing also serves as a carrier box. As a redundant safety measure, it is advisable to use a ventilation bag with a safety valve that limits the maximum pressure to, for example, 60 mbar.

An adapter is attached to the patient-side outlet of the ventilation bag which includes an outlet to a mechanical manometer, as well as enabling the transition to an approved breathing tube. This adapter was manufactured in-house for the prototype. Polyethylene was chosen as material for the prototype.

[1] During the work on the project – as mentioned above – it became apparent that even these components were in some cases only available on the market in very limited quantities at the beginning of the Covid-19 pandemic, which underlines the importance of stockpiling.

The mechanical manometer is a commercial spring manometer with a display range of 0...100 mbar. It is used for visual control of the ventilation pressure. A commercially available industrial manometer was used for the prototype.

An approved commercially available breathing tube is connected to the adapter. This will usually be disposable material.

The inspiratory breathing tube is connected patient-side to an approved patient valve.

For an adjustable limitation of the maximum ventilation pressure an approved PEEP valve can be used as an inspiratory pressure relief valve in addition or as an alternative to the safety valve with fixed pressure limitation in the inspiratory branch. In this case, colour coding is useful to explain the functioning as an inspiratory pressure relief valve to the user, even in stressful situations.

Commercially available PEEP valves allow a pressure limitation between approx. 0 and approx. 20 mbar. For the prototype, a PEEP valve was connected directly to the patient valve using an adapter which was manufactured in-house; the adapter for the prototype was made of polyethylene. For the prototype we tried to combine the springs from two PEEP valves in one valve in order to enable maximum pressures higher than 20 mbar, but **the scale of the valve thereby loses its validity**.

On the patient side, an approved HME viral/bacterial filter is connected. The filter serves to retain the patient's respiratory moisture and heat as well as to protect the patient and staff from contamination transfer via uncontrolled inhalation or exhalation of pathogens.
The semi-quantitative capnometer and viral/bacterial filter will usually be also disposable. The viral/bacterial filter will usually have a connection for quantitative capnometry.
When adjusting and checking the upper limit of the ventilation pressure as well as the end-expiratory pressure, the manufacturer's instructions regarding the pressure drop of the components used, such as the filter, must be observed, as well as instructions regarding their period of use.

Depending on the scenario, an approved and suitable breathing mask or a corresponding tube (unconscious patient) is connected patient-side to the filter. If necessary, a suitable closed suction system can be previously integrated.

After passing through viral/bacterial filters, the exhaled air can be led into a commercially available breathing tube via the expiratory outlet of the patient valve to which an adapter made of polyethylene is attached. This leads the exhaled air back to the device.

For reasons of redundancy and to avoid contamination transfer the exhaled air is led through a second approved virus/bacterial filter and escapes via a PEEP valve, if necessary. The PEEP valve is used to adjust the minimum end-expiratory breathing pressure.

A suitable external sensor system for measuring the expiratory ventilation volume, CO_2 content, etc. can be integrated in front of the PEEP valve.

4. Test measurements

To characterise the ventilation pressure curve in a time-controlled mode, several test measurements were carried out with the prototype on 14 and 15 May 2020.

Some of the test set-ups are shown in the figure below.

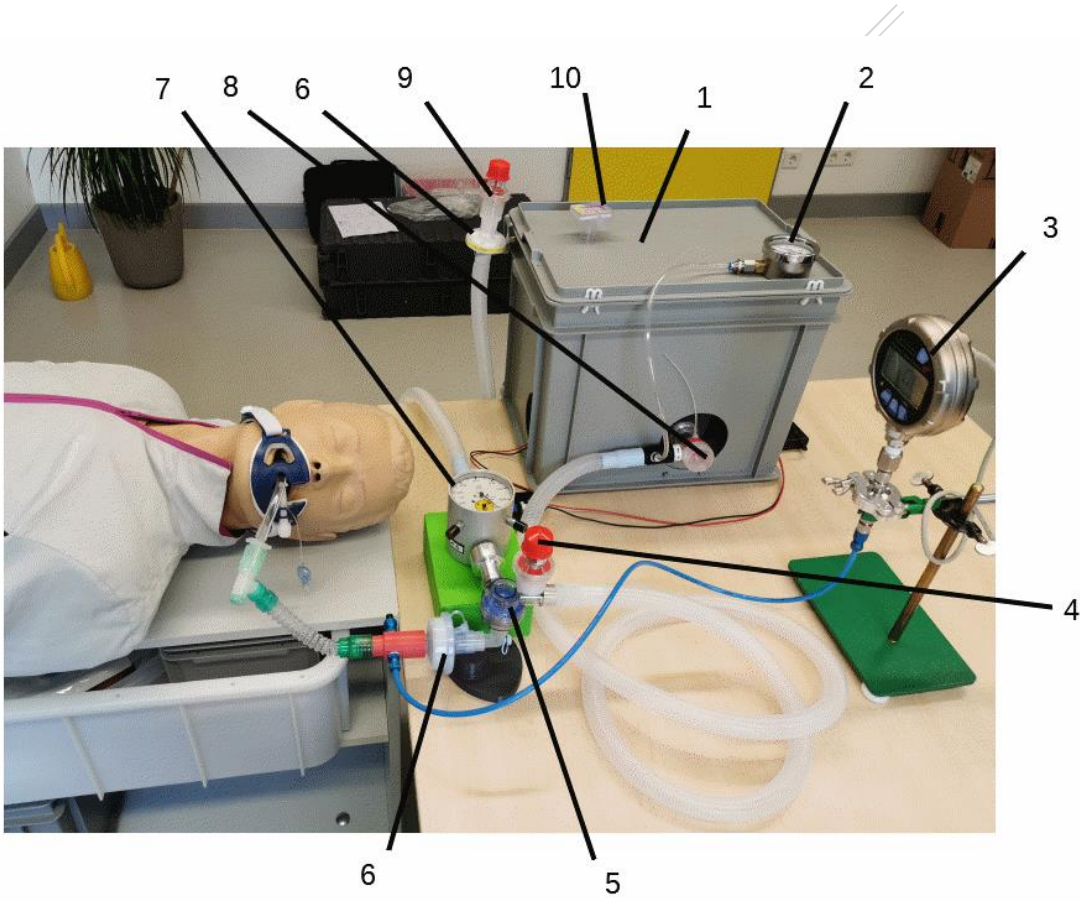

Figure 1: Set-up for the test measurements carried out on the test phantom. 1: Semi-automated ventilation bag in a Eurobox format casing (previous casing variant); 2: Manometer of the device; 3: Calibrated reference manometer for the test measurement; 4: Inspiratory pressure limitation valve; 5: Patient valve (due to the design the gap has been sealed, see below); 6: Viral/bacterial HEM filter; 7: Mechanical volumeter (expiratory) for the test measurement; 8: Outlet of the ventilation ventilation bag valve; 9: PEEP valve to adjust the lower limit of expiratory pressure; 10: Semi-quantitative capnometer (not integrated during the measurement)

5. Installation note

To avoid dust or similar to be sucked in and thus to avoid a reduced period of use of the viral/bacterial filter the device must be installed or fixed in such a way as to ensure that the air inlet is located at a suitable height. If necessary, a suitable coarse filter can also be provided at the inlet but would then have to be checked regularly.

6. Technical data

Power supply: 12 V / 3 A
Electrical power consumption: maximum 36 W
External dimensions: 400x300x320 mm
Weight: approximately 7.5 kg

Ventilation frequency:
Settable, typically 10...30 min^{-1}

PEEP:
Settable, typically 0...20 mbar

Restrictions on volume per stroke:
settable, typically > 800 ml max.

Limitation of the ventilation pressure:
Settable, typically 10...20 mbar, or 0 ...approximately 50 mbar (adapted valve)

7. Cost estimate

(Latest update 6/2020, price of single pieces without business customer or quantity discount or similar)

Component	**(Approximate) price in euros**
DC motor	45
Mechanical components	50
Pulse width modulator	40
Casing	25
Manometer	90
Adapters, sheets etc	100
Switch-mode power supply	30...50
Ventilation bag	8...230
Tubing (inspiratory)	15(?)
Pressure relief valve (inspiratory)	10
Patient valve	20...90
Semi-quantitative capnometer	10...18
Viral/bacterial filter	5
Breathing tube (expiratory)	15(?)
Viral/bacterial filter (expiratory)	5
PEEP valve (expiratory)	10
Total amount	480...780

8. View of the prototype for reasons of illustration

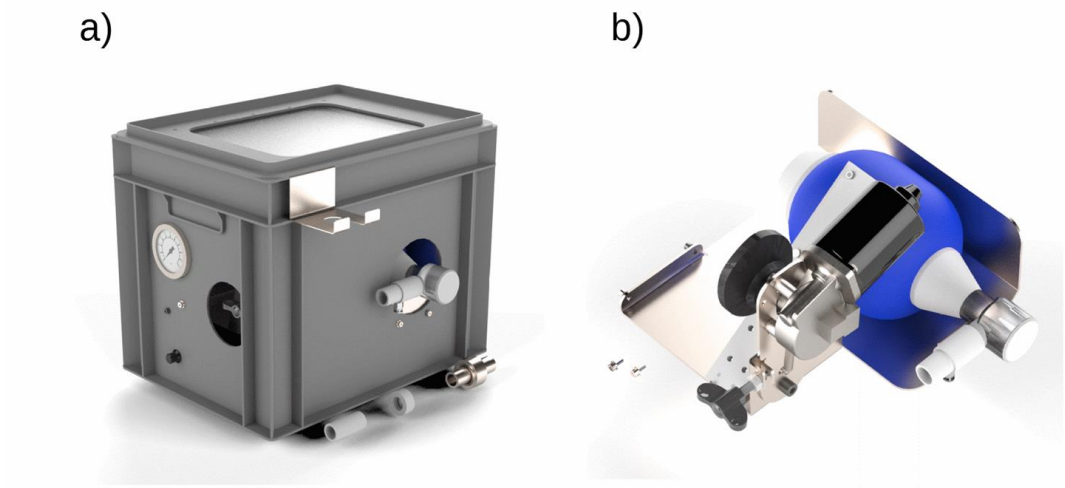

Figure 2: Semi-automated resuscitator (TaBea), 3D rendering of the technical drawing. a) Exterior view; b) Electromechanics for compressing and balancing the ventilation bag inside the casing.

3: Semi-automated resuscitator (TaBea), studio photography with connected breathing tubes, valves, pressure tube, capnometer, filters and breathing mask. (photo: S. Rubrecht)

4: Semi-automated resuscitator (TaBea), view of the prototype from different perspectives (without connected beathing tubes).