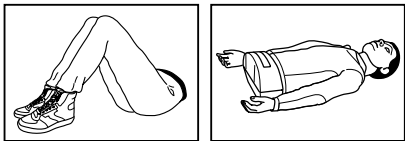


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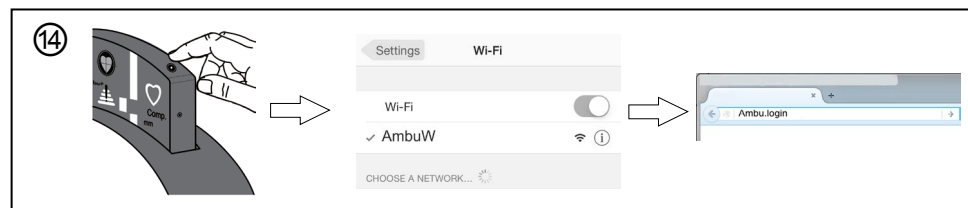
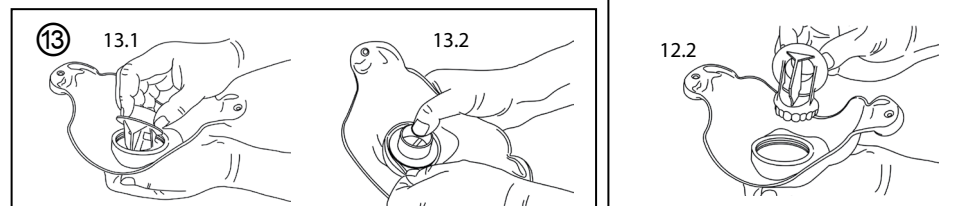
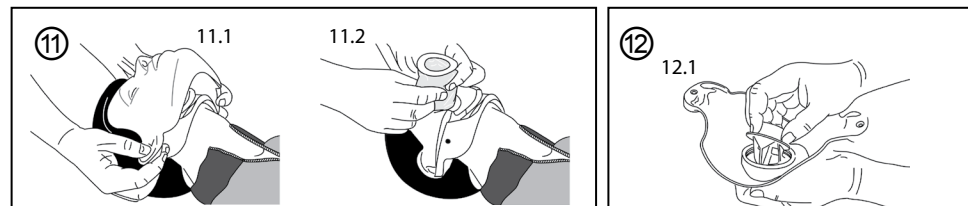
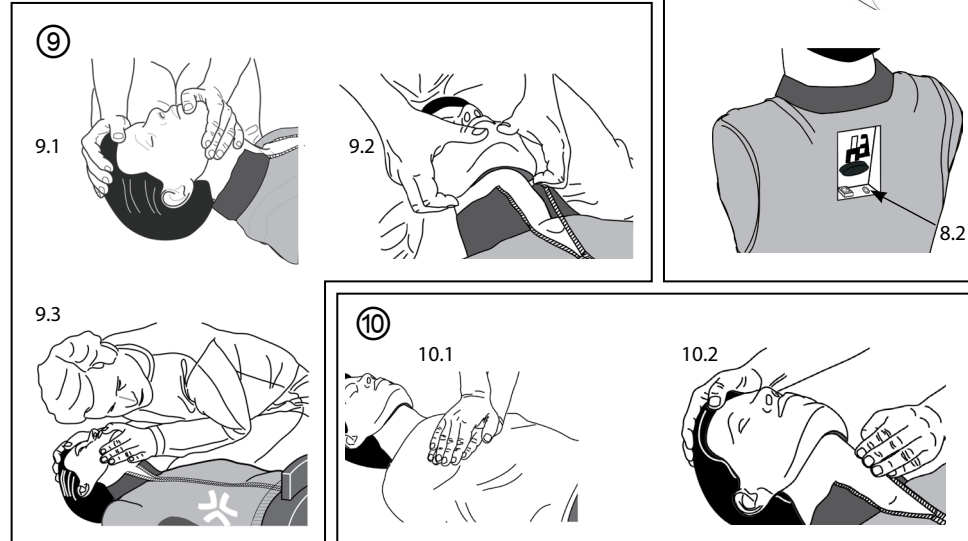
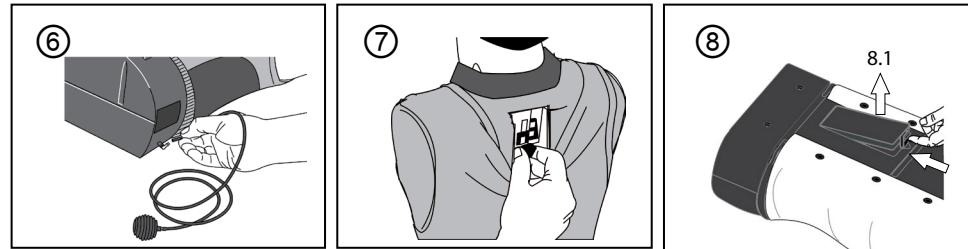
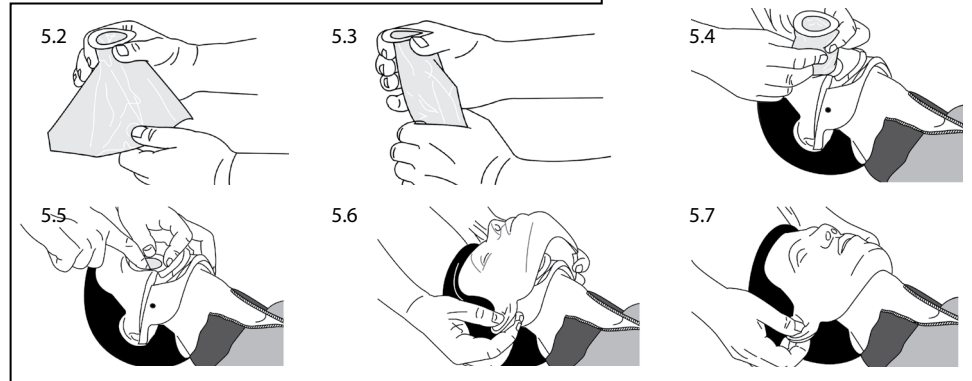
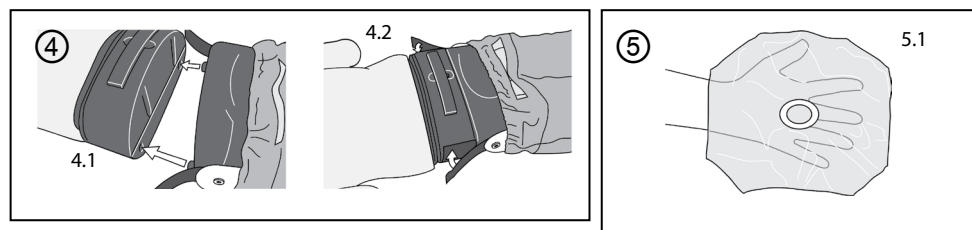
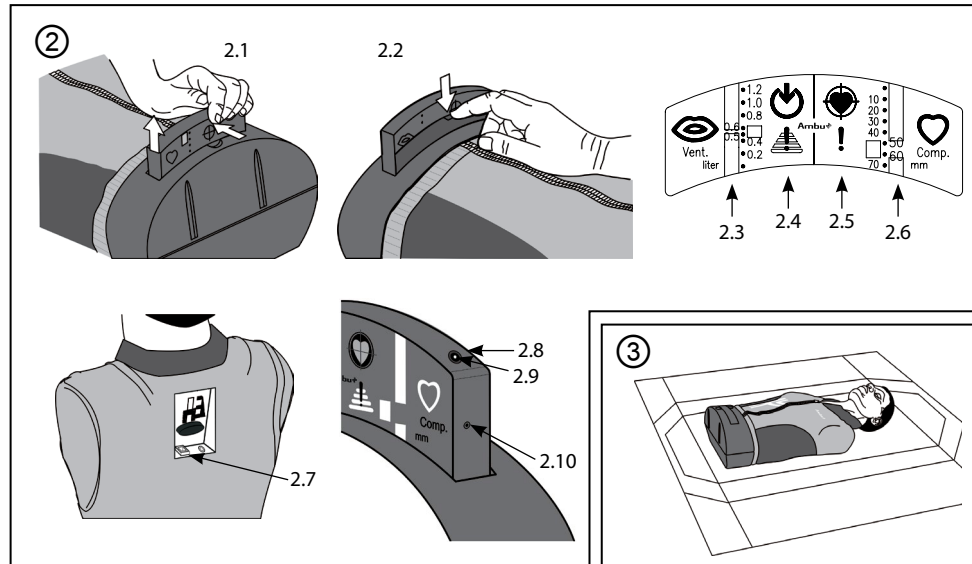
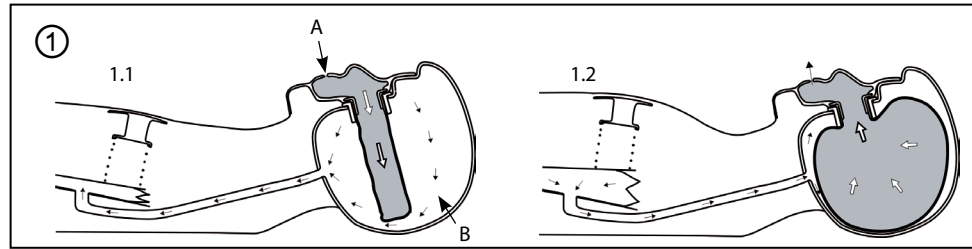
Ambu® AmbuMan Instrument
Ambu® AmbuMan Wireless



Ambu A/S
Baltorpbakken 13
DK-2750 Ballerup
Denmark
T +45 72 25 20 00
F +45 72 25 20 50
www.ambu.com

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Safety and Regulatory Notices

FCC Statement

This device complies with part 15 of the FCC Rules, Operation is subject to the following two conditions:

- 1) This device may not cause harmful interference and,
- 2) This device must accept any interference received, including interference that may cause undesired operations

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules.

These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications to the product are not allowed.

Contains FCC ID: **PD98260NG**

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Ambu® is a registered trademark of Ambu A/S, Denmark.
Ambu is certified according to ISO 9001 and ISO 13485.

This product complies with the essential requirements of Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity.

1. Introduction

The Ambu® AmbuMan is an advanced instruction and training manikin for the simulation of realistic conditions during cardiopulmonary resuscitation by means of rescue breathing and chest compression moreover the AmbuMan will cover all aspect of basic life-support training.

The manikin incorporates a unique, patented hygienic system under which all trainees get their own face piece and head bag, thereby minimizing any risk of cross-infection between the trainees. The hygienic system also features realistic expiration from the manikin through the mouth and nose.

With the special hygienic system, disassembly and internal cleaning and disinfection are rendered unnecessary both during and after training. The manikin has the size of a normal adult and provides an exceptionally lifelike representation of the human anatomy, particularly of those features important to training in modern resuscitation techniques.

The built-in instrumentation shows the effectiveness of the resuscitation, including results achieved for insufflation volume and depth of external chest compression, and indicates any stomach inflation and incorrect hand positioning as well.

1.1. AmbuMan models

The AmbuMan is available in the following configurations:

AmbuMan Instrument:

The AmbuMan Instrument models are equipped with an mechanical monitoring instrument showing effectiveness of the resuscitation, including results achieved for depth of external chest compression, incorrect hand positioning, ventilation volume furthermore indications of stomach inflation.

AmbuMan Wireless:

The AmbuMan Wireless models are equipped with a mechanical monitoring instrument as well as digital sensors showing effectiveness of the resuscitation, including results achieved for depth of external chest compression, incorrect hand positioning, ventilation volume furthermore indications of stomach inflation.

AmbuMan Wireless manikins can be connected to a computer through LAN or WLAN using the software application for a more detailed analysis of the performed resuscitation.

2. Restrictions and Cautions (only AmbuMan Wireless)

Wideband Data Transmission Systems

2400,0 – 2483,5 MHz

The product can be used in EU member states and EFTA countries in respect to the following restrictions.

Country	Restriction
France	Not allowed for outdoor use.
Italy	Not allowed for outdoor use.
Luxembourg	Implemented general authorisation is required for network and service supply.
Norway	Not allowed to be used within a radius of 20 km from the centre of Ny-Ålesund.
Russian Federation	Not allowed to be used before national approval based on the national standard system (GOST) and conformity certificate.

Caution



- Only use the manikin in dry surroundings. Do not expose the manikin directly to any kind of liquid.
- Remove the battery pack if the manikin is not used for a longer period of time.
- If you detect any smoke or smell from the manikin turn off the manikin immediately and stop using the manikin.
- If the manikin has been stored in the cold, let the manikin warm to room temperature before use and assure that no condensation has occurred as this could harm the electronics.

3. Specifications

3.1. Weight:

Torso with carrying case: approx. 12 kg

Full body with carrying cases: approx. 17 kg

3.2. Dimension:

Torso: approx. 80 cm

Full body: approx. 170 cm

3.3. Part/Material

Basic unit	Polyethylene
Instrument part	ABS plastic
Skull	PVC, hard
Chest skin	PVC, soft
Face piece	PVC, soft
Head bag, disposable	Polyethylene
Training suit	50% cotton and 50% polyester
Carrying bag/training mat	PVC coated nylon material

3.4. Battery pack (optional only AmbuMan Wireless)

The AmbuMan Wireless can be equipped with an battery pack.

3.5. Battery lifetime (only AmbuMan Wireless)

The battery lifetime using WLAN is approximately 10 hours using fully charged battery pack.

3.6. Adapter (only AmbuMan Wireless)

AC/DC Adapter

Input: 100-240 V AC / 47-63 Hz / 700 mA)

Output: 12 V DC / 2,0 A

3.7. Operating distance (only AmbuMan Wireless)

The wireless connection has a range of approximately 50 meters outside having no obstacles in between.

3.8. Usage and storage:

Storage temperature (non-condensing): -18 °C (-0,4 °F) to 40 °C (105 °F)

Usage temperature (non-condensing): -5 °C (23 °F) to 40 °C (105 °F)

Humidity: 5% to 95%

4. Functions

4.1. Hygienic System ①

Schematic diagram:

The head bag has been mounted in the skull and the face piece fitted.

Ventilation has just started, see (1.1).

A: Trainee's air B: Ambient air

Ventilation is concluded and expiration has just started, see (1.2).

NOTE: If a leakage occurs around the mask or if insufflation proves difficult, it is normally due to incorrect positioning when lifting the chin or to insufficient hyperextension of the head.

To comply with the requirements of the hygienic system, and to achieve a proper seal and accurate measuring results, a head bag must always be used.

All trainees must use their own face piece and head bag only during training.

4.2. Monitoring instrument ②

To pull out the monitoring instrument depress the catch (2.1) and let the instrument slide out.

The training can also be performed with the monitoring instrument inside the manikin.

Readings on the monitoring instrument can be viewed from two sides. By activating the cover plate on the side facing the trainee, instrument readings can be concealed from trainees undergoing a CPR test (2.2), while allowing the training instructor to monitor the effectiveness of the CPR on the opposite side.

The monitoring instrument is divided into two halves. The left-hand side registers ventilation, including inspiration volume (2.3), and provides indication of stomach inflation (2.4). The right-hand side of the instrument registers chest compression, including depth of compression in millimetres (2.5), and provides indication of incorrect hand positioning (2.6). The gauges for insufflated volume and depth of compression are designed to display green when the correct volume and chest compression have been reached, and red when the measurement recorded is outside the correct range.

If the display is green and red the measurement is at the borderline of the correct range.

The instrument registers inflation in the stomach (2.4) and incorrect hand positioning (2.6) by changing from black to red colour display.

The values on the scale plates on the monitoring instrument are in accordance with the actual guidelines for resuscitation. It is possible to order instrument plates with other recommendations or guidelines.

4.2.1. LAN connector (only AmbuMan Wireless) ②

To connect the manikin to a computer the LAN connector (2.7), can be used, placed on the backside of the manikin.

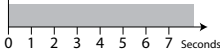
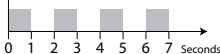
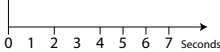
4.2.2. Power button (only AmbuMan Wireless) ②

To turn on the manikin for the use of the software application press the power button (2.8) on top of the monitoring instrument. The green LED (2.09) is flashing while the system is booting and is steady activated once the system is completely powered up.

To turn off the manikin the power button needs to be pressed at least 3 seconds.

If the power button is pressed for 10 seconds and more the system is forced to shut down.

An overview of the different LED status can be seen in the following table:

LED status	LED	Description	Flashing pattern
Green steady	●	System running	
Green slow flashing	○	System booting	
Off	○	System off	

4.2.3. Reset to default settings (only AmbuMan Wireless)

To reset the manikin into the default settings press the reset button (2.10) with a pin.

5. Preparation for training

The manikin is normally supplied in a special carry bag which, when opened, folds out to provide a mat for the trainee during training.

When supplying as a full body model, the legs will be in a separate carry bag.

5.1. Carry bag/training mat ③

Unfold the bag. Make sure that the manikin is firmly secured to the training mat by inserting the fitting on the training mat into the recess high up on the back of the manikin.

5.2. Mounting the legs on the torso ④

Pull down the trousers a little around the hips. Place the legs in a position so that the 2 dowels on the hip part can slide into the corresponding dents at the bottom of the manikin's body, see 4.1.

Press the two Velcro straps firmly to the body, see 4.2.

To remove legs pull off the Velcro straps and the legs will be disengaged.

5.3. Mounting the head bag and face piece ⑤

Unfold the head bag and hold as shown, see 5.1.

Holding the ring of the bag, fold together as shown on the photos, see 5.2 and 5.3.

Insert bag in the head, see 5.4.

Smooth out the edges along the opening in the skull, see 5.5.

Hold the face piece by the ears and position on the skull so that the top is flush with the hairline, see 5.6.

Pull face piece downwards by holding firmly by the ears until in position. Make sure that the edges of the mask are located under the hair at the temples. Fix the openings at the back of the ears on the fixing prongs on each side of the skull, see 5.7.

5.4. Monitoring Instrument

Activate the instrument by depressing the catch. In case the instrument is not activated (pulled out), no damage is done to the manikin nor to the instrument during chest compression.

5.5. Carotid pulse ⑥

Fit the tube with bellows onto the tube connector.

The instructor can now activate the carotid pulse manually by compressing the bellows.

5.6. Adjusting chest stiffness ⑦

The stiffness of the chest can be adjusted as required by loosening the thumb screw on the back of the manikin: For reduced stiffness set to 'LOW' position, for increased stiffness set to 'HIGH' position.

The values shown, approximately 6 N/mm (0,6 kg/mm) and 11 N/mm (1,1 kg/mm), indicate the force, which must be applied to compress the chest by 1 mm.

Example: Compressing the chest by 40 mm at the 'LOW' setting, a force of approximately 240 Newton (24 kg) must be applied.

The normal setting is 'MEDIUM' corresponding to approximately 8,5 N/mm (0,85 kg/mm).

5.7. Battery placement (only AmbuMan Wireless) ⑧

The battery compartment is placed on the backside of the manikin. Depress the catch to open (8.1) and remove the battery pack.

NOTE: Take care that the battery pack is placed correctly in the battery compartment.

5.8. Power supply (only AmbuMan Wireless) ⑧

The manikin can be powered using a universal external AC/DC adapter (output 12 V / 2,0 A) with a straight connection plug (5,5x2,1x12 mm). The connector can be connected to the socket place inside the battery compartment, see 8.2.

6. Usage of the manikin

6.1. Ventilation ⑨

The patented hygienic system of the Ambu enables the trainee to get a realistic feeling for performing ventilation.

The following techniques can be used:

Mouth-to-mouth ventilation
Mouth-to-nose ventilation
Mouth-to-mask ventilation
Resuscitator /mask ventilation

To ventilate ensure there is free access to the airway by using the head tilt and jaw thrust/ chin lift manoeuvre, see 9.1 and 9.2.

The movements of the chest can be clearly observed during insufflation and expiration. The insufflated volume is displayed directly on the monitoring instrument. The expired air can be felt and heard from the mouth and nose of the manikin with no risk of infection, as the air is the same as that insufflated by the trainee into the head bag, see 9.3. Accidental stomach inflation is simulated and can be observed in the stomach region and viewed directly on the monitoring instrument.

NOTE: Remember to change head bags and face pieces for each new trainee.

6.2. Compression ⑩

External chest compression can be practised, and the depth of compression will be displayed on the monitoring instrument in millimetres. It is possible to adjust the stiffness of the chest to simulate a patient with a soft, normal or hard chest.

To ensure that the correct point of compression is applied during chest compression, the instrument also provides indication of incorrect hand positioning, see 10.1.

The carotid pulse can be felt on both sides of the neck if simulated manually by the instructor, see 10.2.

6.3. Removal of Face piece ⑪

Pull the ears outwards to release them from the two prongs on each side of the skull. Pull the mask upwards by the ears until free of skull, see 11.1.

6.4. Removal of Head bag ⑫

Grab the bag on each side, but avoid closing the opening. Pull bag slowly upwards, twisting from side to side if necessary, to facilitate removal, see 11.2.

7. Cleaning and disinfection

With the patented hygienic system of Ambu, incorporating exchangeable face piece and head bag, no internal cleaning and disinfection is necessary.

7.1. Head bag

The head bag is disposable and should always be discarded after training.

7.2. Face piece

The face piece may be reused after cleaning and disinfection. Remove the dental insert by pulling it from the face piece, see 12.1 and 12.2.

7.3. Manual cleaning

- Rinse face piece and dental insert in clean water.
- Wash items in warm water, max. 65 °C (150 °F), use a mild detergent.
- Rinse thoroughly in clean water to remove all traces of detergent.

7.4. Machine washing

The face pieces can be washed in an ordinary washing machine. Apply normal dose of detergent and choose a washing programme with maximum temperature of 70 °C (158 °F). In order to avoid the dental inserts rattling against the drum of the washing machine, the face pieces can be placed in a bag made of loosely woven fabric.

7.5. Disinfection

After separating and cleaning the face piece and dental insert, disinfection can be performed as follows:

- Place the items in a sodium hypochlorite solution with minimum 500 ppm freely accessible chlorine (1/4 a cup of liquid household bleach per gallon (approx. 4 litres) of tap water for 10 minutes). This solution must be fresh and should be discarded after use.
- Place the items in a 70% alcohol chlorhexidine solution for 2 minutes (70% Ethylalcohol and 0.5% chlorhexidine). This method of disinfection is recommended by the Australian Resuscitation Council.
- Chemical disinfection can also be performed using recognised disinfectants suitable for use with polyvinylchloride (PVC). The supplier's directions on dosage and disinfection period should be closely followed.
- Always rinse the items in clean water after disinfection and allow to dry before storing.

NOTE: The face pieces must not be exposed to boiling, autoclaving or gas sterilisation.

7.6. Cleaning of skull, neck and body

The skull, neck and body of the manikin should be wiped over with a cloth moistened in a mild detergent and then wiped over once more using a cloth moistened in clean water. When washing, never allow detergent or water to enter the skull, body or instrument unit. If necessary, cover the connection between body and instrument unit with a cloth. Marks on the manikin left by lipstick or ball pen can penetrate the material and should therefore be removed as quickly as possible using alcohol.

7.7. Cleaning of clothing

The training suit is made of 50% cotton and 50% polyester and is washable at max. 40 °C (105 °F).

7.8. Cleaning of 10-rry bag

The carry bag can be washed in a mild detergent using a cloth or soft brush, rinsed in dean water, and then dried off.

7.9. Assembly of face piece ⑬

Assemble the face piece by fitting the dental insert as shown and press it into the face piece so that only the flange and collar remain outside, see 13.1.

First, press the collar of the dental insert into the slot on one side of the face piece.

Next, take the edge and force it over the flange on the dental insert until the flange is seated in the slot in the mask all the way round, see 13.2.

8. Quick connection guide (only AmbuMan Wireless)

To connect the manikin to a computer device the following step have to be performed:

1. Turn on the manikin.
2. Connect the WiFi of the Computer device with the network "AmbuW".
3. Open the web browser and type "Ambu.login".

Then follow the instructions on the screen.

If an NFC (near filed communication) device is used the connection can be set automatically following the enclosed steps:

1. Turn on NFC on the computer device.
2. Place the device on the manikin next to the Power button to connect to the network.
3. Place the device next to the opposite side of the instrument panel to start the software application.