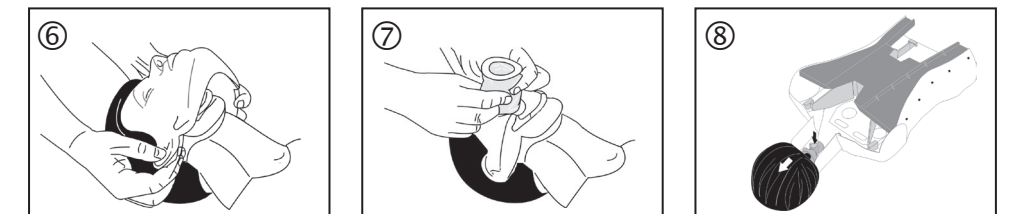
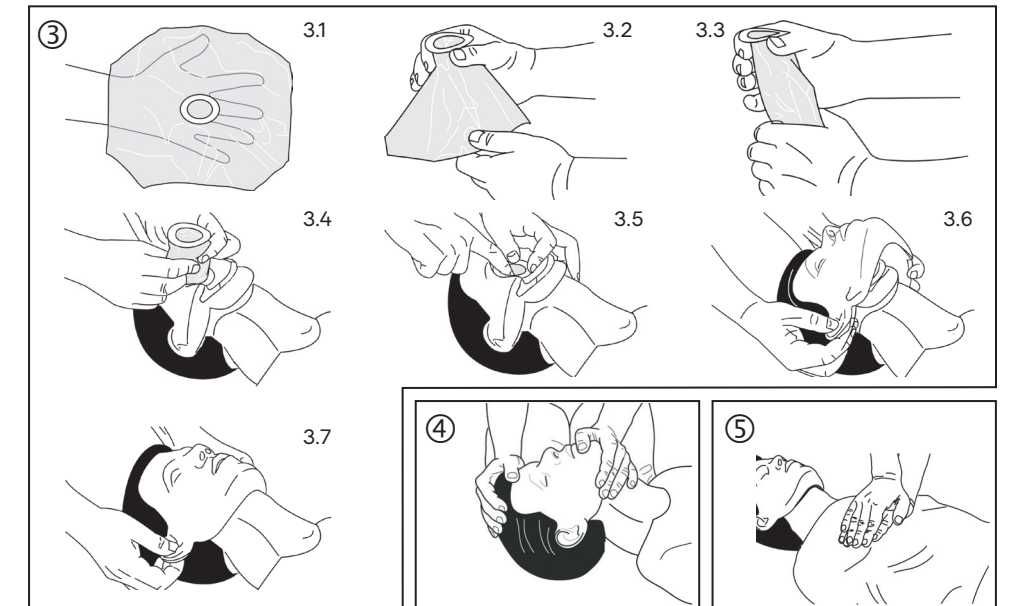
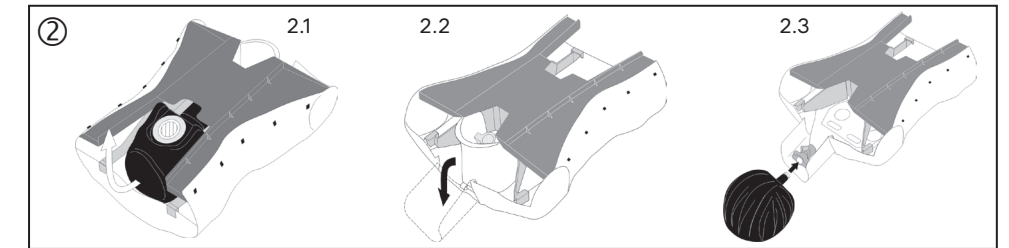
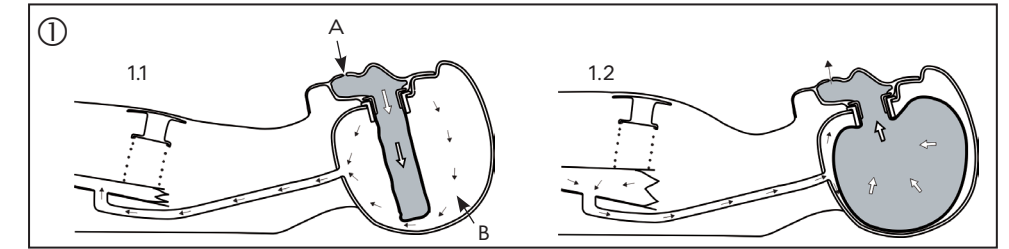
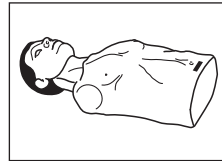


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Instructions for use

AmbuMan® SAM AmbuMan® SAM iQF

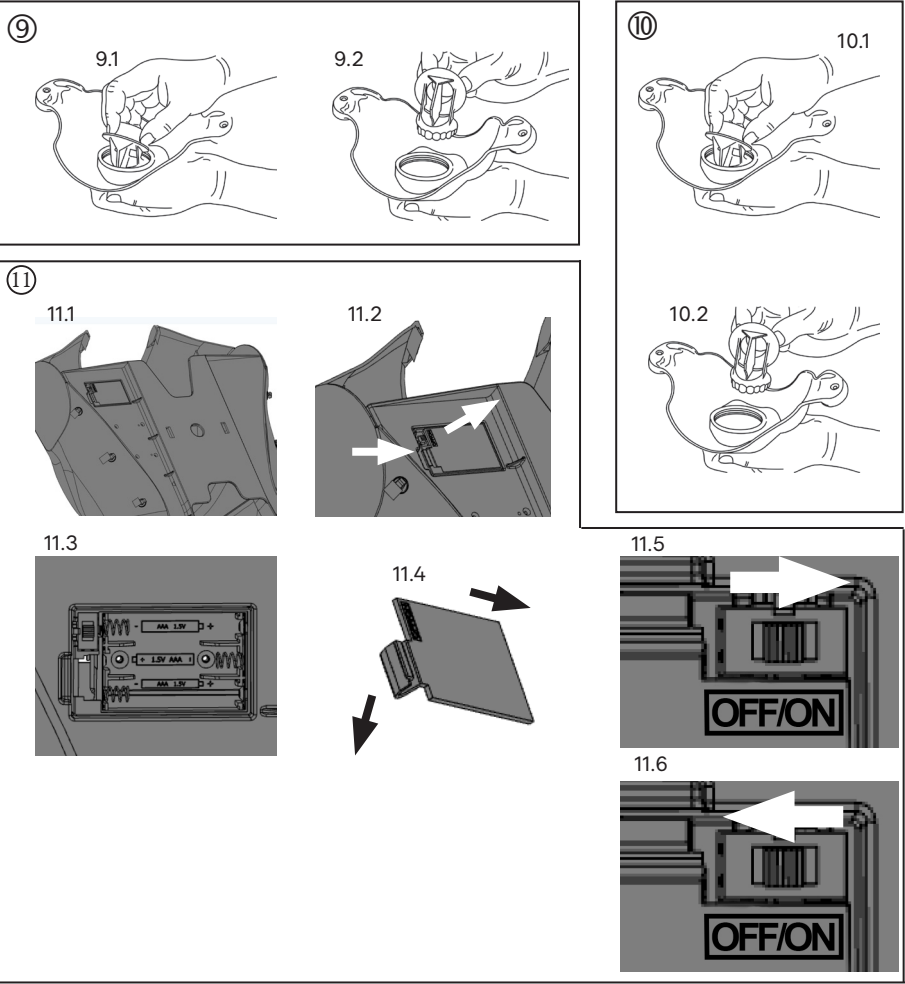


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Safety and Regulatory Notice

US

This device complies with part 15 of the FCC Rules and ISSED Standards. 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 operation.

Note: 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.

AmbuMan® SAM iQF is only compliant if no changes or modifications are made to the device.

AmbuMan® SAM iQF is compliant with the requirement for RF exposure in US with less than 5 mm separation distance between the user and/or bystander of the device.

Canada

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

- (1) This device may not cause interference.
- (2) This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

- 1) L'appareil ne doit pas produire de brouillage;
- 2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Any modifications to a certified product may require recertification with ISSED.

Toute modification apportée à un produit homologué peut exiger une nouvelle homologation auprès d'ISDE.

This equipment complies with ISSED radiation exposure limits set forth for an uncontrolled environment.

Cet équipement est conforme aux limites d'exposition aux radiations ISSED prévues pour un environnement incontrôlé.

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

This product comply with the essential requirements of Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

1. Introduction

The AmbuMan® SAM and AmbuMan® SAM iQF are a basic instruction and training manikin for the practise of cardiopulmonary resuscitation by means of rescue breathing and chest compression.

The AmbuMan SAM 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 AmbuMan SAM 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 AmbuMan SAM is the size of a normal adult torso and provides a lifelike representation of the human anatomy, particularly of those features important to training in modern resuscitation techniques including the placement of AED pads.

The AmbuMan® SAM iQF incorporates electronics, allowing the measurement of the compressions and ventilations. The associated mobile App "Ambu iQF Instructor" and "Ambu iQF Trainee" provide a feedback of the relevant CPR parameters for evaluation of the training session.

2. Restrictions and cautions (only AmbuMan SAM iQF)

Radio Equipment Directive (RED) information:

Tx Frequency band: 2.4 GHz

Technology: Bluetooth® Low Energy

Maximum Tx power: 0 dBm / 1 mW

Bluetooth is a registered trademark of Bluetooth SIG, inc.

AmbuMan SAM iQF is only compliant if no changes or modifications are made to the device.

Human exposure (EMF):

AmbuMan SAM iQF is compliant with the requirement for EMF in EU with no separation distance between the user and/or bystander of the device.

Caution



Do not use the manikin while the skin is removed. Doing so may result in injury.

When using tools during assembly of upgrade kit, ensure that the safety guidelines of the tools used are followed

If placing the product into long term storage ensure that batteries are removed.

Only use the manikin in dry surroundings. Do not expose the manikin directly to any kind of liquid.

If you detect any smoke or a burning smell from the manikin, turn off the manikin immediately and do not use the manikin.

If the manikin has been stored in a colder environment, allow the manikin warm to room temperature before use and assure that no condensation has occurred, as this could harm the electronics.

NOTE:

If there are exposed parts which are damaged in anyway, it is recommended not to use the manikin and to contact your local Ambu representative.

If the power level on the app indicates that the power is low, a replacement battery should be inserted into the manikin.

If the manikin alerts with 3 consecutive short beeps this is an indication that the power is too low and the battery should be replaced.

If the manikin does not power on check batteries are inserted correctly and/or insert new batteries. If the manikin continues not to turn on, contact your local Ambu representative.

3. Specifications

3.1 Physical specifications

Weight: approx. 4,5 kg

Dimensions (L x W x H): 45 x 37 x 25 cm

Maximum insufflation volume: 1,8 Liter

Maximum chest compression: 7 cm

3.2 Materials

Part	Material
Chest Unit	SEBS, Styrene-Ethylene-Butylene-Styrene
Neck	PP, Polypropylene
Skull	HDPE, High-density polyethylene
Face piece	PVC, Polyvinylchloride, soft
Head bag, disposable	PE, Polyethylene
Lung Plate	PP, Polypropylene
Basic Unit	ABS, Acrylonitrile butadiene styrene

For further product information see www.ambu.com

3.3 Usage and storage:

Storage temperature (non-condensing): -20 °C (-4 °F) to 70 °C (158 °F)

Usage temperature (non-condensing): -0 °C (32 °F) to 40 °C (105 °F)

Storage humidity: between 5% and 98% relative

Operational humidity: between 5% and 98% relative

3.4 Batteries (only AmbuMan SAM iQF)

Recommended battery types:

3 premium quality alkaline or rechargeable batteries size AAA.

Battery life time:

With standard quality alkaline AAA batteries > 16h where manikin is connected to App sending sensor data.

The maximum obtainable battery lifetime is dependant on BLE transmission conditions and Manikin usage (idle standby or active sensors)

3.5 Operating Distance (only AmbuMan SAM iQF)

The wireless connection has a range of approximately 10 meters outside having no obstacles in between.

3.6 Associated mobile App (only AmbuMan SAM iQF)*

To use the full functionality of AmbuMan SAM iQF on mobile device you can download the "Ambu iQF Instructor" and "Ambu iQF Trainee".

The apps are available for download on the Google Play™ Store and the Apple® App Store®.

Minimum System requirements:

Android™: Android OS version 8

iOS™: iPhone 6, iOS 12

Recommended System requirements:

Android: Android OS version 10

iOS: iOS 14

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Apple and App Store are trademarks of Apple Inc. registered in the U.S. and other countries and regions

iOS is a trademark or registered trademark of Cisco in the U.S. and other countries

4. Functions

4.1 Hygienic System (see picture 1)

Schematic diagram:

The head bag has been mounted in the skull and the face piece fitted. Ventilation has just started, see picture 1.1.

A: Trainee's air B: Ambient air

Ventilation is concluded and expiration has just started, see picture 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 Compression indicator

The compression indicator shows the correct depth of the chest compression.

When compressing the chest of AmbuMan SAM the indicator will show a red bar until the correct depth is reached. Once the correct depth is reached the indicator will change into a green bar. If the compression is continued too deep the indicator will change back into a red bar.

The compression indicator will show a green bar at a compression depth of 5cm to 6 cm.

5. Preparation for training

The AmbuMan SAM training manikin is supplied in a carry bag. To start the training remove the manikin from the bag.

5.1. Mounting the head (see picture 2)

When the manikin is stored the head is placed inside the manikins and the neck if

folded down.

Pull out the head of the torso, see picture 2.1 and fold up the neck see picture 2.2. Press the head into the connector of the neck until you can hear a "click" sound. (2.3)

5.2. Mounting the head bag and face piece (see picture 3)

Unfold the bag and hold as shown, see picture 3.1.

Holding the neck of the bag, fold together as shown on the photos, see picture 3.2 and 3.3.

Insert bag in the head, see picture 3.4.

Smooth out the edges along the opening in the skull, see picture 3.5.

Hold the face piece by the ears and position on the skull so that the top is flush with the hairline, see picture 3.6.

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 picture 3.7.

5.3 Preparation of AmbuMan SAM iQF (see picture 11)

To use the full functionality of AmbuMan SAM iQF the manikins needs to be equipped with Batteries and turned on, in order to use manikin with the Ambu iQF instructor App or the Ambu iQF Trainee App.

For details about the batteries to be used in the manikin, see section 3.4 of this instruction.

5.3.1 Insertion and removal of Batteries

The battery compartment is placed on the backside of the manikin, see picture 11.1.

Open the compartment pressing the snap fit and lift the lid, see picture 11.2

Insert the batteries taking care that the polarity of the batteries is as displayed inside the battery compartment, see picture 11.3.

Close the lid placing end on the compartment and flip the lid until the snap fit is locked, see picture 11.4

To remove the batteries follow the instruction above in reverse order.

5.3.2 Turing the manikin on/off

To turn on the manikin move the switch into the "On" position, see picture 11.5

To turn off the manikin move the switch into the "Off" position, see picture 11.6

6. Usage of the AmbuMan SAM

The AmbuMan SAM is designed to meet all the training recommendations of the AHA (American Heart Association) and the ERC (European Resuscitation Council). In general, however, it is recommended that instruction should be based on the techniques and provisions applicable locally

6.1 Ventilation

The patented hygienic system of the AmbuMan SAM 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

To ventilate ensure there is free access to the airway by hyperextending the head (see picture 4).

The movements of the chest can be clearly observed during insufflation and expiration. The expired air can be felt and heard from the mouth and nose of the AmbuMan SAM with no risk of infection, as the air is the same as that insufflated by the trainee into the head bag.

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

6.2 Compression (see picture 5)

External chest compression can be practised, and the depth of compression will be displayed on the indicator bar.

6.3 Placement of AED pad

If the training with AED is performed AED pads can be placed on the manikin.

NOTE: The manikin can only be used with Training AED's

6.4 Removal of Face piece (see picture 6)

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.

6.5 Removal of Head bag (see picture 7)

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

6.6. Removal of the Head (see picture 8)

To remove the head turn the manikin around. Press the red button down and pull the head out.

7. Cleaning and disinfection

With the patented hygienic system of the AmbuMan SAM, 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 (see picture 9)

The face piece may be reused after cleaning and disinfection. Remove the dental insert by pulling it from the face piece, see picture 9.1 and 9.2.

7.2.1 Manual cleaning

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

7.2.2 Machine washing

The face pieces and dental parts 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. Leave the parts to dry before packing.

7.2.3 Disinfection

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

- A. 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. This method is recommended by AHA
- B. 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.
- C. 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.

- D. 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.

7.3 Cleaning of skull, neck and body

The skull, neck and body of the AmbuMan SAM 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.

Marks on the AmbuMan SAM left by lipstick or a ball pen can penetrate the material and should therefore be removed as quickly as possible using alcohol.

7.4 Assembly of face piece (see picture 10)

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 picture 10.1.

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 picture 10.2.