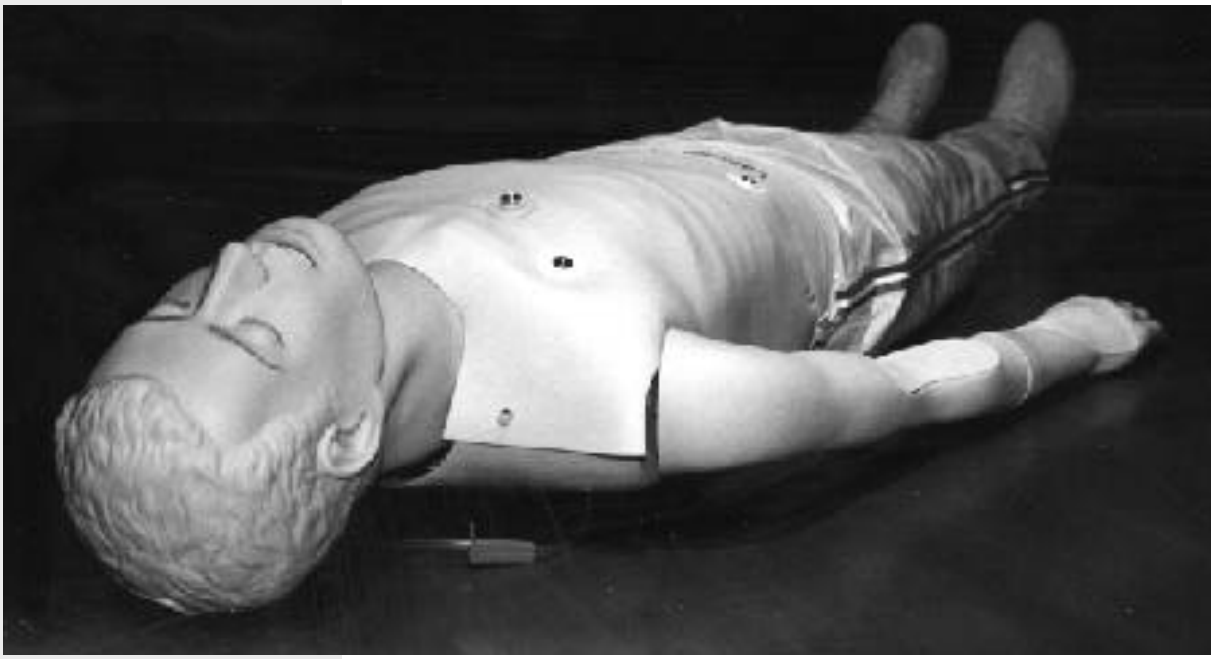
Laerdal ALS Skillmaster

Directions for Use



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Limited Warranty

Laerdal Medical warrants to the purchaser that its products are free from defects in material and workmanship for a period of one (1) year from the date of purchase by the original user. During the designated one (1) year period, Laerdal Medical will, upon receipt of a product found to be defective due to materials or workmanship from the purchaser and notification in writing of the defect at its option repair or replace any parts found to be defective or the entire product.

Products found to be defective and notification of defects may also be sent to the authorized Laerdal Medical dealer from whom the product was purchased. All postage, shipping, or handling charges shall be the sole responsibility of the purchaser.

Laerdal Medical is responsible for the effects of safety, reliability and performance of its product(s) only if:

– service, repair, readjustment or modification is carried out by Laerdal Medical or persons authorized by Laerdal Medical.

– the electrical installation of the room where the product is used complies with pertinent national requirements.

– the product is used in the proper manner in strict compliance with its Directions for use.

Laerdal Medical shall not be liable under this warranty for incidental or consequential damages or in the event any unauthorized repairs or modifications have been made or attempted or when the product, or any part thereof, has been damaged by accident, misuse or abuse. This warranty does not cover batteries, fuses, normal wear and tear, staining, discoloration or other cosmetic irregularity which does not impede or degrade product performance.

Some states in the USA do not allow the exclusion or limitation of incidental or consequential damages, so those limitations or exclusions may not apply to you.

There are no other express or implied warranties, whether of merchantability, fitness or purpose, or otherwise, on the product, its parts and accessories.

Cautions and warnings

- Do not connect the product to a patient.

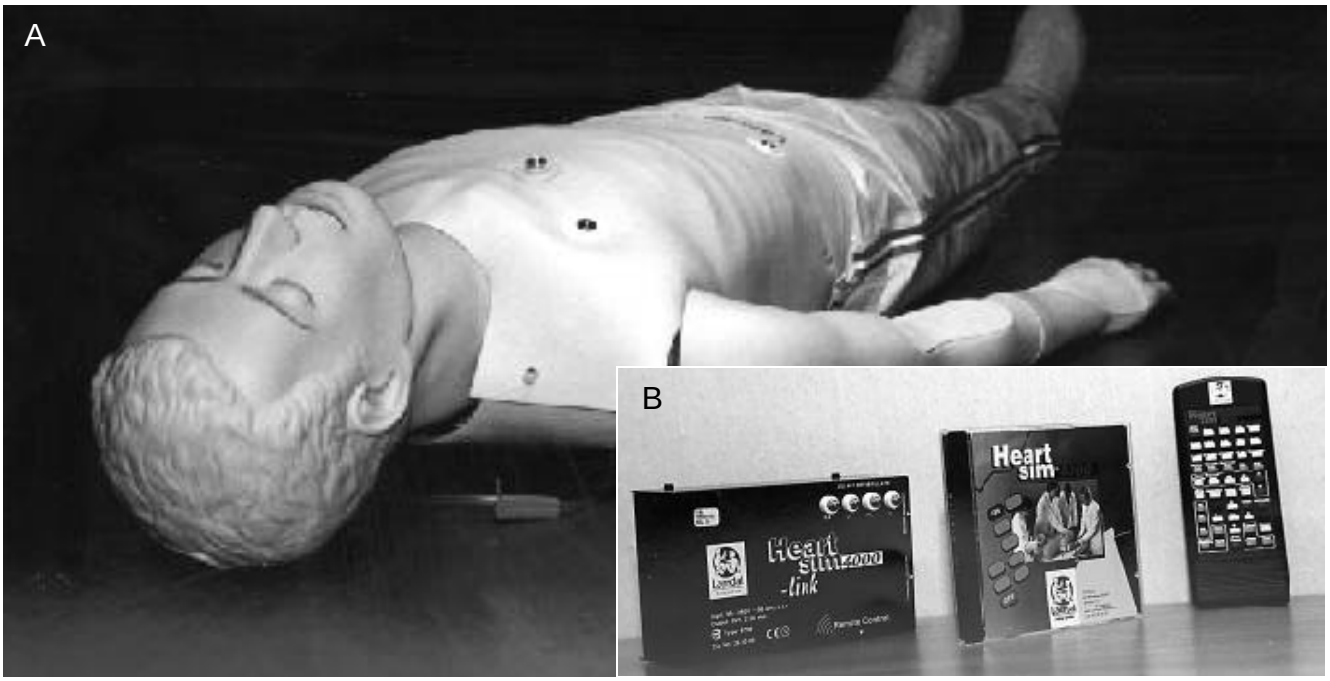
- Use of a defibrillator for training purposes represents an operational hazard equivalent to use of a defibrillator on a real patient since it involves the release of high levels of electrical energy into the training manikin. Consequently:
– All safety precautions for use of defibrillators must be followed, as if the manikin were a patient. Consult the user's manual of the defibrillator being used.
– Defibrillation should be performed on the defibrillation connectors only. If defibrillation is performed over one or more of the ECG connectors, high voltages may be present on the remaining connectors during the shock.
– To prevent overheating do not provide more than three defibrillator discharges (max 360 J) in a sequence. Do not exceed an average of two defibrillator discharges per minute during the training session.
– The manikin must not be in contact with electrically conducting surfaces or objects during defibrillation.
– A flame supporting atmosphere, for example with a high content of oxygen, should be avoided during defibrillation.
– The manikin chest must be kept dry.
– To prevent chest skin electrode pitting do not apply conductive gel, or conductive defibrillation pads intended for patient use.
– Do not use cables or connectors with visible damage. Undo load sensor box with cables and ship chest skin with load sensor box for authorized Laerdal service.
– Do not spill fluids over any component inside the manikin torso, since this could damage the unit and might also present a possible hazard for the operator.

- If a training session has included administering of drugs into the left arm, undo and empty the arm immediately after the training session.

- Do not allow the manikin's skin to come in direct contact with ink or photocopied paper, as this can cause permanent stains on the skin. Also avoid using coloured plastic gloves when handling the manikin, as this may cause discolouration of the manikin's skin.

- This device generates, uses and can radiate radio-frequency energy. If it is not installed and used in accordance with the instructions, it may cause harmful interference to radio communications. In that case the user is encouraged to try to correct the interference by:
- Reorienting or relocating the receiving antenna.
- Increasing the distance between the device and receiver.
- Connecting the device into an outlet on a circuit different from that to which the receiver is connected.
- Consulting the dealer or an experienced radio/TV technician for help.

1. Main Components



The Laerdal Skillmaster ALS Interactive Training System consists of the following main components:

A. ALS Skillmaster Manikin
A full Torso male manikin allowing the simulation of Advanced Life Support skills to develop both individual and team skills. Features are listed below.

Head:
- Intubation - nasal and oral
- Head tilt (with sensor feedback*)
- Jaw thrust (with sensor feedback*)
- Audible feedback if pressure exerted on the teeth during intubation
- Laryngospasm simulation
- Bilateral carotid pulses with normal, weak and absent settings.*

Torso:
- Bilateral lungs
- Auscultation of breath sounds
- Left/right- or bilateral lung obstruction*
- Chest compression sensors*
- Precordial thump sensors*
- 3/4 lead ECG monitoring*
- ECG monitoring via defibrillation connectors*
- Defibrillation connectors for AED or Manual defibrillation*
- External pacemaker training*
- Stomach

Arms:
- Volume infusion into left arm
- Intravenous cannulation sites in right arm

* Heartsim 4000 is required

B. Heartsim 4000

This is the instructor's tool to control the training scenario, it requires a IBM compatible computer:

The computer connects to the manikin via the Laerdal Link Box. Only one lead goes to the manikin which combines power input and connectivity to the Laerdal Link Box. Features are listed below.

CD ROM:
- ALS training controls via computer keyboard and/or remote control.
- Over 2,500 ECG rhythm variations
- Variable extrasystole rate
- Choice of different extrasystole types
- Variable pacemaker threshold (external pacemaker training only)
- Control of manikin functions
  - Sounds
    - Breathing
    - Moaning
    - Vomiting
  - Left/right or bilateral lung obstruction
  - Pulse strength
- Activity log
- Scenario builder / ECG sequence builder for your own training scenarios
- ECG Simulator as a stand alone training tool
- ECG rhythm recognition quiz
- VF recognition quiz
- CPR performance curves and evaluation

Link Box
- 3/4 lead ECG connectors for ECG training
- power in for the Laerdal ALS Skillmaster manikin
- Remote Control Interface

2. System Features

2.1. Manikin Features:

2.1.1 The head

Head tilt: If the head tilt angle is greater than 27 degrees, and Airway Obstruction is not activated, the airway valves will be open.

Jaw thrust: If jaw thrust is performed, and Airway Obstruction is not activated, the airway valves will be open.

Carotid pulse: When the manikin is used with the Heartsim 4000, a bilateral, palpable carotid pulse synchronous to the simulated ECG is generated, the pulse is alterable via the Heartsim 4000 for 3 strengths: Normal, Weak, Absent.

Care should be taken when palpating the carotid pulse so as not to use excessive force as this will result in no pulse being felt.

Laryngospasm:
The instructor can simulate laryngospasm by using the syringe next to the head.

2.1.2 Airways and lungs

The manikin contains two lungs with separate volume detection. Maximum volume per lung is 1000 ml.

The system is not developed to perform PEEP controlled ventilation.

Please note that thorough cleaning of the upper airways, as well as changing the lungs, is necessary if mouth-to-mouth or mouth-to-nose ventilation has been performed on the manikin. See sections 4.3, 4.5. and 4.6.

2.1.3 Intubation
The manikin is intubatable. The instructor can indicate that intubation has been performed. This will cause the airways to stay open, even if the head is tilted less than 27 degrees, and jaw thrust is not performed. If the manikin is intubated too deeply, the tube will pass into the right bronchus and cause only the right lung to be ventilated.

2.1.4 Airway obstruction
Airway obstruction can be induced from the Heartsim 4000. It will cause left/right or complete blocking of airways by shutting the magnetic valves that control air passage to each lung.

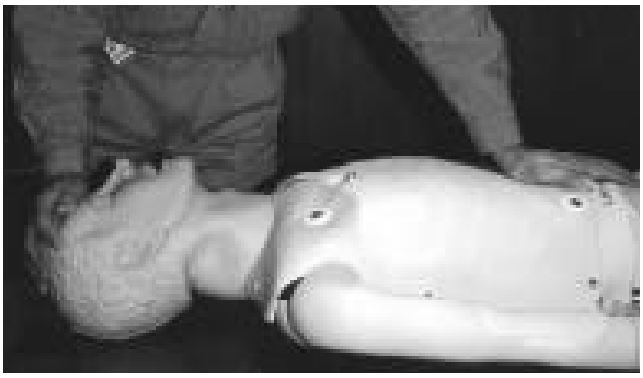
2.1.5 Opening and closing of airways
The airways are opened and closed by two magnetic airway valves located inside the manikin body.

The opening and closing of these valves are controlled through the following algorithm:

a) – If Airway Obstruction is introduced, the airways are closed, regardless of intubation, head tilt or jaw thrust.
   – If the airways are not obstructed, the ALS Skillmaster will check the next step.

b) – If the manikin is intubated, and this is indicated by the instructor on the Heartsim 4000, the airways are open, regardless of head tilt or jaw thrust.

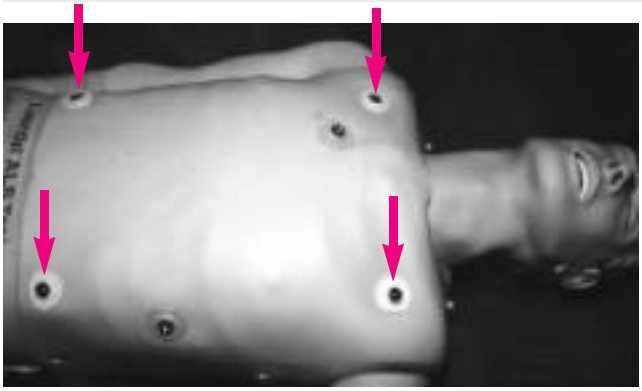
c) – If head tilt or jaw thrust is sufficient, the airways are open.
   – If head tilt or jaw thrust is not sufficient, the airways are closed.



2.1.6 Stomach
The manikin is equipped with a stomach, which will be distended at inspiratory pressures of more than 25 mm Hg, or if the manikin is ventilated after intubation into oesophagus. To expel the air after a stomach distention, place your hand on top of the manikin's stomach and press downwards.

2.1.7 Chest compressions
The manikin demonstrates the correct anatomical landmarks for external chest compressions.

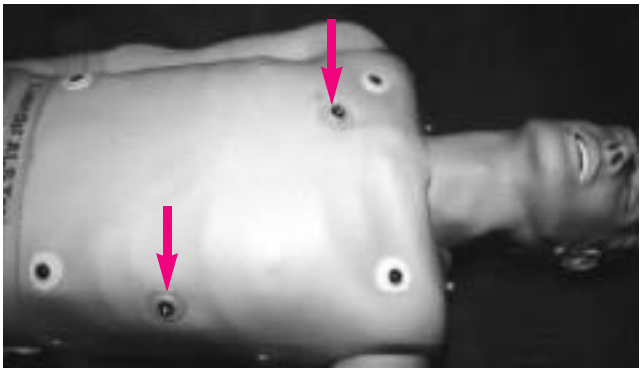
A very fast depression of the sternum with a depth of more than 2 mm will be recorded as a precordial thump.



2.1.8 ECG monitoring

The manikin is equipped with separate defibrillation and ECG monitoring connectors. The system provides 3 lead ECG reading (lead I, II, III).

Caution: These connectors are designed for ECG monitoring only. If defibrillation is attempted over any of the ECG connectors, it may cause high voltages to be present on one or more of the uncovered connectors during the shock. See the "Cautions and Warnings" section. Defibrillation attempt will also damage the internal electronics which may have to be replaced.



2.1.9 Defibrillation

The manikin is equipped with two defibrillation connectors. The ECG signal can also be monitored across these connectors. The instructor can via the Heartsim 4000 use the Ignore Defib function to choose whether or not the defibrillation shall result in conversion to a perfusing rhythm.

Manual paddle adapters are supplied for use with manual defibrillators.

Caution: Defibrillation must be performed over these two connectors only. See the "Cautions and Warnings" section on page 3.

2.1.10 Pacing

The manikin can be externally paced via the defibrillation connectors. The pacing threshold is variable and is set by the instructor via the Heartsim 4000.

2.1.11 Sound

The manikin can make 3 sounds controlled by the instructor via the Heartsim 4000:
- breathing
- moaning
- vomiting

2.1.12 Arms

Left Arm

In the left arm, standard catheters can be positioned in either of the three pre-made holes. The hole on the back of the hand is sealed, and needs to be pierced before first time use. This solution has been chosen to provide optimum liquid storage capacity in the arm for users who do not require using this hole.

Realistic drug dosages can be given. The left arm is a hollow reservoir that can collect injected fluid. After the training session, the arm can be dismounted and emptied through the drain plug located on the back of the shoulder.

The hole on the wrist allows simulated drawing of samples for blood gas analysis. This hole is also sealed when the manikin is new, and needs to be pierced before using it for the first time.

A blood pressure cuff can be positioned on the arm.

Right Arm

The right arm is a Laerdal IV Arm, which is also available separately (cat. No. 09 00 21).
There are two main IV access areas on the Laerdal IV Arm: On the back of the hand, and at the antecubital fossa (ACF) on the upper arm. To gain IV access in these two areas, specially designed soft pads can be placed in the recesses of these two locations.

The pads are pre-filled with blood and can be used for practice immediately after unpacking and assembly. There are two types of pads for the arm; one pad to fit onto the back of the hand, and one to fit into the antecubital fossa.

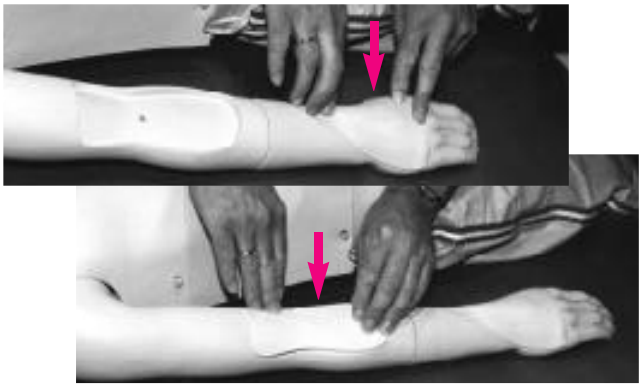
The hand can be turned 180 degrees from palm facing down to palm facing up to obtain the best position for IV access in the hand.

The shoulder link allows for upwards and sideways movement of the arm.

3.1. Assembling the manikin

Unpack the manikin and the arms from the case. Place the manikin on a surface and attach the arms to the shoulder attachments. Make sure that the arms are pushed into place before they are lowered

The procedure to put the IV pads in place is the same for both types of pads:



Unpack the pad from its carton. Snap the pad into place into the recess in the arm that has the shape corresponding to the pad

Fold up the lower part of the stomach skin and attach the lower body to the two pegs on the torso. Fold back the stomach skin and pull up the trouser waistband.

3.2. Connection to the Heartsim 4000

One lead into the manikin provides all power and data communication.

Unpack the Heartsim 4000 "Link" and connect this to the main power and the computer.

Connect the manikin lead to the "Link".

NB. Do not start the Heartsim 4000 program on the computer until all manikin or Link connections have been made.

4. Maintenance and Repair

A cleaning kit for the upper airways is included with the product. Spare lower airways, a stomach bag and a replacement IV pad of each type are also included.

Note: Wear gloves during cleaning. Vinyl gloves are recommended as latex gloves may stain the manikin skin.

4.1 Proper care of the Laerdal IV Arm

4.1.1 Maintenance tips

- When withdrawing a catheter from the pad, press a cotton or gauze pad over the point of venipuncture. This will limit the amount of blood stain on the skin of the pad.
- Use gloves when handling the IV Arm. This will reduce the risk of staining the pads.
- To remove stains from simulated blood on the pads, wipe the pads in lukewarm water and allow them to dry.

4.1.2 Refilling pads with simulated blood

The artificial skin and veins are designed to self-seal after withdrawal of a needle or catheter. However, since the volume inside the enclosed veins is limited, it is sometimes necessary to replace blood that is lost during practice or when "flash back" is insufficient. A 250 ml bottle of simulated blood is enclosed with each Laerdal IV Arm. Simply fill a syringe with up to 1 ml of blood, and inject it carefully into any vein in the pad. This is best done after a successful cannulation before the removal of the cannula, to ensure that the blood enters the veins and not the surrounding "tissue". Be careful not to inject too much blood into the veins at once, since this will cause excessive pressure, leading to leakage of blood out through previous punctures in the veins.

Apart from simple refilling, this technique can be used to simulate various degrees of blood pressure.

4.1.3 Replacing pads

To replace a pad, first use the flat tool enclosed in the pack of the new pad to remove the old pad. Snap the new pad into the recess.

4.2 Opening the manikin

Lift up the edge of the skin on the side of the manikin. Unsnap the clips connecting the rib piece to the back portion. When all four clips have been loosened, carefully lift up the chest and fold it to the manikin's right side.

4.3 Replacing lungs

Pull out the stomach pad and stomach plate.

Unsnap the lung straps on either side of the chest plate and lift the chest plate up from its base.

Disconnect the plastic tubes from the lower end of the magnetic airway valves.

Loosen the plastic lungs from the chest plate by pushing the tubes from below upward through the holes in the chest plate. Lift off the lungs and pull the tubes through the chest plate.

Unpack the new lung set and guide the lung straps through the circular hole in the lungs. Note the colour marked on the tube, and insert the tubes into the holes marked with the same colour on the chest plate. Snap the lungs in place on the chest plate. Check with the illustration to make sure the lungs are correctly positioned, and not mounted upside down.

Connect the ends of the plastic tubes to the lower ends of the airway valves, so that the colour markings on the tubes and on the valves match.

Position the lung plate back into its base.

Snap the lung straps back in place on both sides of the chest plate.

4.4 Replacing stomach

Disconnect the lower stomach tube from the lower end of the stomach valve. Undo the stomach bag by pushing the stomach tube from below upward through the hole in the stomach plate. Pull the tube up through the stomach plate.

Unpack the new stomach. Insert the tube down through the hole in the stomach plate and reconnect it to the stomach valve. Snap the stomach bag in place on the stomach plate.

To reposition the stomach plate, insert the peg at the upper end of the stomach plate into the slot under the chest plate, and then snap the lower end in place over the two steel pins.

4.5 Cleaning upper airways

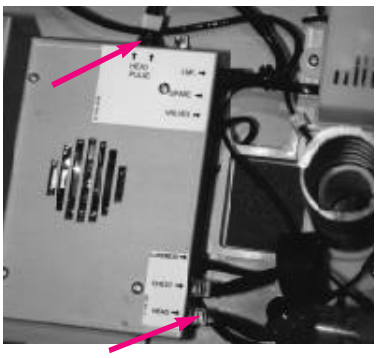
The head must be removed in order to clean the upper airways. First of all, open the manikin as described in section 4.2.

Disconnect the upper airway tubes from the airway valves.

Disconnect the stomach tube from the thick, transparent oesophageal tube.

Disconnect the thin tube connecting to the Y-piece in the neck.

Disconnect the cables from the sockets marked "Head" and "Head Pulse" (2) on the lower box inside the body.



Gently turn the head around until it releases from the circular socket in the torso shell.

Place the trainer's head face down, diagonally in the plastic sanitation kit container filled with liquid to a point just over the internal ridge. Attach stomach and lung connectors to the triple connector of the cleaning pump assembly.

Put the free tube end into the container. Insert the cleaning syringe into the opening of the valve. Circulate liquid through the airways by pumping the syringe plunger.

** A sodium hypochlorite solution prepared for single class use, is an effective and recommended disinfectant. This solution should have at least 500 ppm free available chlorine, i.e. >22 ml of 2.5 –5.0% household bleach per 500 ml of water.*

Use this setup to go through the following four steps, changing liquid in the container for each new step:

1. Use soapy water to remove condensation on interior surfaces.
2. Use clean water to remove soap residue.
3. Use disinfecting solution*. Allow airways to remain completely filled for at least 10 minutes.
4. Use clean water to remove disinfecting solution.

After each step lift the face clear of the liquid to allow drainage.

Allow to dry completely before reconnecting head to manikin.

4.6 Cleaning airway valves

Disconnect the upper and lower airway tubes from each of the valves. Turn the valve houses and lift out of their bases. Clean the valve houses using the 4 steps described in section 4.5, and allow to dry completely before placing them back in their bases.

5. Technical Data

Supply voltage

Supply voltage Link:	100-240 VAC 50/60 Hz
Supply voltage Manikin:	9 VDC 2A max

Physical dimensions

Body, without legs and arms

Dimensions:	80 x 40 cm (31 1/2 in. x 15 3/4 in.)
Weight:	11.6 kg (25 1/2 lbs)

With legs and arms

Dimensions:	173 x 55 cm (68 1/8 in. x 21 5/8 in.)
Weight::	15.8 kg (35 lbs)

Defibrillation/monitor electrodes

Max. defibrillation voltage:	5000 V
Max. energy per shock:	360 J
Max. average energy per minute:	720 J (2 shocks per minute)
Min. energy per shock for defibrillation detection on defibrillation electrodes:	10 J
Pacing detection:	20 - 200 mA

Environmental conditions

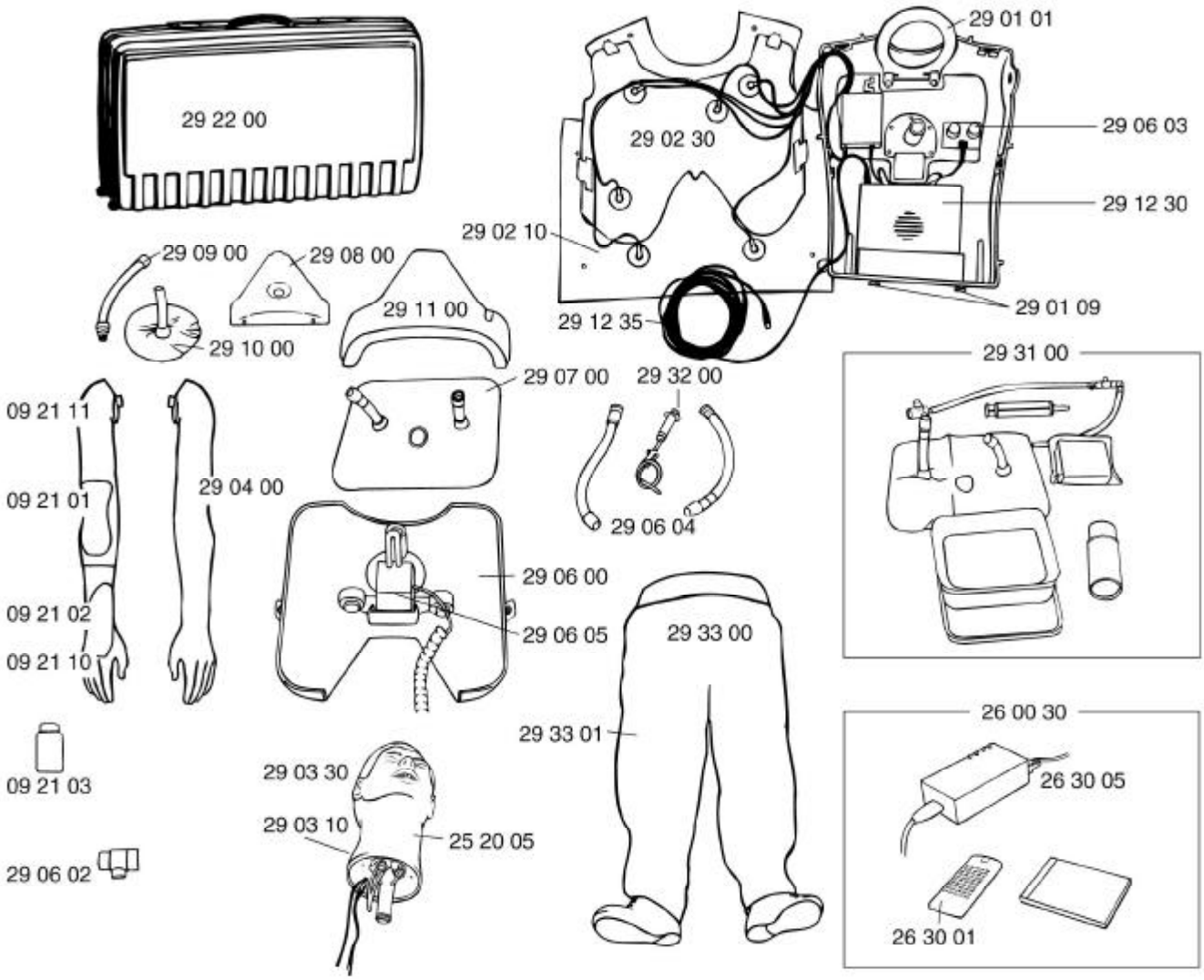
Temperature

Operating:	15°C - 35°C (59°F - 95°F)
Storage:	0°C - 50°C (32°F - 122°F)
Humidity:	15 - 90% RH (non-condensing)

The serial number of each ALS Skillmaster is imprinted in the bottom plate of the torso, on the outer side, facing the lower body.

CE The product is in compliance with essential requirements of council directive 89/366/EEC; EMC-directive.

6. Parts list



29 00 11 ALS Skillmaster manikin

Parts

29 01 01 Head-to-body coupling with head fastener and screws
29 01 09 Retainer set f/lower body
29 02 10 Chest skin ALS, no electronics
29 02 30 Chest skin with 4-lead ECG & loadbox ALS Skillmaster
29 03 10 Neck w/pulse units
29 03 30 Head cpl. ALS Skillmaster
29 06 00 Lung plate with screws
29 06 02 Airway valve housing
29 06 03 Airway valve base
29 06 04 Upper airway tubes (pair)
29 06 05 Comp./vent. sensor unit and plate
29 07 00 Lungs
29 08 00 Stomach plate
29 09 00 Esophageal tube with stomach valve
29 10 00 Stomach
29 11 00 Stomach pad
29 12 30 UMR cpl. w/electronics
29 12 35 Cable ALS to link box
29 31 00 Sanitation kit for upper airways/head
29 32 00 Laryngospasm syringe and tube without Y-piece
29 33 00 Lower body
29 33 01 Trousers
29 04 00 Left arm
09 21 10 IV hand
09 21 11 IV upper arm
09 21 01 Upper arm replacement pad
09 21 02 Hand replacement pad
09 21 03 Simulated blood
25 20 05 Head skin & airways, cpl. w/teeth
29 18 30 Directions for use
29 22 00 Carrying case, ALS trainer

Accessories

26 00 30 Heartsim 4000 cpl.
26 30 01 Remote control
26 30 05 Link box
26 30 20 Heartrhythm CD ROM

Product specifications are subject to change without notice.

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