

SimMan

Important Product Information



English

SimMan - Important Information

Instructions

Read these instructions thoroughly. Observe all warnings, cautions and instructions in the User Guide and in this Important Product Information (IPI) booklet. This IPI applies to the following SimMan products: SimMan 3G, SimMan 3G PLUS, SimMan Essential, SimMan Essential Bleeding, SimMan Crtical Care (Articulated + Lifeshock: Articulated + Defib. skin: Drug Arm + Lifeshock: Drug Arm + Defib skin), SimManTrauma.

Unless otherwise specified, the information contained will apply to all product configurations.

Retain this booklet for future reference.

Marning

A warning states a condition, hazard, or unsafe practice that can result in serious personal injury or death.

M Caution

A caution states a condition, hazard, or unsafe. practice that can result in minor personal injury or damage to the product.



A note states important information about the product or its operation.

Disclaimer

Use of the Patient Simulator system to train personnel should be done under the supervision of suitably trained medical personnel with an understanding of educational principles and recognized medical protocols.

As with all Patient Simulators, there may be approximations, variations, and inaccuracies in anatomical features and the physiological modeling. As such, Laerdal Medical does not guarantee that all features are completely accurate.

The medical equipment and simulated medical equipment included in the product might be modified and should be used for training purposes only.

General simulator handling

It is important to follow the instructions below, as well as other available User Information, in order to maintain optimum performance and longevity of the simulator components.

Mwarnings

- Do not use additional or subplemental oxygen that would increase O. concentration above 21% during artificial respiration and ventilation.
- · Do not use any flammable or corrosive gases.

↑ Cautions

- · Do not introduce fluids into or onto the Patient Simulator (except as directed in the User Guide) as this may damage the Patient Simulator and its components.
- · Do not introduce humidified air into the system during ventilation.
- · Never perform mouth-to-mouth or mouthto-nose rescue breathing on the Patient Simulator. The Patient Simulator's airways are not designed for cleaning or disinfection.
- · Do not use the Patient Simulator if the internal tubing and cabling is disconnected.
- · Do not store or use this product outside its specified operating and storage conditions.
- · Ensure that no liquid leaks into the arms during IO procedures (except as specified in the User Guide), as this may damage the electronics and cause a malfunction.
- · Do not store the simulator with fluid in the IV Arm, Fluid, or Blood Systems,

Note

· When used in a humid environment, some drops of water may leak from the manikin's right lower leg during startup and shutdown.This is normal and does not require assistance.

Defibrillation hazards

The Patient Simulator allows for defibrillation in accordance with AHA 2020 international guidelines for CPR.

A conventional defibrillator may be used on the Patient Simulator. During live defibrillation, the defibrillator and Patient Simulator may present a shock hazard. All standard safety precautions must be taken when using a defibrillator on the Patient Simulator. For more information, consult your defibrillator's User Guide.

Marnings

- Do not defibrillate the Patient Simulator when it is OFF or if it is not functioning normally.
- Do not defibrillate the Patient Simulator without the torso skin.
- The Patient Simulator torso must always be kept dry. Allow the Patient Simulator to acclimate before defibrillating.
- · DO NOT use outdoors in wet conditions.
- Do not spill fluids on the defibrillator plates.
 Wet defibrillator plates may lead to a shock hazard during defibrillation of the simulator.
- Allow the Patient Simulator to acclimate before defibrillating. Sudden changes in temperature (moving the Patient Simulator from a cold environment to a warm environment and vice versa) may result in condensation collecting on the base board and pose a shock hazard.
- Defibrillation must be performed on the defibrillator connectors only.
- The Patient Simulator must not come into contact with electrically conductive surfaces or objects during defibrillation.
- Do not defibrillate the Patient Simulator in a flammable or oxygen enriched atmosphere.
- The ECG connectors are designed exclusively for ECG monitoring and must not be used for defibrillation. Defibrillation on the ECG connectors will damage the internal electronics of the Patient Simulator and may cause personal injury.

⚠ Cautions

- Using a defibrillator in temperatures over 35 °C (95 °F) may cause overheating and shutdown. If automatic shutdown occurs, allow the Patient Simulator to cool down before resuming the training session.
 Open the torso skin to speed up the cooling brocess.
- To prevent torso skin electrode pitting, do not apply conductive gel or conductive defibrillation pads intended for patient use.

Note

 Electrical arcing may occur during defibril lation. This happens when the pads are not stuck properly to the manikin, the gel can become overheated and produce a strong smell. This is not harmful to the user or the product.

Battery

∆Warnings

- Inserting and connecting batteries incorrectly, short circuiting or exposure to fluids pose an explosion hazard.
- Do not mistreat, disassemble or attempt to repair the battery.
- Do not use the batteries if they are visibly damaged, malfunction, or appear to leak electrolyte.
- Take extreme care to avoid direct contact with electrolyte, hot or smoking parts. In case of the above, disconnect and remove the battery when it is judged safe to do so.
- Only use the SimMan Family (except SimMan ALS) external power supply and batteries.
- The external battery charger is for indoor use only.
- · Never store empty batteries.
- Don't store fully charged batteries for longer than a month. Disconnect the batteries from Patient Simulator if stored for months.
- The batteries should only be charged and used at the specified temperature ranges.

⚠ Cautions

- Do not run the Patient Simulator for more than 1 minute on a single battery.
- After the Patient Simulator is turned off, wait 20 seconds before restarting or the Patient Simulator may not function properly.

For other battery related information, consult the user guide.

Waste Handling

Recycle and dispose of the product in accordance with your country's recommendations.

By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product.

For more detailed information about treatment, recovery and recycling of this product, contact your local waste disposal service or local governmental office for waste management.

Battery

This Patient Simulator is operated on a Lithium-ion battery. Lithium-ion batteries should be recycled or disposed of in accordance with local regulations.

Symbol glossary

Symbol glossary		
CE	CE mark	
	Korean Certification (KC) Mark	
&	Australia Radiocommunications and EMC Compliance Mark	
X	Waste Electrical and Electronic Equipment symbol	
***	Manufacturer	
~	Date of manufacture	
REF	Reference Number	
SN	Serial Number	
Li-lon	Li-ion batteries recycling symbol	

Warranty

Refer to the Laerdal Global Warranty for terms and conditions. For more information visit www.laerdal.com

USA Federal Communications Commission (FCC) and Industry Canada (IC) Statements

FCCID: OHQ-212-00001(Drug Arm only)

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

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

⚠ Caution:

Changes or modifications not expressly approved by Laerdal Medical could void the user's authority to operate the equipment.

For SimMan 3G, SimMan 3G PLUS, SimMan Essential, SimMan Essential Bleeding and SimMan Trauma:

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.

Canadian ICES-003 Statement

This Class B digital apparatus complies with Canadian ICES-003(B)/NMB-003(B).

Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.

For SimMan Critical Care:

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Canadian ICES-003 Statement

This Class A digital apparatus complies with Canadian ICES-003(A)/NMB-003(A).

Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada

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CF statement

The product is in compliance with Council Directive 2011/65/EU on restriction of the use of certain hazardous substances (RoHS).

For SimMan manikins with Articulated Arm:

The product is in compliance with the essential requirements of Council Directive 2014/30/EU on electromagnetic compatibility (EMC), and the product is in compliance with cyber security requirements of Radio Equipment Directive (RED) Article 3.3.

For SimMan manikins with Drug Arm (RFID):

The product is in compliance with the essential requirements of Council Directive

Korean Certification

MSIP-CMI-LMQ-SM3G (SimMan 3G/ Essential/Essential Bleeding/Trauma) R-R-Lm1-212-03350 (SimMan 3G PLUS) R-R-Lm1-SimManCC (SimMan Critical Care)

SimMan specificati	on
Size and Weight	
Dimensions (Patient Simulator only)	1800 mm (I) × 550 mm (b) chest (5.90 ft × 1.80 ft)
Weight (Patient Simulator only)	38.5 kg (85 lbs)
Weight (with clothes)	40 kg (88 lbs)
Patient Simulator	Power
External power	Input voltage 24 VDC, 6.25A
Internal batteries (two)	Each 14.8V, 4.6Ah, Lithium-ion
Air & CO ₂ Pressi	ure
Internal air tank	Max 0.9 bar
External air connection	Max 1.4 bar
External CO ₂ to Patient Simulator	Max 1.4 bar
Temperature Lim	its
Operating temperatures	+4 °C to 40 °C (39 °F to 104 °F)
Storage temperatures	-15 °C to 50 °C (5 °F to 122 °F)
SimMan Critical (Temperature Lim	
Operating temperatures	+4 °C to 30 °C (39 °F to 86 °F)

(39 °F to 86 °F) -15 °C to 50 °C

(5 °F to 122 °F)

Storage temperatures

Environment - Patient Simulator Only				
Relative humidity	20% - 90% (non-condensing)			
Not tested with salt spray				
RF Communication (Optional)				
Wi-Fi communication is done by separate Wi-Fi dongle. (Cat no.212-77455) Reference info for the Wi-Fi dongle can be				
found here.*				

- 2.4 GHz WLAN, channels 1-11
- 5GHz WLAN, channels 36, 40, 44, and 48
100 m (300 ft) outdoors
13.56 MHz
< 0.2 m

Material Chart for Patient Simulator		
Clothes	Cotton, Nylon	
Skins (general) and airways	PVC (DEHP free)	
Arm skin (articulated arm)	Silicone	
External hard plastics	PP, PA, PC, PC/PET	
Material Chart for Patient Simulator		
Inner plastics	Silicone,TPU,TPE, PVC, Nitrile PA, PA+GF, PC, ABS, POM, HDPE, PET, PTFE	
Metal components	Aluminum, Brass, Steel	
Head skin		
SimMan 3G	PVC (DEHP free)	
SimMan 3G PLUS	Silicone	
SimMan Essential	PVC (DEHP free)	
SimMan Essential Bleeding	PVC (DEHP free)	
SimMan Critical Care	Silicone	
SimMan Trauma	Silicone	

Recommended Hardware Specifications https://laerdal.mysite.com/HelpCenter/s/article/Will-there-be-a-compatibility-ma-trix-to-help-identify-if-the-hardware-is-compatible-with-LLEAP

Acceptable Fluids for Patient Simulator				
Cleaning fluids blood and fluid ystem)	Distilled water or de-ionized water			
Cleaning fluids	60-70% isopropanol			
Simulated IV fluids				
imulated IV fluids	Distilled water or de-ionized water			

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