PORTABLE SUCTION EQUIPMENT FOR HOMECARE AND HOSPITAL USE 230V AC

DESCRIPTION AND INTENDED USE

This suction pump DOMI AC from Siem nova is a quality suction pump that combines easy handling and cleaning with safety features to ensure optimal operation. The DOMI AC suction pumps are indicated for aspiration and removal of secretions, body fluids and foreign objects especially from a patient's air way. It could be a respiratory support system in the nasal, pharyngeal and tracheal areas of pediatric and adult patients.

The suction pump is suitable for use at home and in the hospital

The DOMI AC suction pump is indicated to clear the airways either through the nose, mouth or tracheostomy tube.

ASPIRATOR FOR UNOBSTRUCTION, a device suitable for use in patients who, as a result of serious illnesses and/or following trauma, manifest stagnation of secretions and have difficulty expectorating due to reduced voluntary muscle control.



INTENDED USERS

The DOMI AC should only be operated by properly instructed users.

SERVICE LIFE

The service life of the device is five years.

COMPLIANCE

ELECTRICAL SURGICAL ASPIRATOR DOMI AC is in compliance with DDM 93/42 CEE (D.Lgs. 46/97) and following updates and integrations (2007/47/CE)

GMDN: 36777 - BD/RDM: 1571592 CND: Z120105)



CE0051

Technical informations:

| Dimensions (h x w x l): | 200 x 150 x 300 mm (7.8 x 6 x 11.8 inches) |
|--------------------------------------|---|
| Voltage: | 230 VAC; 50 Hz; 130 VA (other voltages available on request) |
| Operating cycle: | continuous |
| flow rate (before the filter): | > 30 litres/minute (± 10 %) |
| Standard Canister volume: | 1000 ml |
| weight (without canister): | 2.1 kg / 4.5 lbs approx |
| max. vacuum level: | – 650 mmHg / – 80 kPa- 0,8bar (± 10 %) |
| Operation noise level 1mt: | < 45 dBa |
| CEI EN60601-1 Classification: | Class II device (when connected with AC/DC Adapter). Device with internal electrical poer surge (when used with battery) Applied part type BF Device not suitable for use in presence of flameable anaesthetic mixture with air, oxygen or nitrogen protoxid. |
| DDM 93/42 CEE Classification: | - Class II a |
| UNI EN ISO10079-1 Classification: | - Equipment with HIGH VACUUM level and HIGH FLOW |

SIEM - NOVA SRL is proud to produce surgical aspirators in ALLUMINIUM, one of the greenest materials on the planet, infinitely recyclable maintaining its qualities, environmentally sustainable, it is also non-magnetic and resists corrosion. Technical improvements can be made without prior notice, respecting safety and quality.

SIEM - NOVA SRL - 20089 ROZZANO (MI) - VIA VARALLI 1 (ITA) - Italy - IVA: IT11578000157 - REA MI -1478315 tel: +39 02 57510916 - fax: +39 02 57511879 - export@siemnova.com - info@siemnova.com - www.siemnova.com

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The package contains:

| quantity | description | code |
|----------|---|-------|
| 1 | Suction pump DOMI AC (basic unit) | 66132 |
| 1 | Canister (available different models and capacity up to two liters) (code see above) | 60971 |
| 1 | Reusable policarbonate LID with: "V" Gasket (code 60821) over flow valve with gasket and floater (code 60816) Yellow rubber cap (code 60825) | 60815 |
| 2 | Yellow silicone rubber stripes for fixing the canisters | 66600 |
| 1 | Hydrophobic and antibacterial filter 11x11mm | 66974 |
| 1 | Hydrophobic filter "LIQUID STOP" | 66609 |
| 1 | Suction tube (VACUUM) with two 90° hose 1 L jar (yellow silicone rubber) (code 60819) | 66601 |
| 1 | Patient Tube (PATIENT) with hose F and FM (sterile) | 94139 |
| 1 | Power cord | 66611 |
| 1 | Operating manual | |

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COMPLIANCE:

EN ISO 14971:2012: Medical devices - Application of risk management to medical devices

EN 60601-1:2006+AM1(2013): Medical electrical equipment Part.1:General requirements for basic safety and essential performance.

EN 60601-1-12:2015 (First Edition) for use in conjunction with IEC 60601-1:2005 (Third Edition) + A1:2012: Part 1-12:General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment.

EN 60601-1-11:2015 (Second Edition) for use in conjunction with IEC 60601-1:2012 (Third Edition) + A1:2012: Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

EN 60601-1-6:2010: Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability.

EN 62366:2008: Medical devices - Application of usability engineering to medical devices.

EN 1789:2008+A2:2014: Medical vehicles and their equipment - Road ambulances.

EN ISO 10079-1:2015: Medical suction equipment – Electrically powered suction equipment.

EN 980 (2008); EN ISO 15223-1 (2012); EN 1041 (2008); EN ISO 13485 (2012); EN ISO 10993-1 (2009).

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