



LUISA[®]

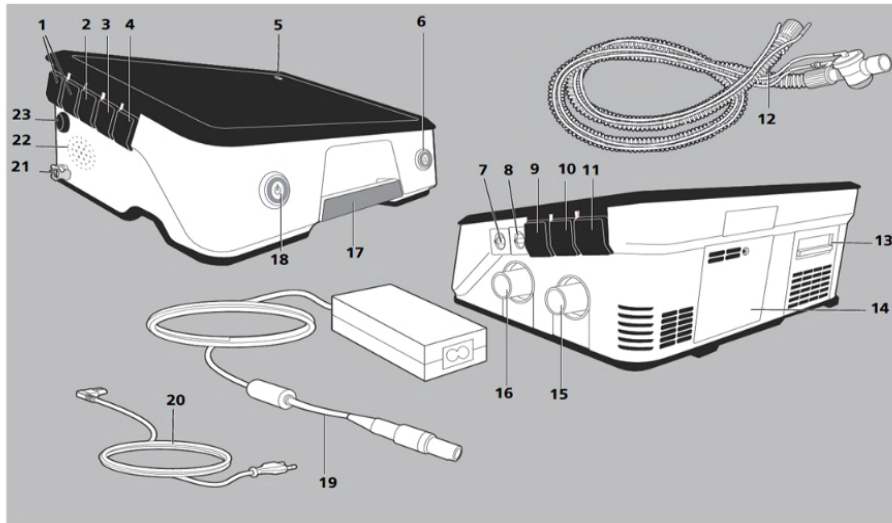
Life Supporting Ventilation
with High Flow Oxygen Therapy



LUISA[®] Quick Start Guide

FOR PATIENTS OR CAREGIVERS

LUISA® Device Overview

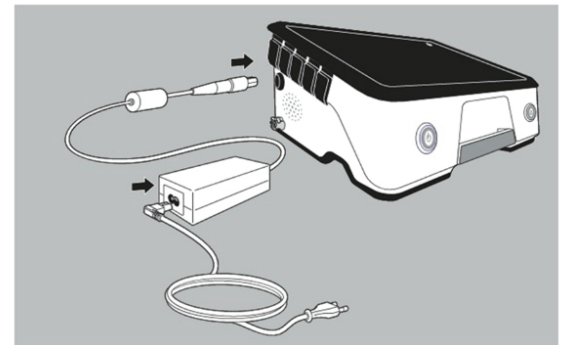


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|---------------------------------|---|---------------------------------|
| 1 External battery connection | 9 SpO2 connection | 17 Handle |
| 2 Connection for monitor/prisma | 10 CO2 connection (not in use) | 18 On/off key |
| 3 USB-C connection | 11 Nebulizer connection (not in use) | 19 Power supply unit |
| 4 Nurse call system connection | 12 Circuit | 20 Power cable |
| 5 Power supply indicator | 13 Filter compartment with dust filters | 21 O2 supply connection |
| 6 Alarm acknowledgement key | 14 Compartment for internal battery | 22 Loudspeaker |
| 7 Pressure measuring connection | 15 Exhalation circuit connection | 23 Power supply unit connection |
| 8 Valve control tube connection | 16 Device outlet port | |

■ Plugging In

LUISA® can be powered by plugging into an outlet or via an internal battery; a fully charged battery can last up to 6 hours.

To plug the device into an outlet for power, connect the power supply cord into the connection on device and the cord into an outlet



■ Turning LUISA® On

- Press the On/Off button
- Once On, the device automatically performs a few function tests and then the start screen is displayed



ON / OFF BUTTON

Starting Therapy | Ending Therapy | Mode Selection

Starting Therapy

Starting Therapy is completed by:

- 1 briefly pressing the On/Off button OR
- 2 pressing the Start Therapy key in display



Ending Therapy

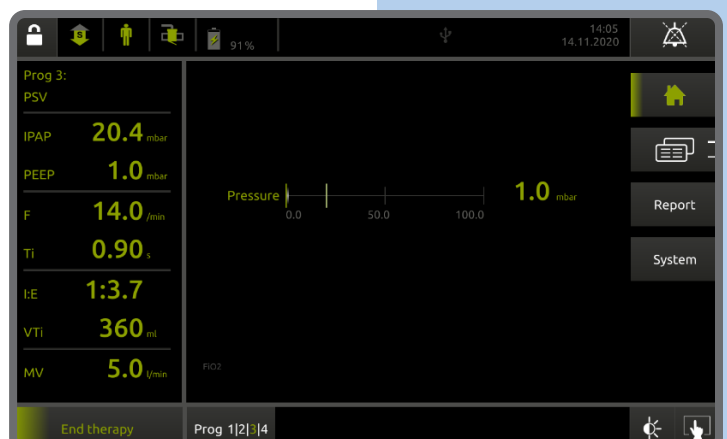
Ending Therapy is completed by:

- 1 holding the On/Off button long enough to allow the green progress bar to fill. Then confirm the end of therapy by pressing the On/Off button again OR
- 2 pressing End Therapy key in display long enough to allow the green progress bar to fill. Then confirm the end of therapy.



Mode Selection

The Program Selection key allows selection between the programmed modes of ventilation your physician has prescribed



■ Filter Changes

- The LUISA has 2 filters to keep dust and other particles out of the device. The filters are found at the back of the device.
- The fine filter (white) is closest to the machine and needs to be replaced monthly. Do not clean this filter.
- The coarse filter (black) needs to be rinsed and dried monthly and replaced every 6 months.



The LUISA has been authorized by the FDA under an EUA but has not been FDA cleared or approved. The LUISA is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. U.S. federal law restricts this device to sale by or on the order of a physician.