Atlan
A300, A300 XL, A350, A350 XL

Anesthesia workstation

Software 2.0n

Supplement

WARNING
To properly use this medical device, read and comply with the instructions for use and this supplement.

Dräger. Technology for Life®

Supplement to the instructions for use

Instructions for use	Part number	Edition
Atlan A300, A300 XL, A350, A350 XL SW 2.0n	9510601	1 – 2021-06

- Keep this supplement with the instructions for use.

This supplement updates the information of the instructions for use in the following chapters.

Safety-related information

The following section has been added:

Application-specific safety aspects in general anesthesia

The anesthesia workstation may only be used by persons who are familiar with the medical procedures of general anesthesia and anesthesia ventilation.

Users of this device must be aware of the clinical risks and side effects of general anesthesia and anesthesia ventilation.

Users must have particular knowledge of the following effects, side effects, and complications and be in a position to respond to these appropriately:

- Respiratory problems, including those involving various artificial airways (e.g., obstruction, dislocation)
- Side effects of mechanical ventilation, including oxygen therapy (e.g., pulmonary complications, cardiovascular depression)
- Interindividual and intraindividual variability in the effect and potential side effects of the anesthetic agents administered, depending on:
  - Dosage
  - Underlying and accompanying diseases
  - General condition of the patient
  - Demographic and other patient-specific factors

Safety instructions

Electromagnetic compatibility (EMC)

The following section has been changed:

Electromagnetic disturbances

Wireless communication devices (e.g., cellular phones) and medical electrical equipment (e.g., defibrillators, electrosurgical devices) emit electromagnetic radiation. When such devices are operated too close to this device or its cables, the functional integrity of this device may be compromised by electromagnetic disturbances. As a result, the patient could be put at risk.

- ► To ensure the essential performance of this device, maintain a distance of at least 0.3 m (1.0 ft) between this device and wireless communication devices such as DECT phones.
- ► To ensure the essential performance of this device, maintain a distance of at least 1 m (3.3 ft) between this device and medical electrical equipment which emits intense electromagnetic radiation such as defibrillators and electrosurgical devices.
- ► The functional integrity of the device must be closely monitored if the use of medical electrical equipment which emits intense electromagnetic radiation is necessary in the immediate vicinity of this device.

Magnetic fields can adversely affect the functional integrity of the medical device and thus put the patient or user at risk.

- ► Do not use the medical device in rooms where devices for magnetic field applications are used (e.g., magnetic resonance imaging).

The medical device meets the applicable limit values for electromagnetic fields. The functioning of pacemakers can nevertheless be impaired by emissions.

- ► Wearers of implanted devices (e.g., pacemakers) must observe the relevant instructions for use and comply with the minimum distances and information on other radiating devices specified therein.

Assembly and preparation

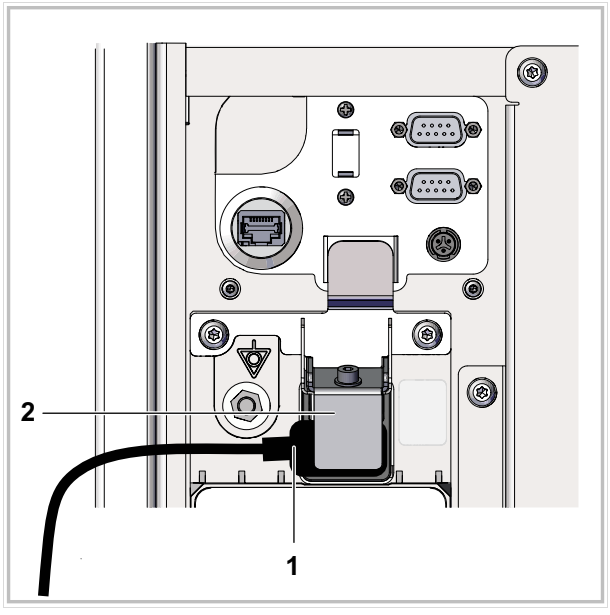
Before first operation

Establishing the mains power supply

The following section has been changed:

The mains voltage must correspond to the voltage range indicated on the rating plate on the rear of the device.

To facilitate getting started, the device is delivered with the power cable (1) already plugged in. To protect from inadvertent disconnection of the power cable, the power inlet of the device is secured with a guard plate (2).



55385

Getting started

Checking operational readiness

The following section has been changed:

Dräger recommends performing the system test every 24 hours. Otherwise, it will not be possible to ensure that the device is functional. To ensure that operation remains possible, the system test must be performed no later than 28 days after the last system test.

Tests

Status of the device functions

The following section has been changed:

Color	Meaning
Green	Successfully tested, fully available
Yellow	A non-critical fault has been detected or the last test result is older than 72 hours. The device can be operated with restricted function.
Red	A serious fault has been detected or the last test result is older than 28 days. Operation is not possible or is forbidden.
Gray	Not tested

Operation

Maneuvers

One-step recruitment

The following section has been added:

Under certain conditions, it is possible that the piston ventilator will not be in an ideal position for starting the maneuver. As a result, the build-up of pressure to the desired level may be temporarily interrupted by a required reverse movement of the piston ventilator.

Alarms

Alarm delay, alarm escalation, and alarm deescalation

The following section has been changed:

Ventilation alarms

Alarm	Priority Low	Priority Medium	Priority High
Inspiratory pressure not achieved	---	After 3 consecutive breaths	---

Technical data

The following sections have been changed:

Fresh-gas delivery

O_2 flow with integrated flowmeter

Resolution of displayed value	1 L/min (in the range from 2 to 10 L/min) 5 L/min (above 10 L/min)

Fresh-gas delivery with mechanically controlled gas mixer

Total flow tube

Range	Off to 10 L/min
Resolution of displayed value	0.5 L/min (in the range from 1 to 10 L/min)

Ventilator

Time-based settings

Ratio of inspiratory time to expiratory time I:E	
Accuracy	The inspiratory time for the ventilator is calculated based on the I:E and RR settings. The I:E accuracy results from the accuracy of the inspiratory time, see the information on Ti.

Volume-based and flow-based settings

Tidal volume VT	
Information	The applied tidal volume is automatically adjusted to compensate for the compliance of the breathing circuit. As soon as CO_2 respiratory phases are detected, the sample gas flow for the patient-gas measurement module is additionally compensated. With set values above 1400 mL, the specified accuracy can be reduced if a very long breathing circuit or a breathing circuit with a very high compliance is used.
Peak inspiratory flow	At least 180 L/min The actual peak flow can be greater and reach values of up to approx. 220 L/min. Results from the following set values: - VT and Ti in volume-controlled ventilation modes - Pinsp and Ti in pressure-controlled ventilation modes Applies for mains operation or in the first 5 minutes of battery operation with a fully charged battery. In other situations, the peak inspiratory flow may be restricted to 75 L/min.

Operating characteristics

Gas supply

Gas cylinders (dimensions)	
Diameter	100 to 140 mm (3.94 to 5.51 in) for versions with upright gas cylinders 100 to 110 mm (3.94 to 4.33 in) for versions with hanger yoke system for gas cylinders with pin-index connections

Noise emissions from device

Sound pressure L(A) of alarm tones at the user's operating location	
Acoustic alarm signal	
Alarm volume (all priorities)	Adjustable from ≥42 dB(A) to <80 dB(A)
Secondary acoustic alarm signal and mains power supply failure alarm	≥50 dB(A) and ≤80 dB(A)

EMC declaration

The following sections have been changed:

Electromagnetic environment

This device may only be used in environments specified in section "Environments of use" (see instructions for use).

Emissions	Compliance
Radiated emissions	Class A, group 1 (30 MHz to 1 GHz)
Conducted emissions	Class A, group 1 (150 kHz to 30 MHz)

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. The radiated emissions testing was conducted according to CISPR 16-2-3 as an alternate test method.

Immunity against	Test level and required electromagnetic environment
Electrostatic discharge (ESD) (IEC 61000-4-2)	Contact discharge: ±8 kV
	Air discharge: ±15 kV
Fast transient electrical disturbances (bursts) (IEC 61000-4-4)	Power cable: ±2 kV
	Signal input lines / output lines longer than 3 m (10 ft): ±1 kV
Impulse voltages (surges) (IEC 61000-4-5)	Voltage, line – line: ±1 kV
	Voltage, line – ground: ±2 kV
Magnetic fields at mains frequency (IEC 61000-4-8)	50/60 Hz: 30 A/m
Voltage dips and short interruptions in the supply voltage (IEC 61000-4-11)	Voltage dips at various phase angles according to the IEC 60601-1-2 standard
Radiated high-frequency disturbances (IEC 61000-4-3)	80 MHz to 2.7 GHz: 3 V/m
Conducted high-frequency disturbances (IEC 61000-4-6)	150 kHz to 80 MHz: 3 V, ISM bands: 6 V
Electromagnetic fields in the vicinity of wireless communication devices	Various frequencies were tested according to Table 9 of IEC 60601-1-2
Proximity magnetic fields (IEC 61000-4-39)	134.2 kHz: 65 A/m 13.56 MHz: 7.5 A/m

Recommended separation distances from wireless communication devices

For further information see: "Electromagnetic compatibility (EMC)", page 3.

Annex

Symbols

The following section has been changed:

Symbol	Explanation
	Warning of hot surfaces
	Manually screw or unscrew the pneumatic connection nozzles into/from the breathing system mount. The corresponding positions are indicated by arrows on the breathing system mount. For further information, please refer to the reprocessing instructions supplied with the product.

This page has been left blank intentionally.

This page has been left blank intentionally.

Manufacturer
Drägerwerk AG & Co. KGaA
Moislinger Allee 53 – 55
23542 Lübeck
Germany
+49 451 8 82-0

9512143 – en

Edition: 1 – 2022-09