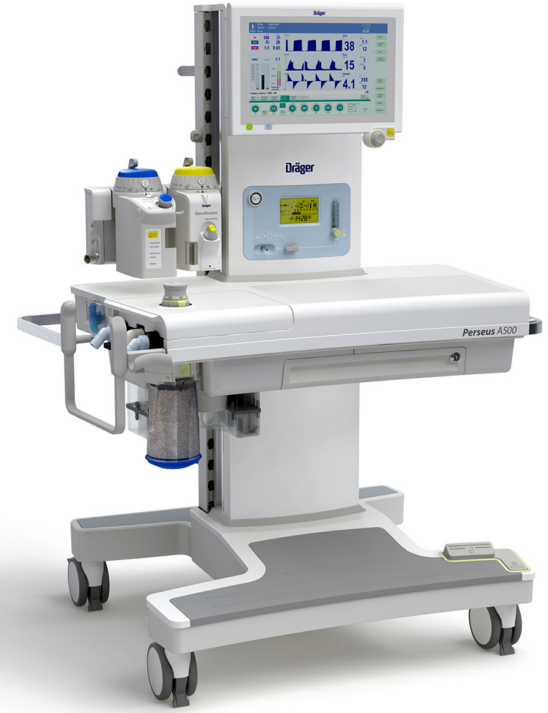
Supplement

# Perseus A500




**WARNING**

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

## Anesthesia workstation
## Software 2.0n

# Supplement to the instructions for use

| Instructions for use | Part number | Edition |
|---|---|---|
| Perseus A500 SW 2.0n | 9510595 | 3 – 2020-01 and higher |

- Keep this supplement with the instructions for use.

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

# For your safety and that of your patients

## General safety 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

### Mandatory reporting of incidents

Serious incidents with this product must be reported to Dräger and the responsible authorities.

## Product-specific safety information

The following section has been added:

**WARNING**

**Functional impairment of the device**

**If, in the event of an error, the startup screen shows that the device is not suitable for clinical use (*Not for Clinical Use!*), the device may no longer be used.**

**Turn off the device. Contact specialized service personnel.**

# Assembly and preparation

## Selecting and connecting patient-specific accessories

### Fitting the breathing circuit and the filters

The following section has been added:

If corresponding accessories of breathing circuits, bag elbow and breathing bag hose are used, the device meets the requirements of the ISO 80601-2-13:2022 standard. Misconnection of the breathing circuit and the breathing bag hose is thus prevented by design.

**WARNING**

**Danger due to incorrect connection of breathing circuit, breathing bag hose and breathing bag**

**If accessories which do not conform to the ISO 80601-2-13:2022 standard are used, the patient may be put at risk as a result.**

**Ensure that the breathing circuit, breathing bag hoses, and breathing bag are connected correctly.**

### Breathing bag

**Attaching the breathing bag**

The following section has been added:

**WARNING**

**Risk due to reversed connection of the breathing hoses**

**If an adapter is used to connect the breathing bag hose to the bag elbow, the breathing bag hose and breathing hoses can be mixed up when connected to the breathing system. As a result, the patient could be put at risk.**

**Do not use an adapter to connect the breathing bag hose.**

# Operation

## Change of patient

### Flushing the breathing system

The following section has been added:

For further information and recommendations for therapy settings for patients with suspected malignant hyperthermia, contact the responsible national Dräger organization. Further information is available at the following web page: www.draeger.com/mh

# Troubleshooting

## Alarm – Cause – Remedy

The following section has been added:

In the following example with 3 active alarm messages, the two ***etCO2 low*** and ***Minute volume low*** alarm messages with medium alarm priority (!!) are displayed above the ***O2 cylinder almost empty*** alarm message with low alarm priority (!). The sequence in which the two alarm messages with medium alarm priority (!!) are displayed is determined by the internal priority number. The ***etCO2 low*** alarm message with the higher priority number of 135 is therefore displayed above the ***Minute volume low*** alarm message with the priority number of 10.

| Alarm | Priority | | Screen display sequence |
|---|---|---|---|
| ***etCO2 low*** | !! | 135 | 1. |
| ***Minute volume low*** | !! | 10 | 2. |
| ***O2 cylinder almost empty*** | ! | 220 | 3. |

If several alarm messages have the same alarm priority and the same internal priority number, the newer alarm message is displayed above the older alarm message.

# Technical data

## Operating characteristics

The following section has been added:

**Declaration of hazardous substances in accordance with Regulation CLP 1272/2008 Annex VI Part 3**

Certain materials of this product contain the following substances in a proportion exceeding 0.1 % by mass:

– Lead (CAS No. 7439-92-1)

This product is safe to use for patients who are sensitive to the indicated substances.

Dräger is aware of the following residual risks:

– None

The following section has been changed:

**Noise emissions from device**

| | |
|---|---|
| Sound pressure level measured in accordance with IEC 60601-1-8 (measuring radius of 2 m) | |
| Average sound pressure level Leq(A) during ventilation with typical settings | ≤42 dB(A) |
| Sound pressure level of alarm tones | |
| Alarm tone sequence | |
| Alarm tone volumes (all priorities) | Adjustable from ≥45 dB(A) to ≤75 dB(A) |
| Secondary acoustic alarm signal | ≥55 dB(A) and ≤80 dB(A) |
| Mains power supply failure alarm | ≥55 dB(A) and ≤80 dB(A) |

The following information replaces the "Classification in compliance with Directive 93/42/EEC, Annex IX":

**Classification**

| | |
|---|---|
| Classification Medical Device Europe | Class II b |

## Connections to IT networks

The following section has been added:

### Information on the security level as per IEC 60601-4-5 standard

This device has been tested in accordance with the requirements of the IEC 60601-4-5 standard.

Further information on the security level achieved by this device and on measures that can increase the security level are available on the following web page: https://www.draeger.com/productsecurity

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# Annex

## Symbols

The following section has been added:

| Symbol | Explanation |
|---|---|
| MD | The product is a medical device (CE conformity assessment procedure) |
| | The product contains hazardous substances |

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