Supplement

Apollo

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

Anesthesia workstation Software 4.5n

Supplement to instructions for use

This supplement is to be used with the instructions for use for the medical devices in the table from SW 4.5n onwards.

Medical device	Part number	Edition
Apollo	9053586	3 – 2014-10 and higher

- Keep this supplement with the instructions for use of the medical device.

WARNING

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

The supplement updates the information of the instructions for use in the following chapters:

Introduction

General safety information

Accessories

This safety information has been changed:

Note: Strictly observe the instructions for use of all accessories such as:

- Water traps
- Flow sensors
- CLIC adapter
- CLIC absorber
- Soda lime
- Breathing hoses
- Masks
- Filters
- Endotracheal suction
- Vaporizer
- Manual resuscitator
- AGSS terminal unit
- SpO_2 sensors and connection cables

Product-specific safety information

This safety information has been added:

NOTE

If a humidifier is used, the following secondary effects may occur that affect ventilation of the patient:

– Possible impairment of flow measurement due to increased condensation.
– Increased water accumulation in the upper diaphragm of the ventilator.

Check the upper diaphragm on a daily basis and empty if necessary.

The text concerning functional safety has been changed as follows:

Essential performance

The essential performance consists of:

General

– Supplying the anesthesia workstation with O_2:
  If the O_2 supply (central supply or gas cylinder) fails, an alarm is issued.
– Supply of the patient with adequately oxygenated breathing gas:
  If the breathing gas contains insufficient levels of O_2, an alarm is issued.
– Patients are not supplied with excessively high anesthetic gas concentrations:
  If excessively high anesthetic gas concentrations are delivered, an alarm is issued.
– Monitoring the airway pressure and the expiratory minute volume:
  Alarms are issued depending on the set alarm limits.

Gas measurement

– Breathing gas monitoring:
  Measurement of the gas composition, accuracy as per ISO standard.
– Monitoring of breathing gas concentrations:
  If the specified alarm limits are exceeded or if the gas measurement fails, alarms will be generated.

The following text has been added:

Additional information

The Apollo is an inhalation anesthesia machine for use with:

– Adults
– Pediatric patients/children
– Neonates

in operating, induction, and recovery rooms.

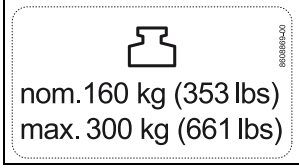
Symbols

The following symbol has been added to the table:

Symbol	Explanation
I O	Switch of the circuit breaker, On/Off

This chapter is new:

Product labels

Product label	Explanation
	Observe the weight of the nominal configuration and the permissible total weight, see "Specifications".

System Setup

Installing the breathing system and flow sensors

The following safety information has been changed:

WARNING
Risk of scavenger becoming blocked

Loose objects such as packaging material or protective foil may block the scavenger.

Make sure that the following locations are free of packaging material and foreign matter:
- **Area between the upper side of the ventilator and the underside of the breathing system (check this before seating the breathing system)**
- **Interior compartment behind the ventilator (check this before closing the ventilator drawer)**

Connecting the scavenger system

Connecting the anesthetic gas receiving system AGS (Optional)

The following safety information has been changed:

WARNING
Risk of scavenger becoming blocked

Loose objects such as packaging material or protective foil may block the scavenger.

Make sure that the following locations are free of packaging material and foreign matter:
- **Scavenging nozzle on Apollo**
- **Connections on the scavenger**

Connecting the patient system

Connecting the patient circuit

The specifications of the tidal volumes for adults and pediatric patients have been changed:

1 Select appropriate accessories for the relevant patient category.

	Adults		Pediatric patients	Neonates
Tidal volume	>700 mL	301 to 700 mL	50 to 300 mL	< 50mL
Breathing bag	3 L	2 L	1 L	0.5 L
Breathing circuit	Adults		Pediatric	Neonates (or pediatric)
Filters	Filter, HMEF, or HME			Use a filter with a low resistance and compliance.

Calculating the resistance of the breathing system and connected accessories

The specifications for the peak flows have been changed:

When calculating the resistance, only accessory resistance values and peak flows must be used that are applicable for the respective accessory category and patient category, e.g.,resistance values for adults at 30 L/min, for children at 15 L/min, or for neonates at 2.5 L/min.

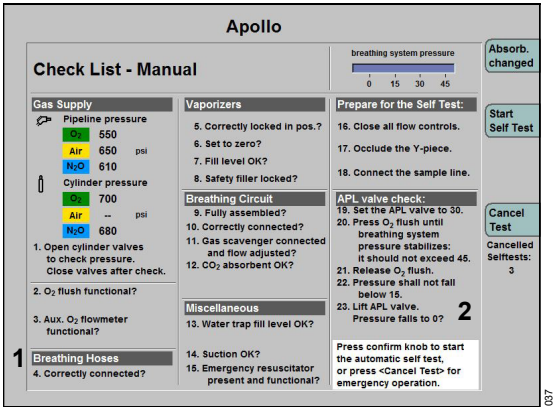
Pre-use Checkout

Checking the Workstation according to the Check List

The heading has been changed:

Check list - manual tests

Figure 37 has been changed:



The following test step (**1** in figure 37) has been added:

Check the correct connection of the breathing hoses:

Verify that the breathing hoses are correctly connected to the inspiratory port and expiratory port. For more information, see "Connecting the patient circuit" in chapter "System Setup".

Check the function of the APL valve:

The following test step (**2** in figure 37) has been added:

5. Lift the APL valve. The pressure must fall to almost 0.

   If the pressure does not fall to almost 0, perform the following:

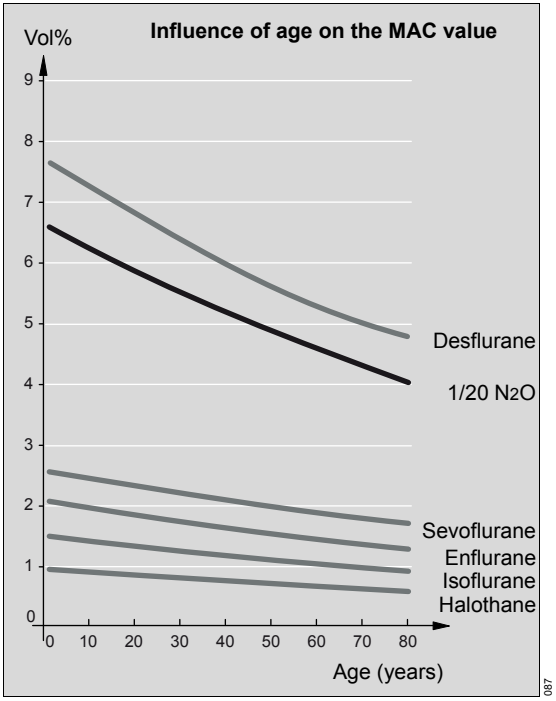
   – Make sure that the following locations are free of packaging material and foreign matter:
     – Area between the upper side of the ventilator and the underside of the breathing system (check this before seating the breathing system)
     – Interior compartment behind the ventilator (check this before closing the ventilator drawer)

   – Repeat test step 5.

Monitoring

Age-dependent MAC values

Figure 87 has been changed. The desflurane graph has been modified:



Screen timer

This text has been added:

The timer function is a stopwatch that can measure up to 99 minutes and 59 seconds. The timer function may only be used for processes related to anesthesia.

SpO2 measurement (Optional)

Selecting a sensor

This text has been added:

Observe the technical data in the instructions for use for the sensors and the connection cables.

Test considerations and oximeter accuracy

Functional testers and patient simulators

The text has been changed. The safety information has been removed:

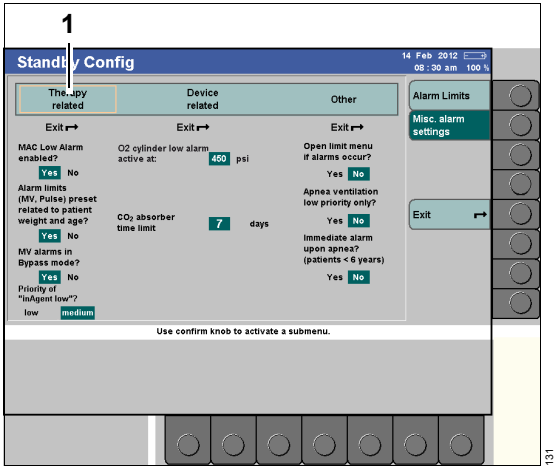
For functional testing of the pulse oximeter sensors and cables with a functional tester or patient simulator follow the individual testing device's operator's manual. Functional testers are not capable of assessing the measurement accuracy of pulse oximeter probes or pulse oximeter monitors.

Configuration

Setting alarm limits

Therapy related

Figure 131 has been changed and one row has been added to the table:



See **1** in Figure 131.

Therapy-related alarm limits	Factory setting
MAC Low Alarm enabled? : Yes/No	***Yes***
Alarm limits (MV, Pulse) preset related to patient weight and age? : Yes/No	***Yes***
MV alarms in Bypass mode? : Yes/No	***Yes***
Priority of "Agent (I) low"? : low/medium	***medium***[2)]

2) The factory setting for this alarm defines a higher alarm priority than specified in the standard ISO 80601-2-55.

Cleaning and Maintenance

Cleaning/Disinfection Objective and Methods

Machine cleaning and disinfection

This safety information has been added:

WARNING

Risk of device failure and patient injury

Impaired operation or device failure may result if the control areas in the valve plate are not dried completely.

Complete drying of the valve plate is required after cleaning and disinfection.

Sterilization

The following text has been added:

Sterilization rids semi-critical medical devices of living micro-organisms.

- Only sterilize cleaned and disinfected items.

For sterilization, use a vacuum steam sterilizer (conforming to DIN EN 285), preferably with fractionated vacuum.

Care list for Apollo components

The following table contents have been changed or added:

Component	Processing Method			
	Disinfection and cleaning			Sterilization in steam
	Cleaning/ disinfection machine 199°F (93°C) 10 minutes	Wiping	Disinfection by immersion	273°F (134°C) 8 minutes
Breathing system cover with APL valve	Yes	No	Yes	Yes
Center part of the breathing system (valve plate)	Yes[2)]	No	Yes[2)]	Yes
Lower part of the breathing system	Yes	No	Yes	Yes

2) Complete drying of the valve plate is required after cleaning and disinfection. Impaired operation or device failure may result if the control areas in the valve plate are not dried completely. To optimize the drying times, the control pressure ducts (for the PEEP valve and the APL bypass valve) can be sealed off. Suitable means can be obtained from DrägerService

Reassembling components

The following safety information has been changed:

WARNING

Risk of scavenger becoming blocked

Loose objects such as packaging material or protective foil may block the scavenger.

Make sure that the following locations are free of packaging material and foreign matter:

- **Area between the upper side of the ventilator and the underside of the breathing system (check this before seating the breathing system)**
- **Interior compartment behind the ventilator (check this before closing the ventilator drawer)**

Visual inspection

This safety information has been added:

CAUTION

Risk of patient injury

Missing or damaged valve plates may increase the rebreathing of gas.

- Make sure that the valve plates are present in the valve cages.
- The valve plates must not show any signs of damage.

Maintenance

Preventive maintenance

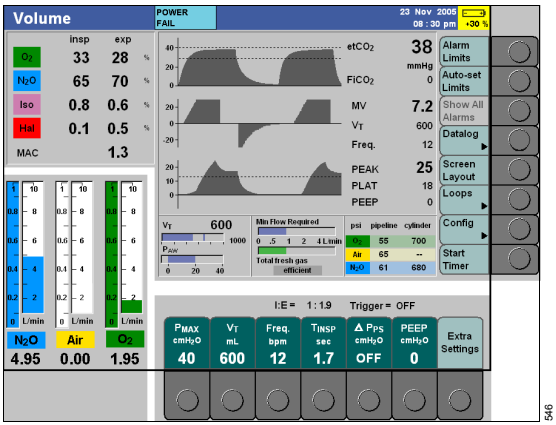
The interval for the flow sensor has been changed; the details for the bacterial filter have been added:

Component	Interval	Measure	Personnel responsible
Flow sensor	– As required. – When calibration is no longer possible	Replace	User
Bacterial filter in the sample gas return line	Every 2 years	Replace	Experts

Troubleshooting

Power failure

Figure 174 has been changed:



Fresh-gas delivery failure

The safety information has been changed:

WARNING

Risk of patient injury

If the fresh-gas mixer fails, the displayed fresh-gas bargraphs and values may be inaccurate.

Close N_2O and Air flow control valves. Check vaporizer setting. Set the O_2 flow to a sufficient level using the total flow meter.

Alarm - Cause - Remedy

The following alarms have been changed:

Priority	Message	Cause	Remedy
Note (1)	***GAS SENSOR FAIL***	Complete gas measurement system failure.	If the alarm occurs in standby mode after the selftest has been cancelled, wait for approx. 30 seconds. Use external gas measuring system. Call DrägerService.
Caution (7)	***O2 SENSOR FAIL***	O_2 sensor is spent or faulty.	If the alarm occurs in standby mode after the selftest has been cancelled, wait for approx. 30 seconds. If present, change the O_2 sensor. Ensure adequate substitution monitoring. Call DrägerService.
Advisory (7)	***POWER FAIL***	Power failure.	Restore power supply. Observe battery capacity. Prepare manual ventilation.
		Short-circuit in one of the devices connected to an auxiliary outlet.	Unplug appliance connector from auxiliary outlet. Restore power supply.

Priority	Message	Cause	Remedy
Caution (24) Warning (31)	***INSP HAL HIGH*** ***INSP ISO HIGH*** ***INSP ENF HIGH*** ***INSP DES HIGH*** ***INSP SEV HIGH***	Caution (24) = insp. MAC value >3 MAC for >180 seconds. Warning (31) = insp. MAC value >5 MAC Warning (31) = insp. MAC value >3 MAC and exp. MAC value >2.5 MAC for >30 seconds.	
		Inspiratory anesthetic gas concentration exceeds 5 MAC.	Check vaporizer and fresh-gas settings.
		Inspiratory anesthetic gas concentration exceeds 3 MAC for more than 180 seconds.	
		Inspiratory anesthetic gas concentration exceeds 3 MAC and the expiratory concentration exceeds 2.5 MAC for more than 30 seconds.	
		Caution (24) = insp. gas concentration > upper alarm limit for 0 to 180 seconds. Warning (31) = insp. gas concentration > upper alarm limit for >180 seconds.	
		Inspiratory anesthetic gas concentration exceeds the high alarm limit for at least two breaths.	Check vaporizer and fresh-gas settings.
Caution (15) or Advisory (10)	***INSP HAL LOW*** ***INSP ISO LOW*** ***INSP ENF LOW*** ***INSP DES LOW*** ***INSP SEV LOW***	Inspiratory anesthetic gas concentration has fallen short of the low alarm limit for at least two breaths.	Check vaporizer and fresh-gas setting. Check breathing system and breathing bag for large leaks. Check soda lime (dried out?)

The following alarms have been added:

Priority	Message	Cause	Remedy
Advisory (7)	***AGENT INACCURATE***	The accuracy of the gas measurement temporarily does not comply with the ISO standard.	If the alarm occurs after the self-test was cancelled, wait for about 3 minutes. Check the ambient conditions. Make sure that the ventilation slots on the rear of the device are not blocked. Check the functional integrity of the anesthetic gas receiving system (AGS). Contact DrägerService.
Advisory (7)	***CO2 INACCURATE***	The accuracy of the gas measurement temporarily does not comply with the ISO standard.	If the alarm occurs after the self-test was cancelled, wait for about 3 minutes. Check the ambient conditions. Make sure that the ventilation slots on the rear of the device are not blocked. Check the functional integrity of the anesthetic gas receiving system (AGS). Contact DrägerService.
Note (7)	***GAS SENSOR INACCURATE***	The accuracy of at least two parameters in the gas measurement temporarily does not conform to the ISO standard.	If the alarm occurs after the self test has been cancelled, wait for approx. 3 minutes. Check ambient conditions. Make sure that the ventilation slots on the rear of the device are not blocked. Check the proper functioning of the anesthetic gas receiving system (AGS). Contact DrägerService.

Priority	Message	Cause	Remedy
Advisory (7)	***N2O INACCURATE***	The accuracy of the gas measurement temporarily does not comply with the ISO standard.	If the alarm occurs after the self-test was cancelled, wait for about 3 minutes. Check the ambient conditions. Make sure that the ventilation slots on the rear of the device are not blocked. Check the functional integrity of the anesthetic gas receiving system (AGS). Contact DrägerService.
Advisory (7)	***O2 INACCURATE***	The accuracy of the gas measurement temporarily does not comply with the ISO standard.	If the alarm occurs after the self-test was cancelled, wait for about 3 minutes. Check the ambient conditions. Make sure that the ventilation slots on the rear of the device are not blocked. Check the functional integrity of the anesthetic gas receiving system (AGS). Contact DrägerService.

Specifications

Weight

The following data have been changed:

Nominal configuration	approx. 353 lbs (160 kg)
Permitted total weight	661 lbs (300 kg)

Operating data

The following data have been changed:

Operating voltage	100 to 127 VAC, 50-60 Hz, 12.4 A max.
Power input	
Maximum	1.5 kW
(with power consumption on auxiliary outlets)	
Auxiliary outlets	
Fuse of power outlet for desflurane vaporizer	T2AH, 250V, IEC 60127-2/V 5x20

Auxiliary O2 flow meter

The following data have been changed:

Fresh-gas flow	0 to 10 L/min
Accuracy of the flow display	±10 % of measured value in the range of 1 to 10 L/min

Breathing system

The following data have been changed:

Compliance (without breathing hoses and flexible arm (optional))

All values apply under STPD conditions:

In ***Man/Spont***	Typically 3.7 mL/hPa (3.7 mL/cmH_2O); which corresponds to 111 mL/hPa at 30 hPa (111 mL/cmH_2O at 30 cmH_2O)
During auto ventilation	Typically 2.3 mL/hPa (2.3 mL/cmH_2O); which corresponds to 69 mL/hPa at 30 hPa (69 mL/cmH_2O at 30 cmH_2O)

The specifications for the fill volumes for the absorber containers have been changed to mL:

Fill volume of absorber container

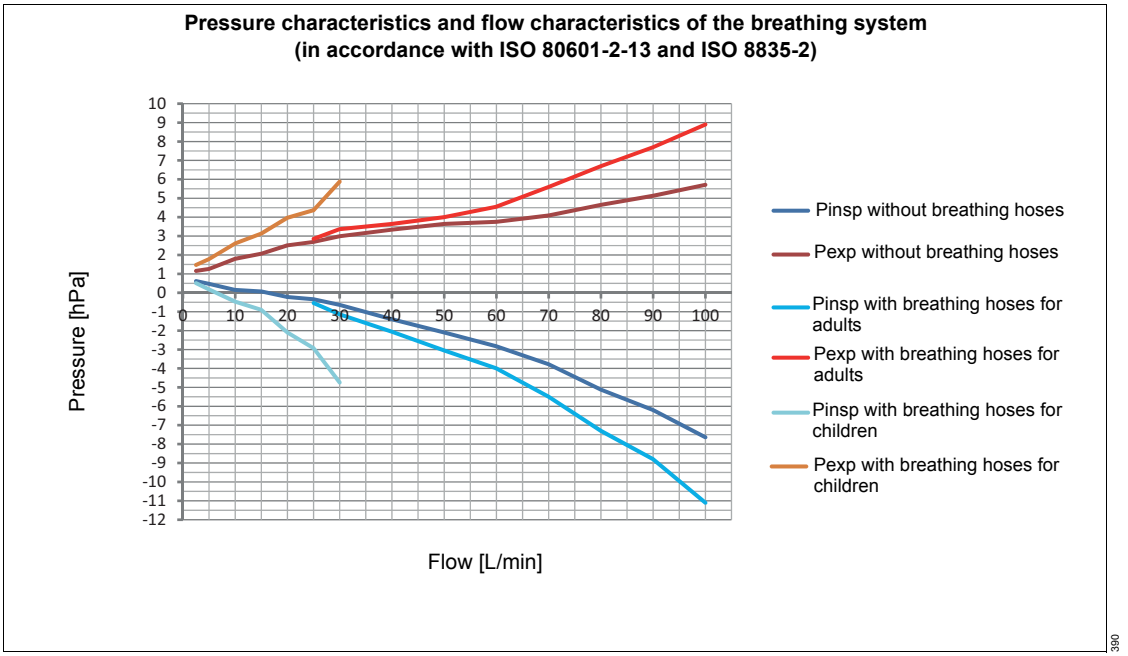
Reusable absorber canister, filled	1500 mL
CLIC Absorber (Drägersorb CLIC 800 Plus)	1200 mL
CLIC Absorber (Dräger CLIC Free)	1200 mL

The following data have been changed:

Resistance

	Peak flow [L/min]	Resistance [hPa (cmH_2O)] MAN / SPON	
		Inspiratory	Expiratory
In accordance with ISO 80601-2-13 and ISO 8835-2, dry, (at 60 L/min, a maxímum of ±6.0 hPa (cmH_2O)), with reusable hose set M30146 and CLIC absorber	60	–4.0	4.6
	30	–1.2	3.4
In accordance with ISO 80601-2-13 and ISO 8835-2, dry, with reusable hose set M27542 and CLIC absorber	15	–0.9	3.2
	2.5	0.5	1.5
In accordance with ISO 80601-2-13 and ISO 8835-2, with CLIC absorber, no hose set	60	–2.9	3.8
	30	–0.7	3.0
	15	0.1	2.1
	2.5	0.6	1.2

The following illustration has been changed:



Measuring systems

Pressure Measurement

The following data have been changed:

Central supply pressure

Range	0 to 142 psi (0 to 9.8 kPa x 100) (0 to 0.98 MPa)
Resolution of the display	1.5 psi (0.1 kPa x 100) (0.01 MPa)
Accuracy	±4 % or ±3 psi (±4 % or ±0.2 kPa x 100) (±4 % or ±0.02 MPa)

Cylinder pressure
(applies for Silverline pressure regulators)

Range	0 to 3600 psi (0 to 250 kPa x 100) (0 to 25 MPa)
Resolution of the display	14 psi (1 kPa x 100) (0.1 MPa)
Accuracy	±4 % or ±87 psi (±4 % or ±6 kPa x 100) (±4 % or 0.6 MPa)

EMC Declaration

Electromagnetic immunity

The following text has been added:

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.	
b)	The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
c)	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device (Apollo) is used exceeds the applicable compliance levels above, the device (Apollo) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device (Apollo).

Connections to IT-networks

Information on connecting to the IT-network

Serial ports

This safety information has been added:

Note: In the following cases, the operating organization or the system manufacturer is responsible for any undesirable effect resulting from the use of the serial interface to transfer data via MEDIBUS or MEDIBUS.X:

- Establishing a connection with another device
- Establishing a connection with a network (e.g., LAN, WLAN) or other systems (e.g., PDMS)

During operation, the alarms and displays of the anesthesia workstation are crucial and must be observed.

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9055049 – enUS

Edition: 3 – 2017-09
(Edition: 1 – 2015-04)

9055049