Instructions for use

# Alarm Management System

**WARNING**

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

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# Contents

# 1 Information about this document

## 1.1 Typographical conventions

| | |
|---|---|
| ***Text*** | Bold, italicized text indicates labels on the device and on-screen text. |
| **1** | Numbers indicate the individual process steps of a sequence of actions. Numbering restarts at number 1 for each new sequence of actions. |
| (1) | Numbers in parentheses refer to elements in figures. |
| ① | Numbers in figures are shown in a circle and indicate elements to which reference is made in the text. |
| ► | This triangle is used in safety instructions and precautionary statements to indicate possible ways of avoiding the risk. |
| – | Dashes indicate lists. |
| | This symbol indicates information that facilitates use of the product. |
| ⇒ | This arrow indicates the result of a process step. |
| ✓ | This check mark indicates the result of a sequence of actions. |

## 1.2 Illustrations

Depending on the configuration, the products and screen content shown in this document may differ from the actual on-site products.

# 2 Safety-related information

## 2.1 Intended use

The Alarm Management System (AMS) is a monitoring and alarm system that is part of the Dräger Gas Management System (GMS).

The AMS records the alarms and information signals at the individual gas supply plants of the central gas supply system and at the critical points of the pipeline system, and makes it possible to display messages at various points in the hospital. The messages can be transmitted by the AMS to a building management system or other external display systems.

## 2.2 Delimitation

**⚠ WARNING**
**Risk of personal injury and/or property damage**
External display systems are not part of the GMS.
If alarms required by a standard are only displayed on non-validated display systems, there is a risk that alarms are ignored or incorrectly interpreted.

► The alarm status displayed by external display systems is for information purposes only and must be regularly checked against the alarm status on a validated display device of the GMS (e.g., monitor L/LL/LLT).

**NOTICE**
**Risk to the AMS network**
It only makes sense to include external data if the data have a relationship to the GMS and do not overload the AMS.

► The suitability of data from external devices must be checked during the project planning stage.

The Dräger Gas Management System transmits gases directly to medical devices and is therefore approved in accordance with the Medical Devices Act in the same way as a medical device. As an integral part of the GMS, the Alarm Management System must also meet the requirements for a medical device. CE certification takes place after completion of the entire central gas supply system on site in the hospital. For further information, see the following chapter: "Getting started" (page 18).

External sensors, alarm contacts, and display systems can also be integrated via interface modules so that the AMS can be integrated into the building services of a hospital (see figure below).

External display systems are not part of the GMS.

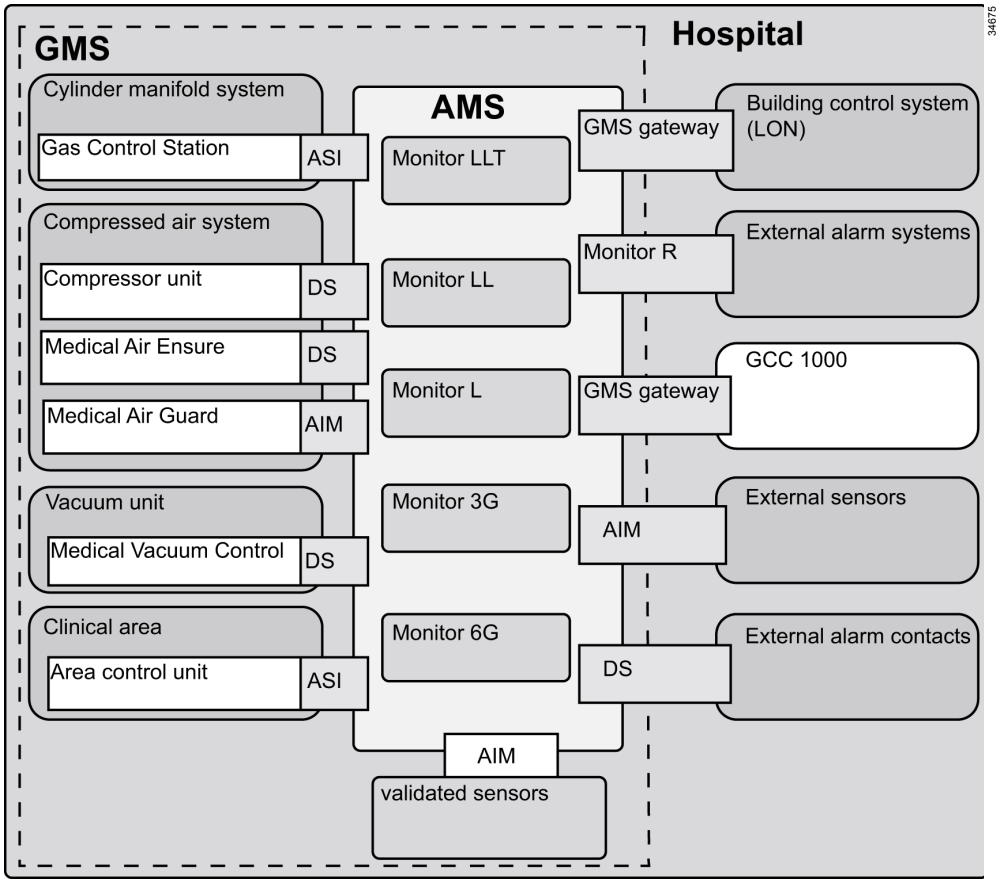


Fig. 1 Delimitation of the GMS from external devices

| No. | Name | Description |
|---|---|---|
| **ASI** | Alarm System Interface | Serves as an interface module for integrating the area control unit and the Gas Control Station into the AMS |
| **DS** | Data collector | Records the operating data of the central gas supply plants |
| **AIM** | Analog Input Module | Used to connect sensors and to monitor parameters |

## 2.3 Emergency procedure

In the event of an emergency, the Dräger Alarm Management System can help to identify the causes quickly and to reduce subsequent damage. In order for this to work, the responsible personnel must know which measures are to be taken in the event of an alarm.

**⚠ WARNING**
**Risk of patient and user injury**
Failure of the central gas supply system interrupts the gas supply and puts patients at risk.

► The operating organization of the healthcare facility must have an emergency procedure in place to ensure that an appropriate response can be provided in such a case.

For this reason, an emergency procedure must be drawn up for the central gas supply system that takes on-site conditions and processes into account. The DIN EN ISO 7396-1 standard "Pipeline systems for compressed medical gases and vacuum" explains in Annex G "Operational management" how to draw up an appropriate emergency procedure.

Generally, this emergency procedure should be based on a risk analysis, prepared by the operating organization, for the central gas supply system. This risk analysis should meet the requirements of the DIN EN ISO 14971 standard "Application of risk management to medical devices".

Annex F of the DIN EN ISO 7396-1 standard contains a list of numerous risk control measures that may be helpful in the systematic preparation and evaluation of a risk analysis.

## 2.4 Environments of use

The AMS is intended for the following environments of use:

- central gas supply system
- clinical areas of a healthcare facility, e.g., nurses' station
- central monitoring facilities, e.g., control room

The components of the AMS are not intended for the following environments of use:

- patient environment
- rooms with an explosion hazard
- transport vehicles, e.g., ambulances, airplanes, or helicopters
- MRI environment

# 2.5 Target groups

## 2.5.1 Duties of the operating organization

The tasks described in this document specify the requirements that have to be met by each respective target group.

The operating organization of this product must ensure the following:

- The target group has the required qualifications (e.g., has undergone specialist training or acquired specialist knowledge through experience).
- The target group has been trained to perform the task.
- The target group has read and understood the chapters required to perform the task.

## 2.5.2 Description of target groups

The target groups may only perform the following tasks if they meet the corresponding requirements. For further information, see the following chapter: "Basic safety instructions" (page 11).

### 2.5.2.1 Users

Users are persons from the technical and clinical departments. Users must have received instruction on the product. For the healthcare facility's emergency procedure at least the following persons should be designated to coordinate actions and communicate in the event of an incident:

- Authorized manager (Authorized Person, AP)
  e.g., the technical manager
- Designated technician (Designated Person, DP)
  e.g., a technician specially trained for gas supply systems
- Designated physician (Designated Medical Officer, DMO)
  e.g., a specially instructed ward physician
- Designated nurse (Designated Nursery Officer, DNO)
  e.g., a specially instructed ward nurse

| Task | Requirement |
|---|---|
| Use of the product in accordance with the intended use | Expertise in alarm systems for medical gas supply systems |
| Monitoring of the AMS signals in the respective areas and initiation of appropriate measures according to the emergency procedure of the healthcare facility | Knowledge of the emergency procedure for the medical gas supply system through instruction |
| | Knowledge of the meaning of the displayed alarms and messages |

#### 2.5.2.2 Specialized service personnel

Specialized service personnel are, e.g., hospital technicians with training for the Alarm Management System.

| Task | Requirement |
|---|---|
| Installation | Specialist knowledge in electrical engineering and mechanics<br>Experience in complex service work on this product |
| Basic and complex service work (inspection, maintenance, repair) | |

Dräger recommends arranging a service contract with DrägerService.

## 2.6 Information on safety instructions and precautionary statements

Safety instructions and precautionary statements warn of risks and give instructions for the safe use of the product. Failure to observe them may lead to personal injury or property damage.

### 2.6.1 Safety instructions

This document contains sections with safety instructions which warn of risks. The type of risk and the consequences of non-compliance are described in each safety instruction.

### 2.6.2 Precautionary statements

Precautionary statements relate to action steps and warn of risks that may arise when executing the action steps. Precautionary statements precede the action steps.

The following warning signs and signal words indicate precautionary statements and differentiate the possible consequences of non-compliance.

| Warning sign | Signal word | Consequences of non-compliance |
|---|---|---|
|  | WARNING | May result in death or serious injury. |
|  | CAUTION | May result in moderate or minor injury. |
| | NOTICE | May result in property damage. |

## 2.7 Basic safety instructions

### 2.7.1 Instructions for use

Use of this product contrary to the information in these instructions for use may result in personal injury and property damage.

► Follow these instructions for use and the instructions for use for all products used in conjunction with this product.

► The product must only be used for the purpose specified under "Intended use".

► Keep these instructions for use in an accessible place.

The instructions for use do not contain any information on the following points:

- Risks that are obvious to users
- Consequences of obvious improper use of the product

### 2.7.2 Symbols and product labels

Failure to observe the symbols and product labels may result in personal injury and property damage.

► Observe the symbols and product labels.

### 2.7.3 Operation of the system by persons outside the defined target groups

The system is fundamentally not intended to be operated by external persons (persons not defined as target groups). The operating organization is responsible for use outside of the intended purpose, in particular by external persons.

However, if the operating organization allows external persons to interact with the system, appropriate instruction and supervision must be provided.

If external persons (e.g., visitors) have access to the system, take the following precautions:

► Inform external persons that unauthorized interactions can lead to injuries and disruption of patient care.

### 2.7.4 Modifications to the product

Modifications to the AMS can lead to malfunctions and, as a result of failure to observe alarms, to personal injury and property damage.

► Do not modify this product.

### 2.7.5 Alarms

The patient may be at risk if alarm signals go unnoticed.

► Check regularly that the display devices are functioning correctly.
Observe the separate instructions for use for the components of the AMS.

# 3 Product description

**NOTICE**

► Observe the separate instructions for use for the components of the Alarm Management System.

## 3.1 System components

ℹ Since the AMS is a configurable alarm system, not all the components described are necessarily included in every system.

The Alarm Management System may include the following system components:

| Component | Function |
|---|---|
| Data collector | Module for recording the operating states of the central gas supply plants<br>The messages from the plants are transmitted to the terminals of the data collector via potential-free contacts. A message is initiated in the AMS when a contact is open. |
| Alarm System Interface | Interface module for integrating the area control unit and the Gas Control Station into the AMS<br>For the transmission of all alarms and information signals. |
| Analog Input Module | Interface module for the integration of various sensors which have a 4 to 20 mA current loop<br>The signals are analyzed and the corresponding measured values and alarms are transmitted to the AMS. |
| Monitor L | Display unit for signals from the GMS<br>Depending on the configured alarm priority, a visual and/or an acoustic message is initiated.<br>For the visual message one of the 22 LEDs is used. |
| Monitor LL | Display unit for signals from the GMS<br>Depending on the configured alarm priority, a visual and/or an acoustic message is initiated.<br>For the visual message one of the 46 LEDs is used. |
| Monitor LLT | Display unit for signals from the GMS<br>Depending on the configured alarm priority, a visual and/or an acoustic message is initiated.<br>For the visual message, one of the 48 LEDs and a two-line text display are used. |
| Monitor R | Relay module for the transmission of single and group alarms from the AMS to external alarm systems |
| GMS gateway | Interface to external systems for the transmission of alarms and information signals |

| Component | Function |
|---|---|
| Gas Communication Cockpit GCC 1000 | Secondary display device for the graphical visualization of alarms, information signals, and measured values from the GMS |
| L-switch (router) | Signal amplifier for large networks (cable length >500 m and/or number of connected devices >64) |
| Terminator | Terminating resistor for AMS network cables |

## 3.2 System concept

This section explains the communication, configuration, and security of the AMS network system.

### 3.2.1 Network

All devices that are part of the AMS are connected to each other by network cables.

Data are exchanged via a communication protocol which any device can process.

To ensure that all devices in the network can communicate with each other, the individual devices are parameterized with a configuration program during commissioning. This determines how the devices respond to messages from other devices in the network.

### 3.2.2 Security concept

An alarm system must ensure that each message will be displayed with the designated priority.

#### Securing bandwidth

Normal communication protocols are not suitable for an alarm system. Transmission errors or overloading could cause signals not to reach their recipient. The Alarm Management System is therefore a closed system with its own cable network.

During commissioning, the configuration program ensures that sufficient bandwidth is always available for the transmission of all signals.

If the cable length (>500 m) or the number of devices (>64) cause the transmission capacity to be exceeded, the network is divided into several segments via routers. The routers amplify the signals sent across segment boundaries, thus ensuring secure transmission.

#### Communication monitoring

In the AMS, the availability of all devices for communication is monitored.

To this end, each display device cyclically queries all devices assigned to it as a data source. If no response is received, the display device shows a communication alarm.

### 3.2.3 Interfaces

**⚠ WARNING**
**Risk of personal injury and/or property damage**
External display systems are not part of the GMS.
If alarms required by a standard are only displayed on non-validated display systems, there is a risk that alarms are ignored or incorrectly interpreted.

► The alarm status displayed by external display systems is for information purposes only and must be regularly checked against the alarm status on a validated display device of the GMS (e.g., monitor L/LL/LLT).

**NOTICE**
**Risk to the AMS network**
It only makes sense to include external data if the data have a relationship to the GMS and do not overload the AMS.

► The suitability of data from external devices must be checked during the project planning stage.

The AMS is prepared, by means of secured interfaces, to receive data from external devices and to transmit alarms and messages to external display systems.

## 3.3 Use in hospital

In the hospital, the AMS forwards alarms and messages to various display devices in different areas simultaneously, so that the responsible personnel are informed directly.

### 3.3.1 Hospital overview

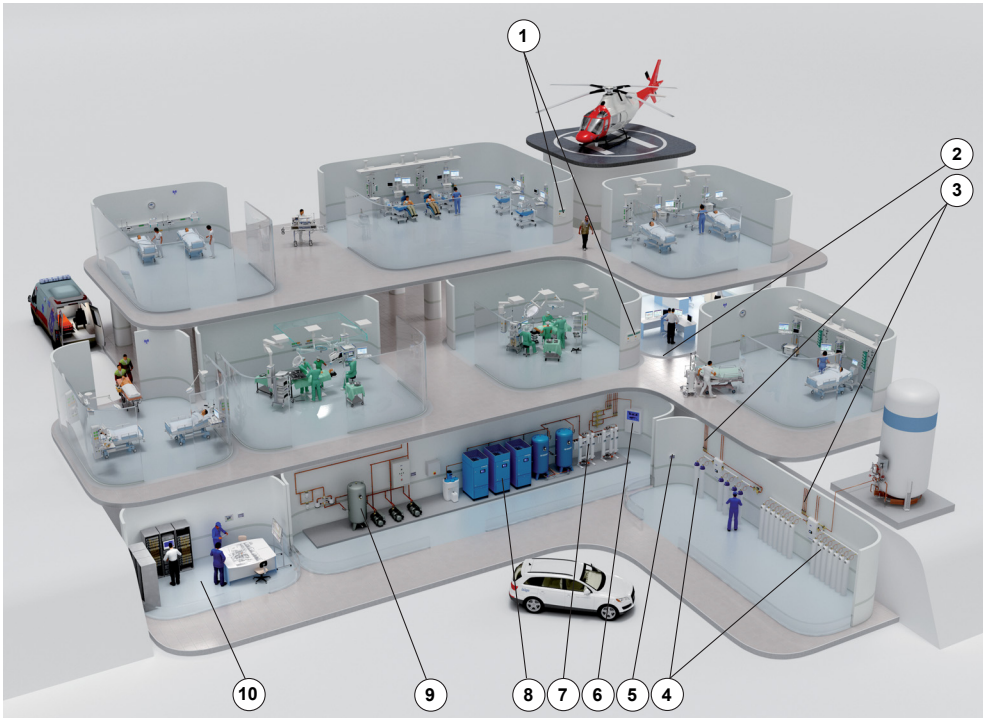


Fig. 2 Example of a hospital with GMS

| No. | Name | Description |
|---|---|---|
| **1** | Area control unit | Pressure control of med. gases and vacuum |
| **2** | Nurses' station | Monitoring on ward, e.g., with Monitor 3G/6G or Monitor L |
| **3** | Pipeline system | Pipelines for the distribution of gases |
| **4** | Cylinder manifold system | Cylinder manifold with Gas Control Station |
| **5** | Local display | Displaying the operating status, e.g., with Monitor LL |
| **6** | Medical Air Guard | Monitoring the purity of the medical compressed air |
| **7** | Medical Air Ensure | Compressed air conditioning unit |
| **8** | Compressor unit | Compressed air generation with compressors |
| **9** | Vacuum unit | Vacuum generation with Medical Vacuum Control |
| **10** | Control room | Central monitoring, e.g., with Gas Control Cockpit or building management system |

## 3.3.2 Network system overview

The following block diagram shows an example of a network in a hospital.

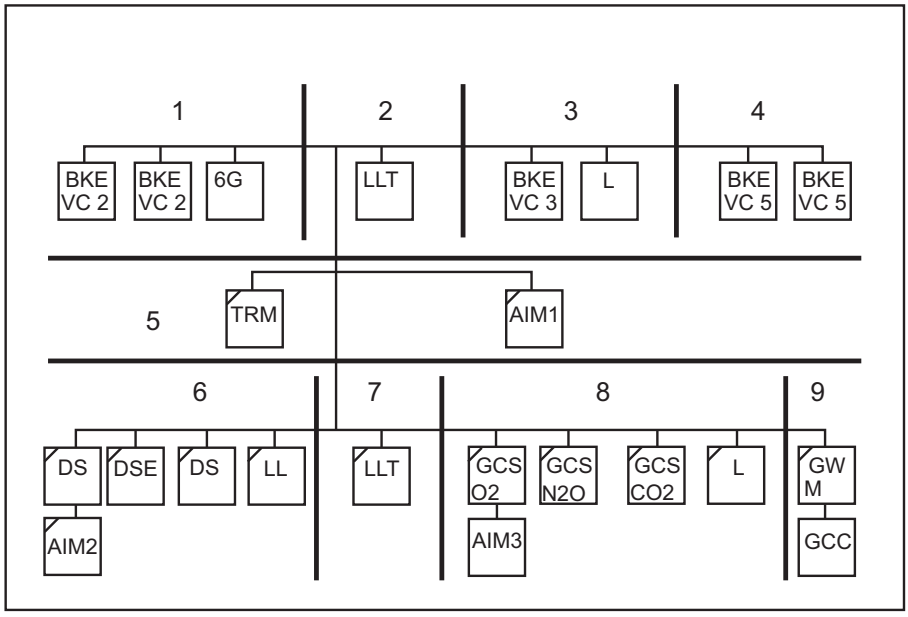


Fig. 3 AMS installation block diagram (example)

| No. | Name |
|---|---|
| **1** | General ward |
| **2** | Reception |
| **3** | ICU |
| **4** | Operating room |
| **5** | Pipeline system |
| **6** | Compressed air plant<br>Vacuum plant |
| **7** | Hallway |
| **8** | Cylinder manifold system |
| **9** | Building management system |

| | Name | Description |
|---|---|---|
| | AIM 1 | AIM with 6 pressure sensors for $O_2$ and air for measurement in the operating room, ICU, and general ward |
| | AIM 2 | AIM with sensors for room temperature and volume flow |
| | AIM 3 | AIM with sensors for $CO_2$ concentration and volume flow |
| | BKE | Area control unit with Alarm System Interface for signals from pressure monitoring and volume flow measurement (VC) |

| Name | Description |
|---|---|
| DS | Data collector for recording signals from the compressed air plant and the vacuum plant |
| DSE | Data collector add-on for recording further signals from the compressed air plant and the vacuum plant |
| GCC | Gas Communication Cockpit GCC 1000 for displaying all GMS data on a touchscreen |
| GCS | Gas Control Station with Alarm System Interface for the signals from the cylinder manifold system |
| GW | GMS gateway for the transmission of all GMS data to building control system or GCC 1000. |
| LLT | Monitor LLT with 48 configurable LED displays and a text display for showing messages |
| LL | Monitor LL with 46 configurable LED displays |
| L | Monitor L with 22 configurable LED displays |
| TRM | Terminating resistor for AMS network cables |
| 6G | Monitor 6G with separate display and membrane keyboard for 6 gases |

## 3.4 Monitoring

### 3.4.1 Local monitoring

Each central gas supply system requires local display devices, e.g., Monitor L. Alarms and information signals are displayed on these devices.

### 3.4.2 Central monitoring

The DIN EN ISO 7396-1 standard requires that all alarms are displayed at a location that is continuously monitored.

# 4 Getting started

## 4.1 Commissioning

**NOTICE**

► The Alarm Management System may only be commissioned by DrägerService.

The AMS is commissioned with the aid of the approved project drawings and a configuration software.

Subsequent changes may only be made by DrägerService. The entire Alarm Management System must then undergo a new acceptance procedure.

## 4.2 Acceptance and handover

The Alarm Management System is part of the Gas Management System, which is approved in accordance with the requirements of the Medical Devices Act.

**⚠ WARNING**

**Risk of patient and user injury**

An incorrectly installed and tested Alarm Management System can endanger the safety of patients and users.

► Before the AMS is handed over to the operating organization, the proper functioning of the system must be verified by the acceptance test.
In this test, a check is carried out to determine compliance with the requirements of DIN EN ISO 7396-1.
Failure to pass this test means that the Gas Management System must not be put into operation.
Upon conclusion of the installation or service activity, the AMS must be tested and accepted by DrägerService before the AMS can be put into operation.

Acceptance of the system has two stages:

1 Acceptance of the network installation

2 Acceptance of the system configuration with verification of all alarm generators and alarm displays

✓ The system is accepted.

The test determines

– whether the safety requirements necessary for the protection of patients and personnel are met and

– whether the performance characteristics of the AMS are met.

The test results are documented in writing.

After acceptance, the AMS is handed over to the operating organization along with the associated documentation. The handover is documented for the files.

The users must then be instructed on how to operate the medical device.

External display systems, such as a building management system, are configured by the respective manufacturer of the display system with the support of DrägerService.

# 5 Operation

The Alarm Management System works fully automatically once commissioning is completed.

**NOTICE**

► Observe the separate instructions for use for the components of the AMS.

The AMS must be permanently connected to the power supply and must not be switched off.

**⚠ CAUTION**

**Risk of patient injury**

The alarm and monitoring information is not forwarded if the mains power supply fails.
Important alarms regarding the status of the medical gas supply may remain undetected and the gas supply may become interrupted.
This can endanger the patients being cared for.

► Make sure that the product is connected to the emergency power supply.

## 5.1 Monitoring alarms and messages

**⚠ WARNING**

**Risk of personal injury and/or property damage**

Failure to observe alarms required by a standard may result in property damage and personal injury.

► The operating organization must ensure that at least one validated display device of the AMS with all alarms required by a standard is continuously monitored by trained personnel.

**⚠ WARNING**

**Risk of personal injury and/or property damage**

External display systems are not part of the GMS.
If alarms required by a standard are only displayed on non-validated display systems, there is a risk that alarms are ignored or incorrectly interpreted.

► The alarm status displayed by external display systems is for information purposes only and must be regularly checked against the alarm status on a validated display device of the GMS (e.g., monitor L/LL/LLT).

An emergency procedure for the central gas supply system should be in place to ensure an appropriate response of personnel to AMS alarms. The emergency procedure - in its latest version - should be known and accessible to the responsible personnel. For further information, see the following chapter: "Emergency procedure" (page 8).

### 5.1.1 Alarms

**NOTICE**

► For details of the device-specific signals, refer to the separate instructions for use for the respective components of the AMS.

**NOTICE**

► Alarms may be displayed differently on external display devices connected to the AMS.

In accordance with DIN EN ISO 7396-1, the AMS issues 4 types of messages:

– Emergency clinical alarms
  Emergency clinical alarms indicate, for example, abnormal pressure in a pipeline and require an immediate response from both technical and clinical personnel.
– Emergency operating alarms
  Emergency operating alarms indicate, for example, abnormal pressure in a pipeline and require an immediate response from technical personnel.
– Operating alarms
  Operating alarms alert technical personnel to the fact that one or more supply sources within a supply system are no longer available for operation and that measures need to be taken.
– Information signals
  Information signals indicate the normal state.

The Monitor L/LL/LLT and Monitor 3G/6G display devices show these messages as follows, in accordance with the standard:

– Operating alarms are indicated by a flashing yellow LED. An acoustic signal is optional.
  Example for operating alarm with acoustic signal: Operating alarm for cylinder replacement
  Example for operating alarm without acoustic signal: Operating alarm for service work due.
– Emergency alarms are indicated by a flashing red LED and an acoustic signal.
  Example for emergency operating alarm: Outlet pressure at the GCS too low
  Example for emergency clinical alarm: Pressure at the ACU too low

  The alarm tone can be suppressed in the case of emergency alarms. It will be reactivated after no more than 15 minutes if the cause of the alarm has not been rectified.

– Information signals are indicated by a permanently illuminated green LED.
  Example for information signal: Compressor 1 operational

  Communication alarms in the AMS network are indicated by the AMS display devices with LED display by a flashing green LED.

# 6 Troubleshooting

## 6.1 Fault – Cause – Remedy

| Status | Cause | Remedy |
|---|---|---|
| AMS display device shows nothing | Device is not active. | Press the reset key until LED test starts, see also separate instructions for use of the device. |
| No response when the reset key is pressed | Power supply is interrupted. | Notify in-house technician. |
| | Device is faulty. | Notify DrägerService. |
| Status changes of the central gas supply system are not displayed | Display device is faulty or communication is impaired. | Notify DrägerService. |
| AMS display device indicates communication alarm (LED flashes green) | Connection to the alarm generator is impaired. | Notify DrägerService. |
| Alarm on an AMS display device is not forwarded to external system (e.g., building management system) | Connection to the external system is impaired. | Notify DrägerService. |
| | External system (e.g., building management system) is not configured correctly. | Notify the manufacturer/ service department of the external system. |

# 7 Cleaning

**NOTICE**

► Observe the separate instructions for use for the components of the AMS.

# 8 Service

Dräger recommends DrägerService for service work.

**NOTICE**

► Observe the separate instructions for use for the devices and sensors of the AMS.

## 8.1 Definition of service terminology

| Concept | Definition |
|---|---|
| Service | All measures (inspection, maintenance, repair) intended to maintain or restore the functional integrity of a product |
| Inspection | Measures intended to determine and assess the current state of a product |
| Maintenance | Regular specified measures intended to maintain the functional integrity of a product |
| Repair | Measures intended to restore the functional integrity of a product after a failure |

## 8.2 Inspection

| Measure | Interval | Target group |
|---|---|---|
| Test the AMS display devices | Daily | Users |
| Compare the messages on the external system with the messages on the AMS display devices | Regularly | Users |
| Inspection and safety check[1)] | Every 12 months | Specialized service personnel |

1) The designation applies only in the Federal Republic of Germany and corresponds to the "Recurring safety inspection" in Austria

### 8.2.1 Safety checks

#### 8.2.1.1 Performing the safety checks

**⚠ WARNING**
**Risk due to lack of safety checks**
If the AMS is not inspected at the prescribed intervals, any defects that may have occurred are not detected and consequently the functioning and safety of the AMS are not maintained. This can endanger the health of patients and users.

► Inspect the AMS at the prescribed intervals.

► Inspection must only be carried out by suitably trained personnel.

1 Check that all AMS display devices are in good condition:
   – All labels are complete and legible.
   – The components have no visible damage.
2 Have damaged components replaced.
3 Check that all display devices are clearly visible and accessible and are not obstructed by furniture or other objects.
4 Check the safety equipment:
   – The optical alarm signals are displayed correctly
   – The acoustic alarm generator is functioning correctly
5 Carry out service activities for AMS devices and sensors (see instructions for use).

## 8.3 Maintenance

The AMS is maintenance-free.

For maintenance and calibration of the sensors, refer to the instructions for use of the sensors.

**NOTICE**

► Observe the separate instructions for use for the devices of the AMS.

## 8.4 Repair

Dräger recommends that all repairs are performed by DrägerService and that only authentic Dräger repair parts are used.

# 9 Disposal

## 9.1 Disposal of the product

At the end of its useful life, dispose of the product in accordance with the applicable legal provisions.

The AMS is a system that is permanently installed in the healthcare facility and must be professionally disposed of when the facility is demolished.

**NOTICE**

► Observe the separate instructions for use for the components of the AMS.

# 10 Technical data

For further technical data, such as electrical connections, see the separate instructions for use for the components of the AMS.

## 10.1 Ambient conditions

| | |
|---|---|
| **During operation** | |
| Temperature | 0 to 50 °C (32 to 122 °F) |
| Ambient pressure | 600 to 1100 hPa (8.7 to 16.0 psi) |
| Relative humidity | 5 to 95 %, non-condensing |
| **During storage and transport** | |
| Temperature | - 20 to 60 °C (- 4 to 140 °F) |
| Ambient pressure | 600 to 1100 hPa (8.7 to 16.0 psi) |
| Relative humidity | 5 to 95 %, non-condensing |

## 10.2 Operating characteristics

| | |
|---|---|
| **Segment size** | |
| Maximum number of network nodes | 64 |
| Maximum cable length | 500 m per segment |
| **Power supply** | |
| Maximum voltage for power supply units | 230 V AC 50/60 Hz |
| **Classification according to Directive 93/42/EEC, Annex IX** | Class I |
| **UMDNS code Universal Medical Device Nomenclature System – Nomenclature for medical devices** | 18-046 |
| **Standards** | |
| Applicable standards | DIN EN ISO 7396-1 |

# 11 Annex

## 11.1 Abbreviations

| Abbreviation | Explanation |
|---|---|
| AIM | Analog Input Module |
| AMS | Alarm Management System |
| ACU | Area Control Unit |
| DIN | Deutsches Institut für Normung (German standardization organization) |
| GCC | Gas Communication Cockpit |
| GCS | Gas Control Station |
| GMS | Gas Management System |
| ISO | International Organization for Standardization |
| LED | Light-emitting diode |
| UMDNS | Universal Medical Device Nomenclature System, nomenclature for medical devices |

## 11.2 Symbols

| Symbol | Explanation |
|---|---|
|  | Manufacturer |

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CE 0123

Directive 93/42/EEC concerning medical devices


Manufacturer

**Drägerwerk AG & Co. KGaA**
Moislinger Allee 53 – 55
D-23542 Lübeck
Germany
+49 451 8 82-0
FAX +49 451 8 82-2080
http://www.draeger.com



9056141 – GA 6916.016 en



Edition: 1 – 2017-05