

Operating instructions

INMATEC oxygen generator

Series POC O₂ med



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1. Risk analysis

The following risk analysis describes the risk assessment and the resulting risk reduction measures for the purpose of the IMT POC med oxygen generator.

O₂ Med: In accordance with DIN EN ISO 7396-1, the operator of the supply system must perform a risk analysis for the entire system.

1.1. Risk management process

The oxygen generators IMT POC med are a Class 2a medical device.

In accordance with their intended purpose, the IMT POC med oxygen generators are used for the auxiliary supply of oxygen at medical facilities. In the context of this intended purpose, they are only part of an overall supply system. The manufacturer [INMATEC](#) is neither the installer of the entire supply facility nor the operator of the supply system. As a result, these operating instructions are not intended for the patients of a medical care institution. These operating instructions are intended for the operator of the generator as part of a supply system.

A comprehensive risk analysis for the entire system must be prepared by the operator in accordance with DIN EN ISO 7396-1.

1.2. Power limitation, inlet

Medical compressed air must be provided for proper operation of the IMT POC med oxygen generators. The compressed air supply is not part of the scope of supply and services provided by the manufacturer [INMATEC](#). The interface or transfer point from the compressed air supply to the generator is the inlet filter on the generator. The connection size depends on the performance data of the generator and is described in the operating instructions.

In order for the IMT POC med oxygen generators to function as intended, the compressed air quality must have medical properties.

In addition to the compressed air supply, the IMT POC med oxygen generators also require the supply of electrical energy for their intended function. A mains connection with 230 V and 50 Hz is required for this purpose. The generator is connected to the on-site electrical power supply via a plug with earthing contact. The electrical power supply of the generator serves exclusively to supply the electrical control device, the Touch Control Panel on the generator. The electrical power supply is not part of the scope of supply and services provided by the manufacturer [INMATEC](#).

1.3. Power limitation, output

After a proper function test of the generator by the manufacturer [INMATEC](#), the medical device (IMT POC med oxygen generator) is handed over to the operator. The interface or transfer point from the generator to the supply system is a mechanical screw connection. The connection size depends on the performance data of the generator and is described in the operating instructions.

After delivery, the generator is integrated into the existing pipe system at the respective medical facility by the operator's qualified and expert service personnel. The commissioning of the entire oxygen supply system, consisting of the compressed air supply, the IMT POC med oxygen generator and the pipe system installed on site by the operator, is the responsibility of the operator. Depending on national law or legislation, the operator is responsible for allowing an appropriate certification or inspection of the entire supply system to be carried out by an approved inspection body.

In addition to the connection to the supply system, the nitrogen-enriched exhaust air of the IMT POC med oxygen generator must be discharged to the outside. For this purpose, exhaust air from the generator must be connected to an exhaust air pipe provided by the customer. The interface or transfer point from the generator to the exhaust air pipe is a mechanical screw connection. The connection size depends on the performance data of the generator and is described in the operating instructions.

1.4. Risk minimisation and elimination during development and construction

All components of the IMT POC med oxygen generator that are in direct contact with the medical oxygen are certified as being compatible with oxygen.

The respective components from the various suppliers are checked within the scope of an incoming goods inspection/invoice verification. For the production of the IMT POC med oxygen generators, the necessary components are sourced from a separate warehouse. This procedure ensures the use of components that are suitable for use with oxygen. For this purpose, the previously identified components from the suppliers are marked "with a blue dot".

All components for the production of the IMT POC med oxygen generators, such as safety valves, pneumatic valves, pressure regulators, flow meters, absorber containers, etc. are subjected to an oxygen conformity process. After successful testing, a certificate/conformity declaration is issued. For this purpose, the certificates are checked to ensure that they refer to the respective components. The oxygen containers are marked white for special identification.

Within the scope of these operating instructions, the operator is extensively informed of risks during operation.

1.5. Risk assessment

The probability of occurrence of the risks mentioned is minimal and therefore justifiable. To date, none of these risks have occurred during the construction and development phases.

1.6. Risk control

Various risk-control measures were defined and implemented within the company:

- Comprehensive incoming goods inspection of the relevant components.

- Inspection of the components before they are introduced into the manufacturing process.
- Final inspection before delivery to the customer (test report).
- Separate warehouse for the components of the IMT POC med oxygen generators.
- Use of components with proof of quality (certificate, proof of conformity).
- Careful storage of the quality certificates, storage in the respective project folder (hard copy and digital).
- CE marking.

The effectiveness of the measures is confirmed (probability of error minimised) and is regularly monitored by the quality management officer (QMB).

1.7. Information from production and downstream phases

Market observation: No incidents were reported based on the oxygen generators sold. As a result, no incidents are integrated into the risk management process.

Within the context of these operating instructions, the end customer is requested to report any incidents immediately to the manufacturer [INMATEC](#). The process will not be completed until [INMATEC](#) has received the signed declaration of commitment.

Incidents are reported by [INMATEC](#) to the competent higher federal authority, i.e. the German Federal Institute for Drugs and Medical Devices .

1.8. Evaluation of the risk management process

Functional, no incidents to date.

1.9. The principle

INMATEC IMT POC med oxygen generators are based on pressure swing adsorption (PSA) technology. Pressure swing adsorption (PSA) technology uses a physical process for selective decomposition of gas mixtures under pressure. The process is based on the adsorption principle (adsorption is the binding of particles to the surface of a substance). Special porous materials (zeolites in oxygen plants) are used as molecular sieves to adsorb molecules according to their adsorption forces and/or their kinetic diameter. Pressure swing adsorption uses the physical property that gases adsorb to surfaces to varying degrees.

The separation of nitrogen and oxygen is possible due to the kinetic effect. Zeolites are used as adsorbents for the production of oxygen. In this process, the separation of nitrogen and oxygen takes place via the equilibrium effect. The nitrogen is adsorbed on the zeolites that are used.

1.10. Structure

INMATEC IMT POC med oxygen generators produce medical oxygen with an oxygen purity of $93\% \pm 3\%$ from medical compressed air supplied by the customer. For this purpose, the pressurised interchangeable tanks with a molecular sieve are fed with compressed air at 7 bar. Air compressors provided by the customer generate the compressed air required for this purpose.

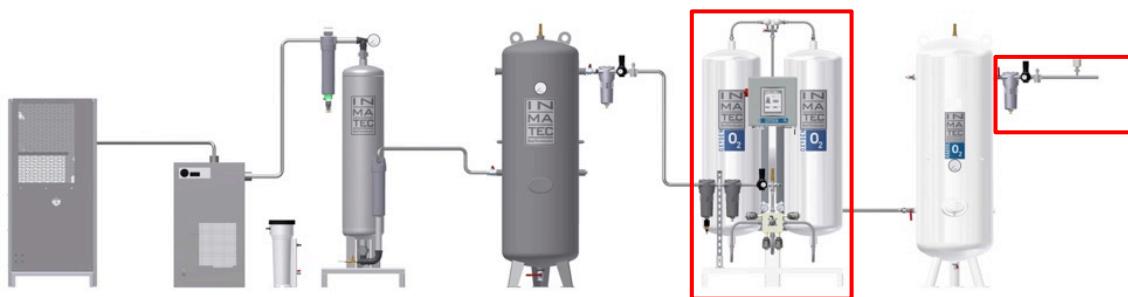


Fig. 1: Basic structure of an oxygen generation system



INMATEC IMT POC med oxygen generators are pressurised during operation. The built-up pressure may persist for a certain time after the compressed air supply has been switched off. Ensure that the system is completely depressurised prior to maintenance or service.

1.11. Intended purpose

The intended function of the IMT POC med oxygen generators is the production of medical oxygen with an oxygen purity of $93\% \pm 3\%$. The performance data of the IMT POC med oxygen generators corresponds to the customer's performance data that specifies Nm^3 oxygen with a purity of $93\% \pm 3\%$.

Within the scope of the intended use, it must be ensured that the oxygen generators are set to an oxygen concentration of $93\% \pm 3\%$. In addition, it must be ensured that the oxygen generators are only supplied with medical compressed air.

Due to its intended purpose, this product is a Class 2a medical device in accordance with the Medical Devices Act (Medizinproduktegesetz, MPG), whereby the requirements of the MPG must be met. The MPG is based on the European Directive 93/42/EEC for Medical Devices and refers in part to this Directive, which is why the 93/42/EEC is also cited below.



A fire hazard exists in case of contact with flammable substances; oxygen promotes combustion. Suitable information signs should be provided in the area of the oxygen system as a warning of this danger.



Even after the oxygen generator has been switched off, dangerous electrical voltages may still be present in the electrical equipment. The oxygen generator must be disconnected from the electrical supply network before maintenance or repair work is carried out.

If the electrical connection of the oxygen generator is not made properly, contact with electrical equipment may result in a hazard.

To ensure proper functioning of the **INMATEC** IMT POC med oxygen generators, the compressed air quality must have the following characteristics:



Medical compressed air

Compressed air of an incorrect quality may damage the oxygen generator.

1.12. Spatial limits

The IMT POC med oxygen generator must be installed in a well-ventilated interior. The room temperature must be between +5°C and +40°C. Operation of the IMT POC med oxygen generator at temperatures below +5°C or above +40°C will cause damage not covered by the manufacturer's warranty.



For proper installation and operation of the **INMATEC** IMT POC med oxygen generators, the operating instructions must be observed.

The generator must be installed at the intended location. Ensure that the IMT POC med oxygen generator is installed in a stable position.



The exhaust air from the **INMATEC** oxygen generator must be conducted from the interior to the exterior.

For this purpose, the operator must connect an exhaust pipe that complies with the technical regulations to the silencer on the oxygen generator.

Failure to meet these technical requirements may give rise to hazards. **INMATEC** accepts no liability for failure to comply with this requirement. In addition, the respective regulations of the place of use apply.

Fig. 2: Silencer connection

O₂ Med: Make sure that the air outlets are fitted with devices to prevent the ingress of insects, particles and precipitation. The vents must be located away from all air inlets, doors, windows or other openings in buildings (DIN EN ISO 7396-1).



INMATEC IMT POC med oxygen generators use electrical equipment that is not explosion-proof as standard. It is not permitted to install or operate the generators in rooms in which explosive or flammable materials are stored.



Depending on the application, the exhaust air from the IMT POC med oxygen generator may contain an increased oxygen concentration. Continued inhalation of concentrations above 75% may cause nausea, dizziness, shortness of breath and cramps. The affected person is to be taken outside, into the fresh air. Then keep the person warm and quiet and consult a doctor. Artificial respiration is required in case of respiratory arrest.

Before entering a closed area in which an oxygen generator is operated, the safety measures must be observed. For safety reasons, the exhaust air must be discharged from the interior to the exterior.



In case of maintenance or repair of the oxygen generator, an excessively high oxygen concentration can lead to dizziness, shortness of breath and cramps if the oxygen generator is emptied incorrectly. Ensure that the installation area is sufficiently well ventilated.

1.13. Oxygen limits

The ambient air consists mainly of nitrogen (approx. 78%) and oxygen (approx. 21%). The following table shows the influence of reduced oxygen content in the ambient air.

Oxygen content	Note
15% – 19%	Decreasing ability to work hard. May interfere with coordination.
12% – 15%	Increase in breathing rate, associated with exertion, increase in pulse rate, impaired coordination, receptivity and judgement impaired.
10% – 12%	Breathing continues to increase in frequency and depth, is weakened. Judgement impaired, blue lips.
9% – 10%	Mental failures, fainting, unconsciousness, ashen face, blue colouration of the lips, nausea and vomiting.
8% – 9%	Exposure time 8 minutes: fatal Exposure time 6 minutes: life-threatening danger Exposure time 4–5 minutes: recovery with treatment
4% – 8%	Coma in 40 seconds, cramps, cessation of breathing or death.

Tab. 1: Oxygen concentration in ambient air

1.14. Manufacturer information

INMATEC oxygen generators comply with the applicable laws. All necessary information for the operation of the generators can be found in these operating instructions.

The year of manufacture and the identification number are indicated on the nameplate affixed to the installation.

Depending on national law or regulations, an approval or inspection of the generators by an approved inspection agency is required before the oxygen generators may be operated.

The operating instructions for the adsorber vessels must be observed. These operating instructions contain information on the load cycles of the adsorber vessels.

1.15. Operator's duty of care

The **INMATEC** IMT POC med oxygen generators were designed and manufactured in compliance with the relevant harmonised standards and other technical specifications. They thus correspond to the state of the art and guarantee a maximum degree of safety.

However, this safety can only be achieved in operational practice if all necessary measures are taken. It is the duty of the operator of the IMT POC med oxygen generators and the operating personnel to plan these measures and to monitor their execution.

O₂ Med: In particular, all requirements of DIN EN ISO 13485, DIN EN ISO 14971 and DIN EN ISO 7396-1 must be observed.

In particular, the operator must ensure that:

1. the oxygen generator is used in accordance with its intended purpose.
2. the oxygen generator is only operated in a perfect, fully functional condition and the safety devices in particular are regularly checked for proper functioning.
3. the necessary personal protective equipment for the operating, maintenance and repair personnel is available and used.
4. the operating instructions are always available in a legible and complete condition at the place of use of the oxygen generator.
5. only technically qualified and authorised personnel operate, maintain and repair the oxygen generator.
6. the operating personnel are regularly instructed in all applicable issues relating to occupational safety and environmental protection and are familiar with the operating instructions and in particular with the safety instructions contained therein.
7. all safety instructions and warnings attached to the oxygen generator are present and are legible.

O₂ Med: In particular, the operator must ensure that the aforementioned requirements of DIN EN ISO 13485, DIN EN ISO 14971 and DIN EN ISO 7396-1 are observed. These include (the following information does not claim to be exhaustive)

According to 5.6.6.1, at least one CO alarm sensor must be fitted to the pipe system downstream of all conditioning units.

According to 5.6.8.6, the operator must provide a sampling port with a shut-off valve immediately upstream of the shut-off valve of the supply system.

1.16. Risks and risk management

Risk	Actions	Likelihood	Solution
Flammability	Suitable information signs should be provided in the area of the oxygen system as a warning of this danger	Depending on the operator's duty of care	Instruction by the operator
Low O ₂ concentration	Continuous monitoring of the O ₂ content via sensor and analysis	Low Observe maintenance intervals	Alarm message in case of malfunction. Forwarding of the alarm message to the operator (service technician). Generator stop when the value falls below the limit value. Switch to backup system
Leak	Regular inspection and maintenance of the generator	Low Observe maintenance intervals	Perform inspection and maintenance. Only use certified components
Corrosion	All components that come into contact with oxygen must be treated with corrosion protection.	Low Observe maintenance intervals	Proof (certificate) of corrosion protection
Overpressure at the generator	Actuation of the safety valves	Low Observe maintenance intervals	Use of certified safety valves
Power supply failure	Installation of an automatic restart control system	Depending on the operator's security of supply	Automatic restart after power failure.
Failure of components	All control components of the generator are monitored.	Low Observe maintenance intervals	Alarm message in case of malfunction. Forwarding of the alarm message to the operator (service technician). Generator stop when the value falls below the limit value.



INMATEC IMT POC med oxygen generators may only be operated by trained personnel. The safety of the personnel is the responsibility of the operator of the oxygen generator. The operator is aware of the risks associated with the operation of the oxygen generators and the accompanying processes. The operator is responsible for the training and safety of the personnel as well as for compliance with the applicable standards, such as DIN EN ISO 13485, DIN EN ISO 14971 and DIN EN ISO 7396-1.



A reserve or emergency oxygen supply shall be provided for the operation of an oxygen supply system. The responsibility lies with the operator of the supply system.

After connecting the generator to the supply system, check all fittings and connections for leaks (screw connections may have come loose during transport – please seal).

O₂ Med: To ensure an uninterrupted oxygen supply, see description in DIN EN ISO 7396-1.

2. Hazard analysis

Life phase	Hazard	Protection goal	Solution
Transport, Installation Unloading, lifting, lowering the generator	Falling down, toppling over, crushing	When lifting/transporting, the centre of gravity of the generator may be disregarded, causing the generator to topple over and/or fall down.	Define and mark contact points for forklift trucks and eyelets for cranes
	Falling down, toppling over, crushing	There is a risk of crushing parts of the body when the generator is lowered. When lifting/transporting, the generator may fall if it is not attached correctly or if unsuitable lifting gear is used.	Only use suitable lifting gear (crane, forklift), check the lifting capacity of the hoist. <i>Note on the operating Instructions:</i> Weight of generator. Do not stand under the load when lifting and setting down, remain outside the danger zone.
	Falling down, toppling over, crushing	If the surface is unable to support the weight or is not sufficiently level, the generator may topple over.	
	Illness	If the location of the generator is not sufficiently ventilated, there is a health hazard.	<i>Note on the operating instructions:</i> The generator must be installed in a well-ventilated interior space.
Commissioning Compressed air connection	Sensitisation	Incorrect assembly, incorrect connection, defective parts, etc. may endanger the personnel during the test run. In addition, the hazard will exist during the operating phase.	<i>Note on the operating instructions:</i> Commissioning checklist Generator connections Connection line min. 10 bar Only qualified personnel may commission the generator.
Electrical connection	Electric shock	Incorrect connection or insufficient earthing could lead to the housing parts being live.	The generator may only be connected to an earthed socket by means of a plug with earthing contact.
Operation Unacceptable excess pressure	Impact injuries due to pressurised parts	The generator has a maximum operating pressure of 10 bar. If the inlet pressure of the compressed air is too high, the personnel may be endangered.	<i>Note on the operating instructions:</i> On the input side, the compressed air is set to the maximum operating pressure via a pressure limiter. The safety valves are triggered above an operating pressure of 10 bar.
Leaks Loss of technical tightness	Illness	If there is a leak, oxygen can escape. If the location of the generator is not sufficiently ventilated, there is a health hazard.	<i>Note on the operating instructions:</i> The generator must be installed in a well-ventilated interior space.
Corrosion due to condensate Ineffectiveness of the required safety-related equipment	Sensitisation	Inadequate drainage can lead to corrosion.	<i>Notes on operating instructions:</i> Regular drainage
	Sensitisation	Insufficient inspection and maintenance may lead to failure of the safety valves.	<i>Notes on operating instructions:</i> Regular function check of the safety valves
Maintenance, repair All maintenance and repair work	Impact injuries due to pressurised parts	Uncontrolled activation could result in injury to personnel carrying out work on the generator.	<i>Notes on operating instructions:</i> Before carrying out any work on the machine: switch off the machine at the main switch, lock the main switch and affix the warning label.
Malfunction Power failure	Failure of the oxygen supply	Failure of the power supply during operation leads to failure of the oxygen supply. Sudden return of the energy supply leads to renewed pressure build-up.	Automatic restart after power failure is ensured via control measures.

3. Alarm system

All set parameters are stored in the Touch Control Panel and buffered via an internal battery source. After a power supply failure of 30 seconds or less, all alarm settings that were set before the power supply failure are automatically restored.

3.1. Operational alarm

The Touch Control Panel monitors and signals two alarms for the IMT POC med oxygen generator.

1. Outlet pressure

An alarm is triggered if the outlet pressure exceeds or falls below the previously set outlet pressure. In the "Alarm output pressure" control menu on the Touch Control Panel, there is an option "Machine on alarm switch off"

If "Select Off / On" is selected, the generator is switched off in the "On" position in the event of an alarm. If "Off" is selected, the generator is not switched off in case of an alarm.

2. Product purity

An alarm is triggered if the product purity exceeds or falls below the previously set value. In the "Alarm product purity" control menu on the Touch Control Panel, there is the option "Machine on alarm switch off"

If "Select Off / On" is selected, the generator is switched off in the "On" position in the event of an alarm. If "Off" is selected, the generator is not switched off in case of an alarm.

In addition to the display in the Touch Control Panel, the two operating alarms "Outlet pressure" and "Product purity" are signalled as an optical signal.

The signal lamp turns yellow and flashes in case of a triggered alarm.

3.2. Information signal

The Touch Control Panel monitors and signals the operating states "Automatic operation" and "Stop".

In addition to the display on the Touch Control Panel, both operating states are signalled as an optical signal.

The signal lamp turns green and lights up in the "Automatic operation" operating state. In the "Stop" operating state, the signal lamp turns off.

4. Maintenance



In order to avoid life-threatening injuries or system damage during maintenance of **INMATEC** IMT POC med oxygen generators, the following points must be observed:

INMATEC IMT POC med oxygen generators may only be operated and maintained by trained personnel. The safety of the personnel is the responsibility of the operator of the oxygen generator.

For safety reasons, regular inspection and maintenance of the oxygen generator (see maintenance instructions) is required.

Maintenance and repair work may only be carried out by certified **INMATEC** technicians.

O₂ Med: To ensure uninterrupted oxygen supply during maintenance, a backup oxygen system must be provided. In addition, the backup system must be designed and constructed so that the maintenance or failure of any component does not require the simultaneous shut-off of two sources of supply. (See DIN EN ISO 7396-1)

All work steps for maintenance or repair of the IMT POC med oxygen generators must be carried out in the specified order.

1. First, secure a large area for maintenance and repair work.
2. Switch off the electrical power supply and secure the oxygen generator against unintentional reactivation.
3. Depressurise all pressure units.
4. Only use the specified operating fluids.
5. Only use **INMATEC** spare parts that are listed in our spare parts lists (use of non-original **INMATEC** spare parts will void the warranty).
6. All maintenance work must be carried out and documented in accordance with the maintenance schedule in the operating instructions.
7. In accordance with the applicable regulations, all system components must be checked in accordance with the Pressure Equipment Directive.

O₂ Med: In accordance with DIN EN ISO 7396-1 section 5.6.8.7, the operator must ensure that, during the maintenance of a supply system with oxygen concentrators, an agent for calibration of the analysis system is calibrated by reference to a mixture of known concentration.

4.1. Inspection and maintenance instructions

Interval	Activity
Daily	Visual inspection of generator (error messages) Control of filtration for condensate Check the quality of compressed air
as required, but at the latest every 4,000 h or 1x per year (depending on which arrives first)	Change the filter inserts
Annually or every 4,000 h within the scope of maintenance by the IMT technician	<ol style="list-style-type: none"> 1. Control of inlet and outlet pressure 2. Adjust the inlet pressure control 3. Control pressure dew point and total pressure 4. Gas purity measurement 5. Reference measurement of gas analysis sensors (reference concentration) 6. Replace the gas analysis sensor if required 7. Check and adjust the gas adjustment valves 8. Leak test of the entire system 9. Check the flow rate 10. Check the pneumatic switching elements 11. Functional check of the entire electrical system 12. Check the function of the floating arresters 13. Check the condensate outlet for leaks 14. Function test of the oxygen generator
Every 4,000 h at the latest	Disassembly and visual inspection of the valves Replacement of valve cores if necessary
Every 24,000 h at the latest	Replace the valves

Tab. 2: Inspection and maintenance intervals



Maintenance intervals may be shorter in the event of heavy use or ambient conditions which differ from the specified conditions.

4.2. Replace the filter elements

The expected service life of the prefilter elements or microfilter elements (0.01μ , A_k , 3μ or 5μ) is approx. 12 months or 4,000 operating hours if the IMT POC oxygen generator is properly maintained.

The filter elements were selected by **INMATEC** on the basis of their suitability for operation under challenging conditions. Use of filters other than those supplied by the manufacturer may cause damage not covered by the manufacturer's warranty. Only original **INMATEC** spare parts may be used. Otherwise, the warranty will be void.

4.3. Proof of inspection and maintenance

Tab. 3: Inspection and maintenance report

5. Disclaimer

We expressly point out that **INMATEC** is not liable for damages caused by incorrect, improper or negligent operation, maintenance or repair.

INMATEC is not liable for any special, indirect, incidental or consequential damages resulting from the use or malfunction of the equipment.

In particular, this also applies to improper use and to modifications to the oxygen generators which could impair safety.

In these cases, the product warranty and any liability will be void.

During transport by land, sea or air, screw connections may come loose and as a result the system may leak. Re-sealing must be carried out by the customer.

On receipt of your **INMATEC** oxygen generator, the system must be inspected immediately and carefully for damage; any sign of damage (external or internal) to the system must be noted on the delivery note and also reported immediately to both the carrier and **INMATEC**.

Transport damage must be reported to the shipping company that transported the oxygen generator. **INMATEC** cannot be held liable for transport damage!

6. Assembly

Before starting the assembly process, all information – and in particular safety information – in the operating instructions must be read carefully.



All fittings and connections must be checked for leaks and resealed if necessary. The screws may have come loose during transport.

6.1. Compressed air supply

The temperature of the medical compressed air at the inlet of the IMT POC med oxygen generator must not exceed 40°C. The temperature of the compressed air must not exceed 40°C.



An excessively high inlet temperature reduces the performance of the oxygen generator and causes damage that is not covered by the manufacturer's warranty. An excessively low inlet temperature can cause frost on some components and damage that is not covered by the manufacturer's warranty.

6.2. Connections

The connection line to the oxygen generator must be designed for pressure values of at least 10.0 bar. The connections are configured as follows:

Generator	Compressed air inlet	Oxygen outlet	Output silencer
POC 8150 med	1/2"	1/2"	DN 63
POC 8250 med	1/2"	1/2"	DN 63
POC 8350 med	1/2"	1/2"	DN 63
POC 8450 med	1/2"	1/2"	DN 63
POC 8550 med	1/2"	1/2"	DN 63
POC 8650 med	1/2"	1/2"	DN 63
POC 8000 med	1/2"	1/2"	DN 63
POC 8100 med	1/2"	1/2"	DN 63
POC 8300 med	3/4"	1/2"	DN 125
POC 8400 med	1"	1/2"	DN 125
POC 8500 med	1"	1/2"	DN 125
POC 8600 med	1"	1/2"	DN 125
POC 8700 med	1 1/2"	1/2"	DN 125
POC 8800 med	1 1/2"	1/2"	DN 125
POC 8900 med	1 1/2"	1/2"	DN 125
POC 8920 med	1 1/2"	1/2"	DN 125
POC 8930 med	2"	3/4"	DN 125
POC 8940 med	2 1/2"	3/4"	DN 125
POC 8950 med	2 1/2"	3/4"	DN 125

Tab. 4: Oxygen generator connections

6.3. Power supply

Mains connection: 230 V/50 Hz



The IMT POC med oxygen generators require a supply of electrical energy for their intended function. A mains connection with 230 V and 50 Hz is required for this purpose. The generator is connected to the on-site electrical power supply via a plug with earthing contact. The electrical power supply of the generator serves exclusively to supply the electrical control device, the Touch Control Panel on the generator. The electrical power supply is not part of the scope of supply and services provided by the manufacturer [INMATEC](#). [INMATEC](#) recommends the use of electrical filters to protect the Touch Control Panel on the generator.

[INMATEC](#) recommends connecting the IMT POC med oxygen generator via a supply line that cannot be switched off unintentionally. An unintended shutdown stops the generator and consequently the production of oxygen.

7. Commissioning



In order to avoid life-threatening injuries during commissioning of the **INMATEC** oxygen generators, the following points must be observed:

1. Oxygen generators may only be used for their intended purpose.
2. Before switching on the oxygen generators, read and observe the operating instructions and the safety and danger information contained therein.
3. The commissioning of the oxygen generators may only be carried out by qualified persons or bodies in compliance with the applicable national rules and regulations as well as the safety instructions (see 1.14).
4. Before the first start, check that all tools and foreign parts have been removed from the oxygen generator.
5. All safety devices must be activated before commissioning.
6. Before switching on the oxygen generators, functional checks must be carried out on the safety devices.

7.1. Installation



Fig. 3: Oxygen generator (figure may differ)

1. Connect compressed air to the inlet filter.
2. Connect the oxygen outlet to the ball valve downstream of the sterile filter.

7.2. Installation of storage tank for oxygen 93 (option)

As an option, the scope of delivery of the oxygen generator can be extended to include a storage tank for oxygen 93.



Fig. 4: Oxygen generator with storage tank

1. Connect compressed air to the inlet filter.
2. Connect the oxygen outlet on the generator to the ball valve of the storage tank.
3. Connect the oxygen outlet to the ball valve downstream of the sterile filter.

O₂ Med: In accordance with DIN EN ISO 7396-1 section 5.6.7, the storage tank must:

- comply with applicable international, regional or national standards;
- be equipped with (a) shut-off valve(s), a pressure gauge and a pressure relief valve;
- be equipped with a device for pressure control, e.g. with one or more pressure switches or pressure transmitters;
- be arranged in such a way that each tank can be serviced separately.

7.3. Initial commissioning



The following instructions for initial commissioning of the generator must be observed.

1. Electrical connection via plug with earthing contact.
2. The oxygen line from the generator to the pipe system must be kept closed.
3. Switch on the compressed air supply to the generator. A secure supply of medical compressed air at 7.0 bar should be available to ensure proper operation of the generator. If this is not the case, check the compressed air supply.
4. The generator must be switched on via the main switch on the control cabinet.
5. The generator should run 5 cycles (pressure load change intervals).
6. Only then can the supply to the pipe system be opened by only half by turning the ball valve 45° (full opening requires turning by 90°).
7. As soon as the pressure in the pipe system has reached a minimum value of 5 bar, the supply to the storage tank can be fully opened by turning the ball valve a further 45°.
8. The removal of oxygen should be reduced to max. 50% of the operating capacity during initial commissioning.
9. If the desired purity is displayed on the Touch Control Panel, the maximum operating power can be applied. A certified measuring instrument must be used to calibrate the agreed delivery quantity.

O₂ Med: In accordance with DIN EN ISO 7396-1 section 13.3.2, the average start-up time for the oxygen concentrator unit – after a restart of the oxygen generator and complete emptying of the storage tank – is at least 3 hours. The start-up times vary depending on the type and production capacity of the oxygen generator.

The exact start-up time is indicated in the corresponding operating instructions.

7.4. Settings for AUTOMATIC operation

By default, the system is delivered with the factory settings.

The customer-specific settings are adjusted on site by the customer or by INMATEC after initial commissioning.

The following steps must be performed on the Touch Control Panel:

Outlet pressure OFF

1. First, the correct outlet pressure OFF must be determined.
2. Close the ball valve to the pipe system.
3. The generator should run in continuous operation for 5 cycles.
4. During this phase, the pressure values in the pipe system must be observed. The highest pressure value is recorded.
5. Outlet pressure OFF is set on the Touch Control Panel. 0.1 bar is subtracted from the previously recorded max. pressure value, i.e. max. pressure minus 0.1 bar.

Outlet pressure ON

1. Once outlet pressure OFF has been set on the Touch Control Panel, outlet pressure ON is now set.
2. The outlet pressure ON must be set according to the purity by means of the following table. For this purpose, the corresponding value from the table is subtracted from the previously set outlet pressure OFF as per the table, i.e. outlet pressure OFF minus the table value.

Purity	from 95%	93%	90%
Minus	0.2 bar	0.4 bar	0.5 bar

Tab. 5: Oxygen generator outlet pressure ON

8. Valves

The externally controlled angle seat valve consists of a pneumatically operated piston actuator and a 2-way valve body. The proven self-adjusting packing gland ensures a high degree of tightness. The flow-optimised 2/2-way valve bodies enable high flow rates.

Specifications	
Nominal width	DN 13 to 65
Housing material	Gunmetal, cast stainless steel 316L
Actuator materials	PA or PPS
Seal material	PTFE
Media	Oxygen
Viscosity	max. 600 mm ² /s
Packing gland	PTFE V-rings with spring compensation
Medium temperature	-10°C to +180°C with PTFE seal
Ambient temperature with PA drive PPS drive Ø 40-80 PPS drive Ø 100-125	-10°C to +60°C +5°C to +140°C +5°C to +90°C, briefly up to +140°C
Installation position	Any, preferably with actuator pointing upwards
Control medium	neutral gases, air
Max. control pressure Actuator size Ø 40-80 Actuator size Ø 100 Actuator size Ø 100 Actuator size Ø 125	PA and PPS 10 bar PA 10 bar PPS 7 bar PA and PPS 7 bar
Line connections	G 3/8 – G 2 1/2 (NPT on request)

Tab. 6: Specifications: valves

9. Materials

O₂ Med: All components of the oxygen generator that are exposed to contact with oxygen-enriched air are certified in terms of their compatibility with oxygen (see DIN EN ISO 7396-1).

Compliance with the requirements of ISO 15001 is the responsibility of the operator.

All components of the oxygen generator that are exposed to contact with oxygen-enriched air are certified in terms of corrosion protection (see DIN EN ISO 7396-1). The operator is responsible for fulfilling the requirements of DIN EN ISO 7396-1 concerning the proof of corrosion protection for the entire supply system.

10. Label

O₂ Med: The oxygen generator is marked as one of the supply sources for supplying the entire system with oxygen (see DIN EN ISO 7396-1)

11. R&I oxygen generator

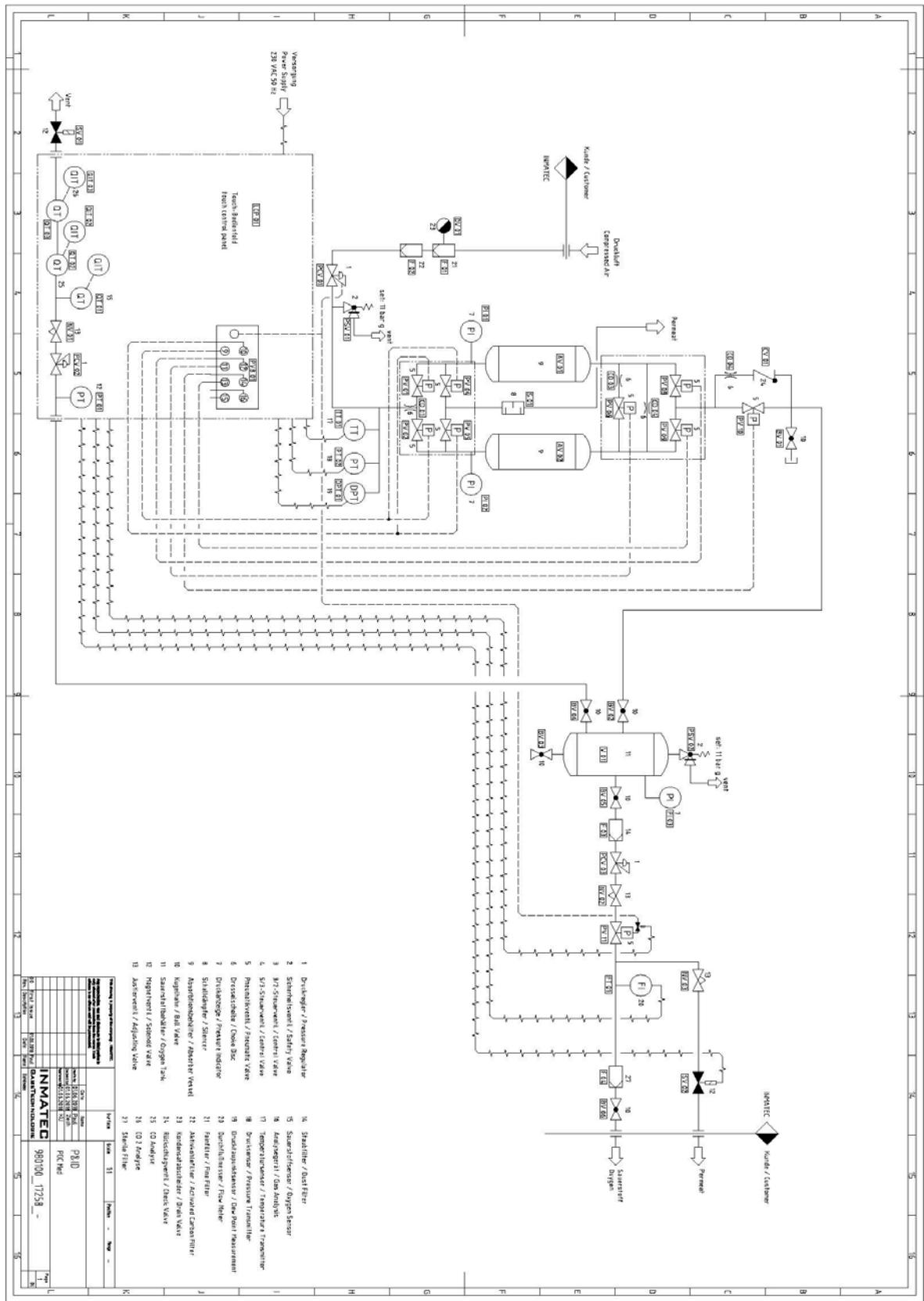


Fig. 5: R&I POC med oxygen generator

Side 33 by 63

INNATEC GaseTechnologie GmbH & Co. KG, Gewerbestr. 72, 82211 Herrsching a. A.
Phone +49(0)8152 9097-0, Fax +49(0)8152 9097-10, Email info@innatec.de

12. Touch Control Panel

The **INMATEC** Touch Control Panel (TCP) controls and monitors all functions of the oxygen generator fully automatically. All relevant operational data can be understood at a glance. Alarms are triggered if limit values are exceeded or not reached. If required, an automatic restart of the generator after power failure can be integrated into the control system.

12.1. Main menu

The generator is started and operated via the TCP main menu. Two operating modes are available: continuous operation and automatic operation.

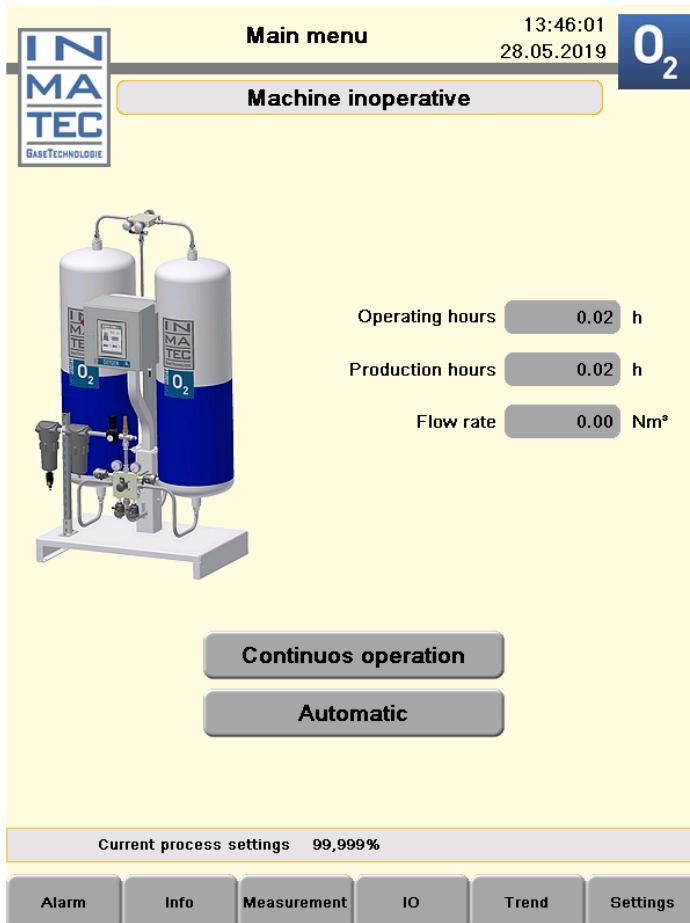


Fig. 6: Operation main menu

Operating mode	Description
Automatic	In automatic operation, the generator produces according to the outlet pressure and outlet purity. If both setpoints are reached, the generator switches to standby mode.
Operating hours	Display of operating hours
Flow rate	Flow rate display
Stop	The stop function stops the generator and switches it to standby mode. The current cycle and the pressure equalisation phase are terminated beforehand.
Standby mode	Before the generator switches to standby mode, the current cycle and the pressure equalisation phase are terminated.

Tab. 7: Main menu

12.2. Settings control menu

In the menu Settings all basic settings of the generator are made.

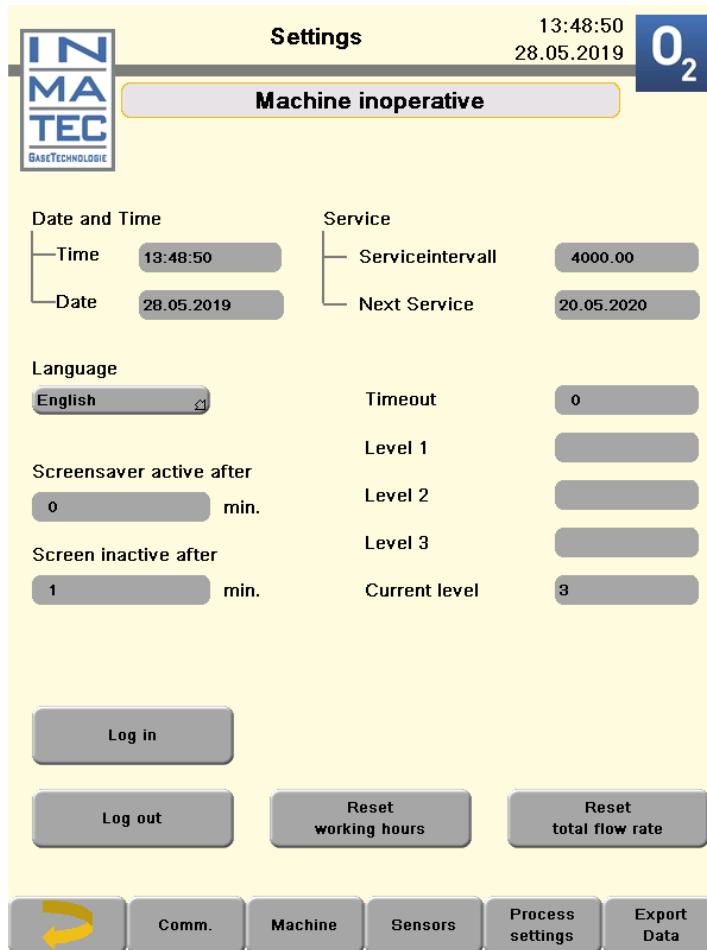


Fig. 7: Settings control menu

Function	Description
Date and time	Set the time Set the date
Service	Service interval: Display of service intervals in operating hours Next service: Display service due date
Language	Select language
Timeout	Deactivate setup mode in ... min.
Screensaver active after	Activate screen saver after set time in min.
Screen inactive after	Switch off screen after set time in min.
Password input	Level 1 password: 123 Level 2 password: 45
AutoRestart Off	Activate AutoRestart after power supply failure
Log in	Opens the input field for password entry
Log out	Exit setup mode

Tab. 8: Settings

12.3. Setup: Sequence parameters

All factory settings for the IMT POC med oxygen generators are displayed in the Setup: Sequence parameters control menu. The following values can be set by the user.

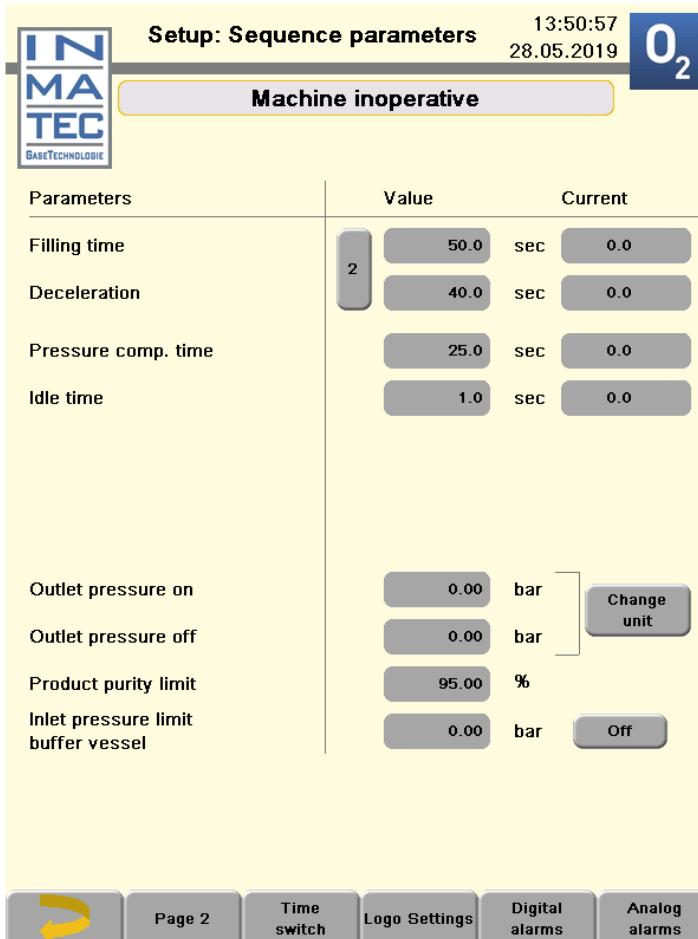


Fig. 8: Setup control menu

Function	Description
Filling time	Filling time of the adsorption vessels, factory setting
Pressure compensation time	Time between load switching cycles, factory setting
Idle time	Time delay for opening the valves, factory setting
Outlet pressure ON	Adjustment as per operating instructions
Outlet pressure OFF	Adjustment as per operating instructions
Product purity limit	Switch to standby mode at limit value, factory setting

Tab. 9: Setup: Sequence parameters

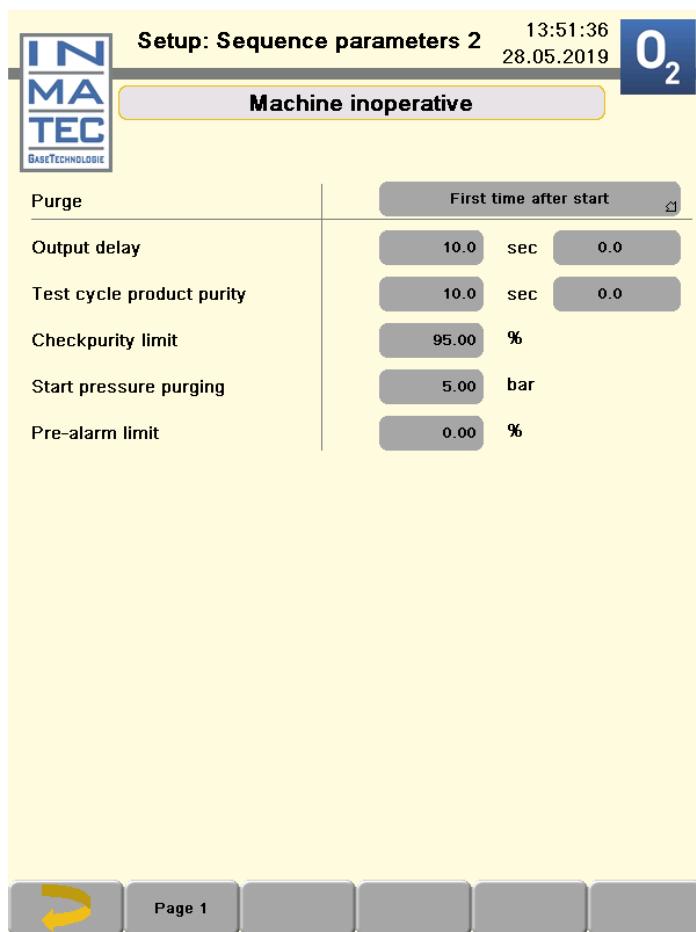


Fig. 9: Setup 2 control menu

Function	Description
Deactivated	Purging is deactivated
One-time at start	Purging is only active once after stop and after start in automatic mode
Continuous testing	Purging is always active after start in automatic mode
Output delay	Delay time of the purge valve before product container test cycle
Test cycle product purity	Cycle time of automatic inspection of product purity when continuous testing is active
Check purity limit	Set purity limit at which the valve downstream of the product container opens
Start pressure purging	Pressure limit for start of purging
Pre-alarm limit	only for base load change: Signal to slave in case of purity alarm

Tab. 10: Setup: Sequence parameters 2

12.4. Alarms

The generator control system monitors the proper functioning of the generator. Alarms are triggered in the event of malfunctions, i.e. if previously defined limit values are exceeded or not reached. The alarm message then appears on each page of the control panel.

All error messages that occur are automatically saved. The alarms can be read out from the data memory at a later time. All alarm messages are displayed in the Alarm menu.

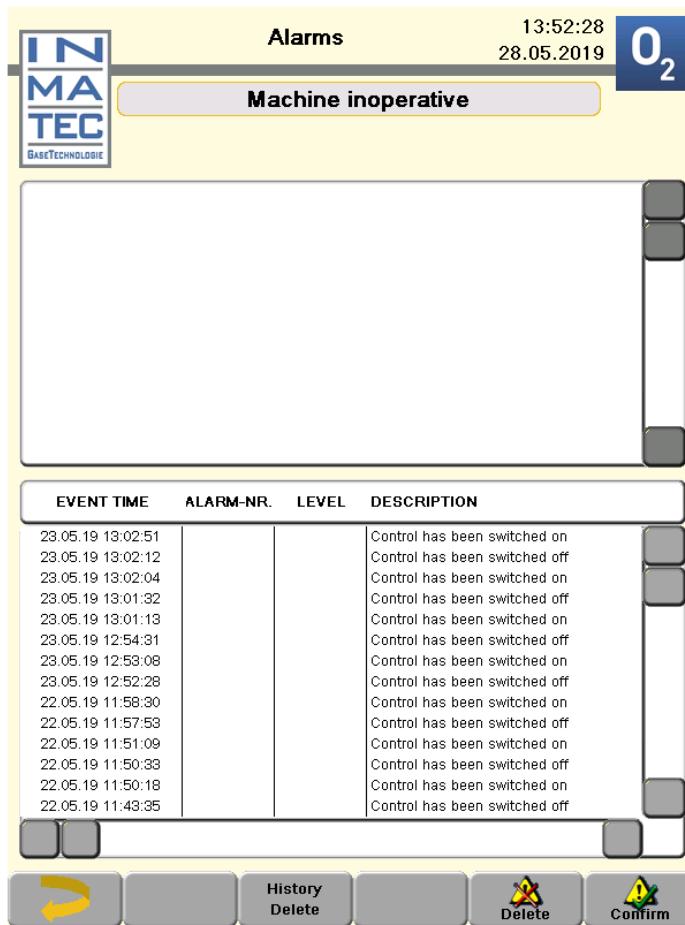


Fig. 10: Alarms

Function	Description
Confirm	Alarm is deleted on the start page Alarm is documented in the upper field
Clear	Alarm changes from the upper field (temporary) in the lower field (history)

Tab. 11: Alarms

12.5. Alarm outlet pressure

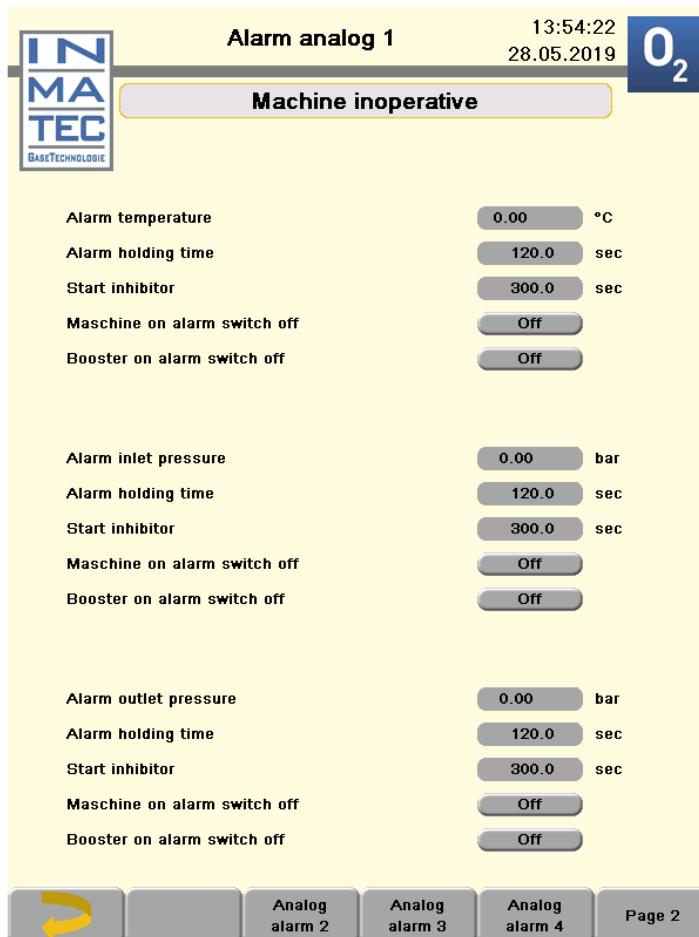


Fig. 11: Alarms control menu: Alarm outlet pressure

Function	Description
Temperature alarm	An alarm is triggered if the outlet pressure exceeds or falls below the limit value.
Alarm inlet pressure	An alarm is triggered if the outlet pressure exceeds or falls below the limit value.
Alarm outlet pressure	An alarm is triggered if the outlet pressure exceeds or falls below the limit value.
Alarm wait time	An alarm that has already been acknowledged is reported again.
Start delay	Suppresses the first alarms when the generator is restarted.
Machine on alarm switch off	Selection Off / On Generator is switched off in case of alarm
Switch off compressor in case of alarm (option)	No function with IMT POC med

Tab. 12: Alarm outlet pressure

12.6. Alarm product purity

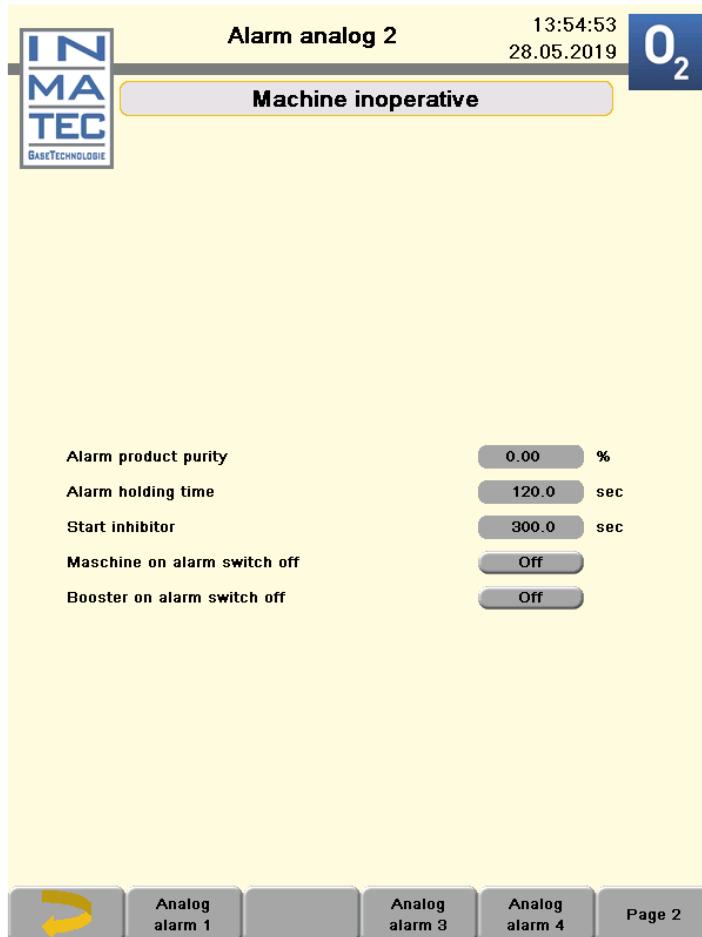


Fig. 12: Alarms control menu: Alarm product purity

Function	Description
Alarm product purity	Exceeding or falling below limit values, alarm is triggered
Alarm wait time	An alarm that has already been acknowledged is reported again
Start delay	Suppresses the first alarms when the generator is restarted
Machine on alarm switch off	Selection Off / On Generator is switched off in case of alarm
Switch off compressor in case of alarm (option)	Selection Off / On Compressor is switched off in case of alarm (option)

Tab. 13: Alarm product purity

12.7. Trend control menu

In the Trend operating menu, the measured values for the outlet pressure, flow rate and product purity are displayed over a time interval of 24 hours.



Fig. 13: Trend control menu

12.8. Export control menu

In the Export control menu, saved generator data can be exported individually or combined into groups by checking the respective boxes.

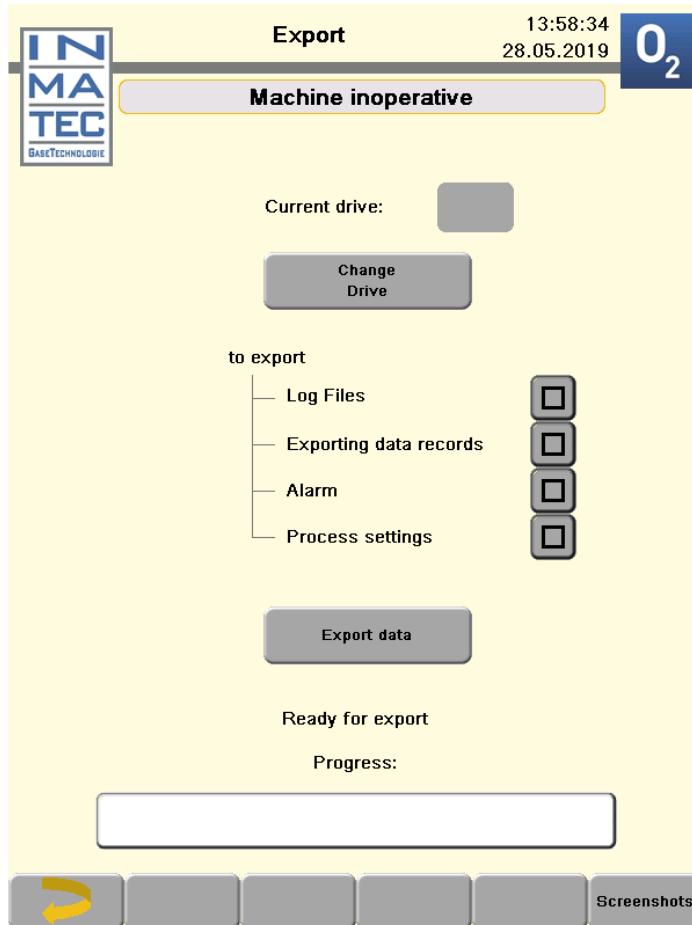


Fig. 14: Export

Function	Description
Export data	1. Selection of the data to be exported 2. Drive selection C: Touch Control Panel F: External data memory USB
Change drive	The current drive changes from C: Touch Control Panel internal data memory F: External data memory USB

Tab. 14: Export

12.9. Setup: Ethernet (option)

The TCP is delivered with the following IP address for communication with other systems.

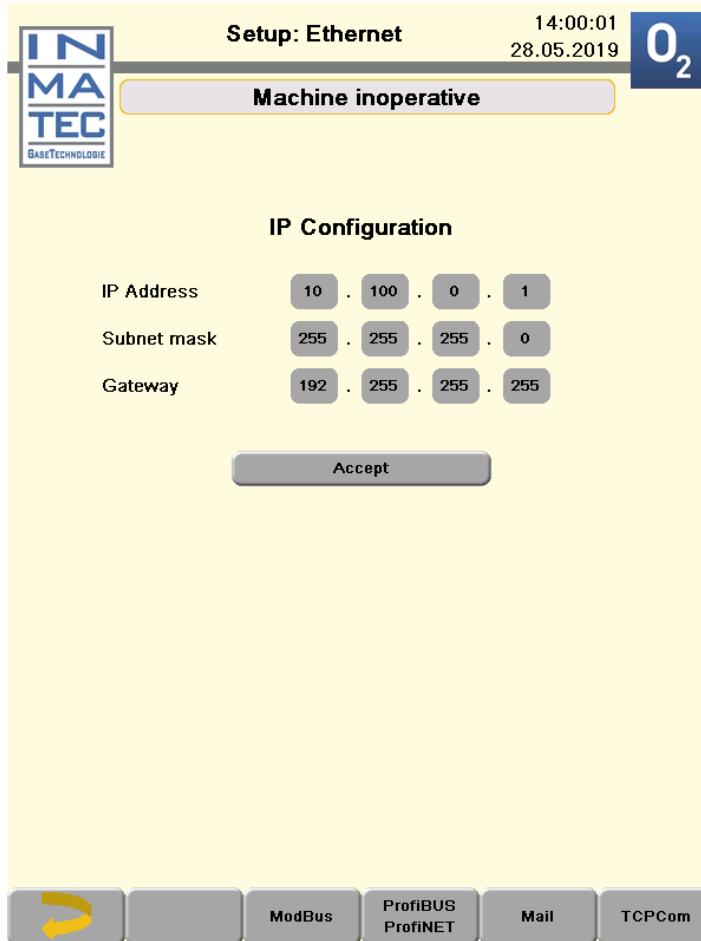


Fig. 15: Setup: Ethernet

Function	Description
IP address	192.168.1.111
Subnet mask	255.0.0.0
Gateway	255.255.255.255

Tab. 15: Setup: Ethernet

12.10. Remote control (option)

The **INMATEC** TCP offers the option of remote control or diagnosis of the generator. For this purpose, the Touch Control Panel is connected to the internet or a network.

If the TCP is accessed outside the network, access to the network must first be granted. To allow external access, the firewall must support port forwarding. For example, port 80 (HTTP) must be forwarded to port 80 on the Touch Control Panel.

Alternatively, the TCP can be connected directly to an internet connection. For this purpose, the IP address specified by the provider is entered on the TCP.

The remote control or diagnosis is carried out via the following steps:

3. As a prerequisite, Java must be installed on the computer
4. Open any internet browser
5. Enter the IP address, e.g. <http://10.10.50.200/LRMview.htm>
6. Enter password: inmategc
7. The Touch Control Panel appears on the monitor

The TCP can also be connected directly to a computer (desktop or laptop):

8. Direct connection via a cross cable
9. As a prerequisite, Java must be installed on the computer
10. Manual configuration of the IP address, e.g. 192.168.1.110
11. Subnet mask e.g. 255.255.255.0
12. Open any internet browser
13. Enter the display's IP address <http://192.168.1.111/LRMview.htm>
14. Enter password: inmategc
15. The Touch Control Panel appears on the monitor

12.11. Remote reading of stored machine data (option)

The following steps are necessary for remote reading of stored data:

16. Open any internet browser
17. Input display's address, e.g. <ftp://192.168.1.111/INMATEC> (not http but ftp)
18. After clicking on "LogFiles", the submenu with the log files opens, these are then available for download.

12.12. Setup: Modbus (option)

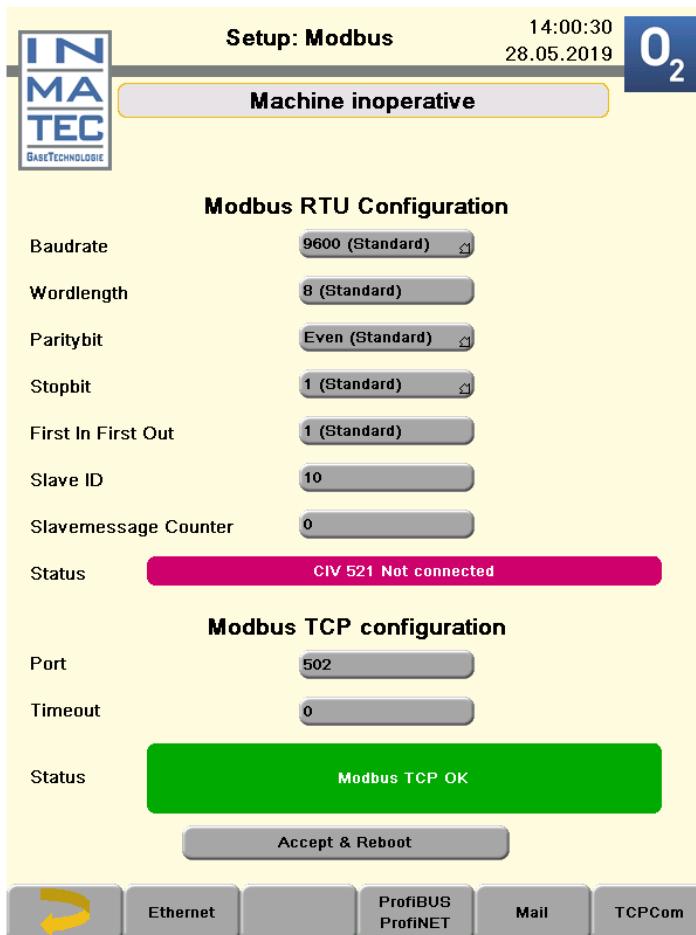


Fig. 16: Settings: Modbus

12.13. Modbus RTU (option)

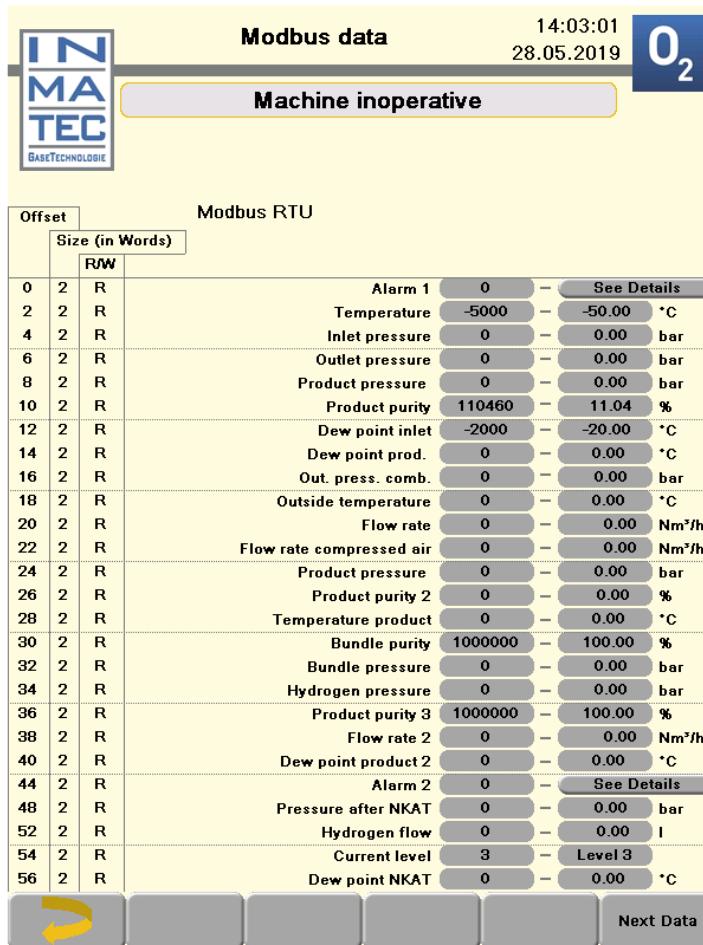


Fig. 17: Settings: Modbus RTU Page 1

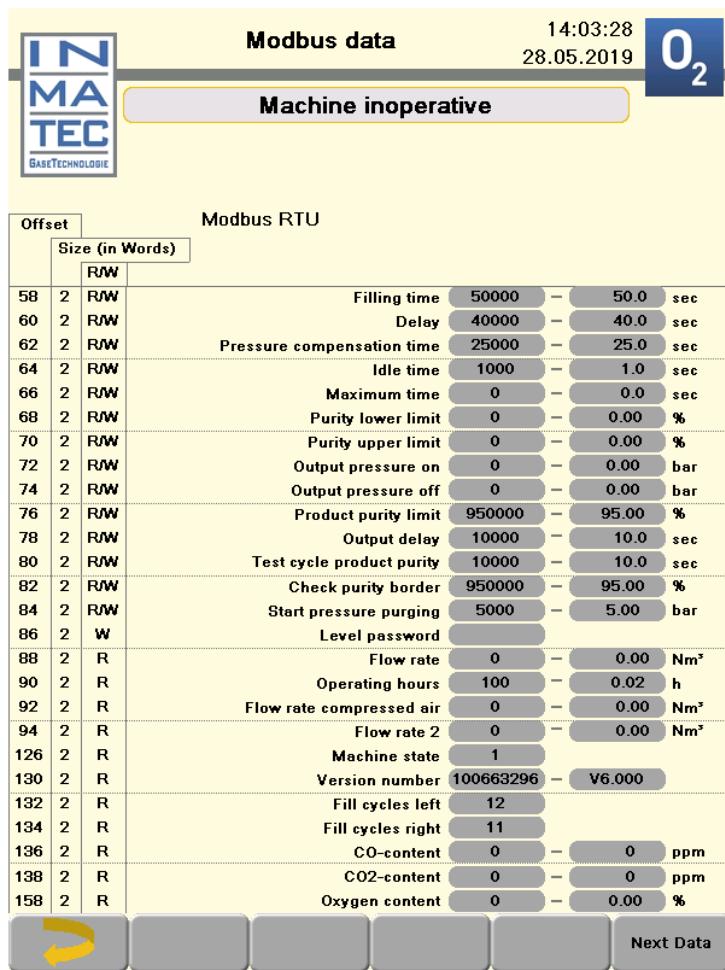


Fig. 18: Settings: Modbus RTU Page 2

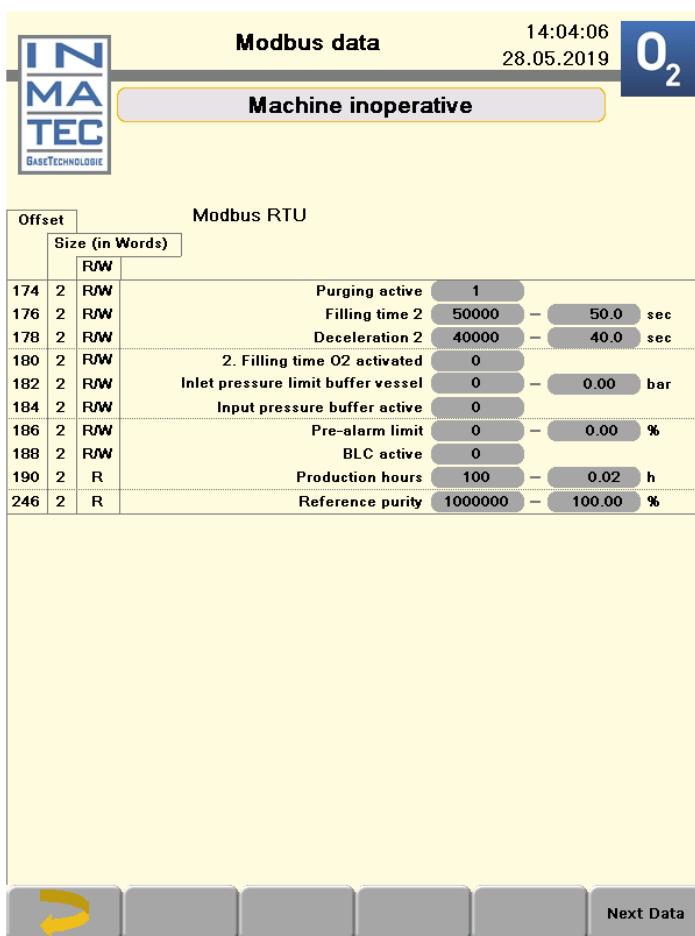


Fig. 19: Settings: Modbus RTU Page 3

12.14. Modbus TCP (option)

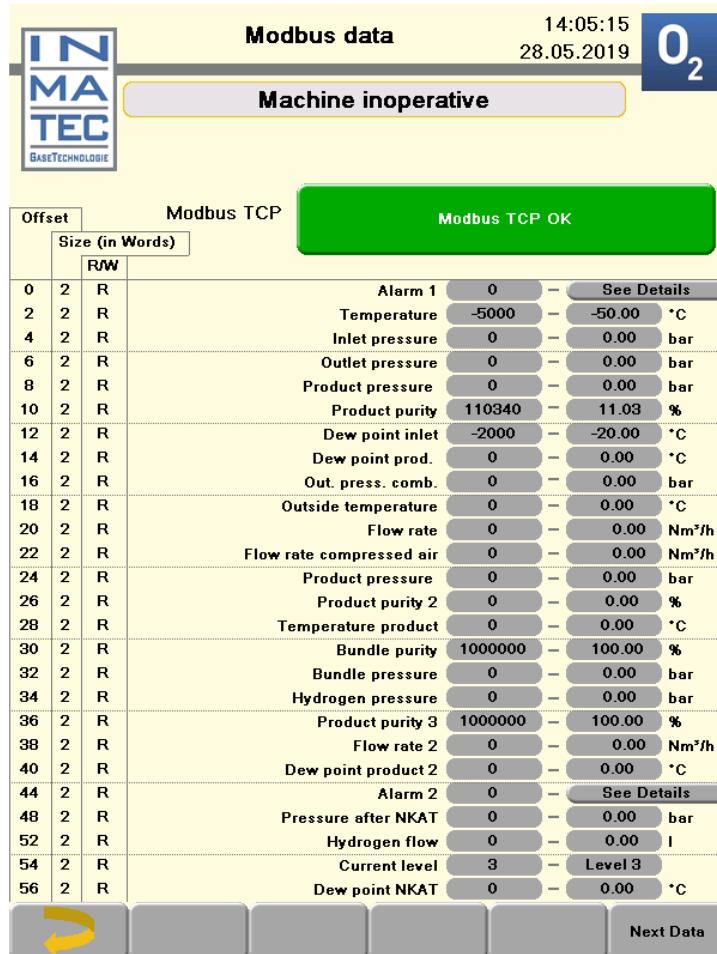


Fig. 20: Settings: Modbus TCP Page 1

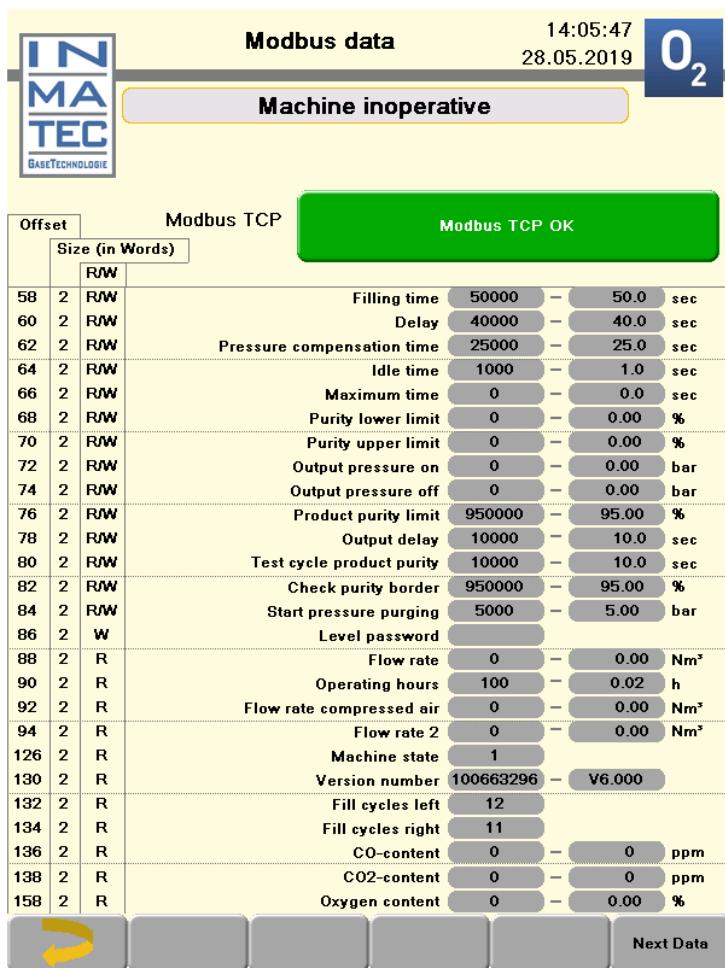


Fig. 21: Settings: Modbus TCP Page 2

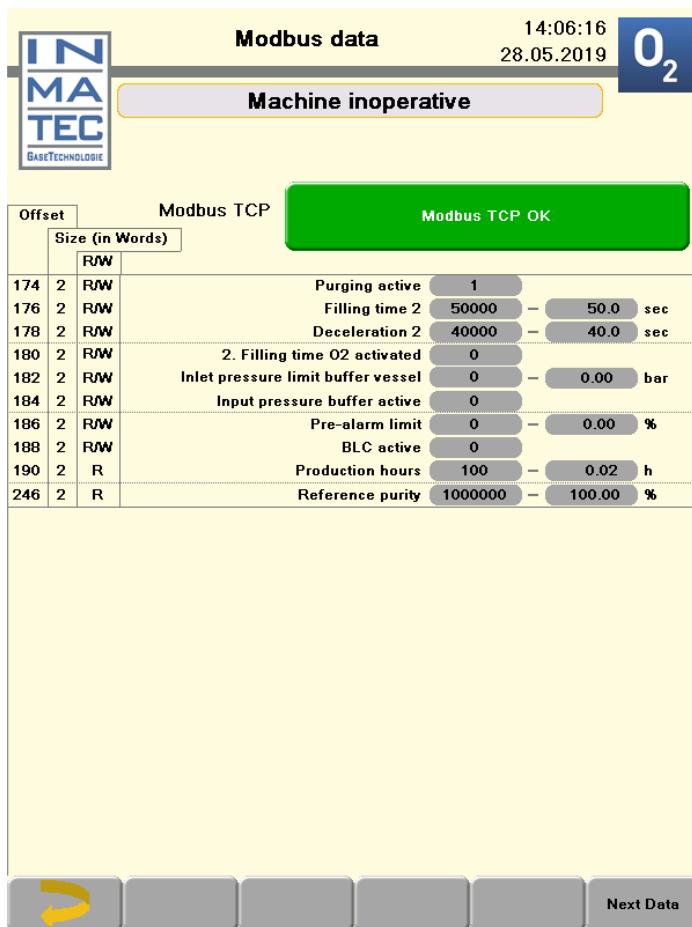


Fig. 22: Settings: Modbus TCP Page 3

12.15. Setup: Profinet (Option)

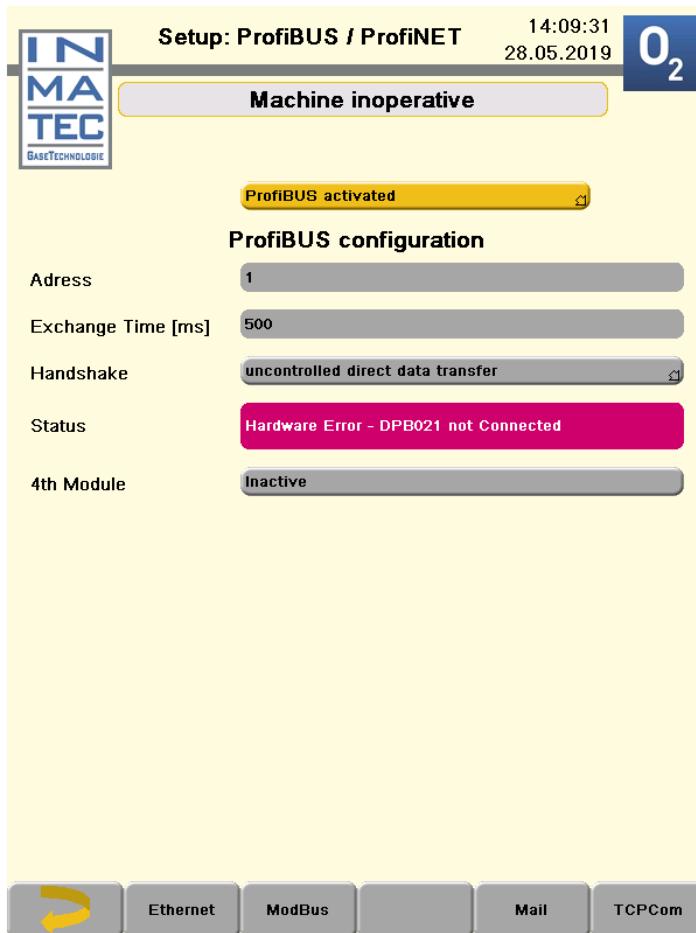


Fig. 23: Settings: Profinet

12.16. Profinet data (option)

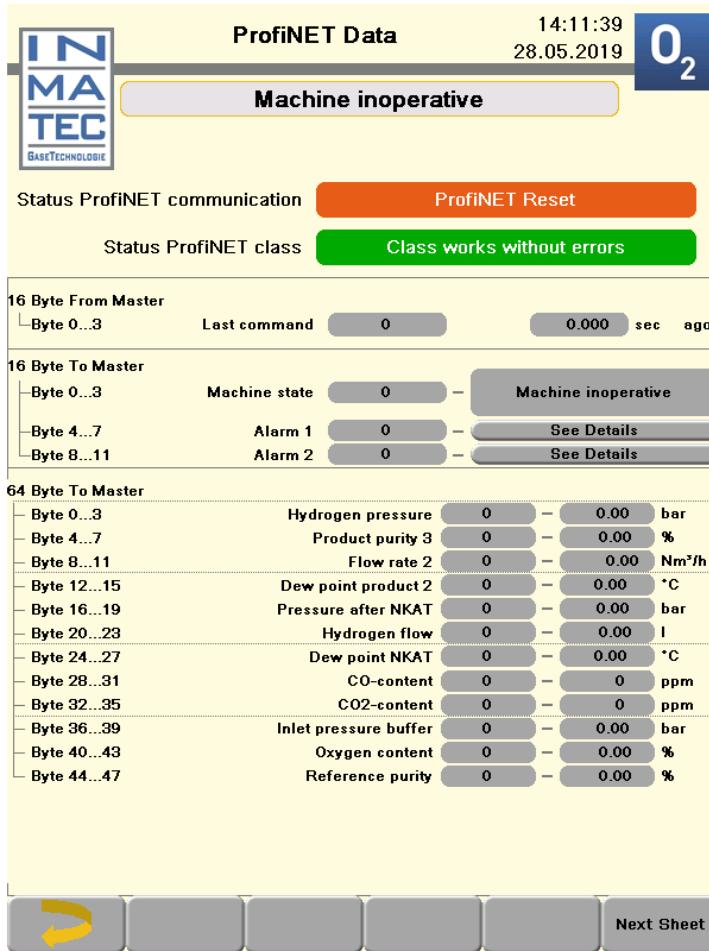


Fig. 24: Settings: Profinet Data Page 1

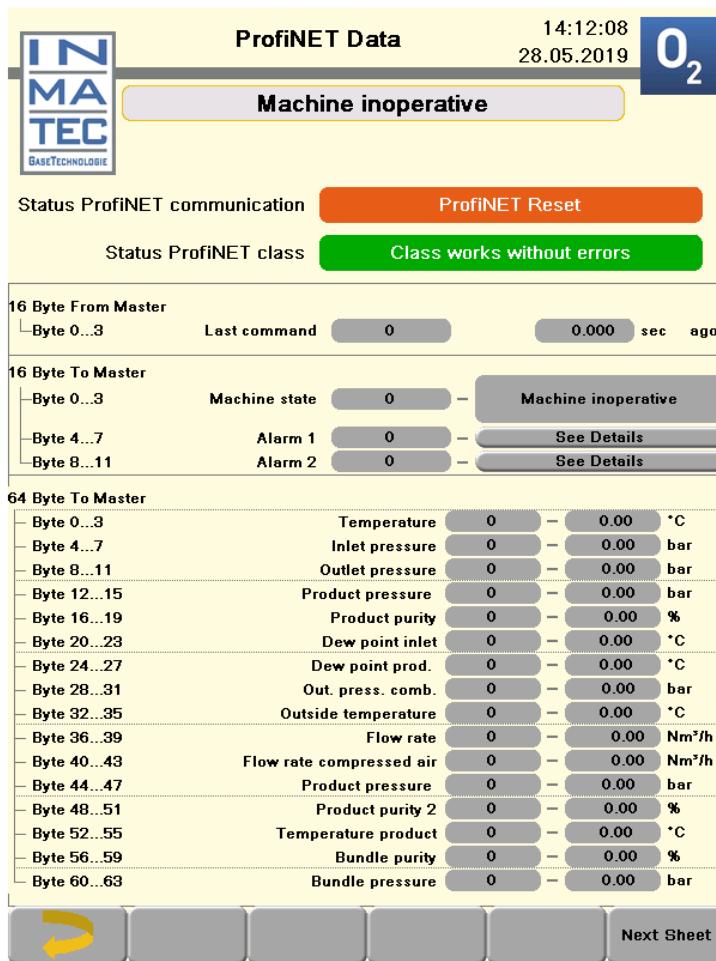


Fig. 25: Settings: Profinet Data Page 2

12.17. Setup: Email (option)

The INMATEC TCP can send optional alarms as a collective message to a freely configurable email address.

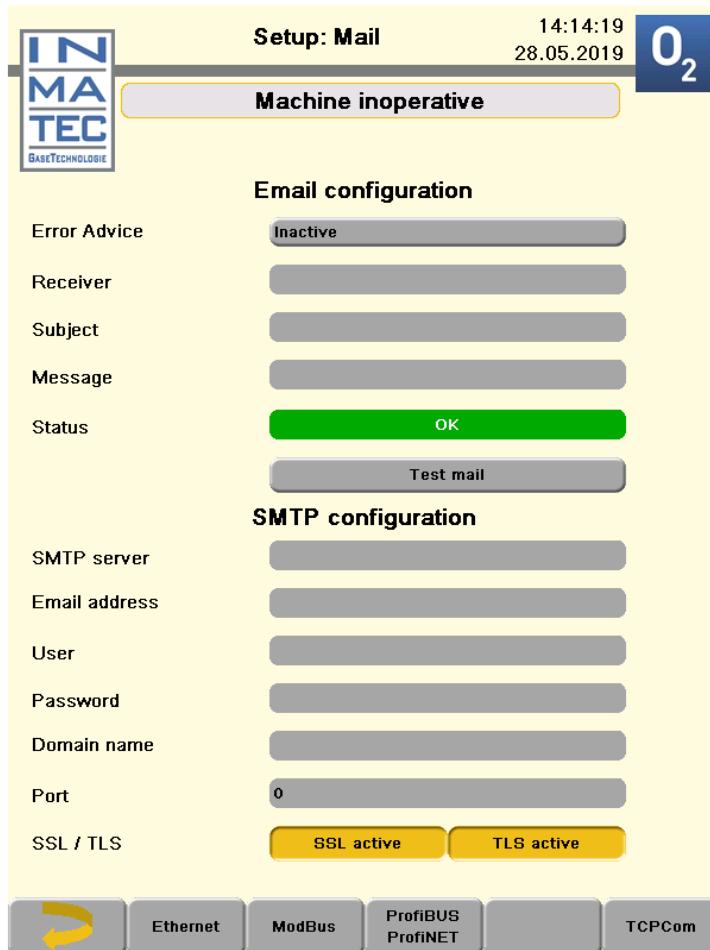


Fig. 26: Email and SMTP configuration

12.18. Email configuration

Function	Description
Error notification	Activates / deactivates the e-mail function
Receivers	Enter email address of recipient
Subject	Free text field
Message	Free text field
Status	Shows the current status
Test mail	Send a test email

Tab. 16: Email configuration

12.19. SMTP Configuration

Function	Description
SMTP server	Enter SMTP IP address Enter SMTP DNS
Email address	Enter email address
User	Enter username
Password	Enter password
Domain name	Enter domain name
Port	Input port
Accept	Accept the set parameters

Tab. 17: SMTP Configuration

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12.20. Info

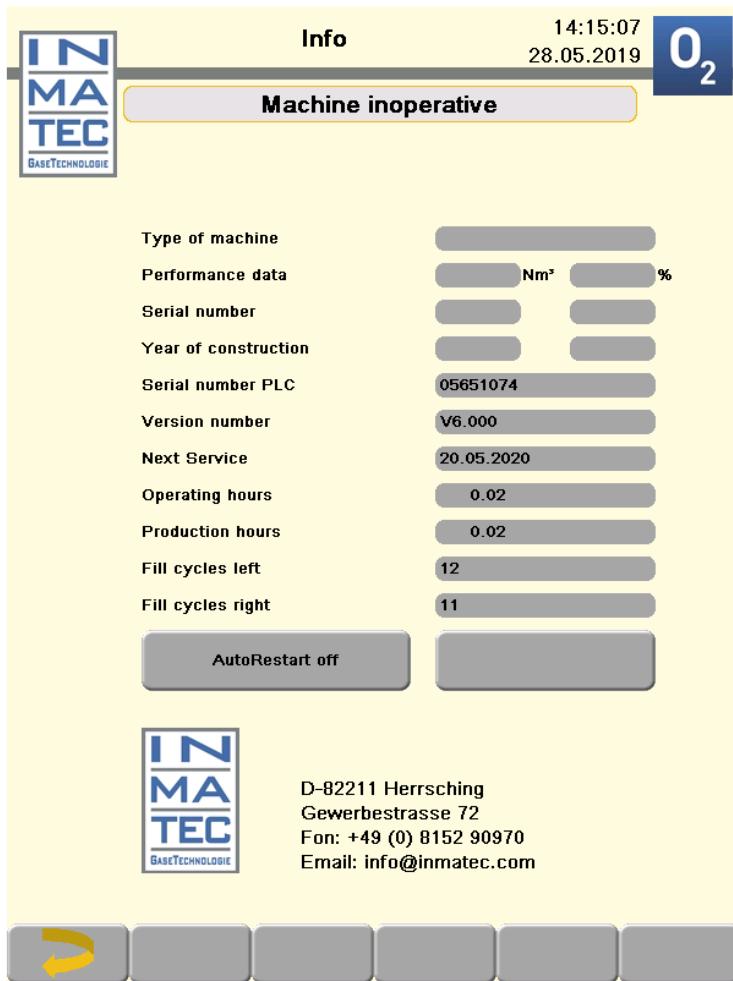


Fig. 27: Info

12.21. Modules active

All analogue and digital signals are displayed in the IO menu.

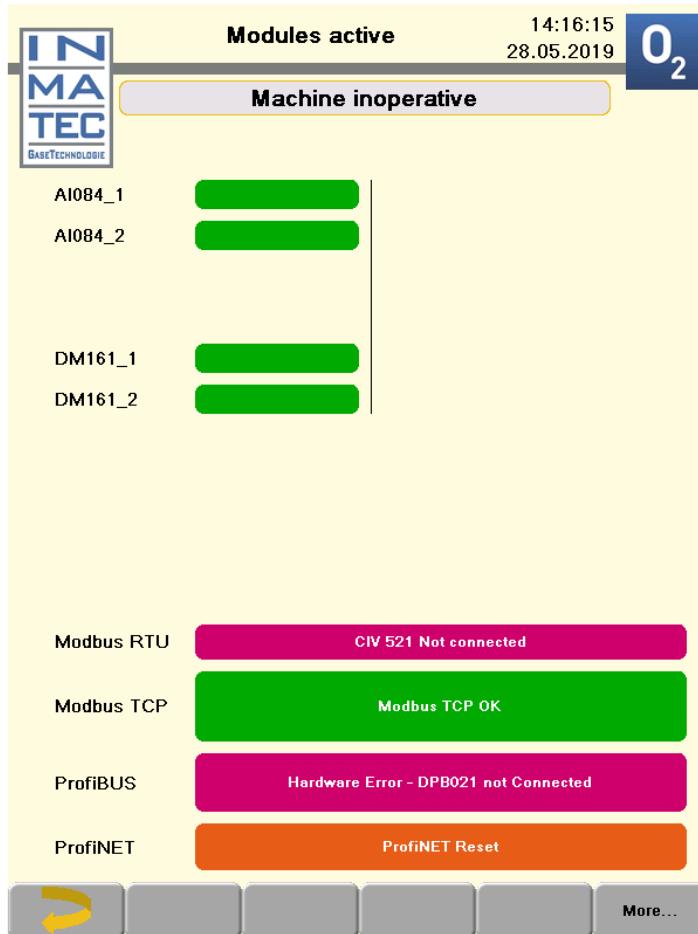


Fig. 28: Modules active

13. Declaration of conformity



EU-Konformitätserklärung / EU Declaration of Conformity

Hersteller Name and address of the manufacturer	INMATEC GaseTechnologie GmbH & Co. KG, Gewerbestr. 72, 82211 Herrsching - Germany
	<p>Der Hersteller erklärt hiermit, dass er die alleinige Verantwortung für die Ausstellung der Konformitätserklärung trägt und das die grundlegenden Anforderungen der EU Richtlinie 93/42/EWG Anhang II erfüllt werden.</p> <p>Die Gültigkeit der Konformitätserklärung bezieht sich auf die Gültigkeit des Richtlinienzertifikats EN ISO 13485.</p> <p>The manufacturer hereby declares that he is solely responsible for issuing the declaration of conformity and that all necessary requirements of EU 93/42 / EC Annex II are met.</p> <p>The validity of the declaration of conformity refers to the validity of the certificate EN ISO 13485.</p>
Sauerstoff/Oxygen Generator Type: IMT-POC med.	8150/8250/8350/8450/8550/8650/8000/8100/8200/8300/ 8400/8500/8600/8700/8800/8900/8910/8920/8930/8940/ 8950

CE 1250

QS-System, Notified Body: SQS Bernstasse 103 CH-3052 Zollikofen, "CE – 1250"
Die Sicherheitsanforderungen des Richtlinienzertifikates 93/42/EWG werden erfüllt.
The safety requirements of the certificate 93/42/EC will be fulfilled.

Konstruktive Änderungen, die Auswirkungen auf die Zweckbestimmung haben, machen diese Konformitätserklärung ungültig!

Constructional changes, which affect the intended use will make this declaration invalid.

Herrsching, 09.08.2018

Guido Kuschmierz, Managing Director
INMATEC GaseTechnologie GmbH & Co. KG

14. Product warranty

The **INMATEC** warranty applies to all oxygen generators, including their fault-free parts and workmanship, for a period of 12 months. The warranty period begins from the invoice date to the buyer. The warranty services apply under the condition of normal use. In this context, it is assumed that the oxygen generators are operated during the day shift for 2,000 operating hours per year. **INMATEC**'s liability under this warranty is limited to repair (all parts and labour costs are free of charge, but filter elements are excluded) or reimbursement of the production price of such a unit. Each generator for which a warranty claim is filed must be returned to **INMATEC** by the buyer upon **INMATEC**'s request, accompanied by documentation of the freight charges, i.e. carriage paid, as well as proof of the date of purchase.

All warranty work is carried out by **INMATEC** in 82211 Herrsching, Gewerbestr. 72, Germany.

Each replacement part is subject to the above warranty for the unexpired portion of the original one-year warranty. This warranty does not apply to a generator or parts thereof if a defect or malfunction has been caused by improper use (the evaluation is carried out exclusively by **INMATEC**), in particular due to:

- incorrect compressed air supply (the compressor air must be less than 40°C before it is fed into the generator); an excessively high feed temperature and a compressed air supply that does not meet the above requirements will cause damage that is not covered by the **INMATEC** product warranty.
- improper maintenance; the maintenance intervals depend on the operating hours, and are at least once a year; if the maintenance is not carried out on time, the **INMATEC** product warranty is void.
- improper maintenance of the filter elements; the filter elements must be replaced depending on the operating hours, and at least once a year. If the filter elements are not replaced on time, the **INMATEC** product warranty is void.
- external influences (in order to avoid damage, the system must be installed in a closed, well-ventilated space with a temperature of between +5°C and +40°C; differing ambient conditions will invalidate the **INMATEC** product warranty).

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The warranty is invalidated (null and void) if the generator has been modified or repaired outside the **INMATEC** premises without the express written permission of **INMATEC**. The foregoing warranty shall supersede any other warranty, expressed or implied, factual or statutory, including without limitation warranties of merchantability or suitability for a particular purpose. It is expressly agreed that the sole and exclusive remedy for defective parts is limited to the enforcement of **INMATEC**'s aforementioned warranty obligation. **INMATEC** is not liable to the buyer or others for any loss of use of the equipment or for any other special, indirect, incidental or consequential damages.

The above warranty applies and will be applied to the generator while it is in the possession of and used solely by the original purchaser.

15. Notification of incidents / declaration of commitment

Within the framework of legal regulations (Medical Devices Act (Medizinproduktegesetz), Medical Devices Operator Ordinance (Medizinprodukte-Betreiberverordnung) an obligation exists to report incidents, including barely averted incidents, (malfunctions) concerning use of medical devices (oxygen generators in the medical field).

We kindly ask you to inform us about all incidents.

Please return the signed declaration of commitment to us.

Declaration of commitment – notification of incidents during the use of medical devices in accordance with §3 of the Medical Devices Operator Ordinance (Medizinprodukte-Betreiberverordnung)

We agree to report all incidents to the manufacturer INMATEC GaseTechnologie GmbH & Co.KG Gewerbestrasse 72, D-82211 Herrsching / Germany.

Place, date

Signature/Stamp