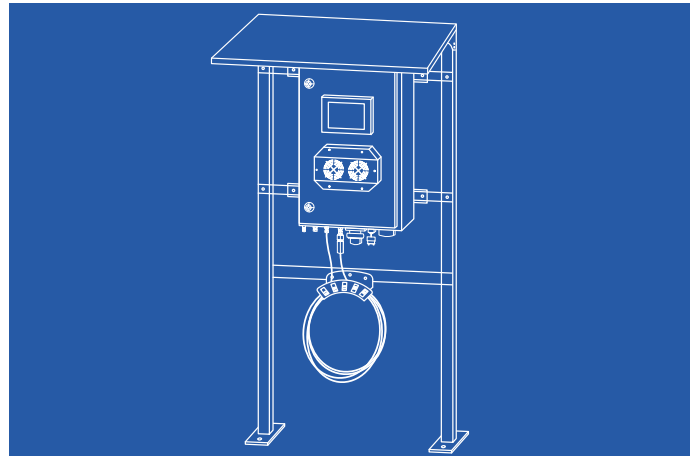


GAS IDENTIFICATION UNIT

- Easy: Gas Identification at a push of a button
- Fast: Test result in less than 5 min
- Simple: One unit for all gases
- Compliant with GMP



The Concept

The **Gas Identification Unit** (patent pending) is a user-friendly, innovative system to identify process gases based on their thermal conductivity. This unit has been developed by Air Liquide in response to the recently updated* GMP regulations regarding the identification of incoming materials. The European Union (EU) GMP guidelines specify in Volume 4/Part 1/Chapter 5 that "All incoming materials should be checked to ensure that the consignment corresponds to the order" and that "there should be appropriate procedures or measures to assure the identity of the contents of each container."

The measurement method is based on the thermal conductivity property of gases (built-in Thermal Conductivity Detector, TCD). At a given temperature, this physical property is specific to each gas molecule, and can therefore be used for identification. The method is validated following current guidelines, including ICH Q2 (R1) Validation of Analytical Procedures. Once installed, the unit is also qualified following a standard protocol that needs to be independently approved by the respective Quality departments of the customer and Air Liquide.

The **Gas Identification Unit** is proposed by Air Liquide on a rental basis. Therefore, there is no need to invest in separate, gas-specific analyzers, which not only result in added instrumentation costs, but also require qualified and trained personnel to operate. Maintenance of the unit is also under Air Liquide's responsibility.

* The new Chapter 5 of the EU GMP Guidelines has been applicable to medicinal products manufacturing since March 2015.

Applicable Industries

The **Gas Identification Unit** is ideally suited to the needs of the bio/pharmaceutical industry, when using gases in a GMP environment. The system makes it safe, easy and fast to perform the mandatory identification of incoming gases, helping to efficiently demonstrate compliance to auditors and regulatory inspectors.

The unit is preconfigured (default factory settings) to address the needs of biomanufacturing facilities, which typically have bulk N₂, O₂ and CO₂ on-site. Depending on the customer's requirements, the unit can be configured to a wide range of gases, pure or mixed, with supply modes ranging from cylinders to bulk, including pipeline supply.

Measurement procedure

The identification procedure is **very fast** and **very simple**. First, connect the gas to be identified to the unit with the flexible hose. Any type of gas container from cylinders to bulk trailers are possible. Then, select the gas to be identified on the touch screen. Some additional information like batch number, user reference, ... can be entered. Those will be reported in the identification protocol. One push of the start button is all it takes to initiate the 5-minute identification procedure. Once completed, the result "Identity OK" or "Identity not OK" is simply displayed on the screen, and an identification report is generated. The electronic identification report is available in pdf format for direct printing and/or transfer to a laptop.

This identification procedure does not require laboratory personnel, qualified and trained on gas analysis instrumentation, such as Gas Chromatography or other analytical systems. A simple introduction to the operation of the Gas Identification Unit is all that is required. Similarly, there is no need to perform periodic calibration. The unit has an integrated auto-calibration procedure, using gas from the bulk storage tank as a reference.

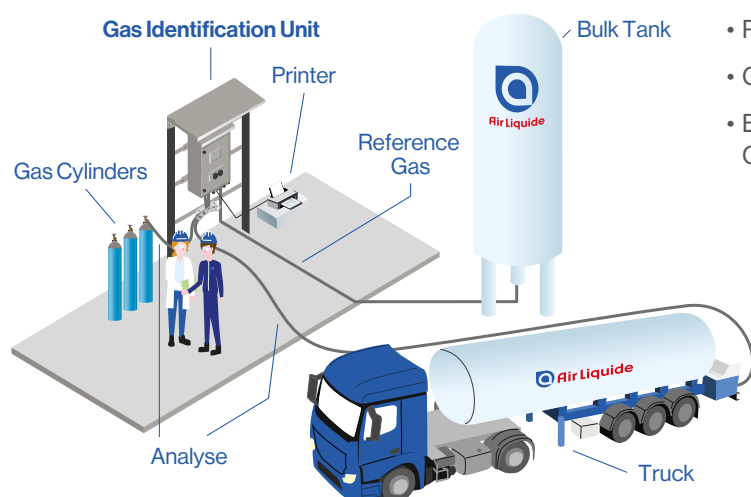
In order to perform the identification, only an operator is needed as well as a QA representative to then release the gas for unloading and production.

The **Gas Identification Unit** measures the thermal conductivity of the gas to be identified. This method uses a cell that is not gas specific. Any type of gas could be analysed as it is simply heated and the heat transfer through the gas is measured to determine its conductivity. Finally, the TCD has no wearing parts and can therefore operate for several years without needing replacement. The system's housing is also equipped with a thermoelectric cooler to provide thermal stability and maintain the detector under constant conditions.

Technical data

	Unit alone	Stand with roof
Height (m)	0.77	2.2
Width (m)	0.61	1.4
Depth (m)	0.28	1.2
Weight (kg)	42	68
Power supply	230 V, 50Hz, 2-phase 800W	
Reference gas	Nitrogen gas 70 l/h	
Data transfer	RJ45 to printer/PC	

Installation layout



Installation of the unit

Air Liquide proposes the Gas Identification Unit on a rental basis. Installation, commissioning, and maintenance are included in the offer.

The unit will be installed at your site by Air Liquide, followed by a full qualification of the unit during commissioning. A complete IQ/OQ/PQ qualification protocol will be provided as part of the standard validation process by both your and Air Liquide's Quality department.

The unit needs a continuous flow rate of a reference gas. This gas (nitrogen) is usually taken from a bulk storage tank on the premises (containing product already released for use). Therefore, for the sampling of the incoming gas, the unit should be installed outside, and in proximity to a liquid storage tank to provide the reference gas supply line to the Gas Identification Unit. All the connections, flexible hoses and pressure reducing valves are provided with the unit. A stainless steel stand with a 4-season protection roof is included in the package, allowing a standalone installation. Once connected to standard electrical supply, the unit is fully installed and ready to use.

Advantages

- Suitable for process gases used in the pharma industry (e.g. N₂, O₂, CO₂)
- Only one device for all gases
- Short measurement time (~ 5 min)
- User-friendly, no need for a highly qualified operator
- No safety risk since no intermediate sampling from the trailer or from the cylinders needed
- No calibration needed
- Report generated and transferable to printer/laptop
- GMP compliant operation
- Easy, simple and cost-saving solution to comply with the GMP identification testing requirement



Contact

Air Liquide Gas AB
Lundavägen 151
212 24 Malmö
Tel. 020-44 01 44
kundservice.sweden@airliquide.com
mygas.se / airliquide.se

Air Liquide Danmark A/S
Høje Taastrup Vej 42
2630 Taastrup
Tlf: 76 25 25 95
kundservice.denmark@airliquide.com
mygas.dk / airliquide.dk