



DATA SHEET

ENDOSCOPE DRYING AND STORAGE CABINET MOD.

GANDY ESC H.9



Summary

| | |
|--|-----------|
| 1. Introduction | 3 |
| 1.1 Preliminary information | 3 |
| 1.2. Certifications and reference standards | 3 |
| 1.3 Scope of application | 3 |
| 2. Device features | 4 |
| 2.1 Materials and general parameters | 4 |
| 2.2 Dimensional parameters | 4 |
| 2.3 Structural characteristics | 5 |
| 2.4 Functional characteristics | 6 |
| 2.5 Traceability | 6 |
| 2.6 Safety | 7 |
| 2.6.1 Safety measures for the endoscope | 7 |
| 2.6.2 Limitation of cross-contamination | 7 |
| 2.6.3 Alarms | 7 |
| 3. Installation requirements | 8 |
| 3.1. Electrical requirements | 8 |
| 3.2 Internet connection requirements | 8 |
| 3.3 Environmental requirements | 9 |
| 3.4 Installation layout | 9 |
| 4. Consumables and accessories | 9 |
| 4.1 Consumables | 9 |
| 4.2 Accessories | 10 |

1. Introduction

1.1 Preliminary information

| PRELIMINARY INFORMATION | |
|-------------------------|---|
| Model | GANDY ESC H.9 |
| Producer | Nuova SB System S.r.l. |
| Manufacturer | Nuova SB System S.r.l. |
| CND | Z12011312 – Endoscope dryers |
| RDM | 2494948 |
| Intended use | Drying and storage of flexible endoscopes |
| Risk class | Class I |

1.2. Certifications and reference standards

| MDR CONFORMITY | CE Certificate - MED 31114 extended in the transitional period until the transition to the new medical device regulation MDR 2017/745 as specified in Art. 120.3c of the MDR as amended by Regulation (EU) 2023/607. |
|----------------------------------|--|
| REFERENCE STANDARDS | |
| UNI EN 16442:2015 | Controlled environment storage cabinets for conditioned thermolabile endoscopes. |
| IEC 61010-1:2010 | Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements. |
| EN 61326-1: 2022 | Electrical equipment for measurement, control and laboratory use - Electromagnetic compatibility requirements - Part 1: General requirements. |
| ISO 22196:2011 | Measurement of antibacterial activity on plastics and other non-porous surfaces. |
| UNI CEI EN ISO 14971:2022 | Medical devices - Application of risk management to medical devices. |
| UNI/TR 11662:2016 | The entire endoscope reconditioning process is guaranteed to be state-of-the-art. |
| COMPANY STANDARDS | |
| UNI EN ISO 9001:2015 | Quality Management Systems - Requirements. |
| UNI CEI EN ISO 13485:2021 | Medical devices - Quality management systems - Requirements for regulatory purposes. |

1.3 Scope of application

The **GANDY ESC H.9 horizontal storage cabinet** has been designed to provide optimal **external and internal drying**, as well as storage in a safe and secure environment, for **9 flexible endoscopes**, of each model and brand. It is also compatible for the storage of **TOE probes**.

2. Device features

2.1 Materials and general parameters

The **materials** conceived and used for the design and workmanship of the GANDY ESC H.9 storage cabinets are shown in the following table.

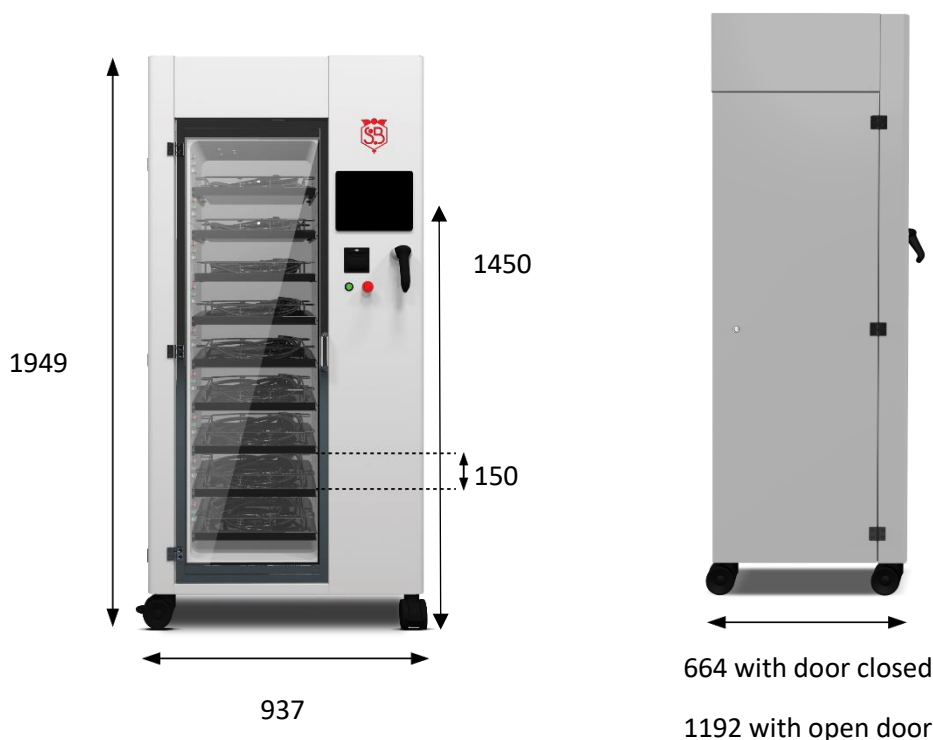
| COMPONENT | MATERIAL |
|-------------------------------|---------------------|
| Interior surfaces | Stainless Steel 316 |
| Material of external surfaces | Painted aluminium |
| Door | Tempered glass |

This other table lists the **general parameters** of the equipment.

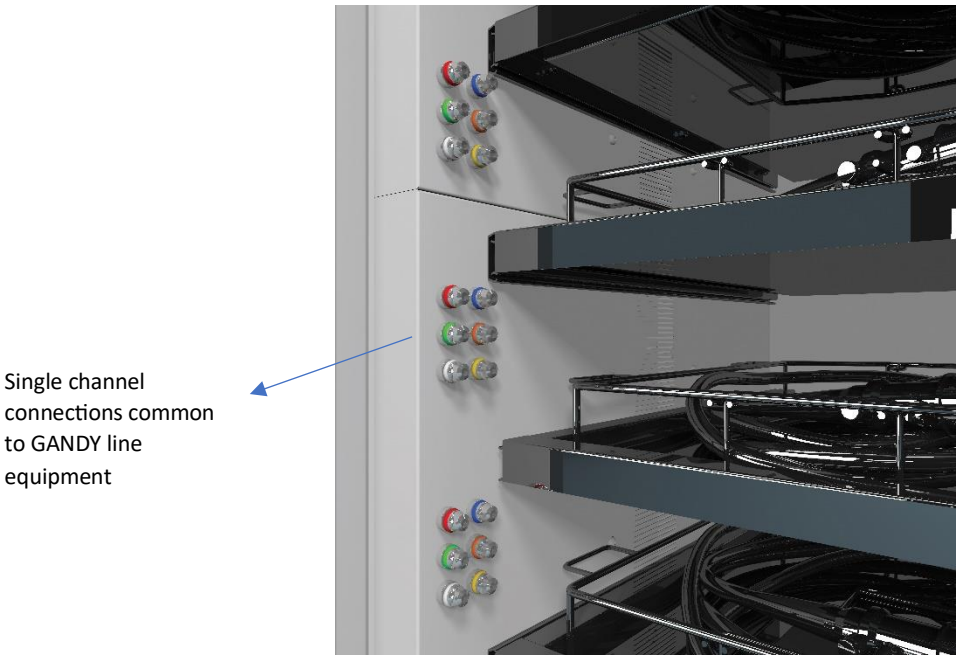
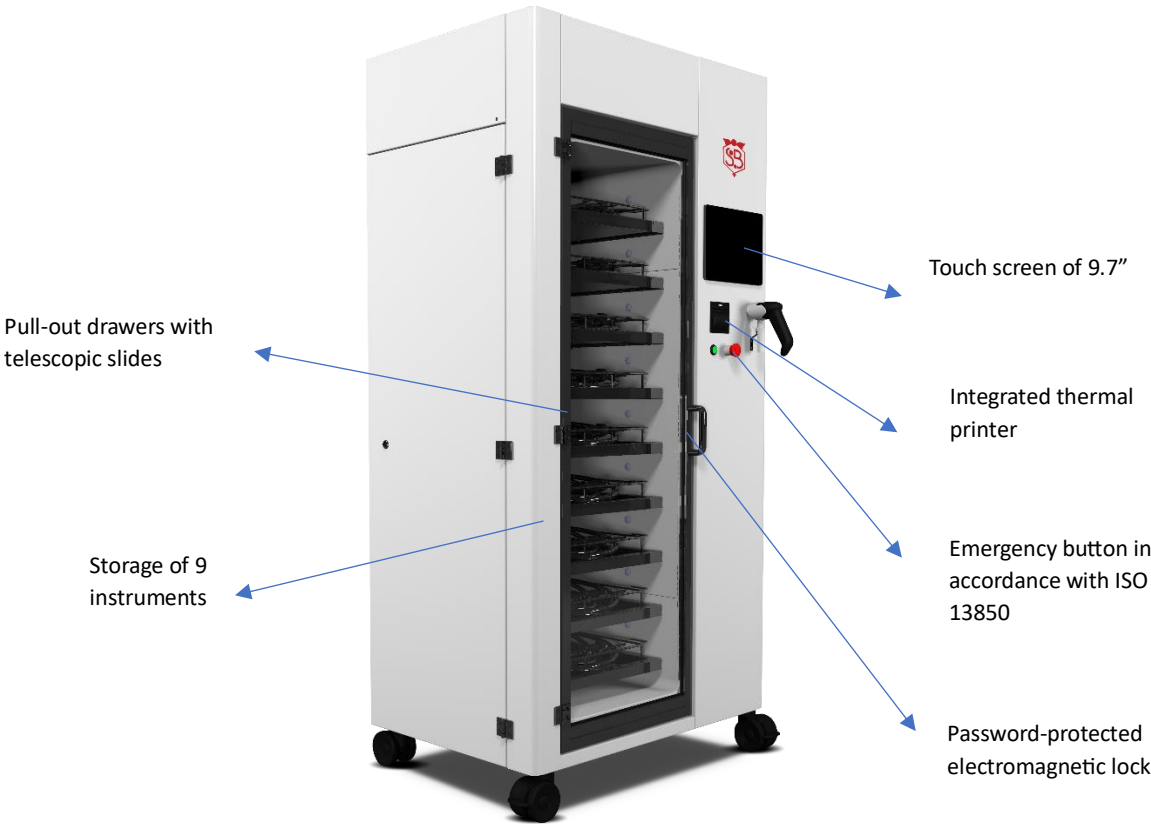
| PARAMETER | VALUE |
|---------------------|--------|
| Weight | 230 Kg |
| Maximum power input | 800 W |
| Noise | 50 dB |

2.2 Dimensional parameters

Below are the **views and relevant dimensions** of the medical device mod. GANDY ESC H.9.



2.3 Structural characteristics



2.4 Functional characteristics

The following table shows the **functional characteristics** guaranteed by the machine.

| GUARANTEED FUNCTIONALITY DURING CYCLES |
|--|
| Guaranteed storage for 31 days. |
| Possibility of continuous flushing with air through all channels of stored endoscopes. |
| Perfect drying of internal endoscope channels in 2 hours. |
| Equipped with a drying system for each shelf, dedicated to each endoscope stored. |
| External drying performed by continuous air flushing at a temperature of 30-35°C, thanks to an internal blower. |
| Equipped with an automatic instrument and operator recognition system using a barcode scanner. |
| Possibility to clearly identify every parameter or process indicator thanks to the wide touch screen. |
| On each shelf there are mini-internal compressors that keep pressure and quality of the air inside the cabinet steady. |
| These compressors, along with the internal blower for external drying of the scopes, make the use of external medical air unnecessary . |

2.5 Traceability

The following table shows the **traceability** characteristics of the ESC H.9 storage cabinet.

| TRACKING CHARACTERISTICS |
|--|
| Complete tracking and recording of endoscope drying and storage data. |
| Paper tracking guaranteed thanks to on-board thermal printer |
| Operators and endoscopes will be identified by their own bar code, which can be registered and identified on the equipment thanks to the bar code scanner. |
| Equipped with bar code scanner. |
| Cycle traceability data can be exported via USB and Ethernet in .csv format. |

The **information and data in the reports printed** on thermal paper for each cycle to ensure paper tracking are shown in the following table.

| INFORMATION IN PAPER REPORTS |
|--|
| Hospital name. |
| Machine serial number. |
| Operator responsible for loading and unloading the instrument. |
| Time and date of loading and unloading the instrument. |
| Total duration of storage. |
| Endoscope serial number and related group. |
| Possible alarm code. |
| Type of channels monitored. |

| |
|---|
| Internal storage humidity |
| Internal storage temperature, monitored by two temperature sensors in accordance with UNI EN ISO 16442. |
| Confirmation of storage validation. |

2.6 Safety

The GANDY ESC H.9 medical device is equipped with all the necessary safety measures to ensure the **safety** of the endoscope and the patient, as well as to limit cross-contamination as much as possible. The following tables show the design solutions adopted to guarantee the safety of all those involved in the endoscope drying and storage process.

2.6.1 Safety measures for the endoscope





| SAFETY MEASURES FOR THE ENDOSCOPE |
|--|
| Single duct control with the possibility of detecting any obstructions or possible lack of airflow passage. |
| Equipped with alarms that signal if the endoscope is removed before the end of the drying process and after 31 days of storage. |
| The status of the endoscope and the advancement of the cycle are clearly visible on the display and the status of the instrument is recognizable thanks to a color code. |
| IO-Link sensor to monitor and register values of temperature and humidity in the internal environment of the device. |
| Encrypted access for the operators ensuring the safety of the endoscopes stored inside of the device. |

2.6.2 Limitation of cross-contamination

| LIMITATION OF CROSS-CONTAMINATION |
|---|
| Positive pressure storage (12 Pa set, can be raised if necessary). |
| Increased air flow inside the cabinet when the door is opened to prevent the entry of any microorganisms. |
| Filtering of air from outside with filters ULPA U17 from 0.01 µm. |
| Additional air filtration with filters ULPA U17 for each shelf by 0.2+0.01 µm. |
| Possibility of using a stainless-steel basket for transport to and from the cabinet, compatible with the storage environment, to limit any touching of the endoscope. |
| The air that enters in the device is filtered, heated and dried in order to remove bacteria, virus and moisture. |
| Quality of the air is tested to be ISO 5 according to the ISO clean room classification. |

2.6.3 Alarms

The mod. ESC H.9 endoscope storage and drying cabinet is equipped with **acoustic and visual** alarms capable of signaling to the operator any type of malfunction that may occur during the drying or the storing phase. The alarms are color-coded according to the severity of the malfunction.

| WASHING | |
|--|---|
| ALARM COLOR CODE | SIGNIFICANCE |
|  | Visual warning only with message on the main page. |
|  | Acoustic and visual alarm, with message. |
|  | Acoustic and visual alarm, with message and error code. |
|  | Acoustic and visual alarm, with message and error code. |

3. Installation requirements

3.1. Electrical requirements

| ELECTRICAL REQUIREMENTS | |
|-------------------------|-----------------|
| Power supply voltage | 230 V \pm 10% |
| Power supply frequency | 50 Hz |
| Input power | 800 W |

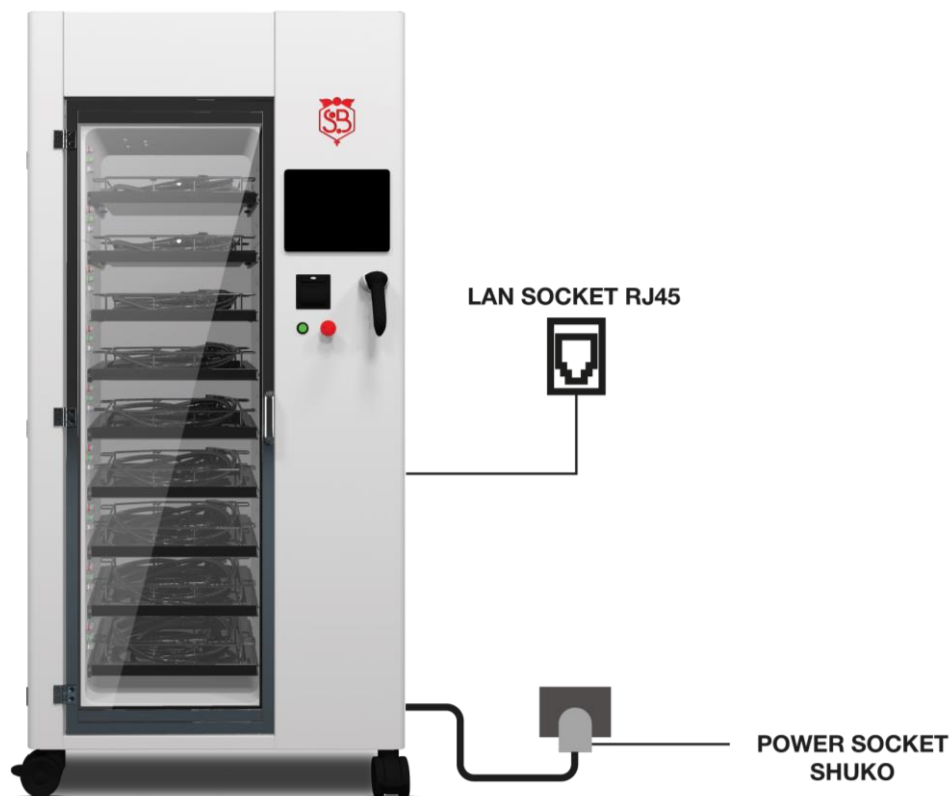
3.2 Internet connection requirements

| INTERNET CONNECTION REQUIREMENTS | |
|----------------------------------|-----------------|
| LAN socket | Socket LAN RJ45 |
| LAN socket data | IP Address |
| | Subnet Mask |
| | DNS Address |
| | Gateway |

3.3 Environmental requirements

| ENVIRONMENTAL REQUIREMENTS | |
|-----------------------------------|---------------------|
| Room temperature | 5°C a 40°C |
| Relative humidity | < 30% |
| Recommended ventilation frequency | > 10 Air changes /h |

3.4 Installation layout



4. Consumables and accessories

4.1 Consumables

| CONSUMABLE | CHARACTERISTICS |
|-------------------------|--|
| Filter WSF-GPFL-0001-05 | Air filter with porosity of 0.01 µm. |
| Filter AF3-IPFHF-0022 | Air filter with porosity of 0.2+0.01 µm. |
| Thermal paper KT 55 FA | Thermal paper with guaranteed 10-year stability. |

4.2 Accessories

| ACCESSORIES | CHARACTERISTICS |
|----------------------------|--|
| Endoscope connectors | Connectors are available for each channel of endoscopes of any model and brand, such as Pentax, Olympus, Fujinon, Storz, Wolf and others. |
| Stainless steel 316 basket | Designed and manufactured to be contained within the wash tank, this basket can be used for handling endoscopes by limiting contact with them. |