

SUPERVISION AND CONTINUOUS MONITORING IN MEDICAL ENVIRONMENTS

The **SINTESY.eagle.easy** supervision system is the flexible and economic solution which meets the need for continuous monitoring of medical environments such as, for example, biological laboratories and biobanks.

Such environments, according to appropriate regulations and specific industrial guidelines, contain many other appliances which need to be constantly monitored: blood bank refrigerators, programmable dropdown freezers, CO₂ incubators, hoods, cryogenic freezers, mechanical freezers and more.

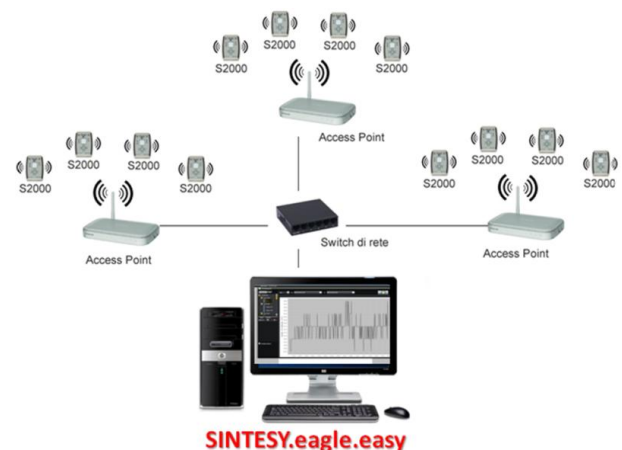
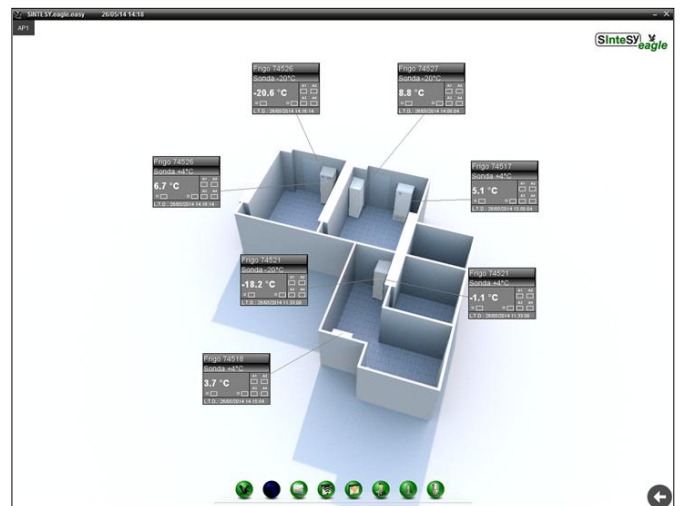
The devices can manage 4/20 mA signals, dry contacts and serial protocols with RS232/RS485 interface. Otherwise other probes, such as PT100 or PT1000, may be included. Environmental control also provides the monitoring of temperature and relative humidity of the laboratories, as well as O₂ and CO₂ rate in areas which may be dangerous to operators' safety (see Legislative Decree 81/2008). These environments can be alarmed and linked to automatic ventilation systems.

Thanks to its simple and intuitive graphical user interface, eagle.easy allows the administrator of the system to fully configure it importing maps, photos and even three-dimensional reconstructions of the monitored structures, thus obtaining a faithful reproduction of the areas that will be monitored.

In addition, each device (e.g. 2000) can be easily acquired from the software and then users can set: alarm thresholds and their intervention delay, range of measurements, measure units, how to submit alarms

to the operators (technical and/or clinical) and more.

The system is based on a powerful database, which requires no license costs, through which it's possible to get the trend of the recorded quantities in tabular or graphical form.



The eagle.easy supervision system consists of:

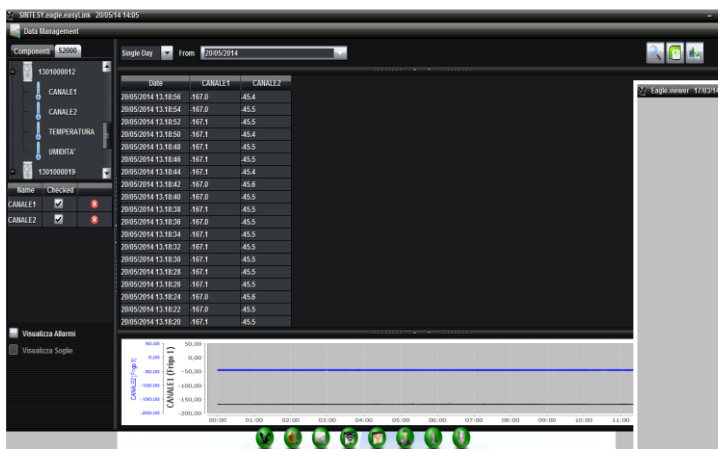
➤ Field devices, such as SINTESY.eagle S2000, designed to detect and record multiple physical quantities like: temperature, level of liquid nitrogen, pressure, relative humidity, O₂ and CO₂ rate, alarm contacts. The transmission of the information happens via Ethernet or Wi-Fi;

it offers clear advantages in the absolute absence of cabling and in the big reduction of installation expenses and management;

➤ A PC/Server which, through the eagle.easy application, runs a powerful database (DBMS) for data storage and visualization on multiple networked PCs.

Key features

- The system can meet the strictest requirements of the directives (e.g. Directive 2006/86 Annex I, C.2, D.6, D.7, Annex II, D.1) and specific guidelines (JACIE, GMP) used for biological laboratories and IVF laboratories (In Vitro Fertilization).
- Certified Medical Device Software (European Directive 93/24/EEC as amended)
- Simultaneous communication with a large number of devices installed in different rooms or buildings, even far from each other, using the existing LAN structure: both wired and wireless
- Visualization of the physical quantities sensed by the devices, their configuration and operating status (regular, alarm, disconnected, in maintenance)
- Storage of collected data with a frequency which can be configured by the system's administrator
- Storage of alarms (exceeding the set thresholds, missed connections, batteries,...)
- Storage of events (users login/logout, connection to remote devices,...)
- Management of alarm conditions sending voice calls/SMS/emails to defined users via the S140 phone dialer which belongs to the SINTESY.eagle® products family, which is certified medical device too
- Possibility to get data both in tabular and graphical format for the highest flexibility in visualizing and analyzing them over the time
- Ability to export data in Excel format and JPEG files for an easy integration with any report created by the administrators of the system (useful function to GMP compliance for the creation of the batch record)
- Management and traceability of the accesses to the computer system by the operators (multi-user system)
- Easy and intuitive data management thanks to the use of multiple search filters selected by the user
- Multilingual and multiuser support, which provide simultaneous access to the system by several operators



CE 0051

The product is certified Medical Device
According to European Directive 93/42/CEE and 2007/47/CE, Annex IX;
Class IIa, following Annex IX, rule 2



SINTESY S.r.l. is certified:
ISO 13485 Medical Device – Quality management systems
ISO 9001 Quality management systems



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