

"TRACECARE"

Monitoring, Reporting & Traceability Solutions







"THE CISA GROUP COMPANY"

COMPANY PROFILE

CISA has been manufacturing and selling sterilization systems for over 60 years for both hospitals and industrial applications for all sterilization needs.

CISA is an Industrial Group which manufactures hospital and industrial machinery having integrated technological production systems with factories in different continents and its headquarters in Lucca, Italy.

Distributor coordination and technical service centres are managed through CISA branches, located in Joinville (Brazil) for Brazil and Latin America, in Amman (Jordan) for Middle East area, and Singapore for Asia,

as well as distributors and sales offices worldwide to ensure a constant presence and complete service in all countries in which CISA operates.

CISA takes part in a very important field, **sterilization**, that is in continuous development. For this reason it has focused its activity on a line of products that includes: infection control solutions, machinery for washing and disinfecting, machinery for high and low temperature sterilization, software systems for management control and medical waste treatments. All the products in the different lines are "made in CISA" from design to manufacture.



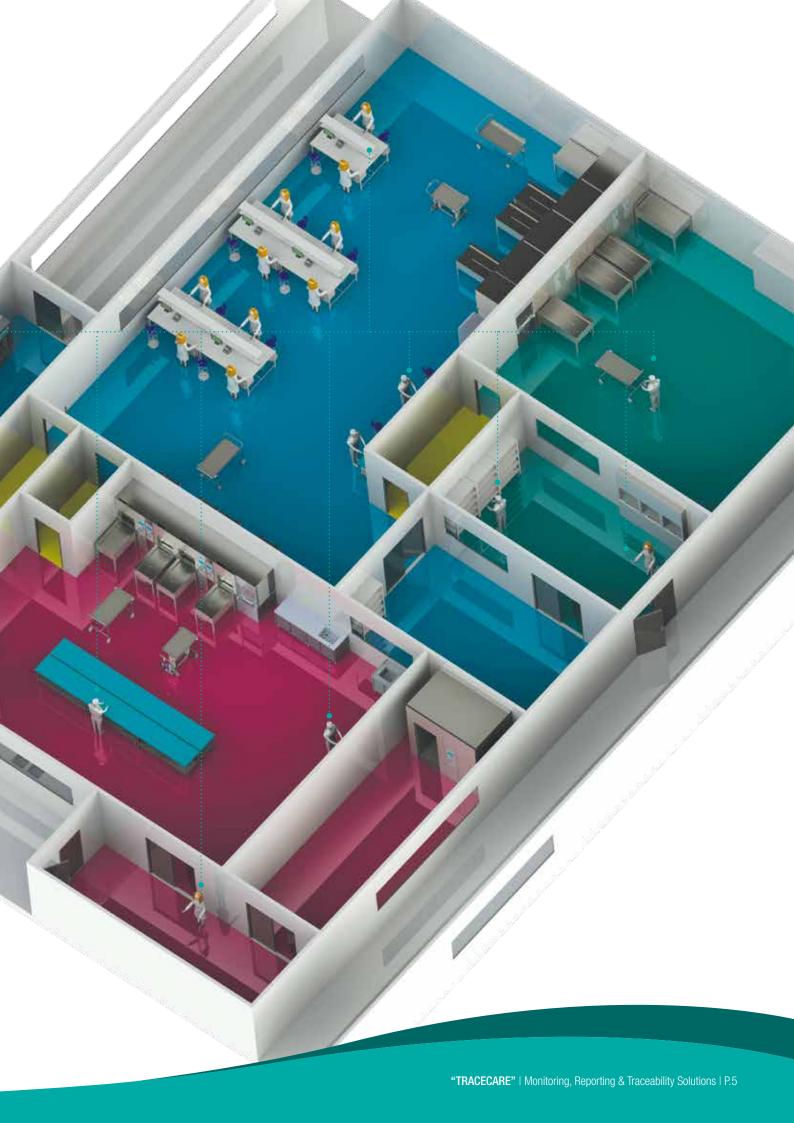
Gabriele Pacini CEO Cisa - Infection Control System

"WITHIN THE CSSD" WHERE YOU CAN FIND ME

The Sterile Processing Department (Central Supply, or Sterile Supply as it is also known), comprises that service within the hospital in which medical/surgical supplies and equipment, both sterile and nonsterile, are cleaned, prepared, processed, stored, and issued for patient care.

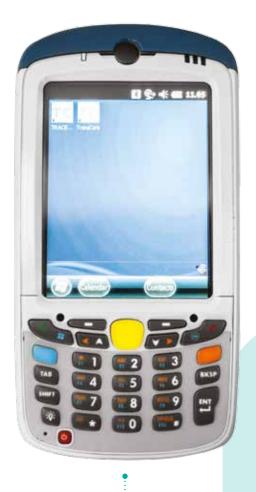
The TRACECARE CISA (as shown on the legend) is the new traceability system developed by CISA which in its full version allows monitoring the kit through all the steps in the CSSD areas (dirty area - clean area - sterile area - operating theatre).





"TRACEABILITY"

TRACECARE SYSTEM



In any CSSD, traceability, whether manual or assisted, is mandatory for the hospital staff. The new traceability system developed by Cisa allows monitoring the kit through all the steps in the CSSD areas. The product's structure is a WEB based system and the operators use mobile devices (PDAS).

The TRACECARE system allows direct communication with the PLCs of the CISA machines, using an own communication protocol.

The three main areas in which the sterilisation unit is divided, dirty, clean and sterile, are physically divided and the machines represent the point of passage from one area to another. The tracking of the generic kit or of the instrument is carried out via a signal on a mobile device, that communicates directly through an wi-fi to the hospital server form.







"DIRTY AREA"

Used kit entry	 Kit entry from the operating theatre The operator reads the basket's barcode and his badge with the mobile device
First manual washing	The operator selects: badge, machine, type of wash
Ultrasonic washing	The operator selects: badge, machine, type of wash
Washing machine load	The operator selects: badge, machine, type of wash



"CLEAN AREA"

Washing machine unload	The operator unloads the machine
Kit Composition	The operator identifies himself and creates the kit according to a packing list. He ticks off the selected items included in the kit
Kit Packing	 He prints the kit's identifying label. Kit Packing and check list printing
Autoclave loading	The operator selects: badge, machine, kit identifier, sterilisation cycle and loads the kit into the autoclave



"STERILE AREA"

Autoclave unloading	 The operator unloads the autoclave The operator identifies himself and selects the autoclave, the machine and the stored kit's ID
Storage	The operator identifies itself and selects the storage location of the kit and the identifier of the stored kit
Despatch	The operator selects the kit identifier and the information for despatch



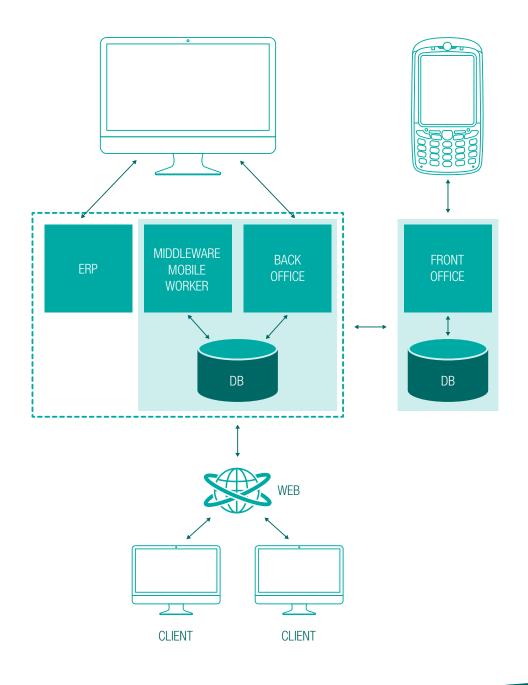
"PRODUCT STRUCTURE"

SET OF FEATURES

The Trace Care architecture consists of a set of features which allows operators to access data wherever they are (via Wi-Fi on the mobile device or PC). The product can be integrated with the hospital information system (HIS).

The following elements can be identified:

- Palmtop Front Office Application (FRONT OFFICE)
 - PC Back Office application (BACK OFFICE)
 - Middleware Application (MIDDLEWARE) •





"FRONT OFFICE APPLICATION"

The Front Office application, installed on an industrial-type mobile device, allows managing traceability processes and the use of a device able to ensure traceability of the activities performed. The following features are guaranteed:

RECEIVING KIT

- It reads the personal badge barcode through the palmtop optical reader;
- It reads the barcode of the type of kit received;
- Confirmation.

TRANSFER TO THE OPERATING STATION

- It reads the personal badge barcode through the palmtop optical reader;
- It reads the barcode of the kits to be transferred;
- It selects the machine/station towards which to transfer.

TRANSFER BETWEEN AREAS

It differs from the previous transfer item as here it indicates a massive transfer of kits positioned at a station on the border between the two areas. It is necessary to select this item therefore when reporting that the washer-disinfector has finished draining; in fact, the feature signals the transfer of all the kits contained in the selected washer-disinfector from the dirty side to the clean side. The same can be applied to autoclaves; in this case it will signal that the autoclave has finished emptying (after the cycle has run without errors) and therefore the transfer from the clean autoclave area to the sterile autoclave area.

By selecting this procedure from the menu, the operator:

- Reads the personal badge barcode through the palmtop optical reader;
- Reads the barcode of the kits to be transferred;
- Selects the machine/station towards which to transfer.

KIT SHIPMENT

- It identifies itself;
- It specifies the shipment;
- It identifies the kits to be despatched.

SOFTWARE UPDATE

Through this menu item, the application will be updated automatically, whenever a new version is available.

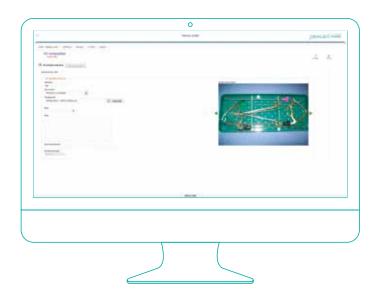




"BACK OFFICE APPLICATION"

The Back Office application is installed on fixed workstations (PCs) and it provides a number of features among which the following are the most important:

- User management and profiling
 - Printers •
 - Station data records
 - Item data records
 - Kit type data records •
 - Operator data records •
 - Machine data records
 - Specialised data records
 - Kit Composition
 - Report
 - Maintenance •



"MIDDLEWARE APPLICATIONS"

The Middleware application allows the Front Office and Back Office applications, the hardware devices and the administrative software in use to dialogue. The data is imported from the existing ERP, within the DCARE database and from there made available, suitably reorganised, to the palmtops. In particular, the middleware application carries out the following tasks:

Communication with the machines' PLC: the application is able to communicate on-line with the machines' PLC if equipped with the Ethernet interface. Communication is one-way (from the machine to the Cisa application). Middleware provides a REST service which may be called up from the PLC to send information of interest;

Importing data records from the existing administrative software: the application allows the possibility of importing various full and operating registers from existing administrative software applications. In particular, it allows you to import the following registers:

- Instruments
- Types of kit
- The management of imports will occur through a display



"TRACECARE MODULES"

The product offers the possibility of choosing modules, with capabilities which can be integrated according to customer needs. A diagram that identifies the modules is shown below.

"TRACECARE IDENTIFICATION"

In detail, the modules can be described as follows:

TRACECARE LIGHT I MONITORING WASTECARE & ENDOCARE REPORTING KIT COMPOSITION CSSD TRACEABILITY 4 TRACECARE FULL TO HOSPITAL THEATRE

MONITORING

It displays the graph of the cycles and generates a "note" (showing information such as the phase, date/time, cycle number, temperature, pressure, machine SN) of N machines, where N is determined by the commercially established license package. Monitoring is not related to the machine's cycle, it acquires data only when the PC is on and the program is running.

Necessary hardware: a PC installation CD is delivered and possibly a hardware key for verifying the license.

REPORTING

It allows extrapolating data from the machine/s and the kits. The operator who must load the autoclave, identifies the kit and the machine into which the kit is introduced with a barcode reader. It is possible to extrapolate data in an electronic format to be determined (for example in Excel). Necessary hardware: barcode reader, label printer, PC. In this case also, an installation CD is supplied with the relative license key for N machines.

KIT COMPOSITION

Software to help in the composition of the baskets based on predefined models (standard kit).

The operator can create the kits according to the list of instruments, the images and videos associated with the desired standard kit.

Software requirement: to have available for import the data records of the instruments, of the kits/baskets and of the pictures/videos/multimedia files in support of the composition.

Necessary hardware: Datamatrix (only for departments which use instruments tagged with Datamatrix).

It is possible to supply the Monitoring module (1) and the Reporting module (2) as stand-alone modules and in fact they may be sold individually.

"TRACECARE LIGHT, FULL, LINK" KIT COMPOSITION MODULES

The union of the Monitoring, Reporting and Kit Composition modules identifies the product TRACE CARE LIGHT. The TRACE CARE FULL version adds to these modules complete traceability from the front desk to the theatre, thanks to the mobile devices; the application in this case is web-based, therefore available throughout the Department's entire network and to all authorised users.

The additional package, TRACECARE LINK is the TRACE-CARE FULL version combined with ORMAWEB software to exchange information, for complete traceability within the hospital.

"WASTECARE" COMBINATIONS

It is the product designed to trace all hospital waste, and it is based on the combination of the Monitoring and Reporting modules. The application is also suitable for all those cases where medical waste must be disposed of through a machine and therefore opportunely certified. A starting point for this product could be the introduction of RFID technology in the disposal process. The tags would be delivered from the CSSD to the hospitals to then be placed on the waste, in order to automate traceability.



"ENDOCARE" COMBINATIONS

It is the product designed to trace all endoscopes and it is also based on the combination of the Monitoring and Reporting modules. We offer this product to hospitals which use storecase Cisa containing the endoscopes to be disinfected. The system consists of two machines: the high-level disinfection is carried out in the first (P-ERS), based on a cycle which the machine itself recognises by reading the RFID on the storecase. The second machine (P-ESS) dries the case and the endoscope it contains, allowing a longer sterility term of the instrument.

The case contains an RFID tag that the P-ERS initialises with the date/time of sterilisation. Before placing it into the P-ESS, the machine verifies that the date/time of the case tag inserted is valid through the integrated RFID reader and if it is not, it notifies the operator. The purpose of the application is to provide traceability and information concerning the endoscope during its journey (which machine, with which cycle, the date/time of each operation, which operator, etc.) and to block transfers should the time and transfer procedures from one to the other not be verified by the machines.



"DATASHEET" HARDWARE SOLUTION REQUIREMENTS

To use TRACECARE, the following minimum configurations from customer side are necessary:

EACH PC PLATFORM

Operating system: Windows XP 32bit;

RAM: 4GB. For server:

Operating system: Windows Server 2003 32bit;

RAM: 4GB; HD: 50GB.

IN ADDITION, THE FOLLOWING APPS WILL BE INSTALLED ON THE MACHINE

Apache Tomcat 7; Sun Java JRE 1.6; ORACLE DB XE version or PostgreSQL

The system offers the possibility of using Datamatrix readers for managing individual surgical instruments, and also envisages the possibility of managing surgical instruments with the integrated RFID.

HARDWARE SOLUTIONS FOR TRACECARE

- PRINTER ZEBRA
- I PAD
- DATAMATRIX





