

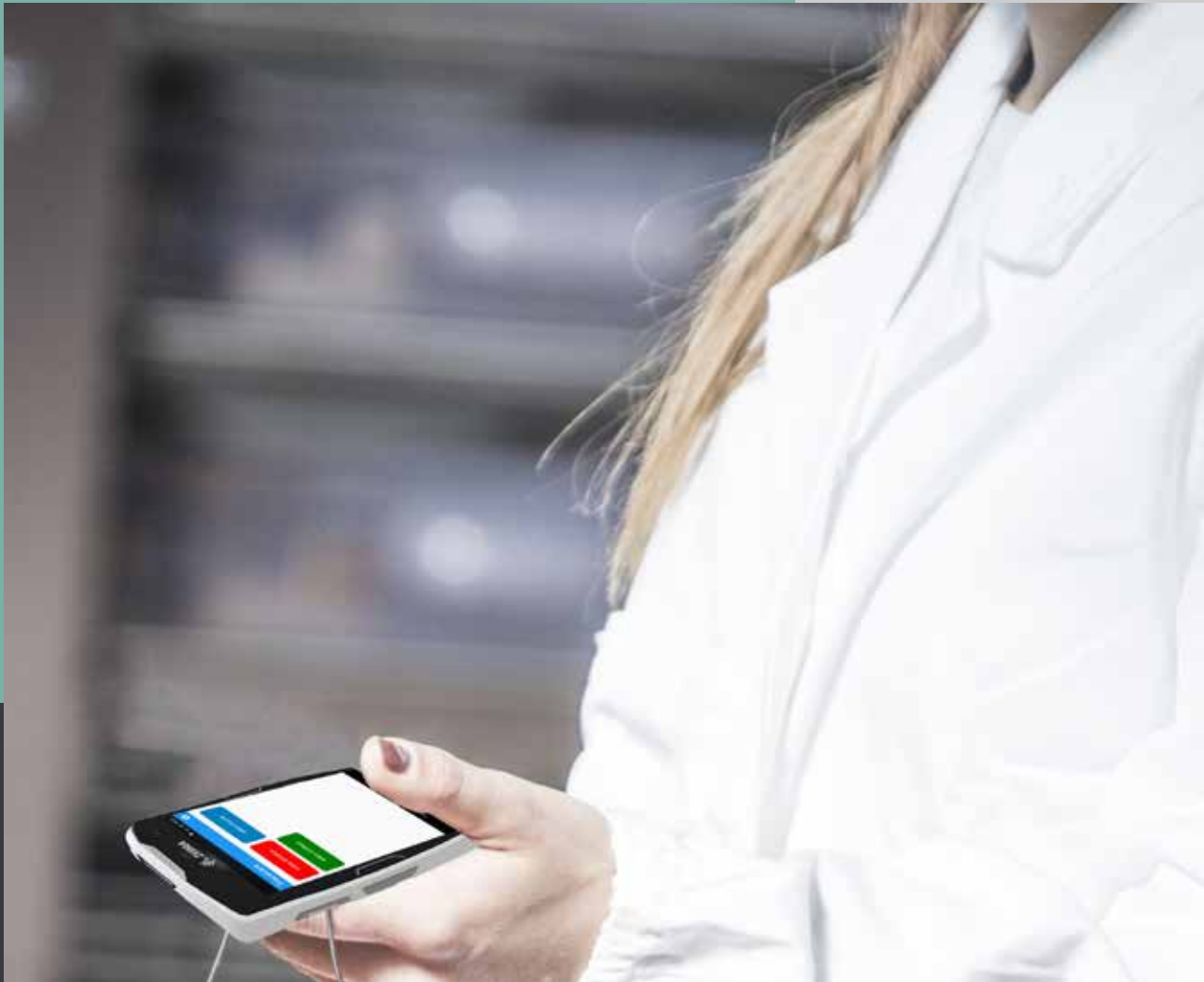


Software



# Tracecare®

TRACEABILITY  
REPORTING  
MONITORING



Healthcare



Life Science



# Cisa Group



**Cisa Group is a global supplier of infection control systems with production plants in Italy and Brazil.**

Founded in 1947, Cisa Group, together with Cisa America and Cisa Brasile, forms an international group that is one of the world's leading manufacturers of washing, disinfection and sterilization technology for infection control for the healthcare and life sciences industries.



HEALTHCARE  
INDUSTRY



LIFE SCIENCES  
INDUSTRY

Creating safer environments in hospitals, healthcare facilities and laboratory applications is a fundamental priority for the well-being of humans worldwide.

This is the commitment that drives Cisa to its claim:

## We care about life

Cisa Group is part of Faper Group, leading Italian supplier of world-class, innovative engineering solutions.

The Group is inspired by its founder, Fabio Perini, and has based its success on the ability to combine invention and simplicity.

Faper Group was established in 2001 as a holding company dedicated to innovation in the fields of tissue paper converting, healthcare and real estate management.

### COMPLIANCE

CEE 93/42  
CE 2007/47/EC  
PED 2014/68/UE  
EN 13445  
2006/42/EC  
2014/30/UE  
014/35/UE

### PRODUCT STANDARDS

CEI EN 61010  
CEI EN 60204-1:2016  
EN 61326-1:2013  
UNI EN 285:2016  
UNI EN ISO 15883

### QUALITY SYSTEM

UNI EN ISO 9001:2015  
UNI CEI ENISO 13485:2016



**MORE INFO  
ON THE  
FAPER GROUP  
WEBSITE**



# Technology

## Healthcare



Cisa Group develops advanced infection control technologies for the safeguard of healthcare workers and the health of patients.

Complete central sterilizing service departments for hospitals (CSSD)

Sterilization for healthcare applications and clinics of all sizes

Disinfection and washing technologies for different operational requirements

Cisa Group is the technology partner for scientists, researchers and engineers who develop life-enhancing products every day.



## Life Science



Washing and sterilization technologies for laboratories and research centres

Sterilization for pharmaceutical production

## Waste



Cisa Group, with 15 years of experience in the treatment of infectious waste, provides ground breaking solutions safe, economical and carbon friendly. Cisa Group is leading the field with the invention of its Waste Sterilization Department (WSD®).

WSD. Complete waste treatment department

WSM. Plug and Play Sterili-Station

Over the years it has developed unique proprietary IT and energy saving systems.



## Software



Tracecare®. Traceability of the sterilization process for the reconditioning of surgical kits in CSSDs

TraceWaste. Traceability of the sterilization process for the treatment of infectious waste using Cisa WSD Waste sterilization departments

# TraceCare®

## Cisa's solution for clinical risk reduction

TraceCare® is the modular system/software developed by Cisa Group that enables full traceability within the CSSD and the operating theatre (OT).

The system supports operators in the correct management of clinical risk.

It is a solution based on a web-based architecture and on the use of mobile devices, developed to fully adapt to the different needs of healthcare facilities.

TraceCare® enables the correct identification of assets, kits and operators throughout the entire reconditioning process of surgical instruments in a convenient and flexible way.

Mobile devices allow, with a few simple steps, to record all operations and movements within the CSSD areas (dirty area, clean area, sterile area) up to the storehouses and OT rooms.

The use of sanitizable mobile devices reduces the interaction between operators and computer keyboard and thus limits cross-contamination.

The only process phase supported by a PC is the reassembly stage, where the operator has a large monitor at his disposal and can easily check the kit contents and view all items more carefully. PCs are also used for master data registry management, machine monitoring and report production.

The direct connection with the PLCs of the Cisa Group machines allows the acquisition of cycle data in real time, allowing the plant managers to immediately control the machines' status and proactively manage the process in progress.

Using standard identification technologies (such as barcode and data matrix), TraceCare® tracks every movement of a kit using the 4W concept, where for each operation the following is recorded:

**Who:** who performs the operation

**Where:** where the operation is performed (at which work station/machine)

**What:** what is being handled (the unique identifier of the specific kit)

**When:** when the operation is performed

TraceCare®'s web-based architecture makes it suitable for managing multiple hospital facilities with a single installation (multi-site), where each facility has its own independent master data registry.

TraceCare® allows a further degree of customisation: with a single installation, it is possible to manage several CSSDs belonging to the same facility (multi-unit), in which case the CSSDs share the same master data registry.

It is also designed to exploit the advantages of service-oriented software architectures (SOA).

It is in fact designed to interface with systems for managing operating theatres, medical records, ERP, HIS and the like. This is possible by developing ad-hoc communication protocols or by using international standards such as HL7.

The TraceCare® system, being based on a centralized installation, allows, in accordance with the hospitals' information systems, an easy management of remote access technical support by Cisa Service staff.

## CSSD and TraceCare®

**Within the CSSD (Central Sterile Services Department) medical/surgical supplies and equipment used for patient care are treated.**

TraceCare® is the traceability system developed by Cisa, which in its full version allows to manage and monitor the kit process through the different areas (dirty area, clean area, sterile area) that make up the CSSD.

### PHASES/WORK STATIONS INVOLVED IN THE PROCESS



# Traceability

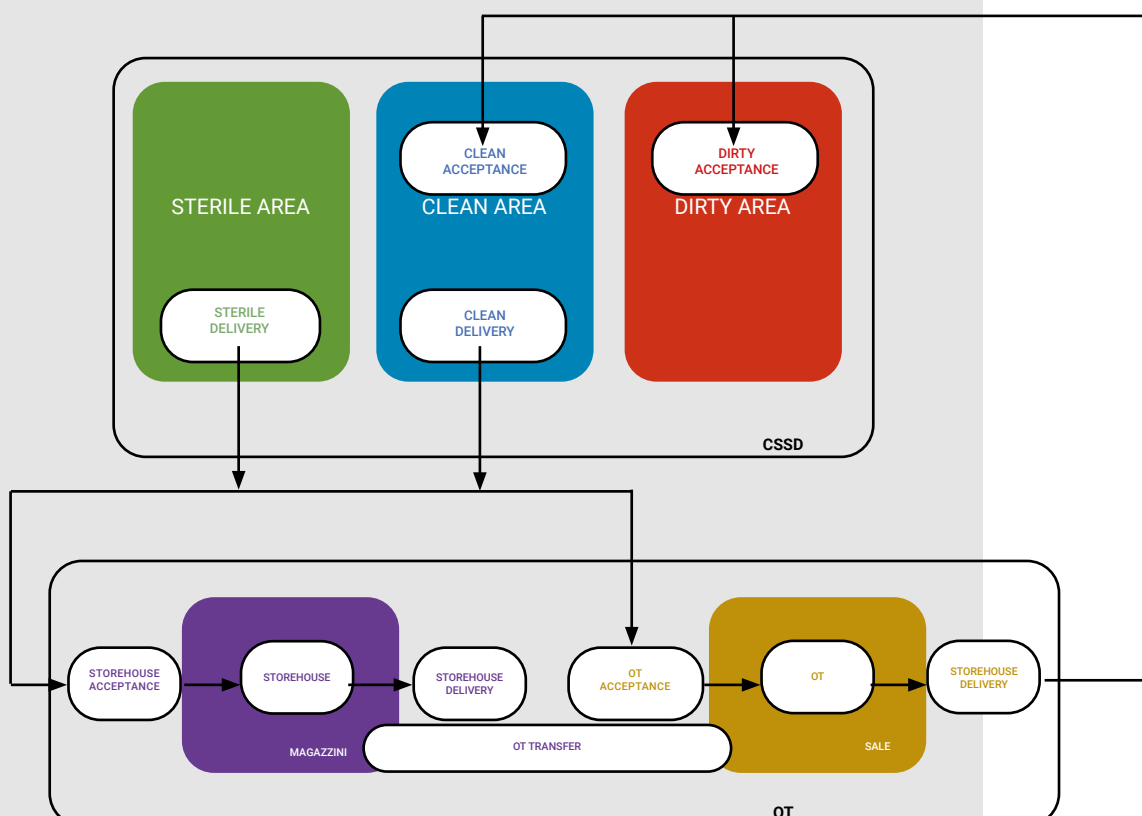
**In any CSSD, traceability, whether manual or assisted, is a mandatory process for hospital staff.**

The traceability system developed by CISA allows the kit to be monitored during all phases in the different CSSD areas.

The three main areas that make up the CSSD -dirty, clean and sterile- are physically separated and the machines represent the transit point from one area to another.

TraceCare® extends traceability to the OT by allowing the flow of a kit to be tracked in the storehouses and OT rooms themselves.

Below is a summarized diagram showing the key points (passage between CSSD, OT and vice versa) at which kits are traced.



Next is a list of standard operations that make up the typical process followed by kits in the CSSD/OT.

## CSSD DIRTY AREA

PHASE	DESCRIPTION	STEP	DEVICE
Dirty kit acceptance	Acceptance of dirty kit from the operating block	Reading of: operator code, station code, kit code	Palmtop
Manual washing	Manual washing of the kit	Reading of: operator code, station code, kit code	Palmtop
Ultrasonic washing	Ultrasonic washing of the kit	Reading of: operator code, station code, kit code	Palmtop
Washing machine loading	Loading the kit into the washing machine	Reading of: operator code, machine code, kit code, cycle number	Palmtop
External Kits	Quick labelling of external kits not in the master data registry (rental)	Reading of operator code, acceptance in clean/dirty area and label printing	Palmtop

## CSSD CLEAN AREA

PHASE	DESCRIPTION	STEP	DEVICE
Washing machine unloading	Unloading the kit from the washing machine	Reading of: operator code, station code, kit code	Palmtop
Clean (kit) acceptance	Acceptance of a clean but non-sterile kit directly into the Clean Area	Reading of: operator code, station code, kit code	Palmtop
Clean (kit) delivery	Delivery of kit from the Clean Area	Reading of: operator code, station code, kit code	Palmtop
Kit assembly	Kit reassembly phase (intended as a set of instruments according to the model registered in the master data registry)	Input of the model kit code, generation of the kit with the specific code of the current reassembly, checking the instruments, printing the label of the newly created kit	PC
Kit labelling and packaging	Labelling and packaging phase of the kit	Input of the model kit code, generation of the kit with the specific code of the current packaging, printing the label of the newly created kit	PC
Autoclave loading	Loading the kit into the autoclave	Reading of: operator code, machine code, kit code, cycle number, cycle type	Palmtop

## CSSD STERILE AREA

PHASE	DESCRIPTION	STEP	DEVICE
Autoclave unloading	Unloading the kit from the autoclave	Reading of: operator code, station code, kit code	Palmtop
Delivery	Sending the kit from the sterile storehouse of the CSSD to the operating block	Reading of: operator code, station code, kit code	Palmtop

## OT - STOREHOUSE

PHASE	DESCRIPTION	STEP	DEVICE
Storehouse acceptance	Acceptance of the kit in a storehouse of the operating block	Reading of: operator code, station code, kit code	Palmtop
Storehouse delivery	Delivery of the kit from the operating block storehouse to a room or back towards the CSSD	Reading of: operator code, station code, kit code	Palmtop
Room transfer	Direct handling of the kit from a block storehouse to a block room	Reading of: operator code, station code, kit code, destination room code	Palmtop

## OT - ROOMS

PHASE	DESCRIPTION	STEP	DEVICE
Room acceptance	Acceptance of the kit in a room of the operating block	Reading of: operator code, station code, kit code	Palmtop
Room delivery	Delivery of the kit from an operating block room to the CSSD	Reading of: operator code, station code, kit code	Palmtop



# The TraceCare<sup>®</sup> network

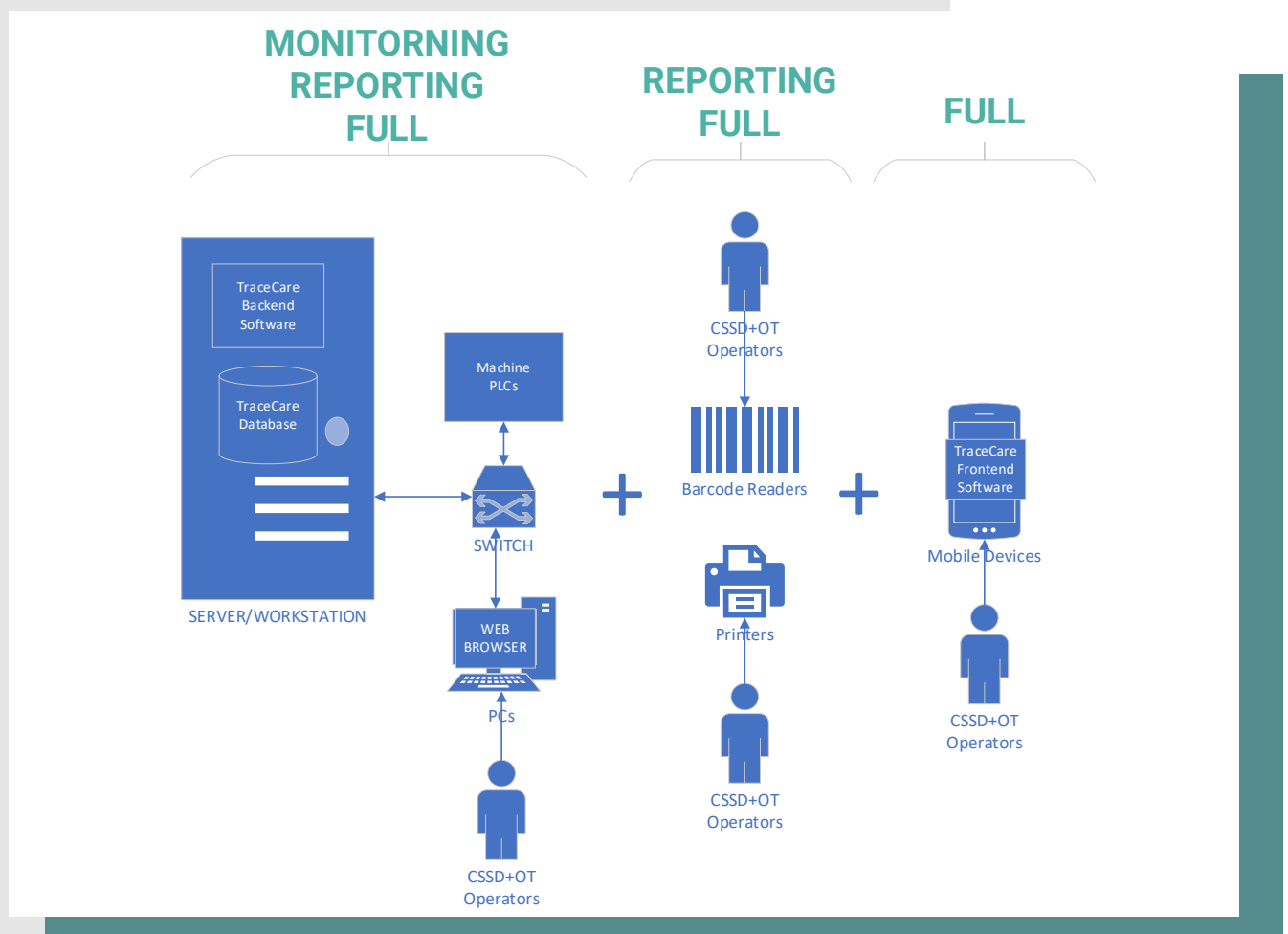
**TraceCare<sup>®</sup>, being a web-based system, allows access to operators from any device connected to the network.**

The system consists of a back office (Java EE) and a front office compatible with mobile devices on the Android platform.

TraceCare<sup>®</sup> allows direct communication with the PLCs of Cisa machines, using a proprietary communication protocol.

The system allows user authentication using the standard LDAP protocol.

Below is an outline of the system architecture, where the hardware and software that needs to be added depending on the chosen package are visualized.



The following software elements can be identified:

- Android Front-Office application
- Web-based Windows Back-Office application
- Data Base (DB)

The following hardware elements can be identified:

- Server
- PC clients
- Mobile devices
- Printers
- Barcode readers
- Network SWITCH (LAN)
- Machine Eth PLCs

# Versions/Packages

**The system offers a number of packages depending on the customer's needs.**

## MONITORING

The Monitoring version allows the monitoring and saving of the cycles of the machines present within the CSSD. Data concerning the main cycle parameters are saved in the DataBase and can be displayed as graphs or shown in summary reports. The communication between TraceCare® and the PLC of the machines is unidirectional, so the system is able to read information from the machines but cannot send commands, thus protecting from possible alterations to the medical devices.

● **MONITORING**

● **REPORTING**

● **FULLL**

## REPORTING

The Reporting version has all the functionality of the Monitoring package. In addition, it allows to track sterilisation activities by creating labels to be affixed to the kits and recording the loading operations in the autoclaves. This version also provides the possibility of viewing and printing additional reports related to the loading activities of the autoclaves.

## FULL

The Full version has all the functionality of the previous packages. In addition, it allows tracking of all CSSD activities. In this version, mobile devices are also used, allowing streamlined tracking during the progress of the kits in the CSSD process flow, and optionally in the OT. The report section is extended by additional detailed reports describing the activities of the CSSD.

**The Full version can optionally include a number of features:**

- Extension of traceability, via mobile devices, also in the storehouses and OT rooms
- Interfacing with Cisa partners' intervention planning system, according to the HL7 standard protocol
- Optimised scheduling of CSSD activities using MES-type systems
- Scalability of the solution according to the number of facilities involved, a single instance of TraceCare® for the management of several facilities with independent master data registries (multi-site functionality)
- Scalability also for the management of several CSSDs within the same facility that want to share the master data registry (multi-unit functionality).

# Requisiti HW/SW



## Minimum HW configuration

### **SERVER**

CPU: i5 Family / Xeon E5-2420 or higher  
RAM: 8 GB or higher  
HDD: 500 GB or higher

### **CLIENT**

CPU: i5 Family or higher  
RAM: 8 GB or higher  
HDD: 500 GB or higher

### **BARCODE PRINTER**

Zebra ZD230

### **MOBILE DEVICE**

Zebra TC21HC/TC26HC

## Configurazioni SW

### **SERVER**

Operating System:  
Windows 10 / Windows server 2012  
or higher  
Apache Tomcat 7  
Java 1.7u80  
Oracle 11g (XE o R2)  
JasperServer 5.6.0

### **CLIENT**

Operating System:  
Windows 10 or higher  
Browser: Chrome or FireFox

### **MOBILE DEVICE**

Android 10

# TRACECARE<sup>®</sup> 2.0

New realese.  
Easier, faster, more reliable.





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