



Pharmaceutical System Plants

REMOIN

L'Azienda

La **Remoin srl** nasce a Cisterna di Latina nel 1982, per la realizzazione e montaggio di impianti industriali per l'industria chimica e metalmeccanica.

Nel corso degli anni l'azienda acquisiva quote di mercato sempre più ampie pertanto si è resa necessaria la realizzazione di una sede produttiva distaccata nel comune di Artena in provincia di Roma. Nel tempo, la Remoin si è specializzata nella progettazione e costruzione di impiantistica specifica per l'industria farmaceutica.

Oggi progetta e realizza impianti chiavi in mano di fluidi puri quali: sistemi di produzione, stoccaggio e distribuzione di acqua distillata WFI, acqua purificata PW, circuiti di distribuzione di vapore pulito, piping di processo, sale preparazione con gestione automatica delle ricette e sistemi CIP/SIP completi di sistemi SCADA specifici per l'industria farmaceutica, chimica e alimentare, secondo le prescrizioni raccomandate da EMA, FDA, GAMP 5, e CFR 21 part. 11.

Costruisce Distillatori multieffetto, Temocompressione, Generatori di vapore puro, Osmosi con EDI, Sistemi di lavaggio CIP/SIP, Preparatori e Dissolutori per principi attivi, Turbo Emulsori, Serbatoi di stoccaggio e Scambiatori di calore DTS per L'industria farmaceutica, chimica e alimentare, secondo le prescrizioni raccomandate da EMA, FDA, e CFR21 part. 11.

La società è certificata ISO 9001 dal 1998.

The Company

Remoin Srl was founded in Cisterna di Latina in 1982, for the construction and assembly of industrial plants for the chemical and engineering industry.

As the time went by, the Company increased its business and grew its market shares, making it necessary to set up a separate production facility in Artena, a town in the province of Rome. Over the years, Remoin has specialized in the design and construction of industrial plants, specifically for the pharmaceutical industry.

Today, Remoin designs and manufactures full turnkey plants of pure fluids, such as: production/storage & distribution systems for PW, WFI and PS, process piping, solution preparation rooms with automatic management of the recipes, and CIP/SIP systems. All of them are complete with specific SCADA systems for pharmaceutical, chemical and food Industries, complying with EMA, FDA, GAMP 5 and CFR21 part 11.

Remoin also manufactures Multi-effect Distillers, Thermo-compression Distiller, Pure Steam Generators, Reverse Osmosis with EDI, CIP-SIP systems, Preparation Tanks, Dissolvers for active ingredients, Turbo Emulsifiers, Storage Tanks, and Double Tube Sheet Heat Exchangers (DTS) for the pharmaceutical, chemical and food industry complying with EMA, FDA, GAMP 5 and CFR21 part 11.

The company is certified with ISO 9001 since 1998.



The units of OSMO-REM are available in various versions from 300 lt/h to 6000 lt/h (higher flow rates available). Skid-mounted system for the production of Purified Water and Highly purified Water, in accordance with the Ph. Eur. And the US Pharmacopoeia.

The design allows each system to be pre-qualified during the Functional F.A.T Test.

The OSMO-REM System is designed to purify water by letting it pass through the membrane. The fluid control provides a means of managing flow rates and pressure, high flow rates and short regeneration cycles minimize micro-biological growth.

The OSMO-REM modules allow hot water sanitization. Hot water prevents the growth of Biofilms, with no need to rinse them out with chemicals.

SPECIAL FEATURES:

- Design and realization according GMP Guidelines and recommendations of the ISPE Engineering guide and of the FDA.
- Parts in contact with the medium made of stainless steel SS 316L with Tri - Clamp connections, no dead zones and with a surface roughness < 0.6 µm.
- Continuous circulation to prevent bacterial growth when the tank is full.
- PLC controller Panel, capable of interfacing with a higher level control system, easy- to-use controller for the acquisition and processing.
- All systems can be provided with an EDI - Module for the production of pure and highly purified water.
- All in a compact SKID - MOUNTED made in stainless steel 304.





APPLICATION:

- Drinking water production from brackish, sulphurous or very mineralized water, which is not treatable for technical or cost reasons
- Drinking water from seawater
- Feed water for distillers to industrial and pharmaceutical cleaning or process water production
- High pure water for electronic industry
- Production of dialysis liquid for the hospital use

ON LINE INSTRUMENTS:

- Conductivity probe
- Flow meter
- Temperature probe
- Pressure gauge



PARAMETERS:

- Pressure: 20÷40 bar
- Temperature: working temperature ~15°C
- Flow speed: ~1 m/sec

TEST:

- According to project specifications
- According to project performance
- Materials, test and qualification certificates

PLC CONTROL:

- System operating report
- Remote control by BUS
- Alarms
- Setpoint

SERVICES:

- Commissioning
- Staff training
- Validation assistance
- On-demand services
- Maintenance and Supervision programs
- Replacement parts and consumables

STANDARDS & REGULATIONS COMPLY:

- USP/FDA
- European Pharmacopoeia

REMOIN's multiple effect stills are identified with the name M-REM and they can produce distilled water from a minimum of 100 lt/h to a maximum of 12.000 lt/h; anyhow, on-demand, it is possible to supply distillers with a manufacturing capacity up to 20.000 lt/h.

The distiller is entirely built in stainless steel AISI 316L; all the inner surfaces in contact with the product have a roughness of $Ra \leq 0,4 \mu$, they are pickled and passivated according to ASTM 967 rules and, as optional, also the electropolishing can be requested. All the external surfaces are mirror polished/satined.

The Hydraulic plant is realized with pipelines made of s.s. AISI 316L according to the ASTM A 270 and ASME BPE rules.

All the connection welding between pipes and fittings will be TIG realized by orbital automatic procedure and a printed report of them will be released. As optional, also the Boroscopy can be asked. Gaskets are the sanitary type made of Teflon.

Distillers are supported by a tubular structure made of stainless steel AISI 304, satined. For the control and management of the production, the distiller is provided with an electrical board with PLC/PC and operator interface.

The operation is completely automatic and gives the following possibilities:

- Sterilization of the plant after a long time of the stop and before its new start;
- Continuous control of the conductivity of the distilled water produced and automatic discharge in case of insufficient clearness;
- Continuous control of the levels;
- Operation according to a weekly program of all the requested phases.



Multi Effect Distiller

Mod. M-REM



Thermo-compression distillers are briefly named M-REM-T and they can produce distilled water from a minimum of 50 l/h to a maximum of 5.000 l/h; it is also possible to supply distillers having a bigger production capacity, on customer request.

The Remoin M-Rem-T Thermocompression distillers always operate with an internal pressure higher than the atmospheric avoiding any possibility of outside air entering the plant.

In every distillation phase, the distillate is always at a pressure higher than the infeed water, thereby ensuring that in the likelihood of leakage of feedwater it will never enter the distillate circuit.

The distillate leaves the plant at a pressure of 1,5 bar.

Distillers are completely stainless steel AISI 316L manufactured; all the inner surfaces, which are in contact with the product, have a roughness $Ra \leq 0,4 \mu m$; all the surfaces are pickled and passivate and it is possible to require electro-polishing optionally.



Thermocompression Distiller

Mod. M-REM-T

All external surfaces are satin/mirror polished.

Plumbing is made of AISI 316L pipes according to ASTM A 270 and ASME BPE rules. All the welds of connecting pipes and fittings will be made by TIG with the orbital automatic procedure and printed report; it is also possible to require for a boroscopy optionally. Gaskets are sanitary type, Teflon made.

The Distiller is sustained by a tubular satin frame in stainless steel AISI 304.

The Distiller is provided with an electrical control board having PLC/PC and user interface (HMI) to control and manage the necessary phases. It works fully automatically and it gives the following chances:

- sterilization of the plant after long stop, before start up;
- continuous conductivity control of distilled water produced and automatic drainage if purity is not enough;
- continuous levels control;
- operation of all required phases, according to a weekly schedule.



The documentation provided by Remoin Srl together with plants includes all phases of the project creating up to final tests at the customer site, and it has all the information needed for plant validation (D.Q.; I.Q.; O.Q; P.Q, instruments calibration and computer validation).

Our M-Rem-T distillers operate:

- with electrical heating
- with steam heating (3 bar)
- both with electrical and steam heating systems



Pure Steam Generator

Mod. RPS

Pure steam generator includes an exchanger with double plates DTS, vertical, and connected to a vaporization chamber, on whose head top a clearing parcel "Vicotex" is placed to avoid any drag of micro drops of water not evaporated and the following contamination of pure steam. The pure steam generator will be connected tri/clamp for all process connections, with a safety device at the overpressure consisting of a bursting disk with support for the vacuum, PLC for sequential control, high-pressure alarms, high/low level, electro-pneumatic diaphragm valve controlled by PLC, all mounted on a polished structure in Stainless Steel AISI 304. The exchanger and the vaporization chamber are insulated by fibreglass with a finish in Stainless Steel AISI 304 polished/pickled.

REMOIN pure steam generators can produce a minimum of 50 kg/hour, to a maximum of 4000 kg/hour.

Type of materials:

- Stainless steel AISI 316L/304L

Application fields:

- Pharmaceutical/Chemical
- Food and Cosmetic

Surface finish:

- Internal: Ra \leq 0,5 μ
- External: Satin/Mirror polished



Electrical Pure Steam Generator

Mod. E-RPS





REMOIN is an industrial company specialized in the design and construction of Sanitary Tanks in stainless steel AISI 316L according to F.D.A. and G.M.P. standards.

Our line of products goes from 50 Lt. to 60.000 Lt..

Horizontal or vertical execution with external thermal insulation in stainless steel AISI 304L.

A satin finish is produced by grinding all the welds and completely sealing.

Type of employment:

Distilled water - Purified water



Sanitary Tanks

Surface finish:

Internal: Mirror polish $Ra \leq 0.3$
(Optional electropolish)

External: Satin or mirror polished



REMOIN s.r.l. is an industrial company specialized in the research, design and construction of sanitary heat exchangers with double plates (DTS), built to avoid contaminations between primary and secondary fluid.

Realized in vertical or horizontal, heated or cooled or with a combination of functions.

Single, double or multiple passages, and auto-drained, isolated and steel in AISI 304, completely sealed.

Type of materials:

- Stainless steel AISI 316L/304L
- Hastelloy

Application fields:

- Pharmaceutical
- Cosmetic
- Biotechnology

Technical data:

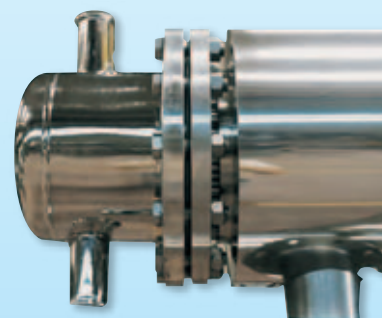
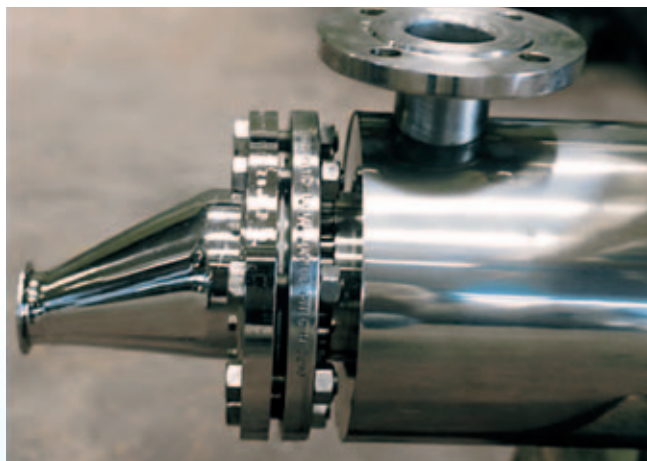
- Straight pipes with double fixed plates

Surface finish:

- Internal: mirror polished $Ra \leq 0,3$, optional electropolished
- External: satin or mirror polished

Type of employment:

- Distilled and bidistilled water
- Purified water
- Pure Steam



Distribution Piping ASME BPE

LOOP PW - WFI & CS

REMOIN is a company specialized in the design and construction of 3A Sanitary piping in ASTM A270 according to FDA and GMP prescriptions:

- Loop Plants WFI (distilled water)
- CIP lines plants
- Loop Plants purified water
- Pure steam line plants
- Loop Plants demineralized water
- Process line plants
- Loop Plants osmosis)
- Gas line plants
- Solution Preparation Plants

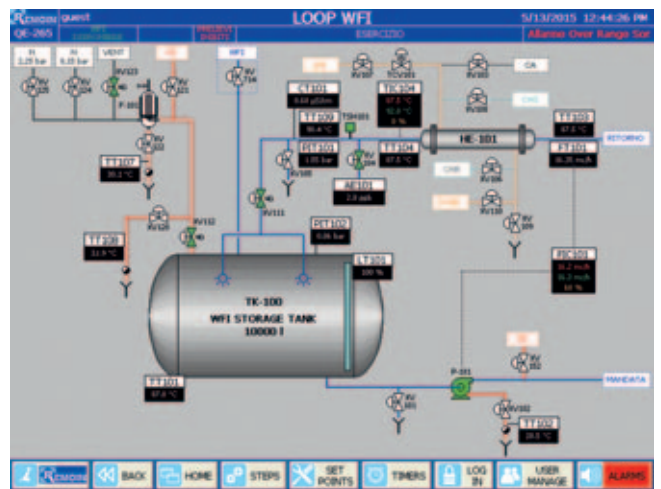
The plants are equipped with all line accessories such as elbows, tees, reductions, ferrules, clamps and gaskets. All fittings such as elbows, tees and reductions are drawn from a tube with single casting to avoid any differences in thickness and to obtain a better quality of welding with automatic procedures.

As for piping systems, **REMOIN** is also specialized in the design and construction of control boards for the control of the WFI loop systems, PW loop, Demineralized water, osmosis loop, process plants, solution preparation and CIP plants.



REMOIN will issue for each plant, the technical documentation needed for cGMP/FDA approval:

- WPS + PQR
- Welder license
- Automatic welding tests format
- Automatic daily welding format
- Certificates of hydraulic test
- Certificates of passivation
- Certificates of X-rays/penetrant liquids
- Roughness certificates
- Dimensional certificates
- Slope certificates
- Conformity certificates
- Materials certificates 3.1B
- Boroscopic certificates
- Certificates of slope
- Conductivity certificates
- Temperature certificates
- P&ID Drawings
- Axonometric drawings with identification of the welding
- Preparation and execution of protocols IQ, OQ



Distribution Piping ASME BPE

LOOP PW - WFI & CS



REMOIN is a company specialized in the design, construction, automation and validation of Solution Preparations, according to the FDA & cGMP requirements. Our Solution Preparation are complete with preparers, sanitary piping made of stainless steel 3A ASME BPE and all the relevant accessories.



Solution Preparation

REMOIN makes also the electro-instrumental plant SCADA system with a control board for the automatic control of the PLC/PC of the system and it supplies all the technical documentation for validation purposes.





Solution Preparation



REMOIN among other things is also specialized in designing, constructing and installation of Solution Preparation complete with an Isolator, on proper skid, suitable to be in Sterile Areas Class A, B and C. Isolators are used in the production of oncological and injectable medicines; they are structured to operate both in positive and negative pressure, depending on the type of product to be treated.

The plant can be made with both fixed and mobile preparation tanks, complete with all the utilities at their service: WFI, clean steam, nitrogen, sterile air, thermostats and product lines. Isolators are designed to be able to handle products in a safe and controlled environment and can be sterilized with Hydrogen Peroxide (VHP). The material of Construction for all components is stainless steel AISI 316L ASME BPE SF1 or SF4. All welds are executed with automatic procedures and controlled by borescopes. All pipes and fittings are passivated according to ASTM 967.

The system is supplied complete with an electro-instrumental system and, on request, it can be monitored with SCADA; it complies with the CFR21 PART 11 Directives and the USP, EMA and FDA Prescriptions.

Main Characteristics:

- Internal Design studied to facilitate cleaning and prevent accumulation of dirt;
- Integrated ejection system;
- HEPA H14 filters on intakes;
- Hepa H14 filters o outlets;
- System of holding and controlling Inflatable seals;
- Pressure control on Chamber and pre-chamber;
- Filters obstruction control;
- Doors made of crystalline PMMA (different materials on request);
- Oval Flanges for better ergonomics.

Optionals:

- Inertization system
- Continuous particles control
- CIP/SIP



Solution Preparation Complete with Isolator

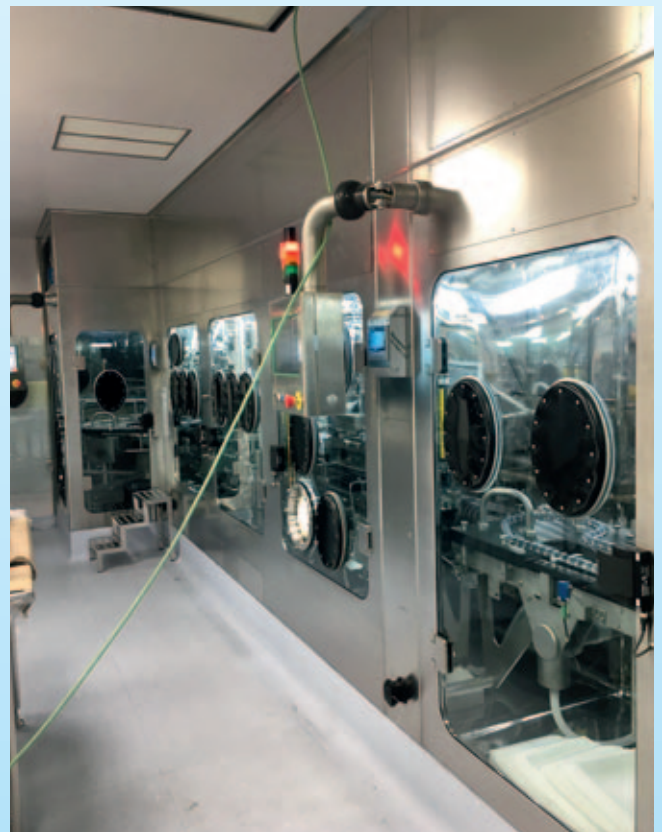
MOD. REM-SP LINE





Solution Preparation Complete with Isolator

MOD. REM-SP LINE



REMOIN is an industrial company specialized in the research, design and construction of preparation tanks according to F.D.A./EMA and cGMP standards. All preparation tank units are complete with a bottom valve, magnetic mixer with fast connection/disconnection, hand hole with fast opening/closing by wing nuts and sight glass with lamps, and tri-clamp connections.

Our line of products goes from 5 Lt. to 30.000 Lt.. Vertical execution, single or double wall, interwall for heating or cooling or combination with external thermal insulation. A satin finish produced by grinding all the weld and totally sealed.



Preparation Tanks



REMOIN is a company that can engineer and build equipment turbo emulsifiers as tracked or fix for vacuum preparation of toothpaste, creams, oils, gel and sterile ointments.

Small and medium scale capacities, having the same features as the equipment engineered for high outputs.

The plant allows different configurations according to process requirements:

- Anchor agitator, with or without scrapers.
- Turbo-emulsifier fitting a wide range of heads to meet any specific requirements of customers.
- Anchor with axial or planetary counter-revolving.
- Magnetic agitator with the possibility of quick connection or disconnection.
- Dispersor in recirculation.
- Equipment for pharmaceutical-grade valves and fittings, 3A/FDA approved.
- Kettle valve.
- Flush mounted valve.
- Weighing system.
- Lifting column complete with mechanical and electronic securities.
- Thermostatc unit with remote controls or main Control Board.
- Deaerating vacuum pump.
- Main Control Board with MPU control unit.
- Synoptic or control screen.
- Variable speed on all equipment installed.
- Parameters and events recording.
- Automatic and/or manual monitoring and execution of the process
- Stainless steel skid.

The machine is designed and engineered in compliance with the most demanding standards ruling on operator safety during process stages.

The machine basically features "IN-LINE" connection to automatic CIP and SIP washing and sterilization systems. The extreme versatility of the machine allows handy and quick servicing thanks to the independence of each component installed. The use of the machine for sterile products and environments requires its compliance to cGMP in that it is manufacture and to 3A/FDA for the class of the material used.



Clean in Place System - Cip

REMOIN is a company specialized in the design and construction of plants for distillation, purification and treatment of water, as well as CIP systems. Our Technical department cares for the design and the final execution of projects, in accordance with all the current rules and laws for each plant.

REMOIN Srl may provide process systems complete with integrated CIP/SIP, in order to give the proper assistance to the customers and grant them correct maintenance perfect efficiency and long life for plants, as well as in order to avoid misunderstandings concerning the interface with various suppliers of some parts of the plants.



System Configuration:

REMOIN Srl can design and construct a system that meets the customer's specific requirements.

CIP Systems configuration depends on the following:

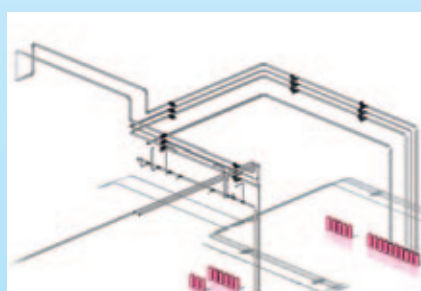
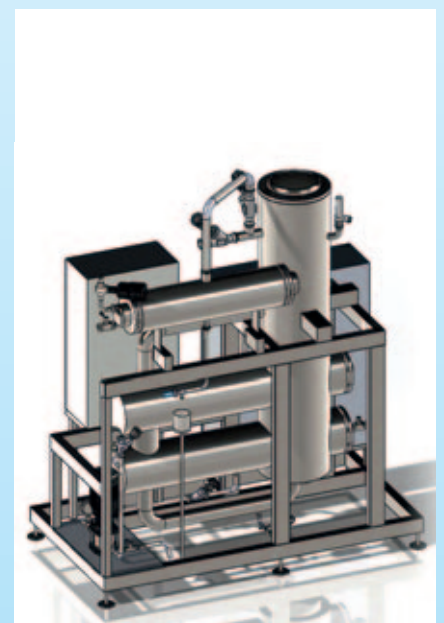
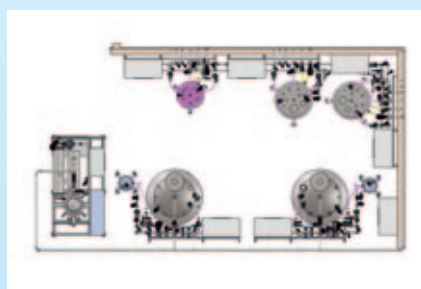
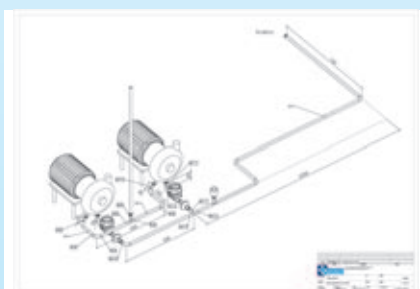
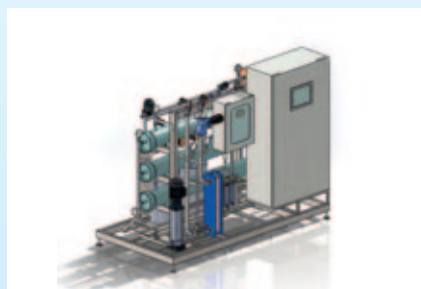
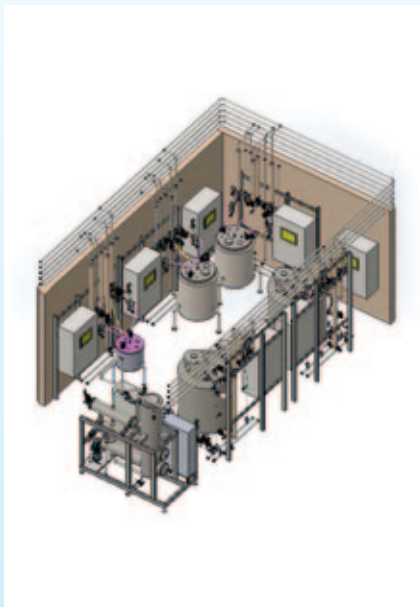
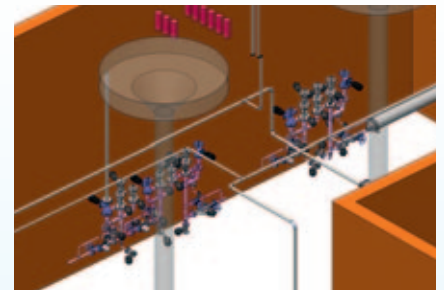
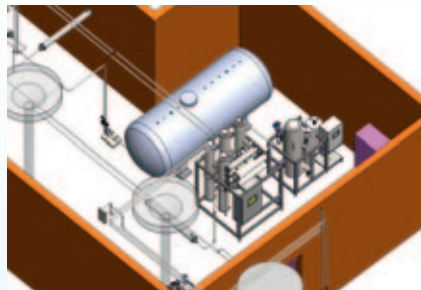
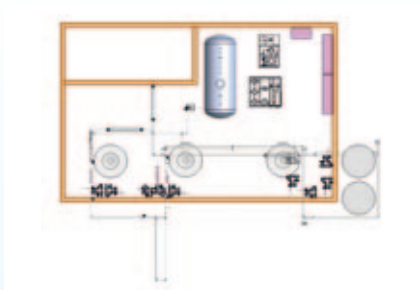
- Single or multi-task
- Recovery of washing solutions and rinsing
- Return by pump or coming systems
- Final rinsing by WFI or DW
- SIP (Steam in place)
- Heating by direct injection of steam or heat exchangers
- Skid mounting
- Control and Maintenance of Conductivity with automatic addition of alkali/acids
- Automatic/Manual control integrated with the process, with supervision system
- Operation according to a weekly program of all the requested phases.

Materials and Finishing:

Stainless steel AISI 304 or 316L, standard 180 Grit with options for 380 and electropolishing



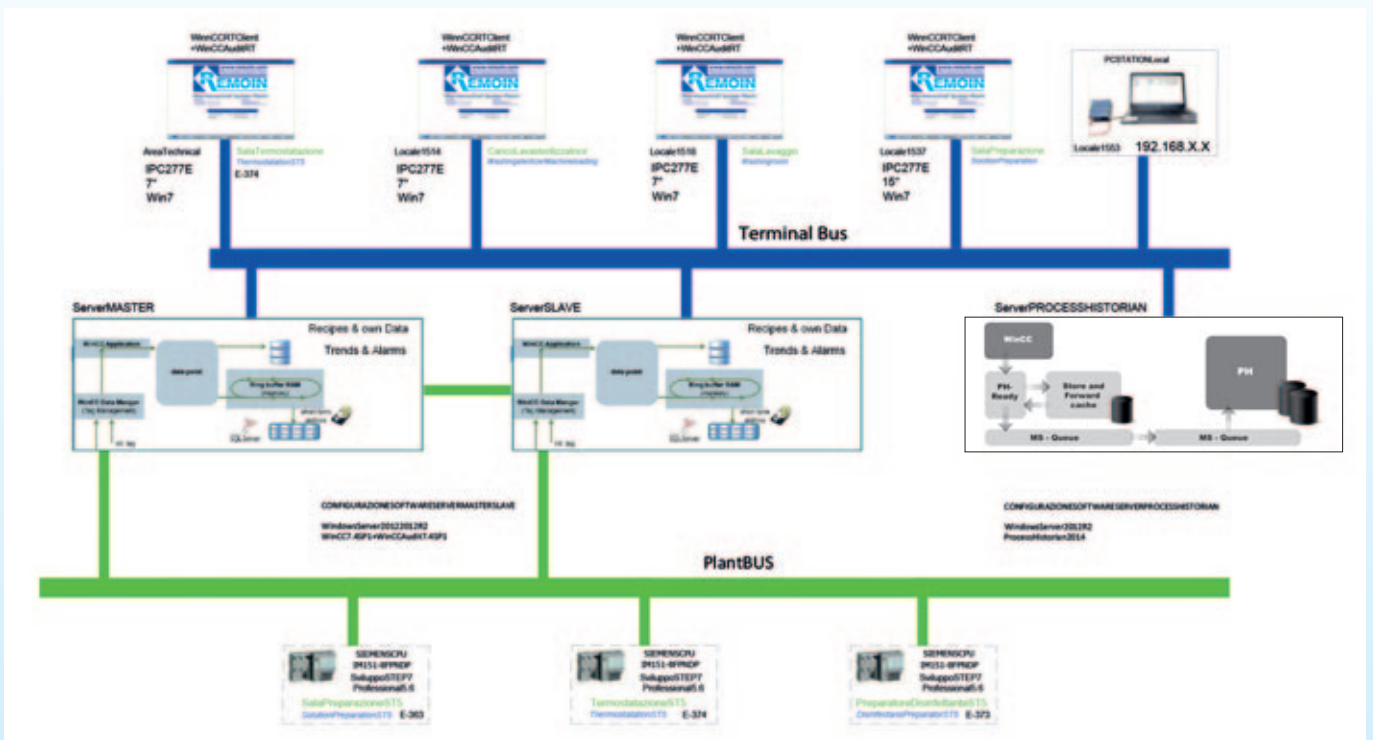
REMOIN can develop 3D drawings, made by Solid Works, for PW loops, WFI loops, Pure Steam Distribution, Solution Preparation, and CIP/SIP systems on Skid.



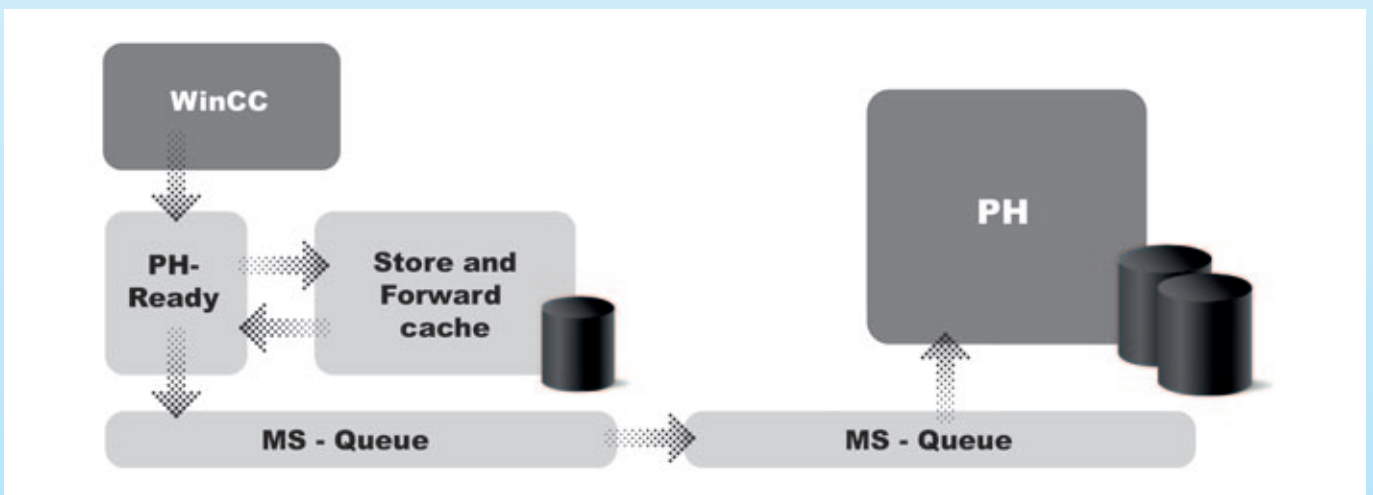
REMOIN can design and manufacture electro-instrumental/Automation plants complete with a SCADA system.

- WinCC
- iFIX
- Wonderware
- Movicon

Complying with all European and International Directives. All the systems also have CFR 21 Part. 11 licenses, Audit Trail and customized recipes complying with ISA 88 Standard.



SCADA System Flowchart



Representation of WinCC data flow - Process Historian

REMOIN HARDWARE SPECIFICATION

1 Server Master Dell PowerEdge R430 rack 19" 1U con la seguente configurazione hardware:



- MS Windows Server 2012 R2
- SIMATIC WinCC V7.4 SP1 (RT 8192)
- SIMATIC WinCC/Audit V7.4 SP1 (Runtime)
- SIMATIC WinCC/Archive V7.4 (1500 Archive Tags)
- SIMATIC WinCC/Redundancy V7.4
- SIMATIC PH Ready

REMOIN HARDWARE SPECIFICATION

1 Dell OpiPlex 3050 Micro Factor con la seguente configurazione:



- MS Windows 7 Ultimate 64 Bit
- SIMATIC WinCC V7.4 SP1 (RT 128)
- SIMATIC WinCC/Audit V7.4 SP1 (Runtime)

REMOIN HARDWARE SPECIFICATION

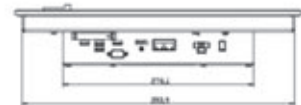
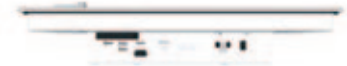
1 Process Historian Dell PowerEdge R440 rack 19" 1U con la seguente configurazione hardware/software:



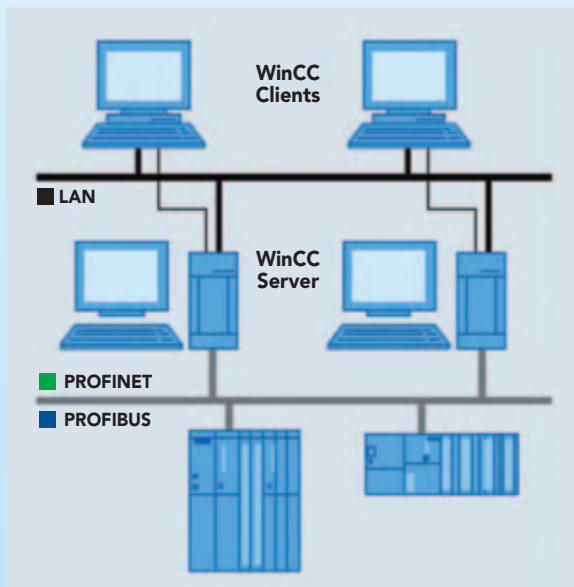
- MS Windows Server 2012 R2
- SIMATIC Process Historian 2014 SP3

REMOIN HARDWARE SPECIFICATION

1 SIMATIC IPC277E (Nanopanel PC 15") con la seguente configurazione:



- MS Windows 7 Ultimate 64 Bit
- SIMATIC WinCC V7.4 SP1 (RT 128)
- SIMATIC WinCC/Audit V7.4 SP1 (Runtime)

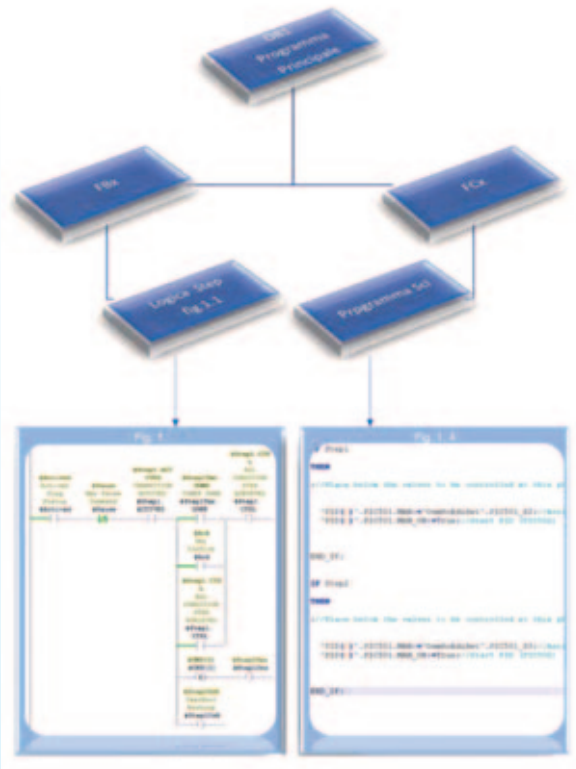


Redundant SCADA System

HARDWARE SPECIFICATION



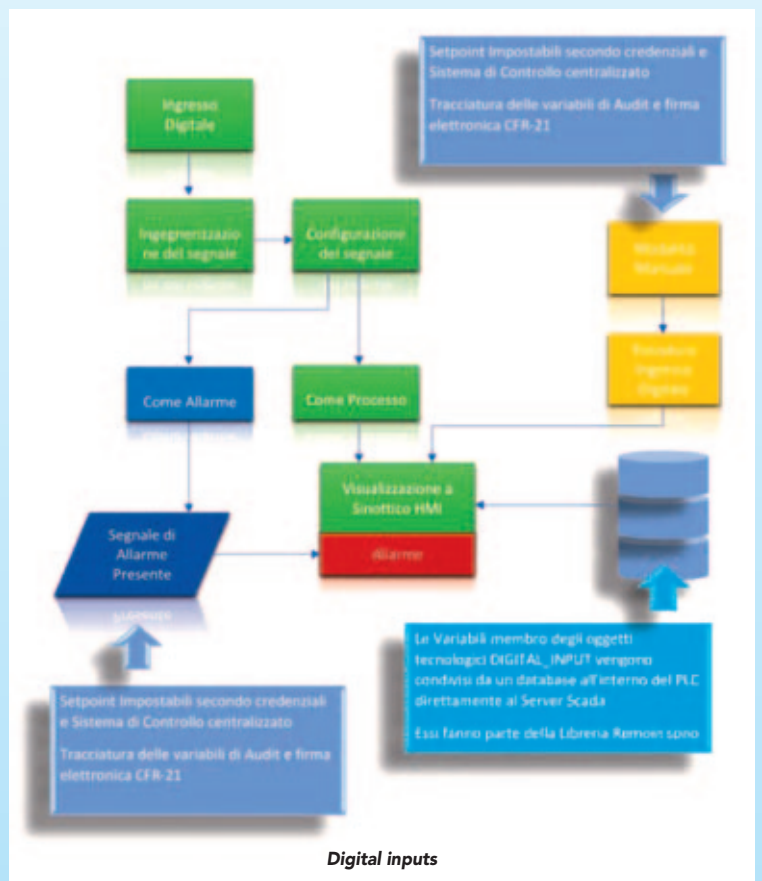
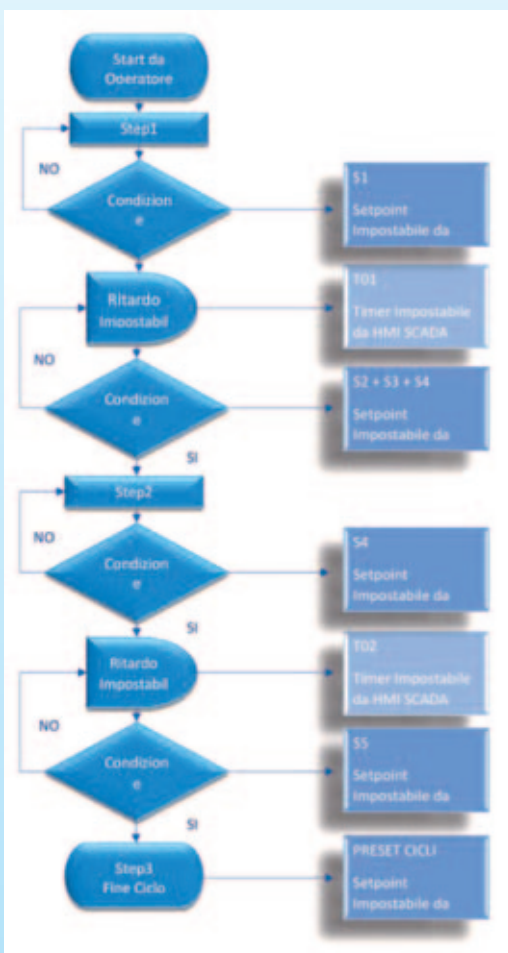
PLC software structure representation



PLC software structure representation library

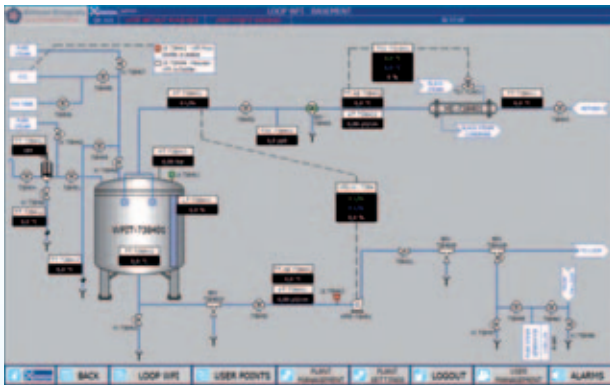
PLC's Software Overview - Structure

Program Flow

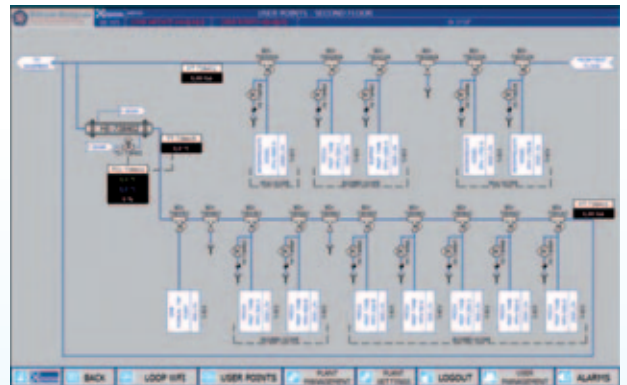


Digital inputs

Automation System



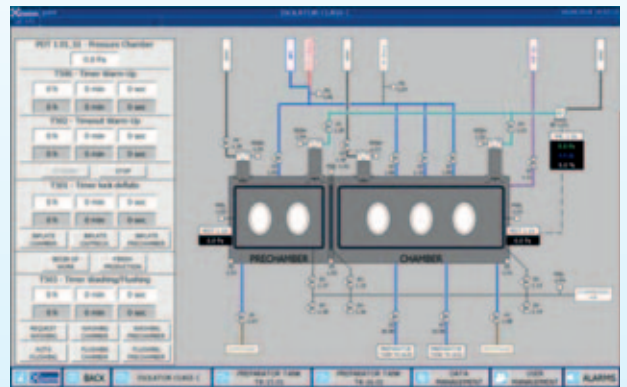
Loop WFI



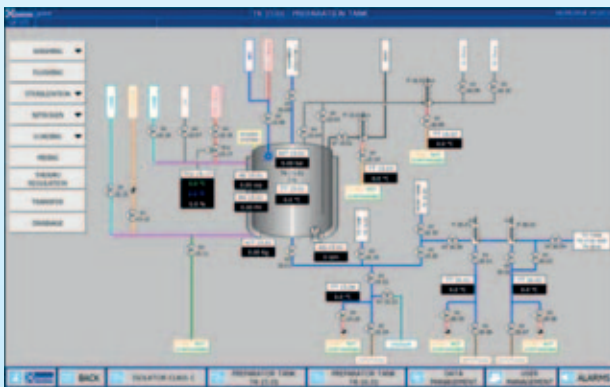
Loop WFI - Distribution



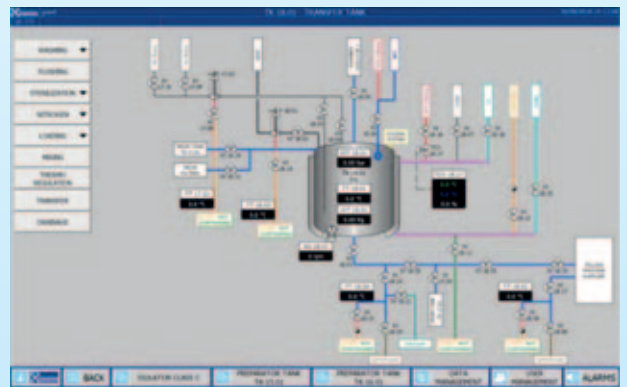
Loop WFI - Distribution



Isolator



Preparation Tank



Trasfert Tank



Syn Cip



Solution Preparation Syn

User safety, product quality and data integrity are fundamental values for REMOIN.

Therefore, the validation protocol supplied to the final customer, are included the Functional and Design Specifications of the machine, as well as all the necessary test sheets in order to perform the tests during FAT and SAT.

The validation documents issued by REMOIN consist of:

Standard documents

Technical folder with:

- P&ID
- Layout
- Isometrics (piping & welding)
- Material certificates in contact with the product
- Borescopes
- Welding specifications and procedures
- Welding reports
- Pneumatic P&ID
- Calculations
- Components list
- Instruments list
- Valves list
- Wiring diagrams and electrical list
- Instruments calibration certificates
- Operation manuals for components and instruments
- Hydraulic test reports
- Pickling and passivation reports
- PED certificates
- Operation manual

Documents provided upon request:

- Design Qualification protocol (DQ)
- Factory Acceptance Test protocol (FAT)
- Site Acceptance Test protocol (SAT)
- Installation Qualification protocol (IQ)
- Operation Qualification protocol (OQ)
- Performance Qualification Protocol (PQ)
- GAMP documentation

Factory acceptance test & Site acceptance test

In Order to verify the functionalities of our plants, we carry out the following activities

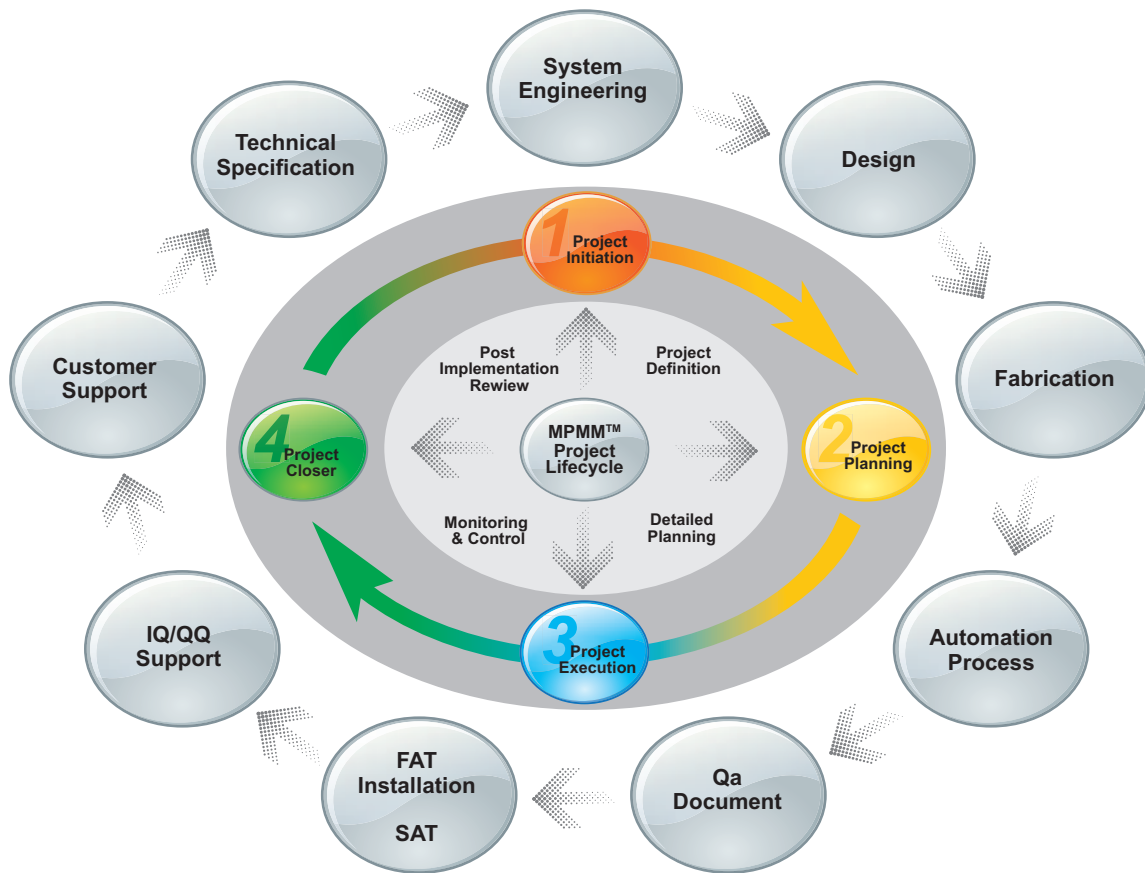
Factory Acceptance Test

Test of the system at **REMOIN** premises: many tests are performed in the REMOIN factory before delivering the plant to the customer. These tests aim to show that the equipment works adequately and that it can be installed and tested onsite. The purpose is also to test the control panel of the plants, to carry out alarm tests and to check the plant performances. During FAT a complete check of the documentation provided together with the plant is performed as well as the quality and the conformity of the whole plant and of each component.

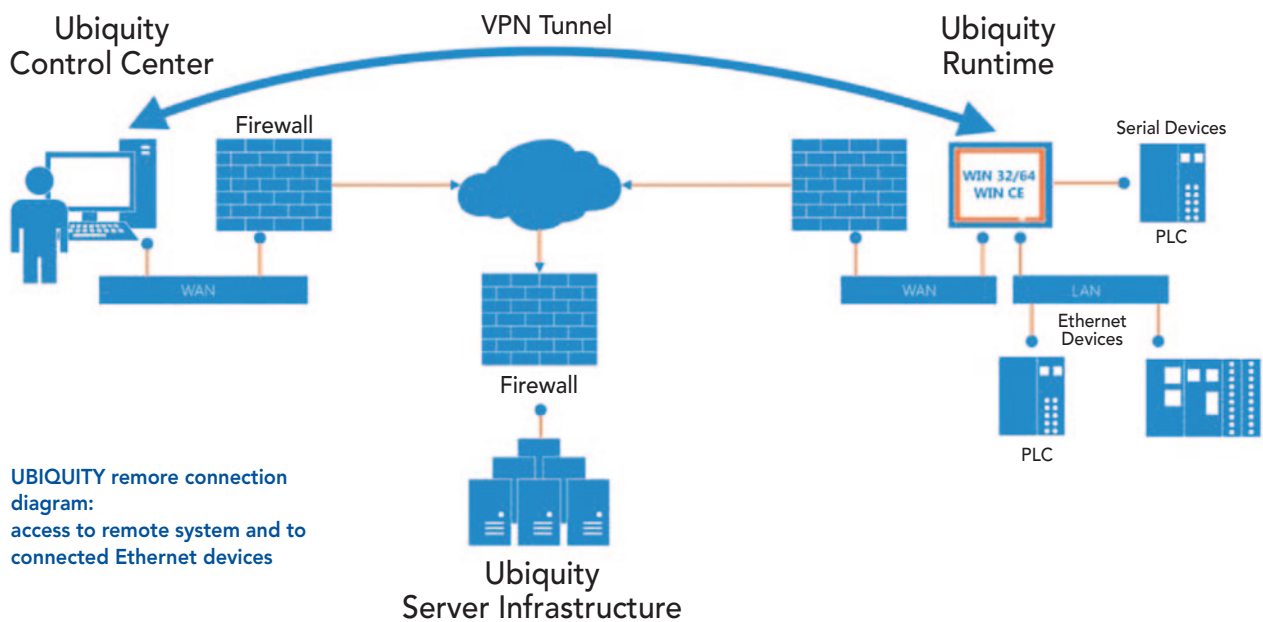
Site Acceptance Test

Test of the equipment at the final user: these tests want to show that the system works in its own defined operative location and that it interacts properly with other systems and devices. During SAT REMOIN technician inserts in the control panel all the necessary set points for the proper functioning of the plant according to the characteristics of the customer's site. He carries out all the tests already performed during FAT and he certifies the conformity.

Management Plan



Remote Assistance



UBIQUITY remote connection diagram:
access to remote system and to connected Ethernet devices



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