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Masters of Science in Management, Economics and Industrial
Engineering

*Expansion and Integration of Customer
Order Processing Application*

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1. Introduction

STERILINE S.r.l. is a company that currently faces a problem that may well be the envy of every other company: business is booming, purchase orders are coming in and the company is growing fast...perhaps too fast.

In a period of just about 6 year the change has been dramatic; the diversity and complexity of the offered products has expanded, many more customers are approaching the company and revenues have increased nearly tenfold.

STERILINE provide the complete solution for an aseptic treatment line, which consists on filling pharmaceutical containers in a sterile environment. The line is typically composed of a washing machine, a sterilizing tunnel, a filling machine and a capping machine; those after the sterilizing tunnel need to be placed inside a sterile room or possess an isolation cabin.

There are a myriad parameters that may change according to the customer: the range of containers is nearly endless; there is a large variety of rubber stoppers and caps; the filling substance can have very different properties; the customer may request more controls points than the standard and there are many more, yet, most importantly, the customer might wish to change the process itself.

The market demands that these machines have to be made customized to order, which makes each sale much like a project. The offer has to be very detailed and much information needs to be gathered from the end user.

Up until now, STERILINE has been appropriately adjusting its productive processes to meet the new levels of demand, yet there comes a point after which other processes need to be upgraded as well. The amount of information that is currently being managed and the rate at which it moves makes several old management processes obsolete.

The current quotation process is carried out using simple Microsoft Windows and Office tools, using generic templates and a spreadsheet to generate every quotation, which, after the final approval, must be manually interpreted into technical specifications for each machine. The system proved to be effective in the past, but now the rate at which quotations are being offered is much faster and the projects are larger and the weaknesses of the system are being revealed. The practicality of its simplicity is beginning to hamper as a bottleneck, without mentioning that the gathered and generated information is quite cumbersome to manipulate for further use.

The Politecnico di Milano, through its Lake Poli School initiative, had already begun to address the problem, laying the groundwork for the current study by developing the initial design of the process and software architecture of a computer application to generate quotations and technical specifications for the Depyrogenating Tunnel at STERILINE.

The following pages will guide the reader through the improvement and adaptation process of the above mentioned application, which will work together with the already existing information system at STERILINE, meant to grant additional support in the creation of offers and processing them into orders, in order to save time and improve the reliability, as well as to back up the information in a manner that renders it practical to manage.

2. Review of the Literature

Given that the following project consists in the development of the logic, procedures and interface of a computer application designed to process offers and order, there are certain areas of knowledge the reader needs to be familiar with.

The application falls into the category of **Information Systems** and, along with the existing information system existing in STERILINE, together they will comprise a **Customer Relationship Management** system, strengthening the platform's capacities.

The interface shall be portrayed through a **Mock Up** of the **Graphical User Interface**, to allow the final software developer a clear vision of what the final product should be.

The implementation of an information system will allow the collection of data in an organized database, data that the current process stores in a way that makes its recall quite impractical. The possibility to easily recall information from past offers and orders will prove an invaluable tool for **Management Control**.

2.1. Information Systems

Information needs to be measured in order to be of use. The bigger the business the more the information that is generated and received.

An information system is an integrated set of components for collecting, storing, and processing data and for delivering information, knowledge, and digital products. Business firms and other organizations rely on information systems to carry out and manage their operations, interact with their customers and suppliers, and compete in the marketplace. For instance, corporations use information systems to reach their potential customers with targeted messages over the Web, to process financial accounts, and to manage their human resources. Governments deploy information systems to provide services cost-effectively to citizens. Digital goods, such as electronic books and software, and online services, such as auctions and social networking, are delivered with information systems. Individuals rely on information systems, generally Internet-based, for conducting much of their personal lives: for socializing, study, shopping, banking, and entertainment (Encyclopædia Britannica).

In a more standard business environment, a corporate information system (CIS) is a fully integrated, company-wide system solution that aims to meet all organizational ICT requirements at all levels. It typically tends to be the administrative software employed to run their everyday accounting, administration, production, HR, acquisitions and / or sales operations, along with the hardware that acts as the server and terminals and the connection system that makes it all work together. Rather than having data being replicated across departments, it is instead held only once; it is “owned” by the organization as a whole and used by different departments; all systems access and update the same data source.

The information is stored in separate databases that can be queried by the user in the form of on screen searches to produce preprogrammed report formats. If the software is intelligently designed, the reports prove very helpful to find specific information or to identify particular trends; examples of reports could be invoices within a period, purchases from a particular supplier, sales by a particular salesman, inventory movements and even performance indicators, yet these are but a minute portion of the possibilities an information systems can provide.

Since the information is stored on databases that are not part of the program itself, this allows two very important things: the linkage of further applications, helping to expand on the functionalities of the system and the migration to another administrative software, should the current one be outdated.

2.1.1. Customer Relationship Manager

A CRM is a system for managing a company’s interactions with current and future customers. It often involves using technology to organize, automate and synchronize sales, marketing, customer service, and technical support (Shaw, 1991).

The backbone of CRM is the database of information, which may come from the company, from the customers themselves or even be self generated. The information may be customer contacts and data, purchasing history, technical support history, among other things. Such a database helps the company in presenting a unified face to its customers, and improve the quality of the relationship, while enabling customers to manage some information on their own.

CRM comes in different levels of complexity. A program that stores the customers' data in order to recall it in a future date is a CRM system; a program used to assemble a quotation for a customer is a CRM system. Others go further, taking a myriad of

information and using it to profiling prospects, understand their needs, and to build relationships with them by providing the most suitable products and an enhanced, more user centric, customer service.

2.2.Mock Up

A mock up is a model of a design, whether full sized or scale, meant to preview how the final device will look like. A mock up lacks functionality, its main purpose is to allow the interested parties (typically the designers) a clear representation; if the final product is something physical (like the body of a car), the mock up can be a full sized model made in clay; if it's a software, the mock up may be a series of screen and pictures showing how the graphical user interface will look like.

Mock ups are used to verify several characteristics early in the design phase, even to capture some feedback from the customers, in order to identify critical points of interest. Addressing these before committing more critical resources, such as in the later design or even in the production phases, allows to keep costs low. Aiming directly for a prototype could result in greater losses should major changes be required.

2.3.Graphical User Interface

Is the interface through which the user interacts with a software program, consisting in screens composed of icons, visual indicators, buttons, textboxes, among others. Abbreviated as GUI, the term was coined to differentiate them from the text based interfaces used at the time, which relied on the user typing the commands. The term is restricted to the scope of two-dimensional display screens able to describe generic information.

2.4.Management Control

2.4.1. The Control Process

Management control is an approach that enables a desired result (generally expressed in terms of "performance") by taking action to achieve those results and by dealing with the dangers brought on by external difficulties, such as the market and the political and

economical context, and the internal difficulties of the organization. It is an approach that is pursued over time, first situated before the action (planning phase) and then after the action (monitoring and analysis of results phase). The approach is progressive, thus called the control process.

Planning

The general function of the planning phase is to prepare for the action. The planning begins with the setting of objectives, which comprises two notions: the kind of result desired and the level of performance desired. When specifying and kind of result together with its desired level of performance, it becomes a targeted objective.

After the objectives, the action plans must be decided, which explain the means to reach the targeted objectives. Last comes the planning of the resources, which, in what quantities and rates and how will they be used.

Longer time horizons allow more room for planning, but carry higher risk levels due to the inherent greater uncertainty.

There are three planning tools:

- Strategic Plan: defines the company's long term objectives, typically aiming 5 years into the future, finding a balance between anticipation and risk.
- Operative Plan: translates the long term strategic plan into mid term objectives, which can be easier to visualize and program.
- Budget: an even shorter time horizon, usually one year, with more specific activities and setting milestones.

A well though planning phase will later serve as a valuable guide to monitor the results, which will be considered in terms of variance in accordance to the original objectives.

Monitoring and Analysis of Results

Planning, however masterfully done, will always be different from the actual result of the process. It becomes essential to monitor the results as they are being obtained. The purpose of monitoring is to overview the implementation of the action plans, giving the managers a chance to react mid stream, should the need arise. The navigation of the path towards goal achievement is done through procedural checks. The control process of planning and monitoring is a constant loop, called a feedback control loop.

Variances in the results and targets can derive in reconsiderations in the action plans and in the objectives themselves. This can be due to internal and/or external factors.

2.4.2. Performance Measurement System

Performance can mean many things, the first task is to define which performance measurements are more aligned with the action plan. Performance can be financial, operational, environmental, social, etc..., the types of performance to be chosen depend heavily upon the type of organization.

The chosen parameters must be the variables that define the function of the targeted objectives. Measurement systems must be established for each said parameter, in order to achieve a quantitative result. To monitor them, these results will be measured constantly against targets.

The parameters are called *indicators*, and knowing how to chose the right set is a valuable skill. Indicators can be absolute values, performance ratios and ratios between past and present absolute values, among other more. The quality of the measurement is key for a good control process.

The Role of Managers and Controllers in the Performance Management Systems

The performance system is used and followed by managers supported by controllers. The manager must act according to the objectives of the company and must rely on the system to assure that he maintains the right track. Straying from the path or, having a performance system with the wrong kinds of indicators, can be detrimental to the accomplishment of the objectives.

3. Company

STERILINE was born in the late 80's with the aim of producing automatic equipment for the pharmaceutical industry.

By the beginnings of the first decade of 2000 the main product was the Depyrogenating Tunnel, for which the company had particular renown, and they also produced Washing Machines.

A sterile line is composed, as a minimum, of a washing machine, a tunnel, a filling machine and a capping machine; not producing the latter two, meant that STERILINE could only sell to resellers, not final users.

They then began to develop the Isolators in 2002, which was a major improvement, yet they need to be installed on top of other machines that they did not make (filling, capping and other machines), again making it difficult to gain market share.

The story took a dramatic turn on 2008, when they acquired shares and partnered with SFM S.r.l, a company that designed and manufactured Filling Machines and Capping Machines. Finally, being able to offer an entire aseptic processing line meant that they could target a wider market and from that point onward the growth of the company has been nearly unstoppable.

Today the company is one of the most popular and successful manufacturers of process equipment in the pharmaceutical sector, worldwide. Company sales reach around the globe: in Europe, Asia, America and Oceania. The countries in which its sales are stronger are India, China and Indonesia.

Currently STERILINE produces the following types of machines:

- Rotary Washing Machines
- Linear Washing Machines
- Depyrogenating Tunnels
- Filling Machines
- Capping Machines
- Decontaminating Machines
- Isolation Cabins

So far STERILINE has been able to satisfy its need for growth not by reacting to the market but by anticipating demand and technologic needs.

However, procedures must also adapt to the needs. Currently STERILINE faces the need of a procedural change, the manual processes for order processing are becoming obsolete, consuming too much time and requiring excessive micromanagement. The information system needs to be updated.

3.1.Previous projects on the matter

From October 2013 to February 2014 the Politecnico di Milano' Lake Poli School (LAPS), through its Cross Boundary Processes course, joined forces with STERILINE and dedicated a project towards finding a solution to its situation.

The solution was to design a Customer Order Processing software that would allow the sales department to develop quotations, manage and modify them and process them into production orders.

The scope of the project was to develop the design of the front and back end, so that in the future it may be programmed under those specifications. One machine was taken to test the model, for which a correlation was made between its commercial and its technical parameters, in order to successfully exemplify the order processing capabilities; said machine was the depyrogenating tunnel.

4. Problem

The previous project with the Politecnico di Milano left STERILINE with a base design, which still required further adaptation to the actual processes and thorough testing, especially regarding the flexibility.

The application design currently addresses the quotation of a Depyrogenating Tunnel and it needs to be expanded to be able to handle a complete line of machines, to create a full quotation and to transmit the information into technical specifications.

Additionally, the Technical Specifications Summary is still carried by hand, a time draining task that results in poor traceability and lack of structure.

5. Scope

The scope of this project is to take the design developed for the Customer Order Processing software, apply the mechanics to the entire line of machines, to elaborate a full Graphic User Interface mock up and carry out appropriate tests, to validate the effectiveness of the proposed solution.

STERILINE shall obtain two definite Graphic User Interfaces, one for an application modules used to create and manage sales quotations and generate technical specification summaries and another one to manage said summaries.

STERILINE shall obtain the necessary correlations between the commercial features with which a machine is purchased and the technical specifications according to which the machine must be designed.

The actual programming of the application is outside the scope of this project.

6. Deliverables

The following is a list of the documents that shall be delivered to STERILINE at the end of the project, which will grant them all the necessary tools to successfully develop the application:

- Mock up for the Graphic User Interface for the Offer Management Module.
- Mock up for the Graphic User Interface for the Order Management Module.
- The correlations between the commercial features of each machine and its technical specifications, in order to map one according to the other.
- The operator's manual for the Offer and Order Management Modules.

7. Objectives

7.1.General Objective

The general objective is to improve the existing application design developed by the Politecnico di Milano so that it has the capacity to generate a full quotation of STERILINE's complete line of products and services, accomplishing a level of flexibility comparable to the current method, while granting all the benefits of a corporate information system: structured process, data storage and traceability.

7.2.Specific Objectives

The following objectives must be accomplished gradually throughout the development of the project, marking the milestones and allowing the study to move forward:

- Understand the workings of all the machines, their function and their place in the aseptic processing line
- Identify all the commercial features of each machine
- Identify the information that must be gathered from the customer to be able to define the design of a machine
- Identify all the information required in order to successfully complete the design of a machine
- Define the correlation between the commercial features and the technical specifications for each machine
- Develop a mock up for a Graphic User Interface that offers the sales department a similar degree of ease and flexibility as that provided by the solution they currently employ
- Develop a mock up for a Graphic user interface to manage the Technical Specification Summaries
- Test both mock ups by simulating the quotation process and the technical follow up process of several existing projects, in order to find weaknesses in the design and to fix them.

8. Situation Review

8.1. Interaction between the Sales Department and the Customer:

The sales department is comprised of three Sales Managers and one Sales Assistant. Only the manager interacts with the client, but all of them create quotations; the Sales Managers create them when requested by a client and the Sales Assistant creates or modifies them upon request from a Sales Manager.

Currently the Sales Department carries out quotations through the joint use of Microsoft Excel and Microsoft Word and manages them as files in Windows Explorer, indexing them manually to achieve a specific ordering logic. A master Excel book works as both database and template, storing all the information related to the features and prices of every model; the user selects/inputs the desired items and makes up a price list, which will then be copied in the final quotation. In parallel, the sales manager or his assistant works on a Microsoft Word Template, which holds all the text descriptions, of the features of every model as well as that of every service and document offered; he leaves the description of the features and services he wishes to quote, makes the necessary modifications in terminology and then erases the rest. After this, he copies the price list from the Excel book. With these merged documents he saves the quotation with a particular code logic and prints it, in order to send to the client.

Offers have different states: Budgetary (first one), Revision (every subsequent modification), Order (after the customer has placed the purchase order and paid the down payment) and Closed (cancelled).

The negotiation process normally involves several revisions of a quotation, as both parties come to an agreement of the specifics of the machine, ending, when successful, with the customer's purchase order.

If the customer requires an additional feature on a machine or a new service (or a modification of any) after the order has been confirmed, the additional items are quoted through an *addendum*, which makes reference to the order, for which a matching purchase order is required.

The disadvantages of the process is that it has a long learning curve for newcomers, it is very dependent on the know-how of the user, it has very high micromanagement and it offers poor back up support and traceability, all this while being subject to accidents should a user

unintentionally tamper with the formulas. The management of the files with Windows Explorer provides only the basic searching support, with the risk of misplacing.

8.2. Interaction between Sales Department and the Technical Office:

Once the client has agreed upon a specific machine, or machines, with a specific set of features, has sent a purchase order and the down payment has been confirmed as effective, the Sales Department formalizes the milestone by producing a document called Order Confirmation, which contains the information of the accepted quotation, along with the conditions of the negotiation; this document is submitted to the Technical Department, in order to proceed with the design of the machine. The specific information collected in the Order Confirmation must be, thus, translated into appropriate technical specifications. The technical specifications are made up by two documents:

- **Electrical questionnaire:** these are the electrical input parameters that the client has in his site. The customer is handed an empty questionnaire, which he has to submit with the correct information.
- **Technical Specifications Summary:** is a document that contains all the relevant information concerning the order: client's information, the specifications of the machines involved, electrical information, documents required, services required, shipping information and site information, among others. It's the document that defines the project.

Currently this process is carried out manually. The Sales Department hands the Order Confirmation, along with the filled Electrical Questionnaire, to the project manager, who then proceeds to translate the information into the corresponding technical specifications and create the Technical Specifications Summary for the order.

He then distributes this document among the involved parties: mechanical, electrical and electronic design, production department and the documentation and validation department.

The main disadvantage is that the process is extremely prone to human error and time consuming.

8.3. Interaction between the Technical Office and the Customer:

Once the sale has been formalized, the project manager takes the salesman's place as the contact between STERILINE and the purchasing company, ready to define all the remaining details. During this definition phase, the Technical Specifications Summary may (and typically will) be subject to changes. With every modification an additional revision is issued, communicated and distributed among the involved parties.

There is a color code to the creation and modification of the Technical Specifications Summary:

- Yellow Highlight: means uncertain information, that requires further approval or deeper level of clarification.
- Blue Highlight: means updates. Information that is new on the current revision
- Red Highlight: means cancelled information, that no longer applies. It's left visible to remark the fact that it no longer applies.

The fact that the highlighting is done manually means that updates are seldom, for lack of a better word, updated, meaning that what was signalled as an update from version "x" to version "x+1" will still be highlighted as an update in version "x+2"; thus, sometimes resulting in a document with over 50% of the text considered as an "update".

Additionally, just as with the above mentioned processes, this manual updating is also liable to suffer from human errors and delays.

9. Methodology

9.1.Phase 1: Learning

The first phase will be focused on information gathering and its analysis. The thorough comprehension of the technical workings of all the machines is required to identify the most appropriate parameters for commercial and technical purposes. Afterwards, the entire sales process will be studied in depth, covering the time from the offer up until the order has been successfully delivered, commissioned and tested. Many changes may occur during the design and manufacturing process and the system must be flexible enough to assist with them.

The two main sources for information shall be the sales department, for all things related to the commercial aspect and how the offering and later sales process of each machine is carried out, and the project managers, to understand what information and which parameters are required to design each one of the machines, as well as which is the best way to display them.

Additionally, the technical details of each machine shall be consulted directly with the mechanical, electric and software designers.

9.2.Phase 2: Building

The second phase will be to establish a set of commercial and technical characteristics for each machine. The former will be available for quoting purposes to propose to the customer and as internal information requirements to be gathered from the customer; the latter will be to provide the technical department with a list of all the necessary information to successfully design the machines.

The commercial characteristics will be discussed with the commercial department, seeking to optimize the offered features by leaving only the characteristics that apply to the specific machine model chosen.

The technical characteristics will be discussed with the designers, taking into account the current procedures and standards.

Afterwards, the sales process will be structured, with a strong emphasis on the flexibility issue and understanding where it is most necessary.

What will follow will be an extensive review of the existing application model, integrating the new sections and adapting it to the new process.

9.3.Phase 3: Troubleshooting

The third phase will be dedicated to testing the system, by running simulations of quotations already done in the past, to verify whether the new system can provide the same results, offering the same flexibility, with greater efficiency. Since the system will not yet be a functioning program, this testing will be run manually, expecting to encounter additional scenarios to further enrich the design.

It is expected that certain modifications will have to be made on the initial system design achieved during the project by the Politecnico di Milano, since it was made for only one machine and, although it considered the integration of other machines, some characteristics of the other machines may make it necessary to modify part of the structure.

10. Results

10.1. Machines

STERILINE manufactures and sells several machines and accessories that together make the aseptic processing line. There are main machines, auxiliary machines and isolator/CRABS accessories.

10.1.1. Main Machines

Washing Machine:

The first machine in the line, it's used to remove particles from the containers by means of jets of pressurized water and compressed air. It's typically handled by an operator and, after washing the containers, it delivers them into the Depyrogenating Tunnel.

- Rotary Washing Machines: a motor that rotates on a vertical axis provides the motion, the containers are picked at one point and, during their trip around the rotating body, special needles are used to spray them with pressurized water and compressed air, both on the inside and on the outside, several times. The configuration of the spraying stations has a default state, but can be configured according to requests; the Rotary Washing Machines can be Alternate or Continuous.
 - Alternate: the needles are fixed in determined positions and the motor stops rotating at specific intervals, synchronizing the stop with the spraying action. Employed for the smallest capacities.
 - Continuous: the motor does not stop rotating and the needles are mounted into the rotating body. Employed for medium to large capacity.
- Linear Washing Machine: the containers are loaded into a conveyor belt filled with baskets. The basket belt stops at determined stations, in which special needles proceed to spray pressurized water or compressed air. These washing machines offer a high degree of customization possibilities, since the belt can be made longer or shorter, depending on the amount of operations required. Employed for large capacities.

Depyrogenating Tunnel:

The tunnel is used to sterilize the containers, by eliminating the remains of bacteria. It consists of an inlet chamber, a heating chamber and a cooling chamber. The model of the tunnel depends on the desired production rate and on the size, material and shape of the container; there are many models, based on the area of the heating chamber, the greater the area, the greater the capacity. The Depyrogenating Tunnel is mostly mechanically fed by a Washing Machine and delivers the sterilized containers into a sterile environment, which may be a sterile room, a filling machine encased in an isolator or any other machine encased in an isolator.

Filling, Stoppering and Capping Machine:

It's a machine that fills the vial with the desired fluid (or powder), puts a rubber stopper on it and then seals it with an aluminium cap. The process needs to be carried in a sterile environment, which is why the machine needs to be either in a sterile room or encased in an isolator. The design of the machine depends on the type of containers it must process, which affect the transportation system and some of the mechanisms. Depending on the container type, the capping function may be separated and managed as a standalone machine, for processes that have intermediate activities. The motion is intermittent and the capacity depends on the number of containers that move "per step". There are four basic models, all maintaining the same "step" interval, but each one increasing the number of containers per "step" (meaning that the stations have more tools).

It's usually fed by a Depyrogenating Tunnel and it may deliver into several machines; the stoppered product may be immediately capped or may be delivered into a Freeze Dryer, after which it will then head on to a standalone capping machine; the capped product may be considered finished, may be delivered into a Tray Loader or may be delivered into an External Decontaminating Machine.

External Decontaminating Machine:

Employed to clean the external surface of the containers after they have been filled with a toxic product. The machine moves in a continuous motion and the containers are subject to a series of special needles which spray them first with pressurized water and afterwards with compressed air; the design guarantees that no part of the surface is left unwashed. The machine is encased within a negative pressure restricted access barrier, which works in a vacuum, assuring that no contaminated particles come out. There are 4 basic models, each one increasing in size, increasing the speed of the line and, thus,

allowing a greater capacity. It's often fed by a Capping Machine and its output may be considered finished or may be delivered to a Tray Loader.

Isolators / Closed Restricted Access Barrier System (CRABS):

Isolator and CRABS are specialized hoods that are installed on top of certain machines to guarantee the sterility of the process within, sealing the inside from the outside environment. Through a special ventilation system and tight controls, it provides a pressure cascade that assures the direction of the airflow between the control volumes, so that no undesired particle travels where it shouldn't.

CRABS maintain a complete seal between the inner and outer environment, but once opened (mostly for set up and/or maintenance), they need to be sterilized within a sterile room in order to remain sterile when they are closed. Isolators have their own built in sterilization system, which means they can operate in a non-sterile room.

Isolators and CRABS do not have a standard, they are custom made specifically for each machine. They are typically installed on Filling and Capping Machines, Freeze Dryers and in auxiliary machines between the Depyrogenating Tunnel's output and the final exit machine.

10.1.2. Auxiliary Machines

Tray Loaders:

A machine that takes the containers and employs an indexing system to arrange them in a honeycomb pattern within a tray or a frame (a bottomless tray). Used to assure a uniform amount of containers per tray or frame, whether for packing purposes or to maximize the efficiency of the Freeze Dryer. The Tray Loaders come in Single and Double versions. It's typically installed at the end of a line or after the Filling and Stoppering Machine (which, in this case, is separated from the standalone Capping Machine).

Rotating Tables:

A rotating dish used as a buffer and/or as an intermediary between transport systems. It can have a narrow or a wide input and it has a narrow output. It's main use is to produce a single line output for the next machine. There are three diameter sizes, to adapt to different capacities. It can be placed at the input of a Washing Machine, at the input of a

Filling and Stoppering Machine, at the input of a Capping Machine and at the output of a Freeze Dryer.

Transport Belts:

Conveyor belts to transport the containers between machines. There are three adjustable lengths to choose from.

Positive Diverting System (PDS):

A mechanism used to change the direction of the flow of containers. It may be composed out of a combination of Transport Belts, Rotating Tables and Star Wheels (dented rotating wheels). It's designed according to the machine layout.

10.1.3. Isolator / CRABS Accessories:

HVAC System:

Comprises the ventilation system employed to provide enough airflow to accomplish the desired air recirculation within the CRABS and the Isolators. It's quoted according to the volume.

Vaporized Hydrogen Peroxide (VHP) Generator:

Isolators are equipped with a VHP cycle system that employs VHP to automatically sterilize the machine from the inside. The generator is sold to provide the VHP. Several brands are quoted.

Control Cabinet

The control cabinet for the CRAB / Isolator system is designed according to the total number of volumes and whether the system is designed for STERILINE machines or for third party machines.

Air Monitoring

Consists on an in line particle counter which connects to the viable and non-viable sampling ports installed in the machine. It may also be connected to a PC to register data in compliance with title 21 of the Code of Federal Regulations, part 11, from the FDA.

10.2. Formats

A machine, or line of machines, is physically configured in such a way that it is able to process a specific container (type and size), a specific stopper, a specific cap and a specific filling system. If one of these four inputs changes, the machine needs to be set up accordingly. A specific combination of this four parameters is called a *format*, and all the parts used in the set up to adapt the machine to a *format* are called *format parts*.

Format parts may be: needles and pincers (for washing machines); needles and pumps (for the filling systems); bowls and chutes (for the stoppering and capping systems) and any number of interchangeable plastic parts in the transportation devices throughout the machine.

10.3. Application Development

The development begins where the project with the Politecnico di Milano left off. Taking the mock up and the use cases the first goal was to evaluate its adaptability to the new requirement, that of being able to handle a full quotation, incorporating all the machines.

The mock up underwent four key modifications to expand its scope, in order to render it capable of fulfilling the desired purpose.

10.3.1. Add Machine Line, instead of Add Machine

The main change that must be done to the original design is in the “Add Machine” process. Originally the function of “Add Machine” would let the user add individual machines to the quotation, allowing him to choose a set of glassware for each.

Upon deepening the comprehension of the quotation process, it’s understood that it’s more appropriate to take each machine as one part of the entire machine line. Thus, the process of “Add Machine” should, more adequately, be renamed “Add Machine Line”. The steps of the process shall be as follows:

1. Add Machine Line: this action will enable the user to add a group of machines that will work together with the same selection of glassware.

More than one machine line may be introduced in one offer and they will both have their independent glassware selection.

2. Input Glassware: in this step all the glassware containers that will be present within the line are introduced, whether they are present in all the machines or even in as few as only in one of them.

They are introduced in a table composed of the following fields: type (vial, ampoule, cartridge, syringe or *custom*), format (if standard format is available); volume, diameter and height (three separate fields, which fill automatically if it’s a standard format or are filled manually if it’s not) and desired production rate.

If the container type is not one of the available ones, then by selecting *custom*, the user can again input all the data manually.

The first container introduced is taken as the Main Format, meaning that it will be employed to evaluate machine selection (according to capacity) and design.

3. Select Machines: a listbox will allow the user to select the machines from a selection (Washing Machine, Depyrogenating Tunnel, Filling/Capping Machine, Decontaminating Machine, C-RAB/Isolator, PDS, Tray Loader, Rotating Table, Conveyor Belt) and a “+” symbol will allow him to add the next machine in the line. For the Filling/Capping Machine, the additional functions of “filling” and “capping” must be appropriately checked or unchecked.

Once all machines are added, the next screen will show a table with all glasswares in the line and a check box under each machine, so as to specify through which machines will each container go through.

4. First view of “Machines” list: once the machine selection is finished, they can all be seen in the list, but they still have to be configured with the options. They are highlighted in yellow and only after they are configured will they cease to be; additionally, the offer will not allow to generate quotation until this is done. This will be to avoid leaving a machine unconfigured.
5. Configure Machine: to configure a machine according to the customer’s request. The first screen is devoted to the model (size), which is first suggested by identifying the smallest machine in the line that can satisfy the desired production rate of the main format (provided that the main format must go through said machine) and then providing the model that matches that production rate. The user is entirely free to change the model according to his own criteria.

Below, in the same screen, there will be a table that shows glassware, desired capacity and machine capacity. If the machine capacity is below desired capacity, then it shall be colored in red, otherwise, it shall go in green.

The next screen is the proper machine configuration screen, in which the user selects the additional features to quote, inputs the custom features to quote and inputs the information requested from the customer. This part remains unchanged from the original design.

6. Price list: as each machine is configured, it appears in the Price List with all of its quoted features. Each feature is a visible item with its visible price. However, the user has the option, for every individual price, to let it visible or to hide it as *included*.

10.3.2. Configure Machines, for each type

The existing *Configure Machine* screen interface was specific for the Depyrogenating tunnel. A new screen had to be created for each new machine; four different formats were designed: *Machine*, *RABS/Isolator*, *Auxiliary Machines*, *RABS/Isolator Accessories*.

The appropriate *Machine Details* screen were designed, giving special attention to the Filling and Capping Machines, due to the degree of complexity involving the different formats.

10.3.3. Addenda

The next structural change, or better put, addition, is the inclusion of an “Addenda” section, in order to quote additional items (extra features, another machine, another service, etc) without the need to redo the entire quotation.

Once an *offer* has been upgraded to *order*, the option for “Addenda” is enabled. This new option allows the user to create a follow up quotation by first writing the new introductory text and the description of the new quotation and then adding the new quoted items through a structured process.

Every change carried out in this manner will indeed affect the general quotation. The “Addenda” section is not a separate quotation process, but more like a different user interface, to offer a simpler interaction to the user and to simplify the printing procedure (since only the new modifications are to be printed).

10.3.4. Order Management Module

The last modification, also an addition, is a separate module to manage the Technical Summaries much like the one to manage the offers. The main difference is that a Technical Summary cannot be “created”, it is generated only through the corresponding option in the offer once this one has been confirmed. The user will be able to browse through the list of Technical Summaries, filtering and arranging them according to many parameters (of special importance is the possibility to separate the ones that are “in house”, from the ones that have already been delivered, but are still not finished; this can be done employing the “delivery date” column).

The new system will keep track of the modifications between revisions, allowing the user to highlight in yellow the parts that need further clarification, select the parts that would be

cancelled and relieving him of the task of signalling the updates; the system would automatically highlight in blue every modification from the previous version, as long as the modification was not previously marked as a cancellation.

Only Project Managers can access the Order Management Module, meaning only they can modify the Technical Summaries directly. The sales department can modify the Technical Summaries only through updates in the *Confirmed Order*.

Each Technical Summary is structured in similarity with the existing format currently managed through Microsoft Word. Major innovations include:

- Dual comment fields: since the sales department cannot access the Technical Summaries, to avoid a conflictive comments during updates, the comments fields shall be separated in every case, independent for *Comments...by Sales Department* and *Comments...by Project Manager*
- Easy visualization of Deadlines
- Easy accessibility to the customer's technical documents related to the order, through hyperlinks
- Ease of viewing changes done through an addenda and understanding their origin
- Machine Technical Specifications: a practical and thorough list of all the technical specifications required to design a machine, coming directly from the quoted characteristics of each machine. Additionally, it allows the user the possibility of adding a specific pop up comment for each characteristic, in which he can write, among other things, the User Requirement Specification that justifies said characteristic
- More information on Spare Parts: the price paid for each set of spare parts, per machine, is detailed, to facilitate the assembly of the spare parts package
- A thorough view at the information pertaining every service, including the personnel quoted for the interventions

Additionally, several minor changes took places at different instances of the preceding mock up, which came from either the need to adapt it to the current requirements or from further requirements to assure an increased degree of flexibility. Some of these tweaks are:

- Customer's documents upload: to allow for a quick file sharing
- Removal of not required, excessive electrical information during the offer phase
- Possibility to edit the output of a machine

- Possibility to override a calculated price in the price list
- Possibility to hide or unhide prices in the price list
- Rearrangement of the documents screen and it's corresponding information input screen
- Assessment and modification of required information for F.A.T. and modification of displayed F.A.T. information on the price list

10.4. Adapting to the current system

Currently the gestionale has a Sales module which works independently from the quotation process. It's used to introduce the offer in the system, turning it into "essecutiva" once it's approved in order to proceed with the production and accounting process.

The creation is exceedingly simple and proposes no mayor inconvenient towards the adaptation with the new proposal.

Among the most important inputs, the gestionale prompts the user with the customer's information, to specify whether it's a standalone machine or a line of machines and to introduce the individual machines (matricola), which are only identified as a code, without further detail. However, certain items that in the offer are considered as accessories, in the technical department are considered machines on their own right, which forces a relationship of "one to many" when converting the quotation into a Technical Specification.

In this regard, if a machine has certain features and the Technical Specifications are generated, not only will the matricola of that machine be created, but also that pertaining to the particular features, though a link will exist between them.

10.5. New Mock Up

A new version of the mock up was generated, showing all the modifications described above along with minor visual and functional modifications.

The mock up is available in digital form.

10.6. User's Manual

A user's manual has been written to guide the new users through the new system. A copy is included in the Appendix A.

10.7. Mapping of Technical Specifications

The sales department sells the equipment by offering the base machine plus certain additional characteristics. These characteristics directly relate to technical specifications in the machine, correlating in a one to one or one to many basis. A *mapping* of technical specifications is the document that dictates the logic of these correlations, by means of which the technical specifications of one machine can be obtained based on commercial characteristics.

The *mapping of technical specifications* for all the machines is included in Appendix B.

11. Conclusions

Often standard information systems cannot be customized for particular problems, the costs of such work might be prohibitive and the results tend not to be as expected. In these cases, the optimal solution is to build from scratch, based directly on the requirements.

The process of developing a specialized solution starts with a thorough understanding of the process and must be provided with a reliable communications channel between the developer and the end user. The core of the process must be studied and the propositions must be continuously discussed with the end user.

After the successful completion of the project, there are several conclusions that can be drawn from the results:

- The pre selection of machine types before further configuration gives the system the capacity to suggest a model when configuring the machine based in the capacity of the bottleneck machine. Without the pre selection, the system would only be able to suggest a model based on the capacity of the machines already selected, ignoring those that the user has yet to input.
- There is much information that is not required for the quotation but essential for the design. With the current method those bits of information are requested to the customer sporadically and typically when the designers need it. In the new application the *Machine Details* screens serves to gather much of that information, showing the questions clearly, so as to serve as an explicit reminder. However, the input is not mandatory, allowing the quotation process to proceed.
- After extensive testing with different scenarios, taken from several quotations concerning complex machines between 2011 and 2014, the current design has proven to be flexible enough to consistently handle all the necessary aspects of the quotation process. The possibility to introduce custom characteristics for each machine and text comments in nearly every section allows the user to overcome every flexibility constrain the system could otherwise present.
- The fact that most databases will be fully installed in the portable computers of the Sales Department, along with the function to synchronize with the local databases upon connection at STERILINE, will grant the Sales Department ample mobility to

develop quotations while working away, without fear of conflicting information upon their return.

- The *Addenda* option modifies the data in the same way as can be done by editing the offer directly, yet when doing it through the addenda tab the program will emit the *Addendum* quotation only with the modified items.
- The new system will dramatically reduce the time required to make a quotation and that required to make and manage a Technical Specification Summary. No longer will the Sales Department have to sift through databases of descriptions and prices, they will simply need to select the desired items from comprehensible lists for each machine.
- The probabilities of human error will greatly diminish, since the Sales Department will no longer have to manually edit a template and the Project Manager won't have to manually write or copy and paste information into the Technical Specifications Summary.
- Designing a parallel system to manage the Technical Specifications Summary coming from the processed orders relieves the Project Manager of the manual manipulation of the Summary, of the interpretation process of converting the commercial characteristics of a machine into technical specifications and of highlighting updates and cancellations.
- The new Technical Specifications Summary will provide the designers with a clear list of specifications for each machine, without omissions and in a fixed order, which is more visually aesthetic and, thus, easier to grasp. More organizations leads to better readability and repeatability.
- Currently the Confirmed Order is not updated after it has been issued, usually resulting in differences between it and its corresponding Technical Specifications Summary. The new two applications will work in direct cascade, the users of the Offer Management Module produce the inputs of the Order Management Module; the users of one module cannot access the other. Should a change in the characteristics be requested during design or production, one that carries no additional cost, the Project Manager needs to request the modification to the Sales Department. This streamlining of the flow of information and clear definition of the responsibilities solves traceability problems, assuring that the last versions of the Confirmed Order and the

Technical Specifications Summary will be congruent with each other as well as with the final machine.

- By incorporating the process into an information system, one that, together with the current gestionale, makes a more robust Customer Relationship Management system, there is much more information available to play with. This information will serve to establish new performance indicators and to ease the way in which much sales information is analysed.
- With the newly developed Graphic User Interface mock ups, the Mapping of Technical Specifications and the Software Design Documents produced by the Politecnico di Milano, STERILINE is provided with all the tools to successfully develop the software application. The User's Manual will serve as a comprehensive guide to instruct the future users.

12. Recommendations

Having concluded the study, a look back into its development with a refreshed perspective allows to identify which were they most decisive factors that contributed to the advance of the investigation as well as which were the main deterrents. This retrospective gives rise to a set of recommendations that concern similar projects that involve developing a custom made information systems solution. The following advises are based on the for similar development projects:

- Gathering information is a key process, if done incorrectly it can hamper development and lead to much reworking. Information is seldom found in one place or in one person; the researcher must strive to follow the thread of information to the very source in every particular case.
- Design and test in quick, repetitive cycles; design is an internal process, carried out by the designer, and the feedback comes through testing. To minimize down times and backtracking, the design should be tested as soon a each new phase is achieved.
- Design and get feedback in quick, repetitive cycles. Without feedback the designer will never know for certain whether he's on the right track, since he will not be the end user of the application and, therefore, doesn't have the final say.
- The closer the proximity to the client/end user, the quicker the design process will progress, since down times are kept to a minimum thanks to the availability of information and opportunities for feedback.

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Appendix A: User's Manual

User's Manual

Offer and Order

Management App

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Offer Management Module

The Offer Management Module allows the Sales Managers and Sales Assistants to develop new offers for customers and to manage and modify existing ones, providing an intuitive and logical structured process.

Login in / Unlocking

If this is the first time he starts the application, or if he logged out in the previous session, the system will request him to log in, by inputting his credentials in order to authorize access and to identify all actions with said username, for traceability purposes.

If, however, the user did not log out in his previous session, but rather **locked** or closed the application, he will not be requested to **log in**, but rather to **unlock**. The user must introduce his four digit PIN code, which is linked to his username.

A **locked** application will still have the credentials loaded. In order to change users, the logged user must **log out**.

Offer List

The Offer List screen displays all the offers in their most recent version. The columns allow sorting and filtering in all the fields:

- Identification 5 digit number
- Status: whether it is a **budget offer**, a **revision**, a **confirmed order**, **concluded**, a **closed offer/order** or an order placed **on hold**
- Creation date: when the first revision was saved
- Last modification date: when the current revision was saved
- Customer name: end user
- Customer's country: country where the machine will be installed
- Agent's name: agent that is mediating the sale
- Sales Manager: the responsible for the offer

Several options are available from this screen.

Searching Offers/Orders

Introduction

The Offer and Order Management App is an application for commercial and technical use, to allow both parties a simple, yet powerful interface through which to manage the two main documents involved in the lifecycle of a sales order: sales offer and technical specifications.

It is comprised by two separate modules with separate access, one for the sales department and another for the project management department.

Through it the sales department can create, search and modify and delete a commercial offer. They can confirm it as an order and, therefore, generate the appropriate technical specifications, and can continue to modify it, generate addenda and always updating the technical specifications.

Meanwhile, the project managing department can search and modify the technical specifications generated by the sales department for all the sales orders, perform technical modifications and insert comments.

The information flow guarantees coherence among the related documents, to assure traceability.

This user's manual shall guide the reader through the process from offer creation up to the final stage of the definite technical characteristics of the order.

Users

The application is aimed at the sales department and at the project management department.

The sales department will have both online and offline access. To allow offline access a local mirror of the database is required, in which case the changes when no connection to the server is detected will be made only in the local database, requiring a synchronization once connection is restored, in order to update the server database.

There will be two user types for the sales department, Sales Assistant and Sales Manager.

The project management department will have only online access.

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The search box allows to find an offer by looking for the inputted text among the 9 column fields.

Lock

Allows to **lock** the application to block access for security reasons.

Synchronize

Used to synchronize the server database with the changes made in the local database. If there is a conflict, a window will pop up, requesting the user to select from the two options, displaying an array of information for the two files, to allow the user to decide.

There is no automatic synchronization. If the user does not manually synchronize after he connects to the server, the work performed while working online will not be made available and, furthermore, the local database will not be updated with changes made in the server database.

Log out

Used to change user or for additional security reasons.

WARNING: Should the user **log out** while offline, he won't be able to **log in** again until he connects to the main server.

Change PIN

Used to change the user's PIN. The system will prompt the user to introduce his old PIN, his new PIN and to reintroduce his new PIN.

Create Offer

This initiates the process of offer creation. A window pops up requesting the user to introduce a series of information:

- **Sales Manager:** this field is filled automatically if the user is a sales manager. If the user is a sales assistant, it's left free to select the appropriate sales manager
- **Customer:** chosen from the list of registered customer
- **Contact:** chosen from the list of contacts registered within the chosen customer
- **Agent:** chosen from the list of registered agents
- **Comment:** free text field to input a general comment regarding the offer

Edit Offer

Allows the user access into a previously created offer. If the offer was created by the same user or if the user is a sales assistant, then it also grants permission to modify all the contents, perform all actions and save a new revision. If the user, however, is a different sales manager, he can only view the contents.

Offer Creation

The offer creation is comprised of six sections: **Offer Details, Price List, Machines, Services, Documents** and **Addenda**. Through this six sections the user inputs the necessary information to generate a quotation.

Saving: the user can choose to save the offer/order at any point during the creation or modification process.

Canceling: the user can choose to exit the offer/order at any point during the creation or modification process, thus, disregarding all changes done since the last save.

Offer Details

Here the user will find the general information regarding *customer, contact, agent, electrical inputs, software requirements, shipping options and payment conditions*, as well as the actions that can be performed with the offer, which are *generating a quotation, confirming the order, closing the order, generating the electrical questionnaire, generating the technical specifications and updating the technical specifications*.

General Info

Displays creation and last modification date, which are not editable. The responsible Sales Manager is taken from the previous window and is editable only by a Sales Assistant. The comments are also taken from the previous window and are fully editable by both.

Finally, the price modification factors are introduced, **Mark Up and Discount**.

Setting Price

By pressing **set price** the user opens a new window that will allow him to set the parameters of **Mark Up and Discount**.

- **Mark Up:** there are two possible ways for modification. The first is through the **Sales Price** box, which displays the current gross price of the offer (provided that the user has introduced machines, services and/or documents) and allows the user to input directly a desired gross sales price, and automatically calculating the **Mark Up** percentage on the basis of the base price of the offer. The second way is through the **Mark Up percentage** slider, which allows the user to set the desired percentage, which calculates the new gross price. The methods are dependent of each other.
- **Discount:** works in the same manner as the **Mark Up**, the box called **Net Price** is used to input directly the desired net sales price, automatically calculating the appropriate discount, on the basis of the gross sales price (affected by **Mark Up**), and the slider called **Discount percentage** is used to set the percentage and calculates the **Net Price**. Again, both methods are dependent of each other.

To facilitate the process, a standard **Mark Up** is automatically loaded from the beginning based on the customer's country, which can then be freely manipulated from the **set price** screen.

Customer Info

Shows information from the customer, including the contact person. The user can only select from the list of registered Clients and from the registered Contacts for that specific client. Any changes on the Client's data can only be managed through the CRM application.

End User Info

Shows the name of the end user and the machines destination country. The user can only select from the list of registered Clients. Any changes on the Client's data can only be managed through the CRM application.

Agent Info

Shows information from the agent. The user can only select from the list of registered Agents. Any changes on the Agent's data should be managed through the CRM application.

Offer Status

Used to view the status of the offer and the relative measure of the progress.

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- **Budget:** set automatically when the offer is created
- **Revision:** set automatically from the second version until closure or confirmation
- **Confirmed:** set automatically when the offer has been accepted and confirmed into an order
- **Concluded:** set automatically when the order has concluded successfully
- **On Hold:** set automatically when the order has been put "on hold"
- **Closed:** set automatically when offer/order has been closed

The progress is set manually through the slider, depending only on the "feel" of the Sales Manager. The limits are 25%, which is set automatically as the minimum when the offer is created, and 100%, which is set automatically when the offer is confirmed.

Adding/Editing Customer Documents

By selecting **Add Customer Documents** from the **Actions** menu, a window will appear, which will prompt the user to upload the user's documents (URS, Plant Layouts and others) into the server, generating a link for other users to access them. Should the user desire, he can also introduce a comment. The user finishes by accepting.

Once the appropriate **Customer Documents** section is created, the user can **edit** the contents at any time, by pressing the **edit** link at the upper right corner, which brings back the window for edition.

Adding/Editing Electrical and Electronic Information

By selecting **Add Customer Documents** from the **Actions** menu, the **Add Electrical & Electronic Information** window will appear. From here the user can input the electrical **Norm** that the machine must comply with, the **infeed voltage** and **frequency**, the presence or absence of the software to comply with **CFR21 part 11** and any additional **comments** that he may deem necessary. The user finishes by accepting.

Once the appropriate **Electrical & Electronic Information** section is created, the user can **edit** the contents at any time, by pressing the **edit** link at the upper right corner, which brings back the window for edition.

Adding/Editing Shipping Information

By selecting **Add Shipping Information** from the **Actions** menu, the **Shipping Information** window will appear. From here the user can input the **delivery**

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terms, address, price and any additional **comment** that might be required. The user finishes by accepting.

Once the appropriate **Shipping Information** section is created, the user can **edit** the contents at any time, by pressing the **edit** link at the upper right corner, which brings back the window for edition.

Adding/Editing Payment Conditions

By selecting **Add Payment Conditions** from the **Actions** menu, the **Payment Conditions** window will appear. From here the user can select from the preset **terms and conditions for payment** (Europe and Extra Europe) or input a custom condition. When selecting **custom**, the user must introduce the conditions by means of the table that appears below, adding rows which can be modified or deleted. The user finishes by accepting.

Once the appropriate **Payment Conditions** section is created, the user can **edit** the contents at any time, by pressing the **edit** link at the upper right corner, which brings back the window for edition.

Generate Offer Quotation

By selecting **Generate Offer Quotation** from the **Actions** menu, the **Generate Offer Quotation** window will appear, prompting the user to fill in the following information:

- **Object:** the subject of the quotation
- **References:** the reference documents or conversations that served as indications to produce the quotation
- **Comments on URS:** specific comments regarding the URS document
- **Introduction text:** the text that introduces the quotation on the first page
- **Scope of supply output table:** selection of whether to show, or not, a table displaying all the containers' information and the line output and a table showing the individual output per machine per container type.
- **Explanation on scope of supply:** the explanatory text that explain the scope

After introducing and accepting the information, the user is asked to select the location in which to save the exported PDF quotation document.

Each quotation generated automatically increases the offer / order version by 1.

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Confirm Order

By selecting **Confirm Order** from the **Actions** menu, the **Order Confirmation** window will appear, prompting the user to introduce the commitments from each party, which will go into the contract. They are introduced in the form of rows into each table, accordingly, with the possibility to add more rows or to eliminate them. The user finishes by accepting, which formalizes the confirmation of the **offer**, upgrading it into an **order**.

Placing Order "on hold"

If by external events the order needs to be halted (lack of funds, further information required, etc...), but with the honest intent of retaking it once the problems are overcome, the user may set the order as "on hold", which will change the status to assist in keeping track of it.

Close Offer/Order, Enable Offer/Order

Depending on the status of the order/offer this action may read differently:

- **Close offer:** give the status **closed** to the **offer** and disables further modification
- **Enable offer:** enables a previously closed **offer**, returning it to its previous status
- **Close order:** give the status **closed** to the **order** and disables further modification
- **Enable order:** enables a previously closed **order**, but returns it to the status of **revision**

Generate/Update Technical Specifications

Selecting **Generate Technical Specification** from the **Actions** menu creates the **Technical Specifications** of the **order**, which is the technical document that defines the order. Each **Technical Specification** created feeds the **Order Management** Module used by the project management department.

Once a **Technical Specification** is generated, this action becomes **Update Technical Specifications**. Should a further modification on the **order** be confirmed, the user shall have to update in order for the modifications to be reflected on the **Technical Specification**. Without updating, modifications in the **order** will not affect the already existing **Technical Specification**. Every update will increase the version of the **Technical Specifications** by 1.

When updating the technical specifications, the user will be requested to

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introduce the **references** for the update and **comments**, should he have any.

Generate Electrical Questionnaire

Generates a blank PDF Electrical Questionnaire, requesting the user for a location to save the file, which the user then sends to the customer in order to request the necessary data.

Saving an Offer

At any point the user may choose to **save** the order. For assurance, the system will request confirmation.

The changes are immediately carried onto the server database; if the user is working offline, then only the local database will be updated. Saving an offer **does not affect** the revision number of the offer.

Cancelling changes in an Offer

In order to abort all the changes done since the previous **save**, the user may press the **cancel** button to undo all modifications. The function is accessible in every section. For assurance, the system will request confirmation.

Machines

This section allows the user to introduce the different machines into the offer through a step by step process. The main screen offers the list view of the machines, total price per machine and for the ensemble of machines and a review of the containers and output of the line of machines.

When creating the first version of the offer, the only possible action is to press on **Add Line**. A **line** of machines is a group interconnected machines that processes one, or more, common containers.

Input Containers & Capacity

By pressing the **Add Line** button, the **Input Containers & Capacity** window appears, prompting the user to introduce all the containers that will be in, at least, one machine within the desired line. The information is introduced in a table and lines are added, removed or modified. The fields are:

- **Container:** model of container to be selected from vial, ampoule, cartridge, syringe and custom

- **Material:** the material from which the container is made: glass, plastic, metal, ceramic
- **Type:** the type of container within the chosen model. For vials the standard type are "H" and "R" in many measures, which can be selected from the list. If the vial is not of a standard type or if the container is of any other models, the option to be selected is "custom", which will allow free text. Typically the notation for custom types is the volume (ml)
- **Diameter:** the diameter of the container. If a standard vial is selected, this field is automatically filled
- **Height:** the height of the container. If a standard vial is selected, this field is automatically filled
- **Maximum Filling Volume:** the maximum filling volume that will be poured in that container
- **Required Output:** the production capacity required by the customer
- **Format Labels:** the label that shall be written on the format parts to identify them
- **Observations:** for any particular comments on a specific container

The user must then **continue**.

Add Machines

The next step in configuration is to add the generic machines that will make up the line. Here the user adds the generic type of the machine by means of adding or removing rows and selecting the type from a list. One item is required for each individual machine or accessory.

Example: should the Sales Manager wish to quote, along with the rest of the machines, two options for Washing Machines, a rotary and a lineal, for the customer to choose, he would need to introduce two items called **Washing Machine**, which he will then configure accordingly.

The user must then **continue**.

Select Containers for each Machine

Not all container types will go through each machine in the line. This screen displays a table with the introduced containers, along with their main characteristics, in the rows and the introduced machines in the columns. The user must select the checkboxes appropriately, indicating which the container types that each machine must support.

This information will be used to calculate the capacity of the line. The user

must then finish by accepting.

After the first line of generic machines are added, the user will be presented with a generic listing with no prices and with the options to add a new line, edit the existing line, view/edit the machines in the line and edit the container in the line.

Adding a New Line

By pressing **Add Line**, the user will add a new, independent line of machines, repeating the steps of **Input Containers & Capacity, Add Machines and Select Containers for each Machine**.

The different lines are selected through the tabs at the upper left corner.

Edit Line (Adding, Changing or Removing Machines)

In order to change the types of the machines of a line or to add or delete a machine, the user must press **Edit Line** while viewing the line he wishes to edit. The **Add Machine** will open, allowing edition. The user must then continue to **Select Containers for each Machine** prior to accepting.

Viewing/Editing Machines

This is the option through which the machines are appropriately configured for the offer. The configuration path depends on the type of the machine.

Washing Machines, Depyrogenating Tunnels, Filling / Capping Machines and CRABS/Isolators

Configuration of the main machine starts with the **Select Machine Model** window, here the user chooses:

- **Machine Type:** Rotary or Linear, for **Washing Machines**; Filling, Capping or Filling and Capping, for **Filling / Capping Machines**; CRABS or Isolator for **CRABS/Isolator**. Since there only one type of **Depyrogenating Tunnel**, no option is available for them
- **Machine Model:** displays a list of the available models for the chosen type of machine. Model selection is not available for **CRABS/Isolators**
- **Installed on:** selection or input of the machine upon which the CRABS or Isolator will be installed. Only available for **CRABS/Isolators**
- **Size Range:** the size range of the CRABS or Isolator. Only

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available for **CRABS/Isolators**

If the selected machine is a **Washing Machine, Depyrogenating Tunnel or Filling/ Capping Machine**, a table will also be present, displaying all the supported containers chosen for that machine, their main characteristics, the output required by the customer, the output of the line (considering all the containers: it must process) and the output of the machine. This last number will be green if the machine output is higher than the required output and red if is lower than the required output. Should the line output and the machine output be the same, it indicates that the machine is a bottleneck.

For **Washing Machines and Filling/Capping Machines** the user must also choose a **main format** from among the supported containers, which denotes the container that will guide the design of the machine.

Additionally, the user can configure the output of the machine, fine tuning it within a certain range. **NOTE:** there is no limit for fine tuning, this shall be at the criteria of the Sales Manager, meaning it is possible to erroneously input a speed that cannot be achieved by the machine.

The user must then **continue** and will reach the **Machine**, composed of several sections:

- **Machine Info:** shows the basic information of **Machine Name, Machine Model, Price** (calculated from the chosen features) and allows the user to introduce a **comment**. Should the user wish to change the model, he may press on **change**, and activate the list box. Certain chosen features will not be available for all models
 - **Basic Features:** the features that come with the basic configuration for the chosen model, which are included in the base price. These cannot be modified. **CRABS / Isolators** do not have **Basic Features**
 - **Additional Features:** all the additional characteristics that the customer can purchase available for the chosen model. They are arranged according to category, which can be expanded and collapsed, to improve visibility; the chosen features are checked and the quantities, when it applies, are set
 - **Technical Information:** is the information required for design that does not affect pricing, this information must be gathered by the Sales Manager from the customer and is specific to each type of machine. **CRABS / Isolators** do not have **Technical Information**
- Additional technical information requested only for the **Filling / Capping Machines** is **formats**. The link opens a new window with

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up to three tables. Here the user must input information regarding the filling, the stoppering and/or the capping:

- **Container formats:** for each supported container the user must fill in the following information:

Filling Volume: the required volume to fill

Filling Temperature: the temperature of the filling fluid
Pump Type: whether volumetric, peristaltic or mass flow and the dimension, when applies

Pump Material: whether made of stainless steel or ceramic and if it will work for CIP-SIP or not
Filling Steps: the required dosage steps to achieve the final volume

Formats for transport: if plastic formats for transport across the machine must be provided

Formats for unloading device: if plastic formats for the unloading device must be provided

Formats for rejects' station: if plastic formats for the reject's station must be provided

Material: the material from which to make the plastic formats. Choice of DELRIN (standard) or PEEK (for sterilization)

- **Stopper and plug formats:** for each stopper and/or cartridge and/or syringe plug the user must fill in the table with the **description** and **container type**, by adding and or subtracting rows

- **Cap formats:** for each cap the user must fill in the table with the **description** and **container type**, by adding and or subtracting rows

- **Custom Features:** if the customer desires a feature not available for the machine model, it can be introduced as a **custom feature**. By pressing **add custom** a window appears showing a table with all the available features for that model, prompting the user to select one in which to base the custom feature or to enter a new one from scratch. The next window will show:

- **Feature Name:** which will appear on the feature and price lists
- **Price:** at the Sales Manager's discretion
- **Quantity:** or n/a, if quantity does not apply
- **Description:** which will appear in the descriptive section in the offer quotation. If the custom feature is based on an existing feature, the fields will be filled with the chosen feature's information and the sales manager can edit them

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at his leisure. If it's a custom feature from scratch, they will be empty

- **Containers:** an informative, non editable, section that displays the containers supported by the machine. **CRABS / Isolators** do not have **Containers**

The machine configuration process is finished by accepting the desired configuration.

Miscellaneous Machines

Configuration of the miscellaneous machines starts with the **Select Machine Model** window, here the user chooses:

- **Machine Type:** from Rotating Tables, Transport Belts, Tray Loaders, Diverting Tables and PDS
- **Machine Model:** displays a list of the available models for the chosen type of machine

After the **model** is selected the user must decide upon which **features** to include, using a table in which the features are grouped in categories, which can be expanded and collapsed, to improve visibility; the chosen features are checked and the quantities, when it applies, are set.

Finally, a **comment** can be added regarding the machine. The machine configuration process is finished by accepting the desired configuration.

CRABS / Isolator Accessory

Configuration of the miscellaneous machines starts with the **Select Accessory** window, here the user chooses:

- **Accessory Type:** from VHP Generators, HVAC Systems, Air Monitoring Systems, Glove Testing Systems and Control Cabinets
- **Manufacturer:** when it applies

Afterwards the table below will show a set of **features** for the user to choose from, by checking those desired and setting the quantity, when it applies. This set of feature is particular for each accessory type.

As a final option, the user may enter a **comment** regarding the accessory. The accessory configuration process is finished by accepting the desired configuration.

As each machine is configured it will appear in the **Machines** section with its appropriate name and price. Should they require modifications, the link **view/edit** shall take the user directly to the **Machine Details**, **Select Machine Model** or **Select**

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Accessory windows, accordingly, in order to make the desired changes.

Services

In this section the user can set up the services required by the customer. The fields are:

- **Id:** the identification number for the selected service
- **Description:** the name of the service
- **Duration:** the amount of days of service quoted to the customer for that service
- **Price:** the price of the items that make up the service
- **View:** the appropriate link is clicked to view and edit an already created service
- **Remove:** to remove an undesired service

Adding a Service

By pressing **Add Service** the user brings up the **Select Service** window, prompting to select between: F.A.T., Installation, Start-Up, Training and S.A.T. After choosing one, the user proceeds by pressing **continue**.

Adding F.A.T.

When the user chooses to add a Factory Acceptance Test, the **F.A.T.** window appears, in which the user must introduce:

- **Execution Date:** given in number of months after receiving the order
- **Days Free of Charge:** the amount of working days of testing complimentary given to the customer free of charge. A default of 5 is set
- **Formats to Test:** the amount of formats the customer wishes to test
- **Additional Duration:** the number of additional days (after the entire machine, when the length of the test, due to the machine's size and additional formats requested, exceeds the **Days Free of Charge**) required to actually finish the testing of the machine
- **Travel Expenses:** the expenses related to bringing the customer's representatives to the factory to take part in the F.A.T.. Typically comprised of: flight tickets, lodging, transportation and meals.
- **Comments**

The user finishes by accepting.

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Adding Installation, Start-Up, Training and S.A.T.

The configuration process for this four services is the same. After choosing one, a window with the service's name will appear, prompting the user to introduce:

- **Execution Date:** given in number of days after delivery of the order
- **Country:** the destination country
- **Travel Expenses:** the expenses to cover for the personnel's travel to the machine's installation site
- **Comments**

Along with the above information, the user must fill a table with the required personnel, indicating the type of **specialist**, how many of each and the amount of days they will be at the customer's site. The field **Days (total)** is the amount of total days they will be away from the office, which adds the days of travel to working days already entered; the days of travel are taken from a table after specifying the destination country. The user may add as many specialists as required or remove them.

The user finishes by accepting.

Editing a Service

To **edit** a previously added service the user must click on the appropriate **view/edit** link, which will open the corresponding configuration window, so that the required changes can be made.

Documents

This section allows the user to add and configure the required documents for the offer. The fields are:

- **Id:** the identification number for the selected document
- **Document:** the name of the selected document
- **Language:** the language in which the document is written
- **Format:** specifies the number of hard copies and digital copies
- **Price:** the price for the total amount of copies of the particular document
- **Remove:** removes the undesired document

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Adding Documents

By pressing **Add Document** the **Select Documents** window will appear, which presents a list of all the available documents for the user to choose from. The documents are arranged in categories, that can be expanded or collapsed, they are chosen through a check box and for each the user must configure the language of the document (English by default), number of hard copies and the number of digital copies.

If a custom document is required, the user can do so through the **Add Custom Document** button, which will open a further window prompting the user to fill the following fields:

- **Document name:** the name given to the document
- **Price:** price for developing the document
- **Price for additional printed copy:** the price for each hard copy beyond the first
- **Description:** the description of the document that will be readable in the quotation text

After all the desired documents are selected/added, the user finishes by accepting.

Editing Documents

Should the user need to change, add or remove documents to the offer, he can do so via the **Edit Documents** button, which will once again open the **Select Documents** window, in order to make the desired changes.

Addenda

Addenda are additional quotations that contain modifications requested after the order has been confirmed.

The possibility to add an addendum is disabled for revision #1 and enabled from #2 and onwards.

Adding an Addendum

The process of creating an addendum begins by pressing **Add Addendum**, which opens a Tab for each one created. The first inputs are the **references** for the addendum and the **introductory text** that explains the quotation (a default text is loaded with blanks slots).

The user proceeds through **Add Items**, by means of which new items can be

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introduced and existing items can be modified. The window **Adding Item** appears with the following fields:

- **Category:** the type of item to add or modify, the choices are **Machine, Services, Documents** and **General**. The first two open up a second list:
 - **Machine:** shows all the existing machines in the offer plus the item **New Machine**. Selecting any existing machine will take the user to the **Machine Details** screen for that machine, to allow for all necessary changes. Selecting **New Machine** will open the following process:

Take the user to the **Add Machines** window, in which he will chose the type of machine. The modification of the other machines will be disabled. The user must **accept** or **cancel**.

The next window will again be **Select Containers for each Machine**, again modification on other machines will be disabled.

After selecting the containers, the user is directly taken to the **Select Machine Model** window, followed by the **Machine Details**.

- **Services:** shows all the existing services in the offer plus the item **New Service**. Selecting an existing service takes the user to the appropriate service's detail window. Selecting a **New Service** takes the user to the **Add Service** window.
 - **Documents:** does not open a secondary list. After accepting, the user is taken to the **Select Documents** window, in order to add, remove or modify documents.
 - **General:** does not open a secondary list.
 - **Addendum Description:** a description of the addition, modification or requirement being quoted in the addendum, which will be visible in the technical specifications to further understand the update. If the item type is **General**, then this **Addendum Description** serves as the item's name as well, which will appear in the **price list**.
- As the user adds the items, the modifications will be visible below. Both added and removed features are displayed, as price additions and price deductions, accordingly, grouped into expandable and collapsible categories. Each modified machine can be **edited** or **removed**.
- Additionally, the user must establish the payment terms for the addendum, using the same mechanism described in **3.1.10 Adding/Editing Payment Conditions**.

Deleting an Addendum

At the bottom of each addendum the user will find the **Delete Addendum**

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option. For assurance, the system will request a confirmation.

the **Mark Up** set for the offer. If the user has set a discount, then the discount and the final **Net Price** will be below the **Sales Price**.

Generating Addendum Quotation

To generate the quotation for the addendum, the user must press **Generate Quotation** in the bottom part. The user must then select where to save the PDF Quotation. The printed quotation will carry the date it was generated on and will be identified by an **addendum number** a well, that will **index automatically** with every further addendum quotation generated.

Price List

The price list section serves to review the offer and select which prices will be visible in the quotation and which not. It's divided into 4 parts, expandable and collapsible up to its basic component:

- **Machines:** contains all the machines in the offer, and each machine's features. The fields are: ID, Machine, Quantity and Price. Each single item has its price visible
- **Services:** contains all the services in the offer with their details. The fields are: ID, Service, Duration, Quantity and Price. Each single item has its price visible
- **Documents:** contains all the documents in the offer. The fields are: ID, Documents, Language, Printed and Digital Copies and Price
- **Shipping and Handling:** contains the packing and shipping costs for all the machines

Hiding Prices

Individual prices can be hidden, in order to allow a more holistic view of a greater price. Next to each item's price there is an hide/reveal icon, which upon pressing will replace the item's price with the word "included". Prices of Machines, Services and Documents can also be hidden, which, in turn, hides the prices of their components as well.

i.e., if the user hides the price of an RA-4V, then the features of the washing machine will also be hidden; if the user hides the price of the **Service** category, then the prices of all the services and all their components will be hidden.

With a few clicks all prices can be hidden, leaving only one final price.

Final Price

At the end of the list, the total **Sales Price** is indicated, which is affected by

Order Management Module

The Order Management Module assists the Project Managers in the creation and management of the Technical Specifications that define a project. Once the version zero of a Technical Specification is generated after an order is confirmed, the Project Managers can keep track of further modifications, demand modifications and perform modifications themselves. They will be able to print the Technical Specifications to distribute among the team members.

[Log in](#)

The user is required to log into the program, by inputting his credentials in order to authorize access and to identify all actions with said username, for traceability purposes.

[List of Technical Specifications](#)

The **List of technical Specifications** screen displays all the Technical Specifications in their most recent version. The columns allow sorting and filtering in all the fields:

- Identification 5 digit number, taking the same number as the offer from which they generated
- Status: whether it's **open, delivered, concluded, closed, or on hold**
- Creation date: when the first version was generated
- Last modification date: when the current revision was saved (by the project management department) or updated (by the sales department)
- Current Revision: the number of the current revision
- Last Modification By: the name of the user who created the current revision / did the last modification
- Customer: the customer who is purchasing the order
- Agent: the agent who is mediating the sale
- End User: the final user of the machine
- Destination Country: the country in which the machine will be installed
- Sales Manager: the responsible for the offer

[Searching Technical Specifications](#)

The search box allows to find an offer by looking for the inputted text among the 11 21

column fields.

[Show Updates](#)

It's possible to view a broad review of the changes between the current version and the previous one. By clicking on the **show updates** link, the table will expand and show which sections suffered changes, indicating if they were **added, removed or modified**. The table can be collapsed by clicking on **hide updates**.

In order to view the actual changes, the user must **view/modify** the Technical Specification.

[View / Modify](#)

Once a Technical Specification has been generated by the sales department, they become the responsibility of the project managers. **View / Modify** takes the user into the **Technical Summary**, allowing him to view all the details and to modify as required on the allowed fields.

[Log Out](#)

Logs the user out of the program.

[Technical Summary](#)

The Technical Summary is the document that, along with the drawings, defines the design of the machine.

The document is comprised of six sections: **Summary, Formats, Machines, Additional Information, Services, and Documents**. Through this six sections the project managers keep track of the order, to guide its entire lifecycle, from the drawing board up to the final requested service and its conclusion.

Saving: the user can choose to save the Technical Specification at any point during the modification process.

Cancelling: the user can choose to exit the Technical Specification at any point during the modification process, thus, disregarding all changes done since the last save.

Printing: the user can "print" the Technical Specification at any point of the modification process. Printing formalizes a revision and each print will increment the revision number by 1.

Comments on the Technical Specifications: throughout the document many entries for comments have two fields, one of which is disabled. The disabled field displays the corresponding comments made by the sales department. The enabled field is free for the project managers to write in them. Keeping separate comment fields, assures that there will be no conflict between the updates from the sales department and those from the project management department.

Visualization Criteria:

- **Uncertain Information:** if the user needs to type an information that still needs further approval, he will highlight it in Yellow
- **Additions:** addition and modification updates from the previous version will be highlighted in Blue. That includes free text as well as table rows, fields, tabs, radio buttons and checkboxes
- **Removals:** deleted text or removed features from the previous version will be kept visible, but crossed and highlighted in Red

Summary

Contains the most general information:

- **General Info:** displays the date of creation and last modification, the responsible for said modification, the current revision number, the Sales Manager responsible and the reference documents
- **Customer Info:** displays the name and country for the customer, the end user and the agent, should there be any
- **Customer Documents:** provides the links to open the documents uploaded by the sales department during the offer/order
- **Customer Contact Data:** a blank field for the project managers to write any information regarding contacts on the customer's side, such as technical contacts.
- **Comments on URS:** two fields for comments, one to view the comments from the order and another to type in new comments
- **Deadlines:** a table that shows the scheduled deadlines for the required activities, their execution date, once they have been performed, and whether there are penalties or bonuses associated with delays or early deliveries. A free comment field is available
- **Machine Summary:** a table displaying the machines' names, models, serial number and a field of notes from the project managers. The user can:
 - **Edit:** to edit **serial number** and **notes** on machines and accessories and to edit **machine name, model, serial number** and **notes** on Control Boards
 - **Add Board:** to add Control Boards
 - **Delete:** to remove Control Boards
- **Comments on Machines:** a free field for comments

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Formats

Contains all the information regarding the containers, stoppers, plugs and caps which the machine must process in order to define the required format parts, along with all the possible combinations it must handle.

Containers in the Machine

This section is comprised of three tables, one for the containers, one for the stoppers and one for the caps.

Containers

- **Container:** model of container to be selected from vial, ampoule, cartridge, syringe and custom
- **Material:** the material from which the container is made: glass, plastic, metal, ceramic
- **Type:** the type of container within the chosen model. For vials the standard type are "H" and "R" in many measures, which can be selected from the list. If the vial is not of a standard type or if the container is of any other models, the option to be selected is "custom", which will allow free text. Typically the notation for custom types is the volume (ml)
- **Diameter:** the diameter of the container. If a standard vial is selected, this field is automatically filled
- **Height:** the height of the container. If a standard vial is selected, this field is automatically filled
- **Maximum Filling Volume:** the maximum filling volume that will be poured in that container
- **Output:** the production capacity offered by the machine
- **Format Labels:** the label that shall be written on the format parts to identify them
- **Observations:** for any particular comments on a specific container

By pressing **edit** the user may modify any field for any container, however, to add or remove containers he will need to request the sales department to perform the modification through the corresponding order.

The **Split Output** button will divide the output field in two, for those cases in which two different production rates can be established for the same container (i.e. bypassing freeze dryer and unloading freeze dryer). By pressing it, the **Split Output** window will appear, showing two tables, one for **Output A** and another for **Output B**, in which the user must

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specify which machines are involved in which output and describe the condition for each one. After accepting, the table will display both outputs. The changes can be undone by pressing **Merge Outputs**.

Stoppers and Plugs

- **Description:** text description of the stopper or plug; its dimensions, type, functions and any additional information of interest
- **Container:** text description of whether it goes on a vial, cartridge, syringe or another sort of container
- **Edit:** to modify the contents of either of the two fields

Caps

- **Description:** text description of the cap; its dimensions, type, functions and any additional information of interest
- **Container:** text description of whether it goes on a vial, cartridge, syringe or another sort of container
- **Edit:** to modify the contents of either of the two fields

Comments

Two fields for comments, one fixed, containing those from the sales department, and one open to free text.

Combinations of Containers/Stoppers/Caps

This section allows the user to establish the different combination between containers, stoppers or plugs, caps and filling volumes. Rows may be freely added through the **Add Combination** button and removed through the **remove** link found in each one:

- **Label:** to select the container the user chooses the label, which is unique
- **Container:** filled automatically after selecting the label
- **Filling Volume:** the amount of liquid (or powder) that the container must be filled with for a particular recipe.
- **Stopper/Plug:** to select the stopper or plug
- **Cap:** to select the cap
- **Comments:** a free text field

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Addendum

If an addendum was made involving formats, the **Description** of that addendum will be displayed here.

Machines

The **Machines** section presents the technical specifications for all the machines and accessories. Through the tabs on the left side the user chooses the machine to review.

For each machine the user may:

- **Expand and collapse the category menus:** for ease of visibility
- **Introduce specific comments:** by clicking on the "+" icon at the right of each item, the user may introduce a unique comment for that item, i.e., the user may introduce the reference in the URS. Once a comment is introduced, it may be removed by clicking on the "-" icon and confirming
- **Introduce a main comment:** below the specifications the user may find a fixed comment field, which may contain a comment from the sales department, and a free field to introduce his own comments
- **See an Addendum:** if an addendum was approved for that specific machine and updated by the sales department, the user will see the addendum description there

Additional Information

This section is meant for information that is common to all the machines and/or the installation site.

Electrical and Electronic Information

Contains the information inserted through the offer plus additional required information to develop the Control Boards. By clicking on the **edit** link, the **Edit Electrical and Electronic Information** appears on the screen:

- **Norm:** the norm that guides the electrical design
- **Power Supply:** input voltage, frequency, amperage and whether it is in star or delta arrangement
- **Control Board Location:** to specify whether it's on the same room, on the same level, on a level above or on a level below
- **Cable Connection:** to specify top or bottom entrance for the input cables on control board, for the exit cables of the control board and for the input cables into the machine
- **Cable Length:** a table to specify distance between the control boards

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and the machines they feed. The **Add Row** button serves to add additional distances and the **remove** link on each row serves to delete an undesired one

- **HMI Language:** the language in which the user interface in the HMI will be read.
- **Conformity with CFR21 part 11:** whether the software to comply with CFR21 part 11 is installed in the machine or not
- **Comments:** free comments

The dual **comments** field displays the sales department's comments, introduced through the offer, and the project manager's comment, introduced through the **Edit Electrical and Electronic Information** screen.

Spare Parts

Describes for which machine were spare parts requested, whether with or without filters, and the amount paid for each spare parts set.

A **free comments** field is allowed for the project managers

Shipping Info

Displays the information introduced by the sales department through the offer:

- **Delivery Terms:** INCOTERMS
- **Delivery Country:** the destination country
- **Delivery Address:** the destination address
- **Packing Type:** the packing selected for the order
- **Delivery Date:** displays the scheduled delivery date

Two separate comments fields, one fixed for the sales department's comments and one open for the project managers' comments.

Installation Site

A free text field to type in all pertinent information on the installation site: measurements and dimensions, water input, compressed air input, water discharge and whatever else is considered relevant for the design and installation of the machines.

General Notes

Displays the general comments introduced by the sales department and

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allows a free text field for the project managers to introduce whatever information they deem necessary and that does not belong in any other section.

General Addendum

If an addendum from the category **general** was approved and updated, it shall be reflected here.

Documents

In the **Documents** section, the user may review the requested documents, the language and the amount of printed and digital copies to be delivered.

There is a fixed field for comments made by the sales department and an open field for free comments.

If an addendum was made in the **Documents** category and updated, it will also appear here.

Services

Displays the services to be performed as per the information introduced through the offer.

Factory Acceptance Test (F.A.T.)

The F.A.T. section contain a table for the project managers to configure the precise combinations of containers / stoppers or plugs / cap / filling volume to be tested during the F.A.T., according to the customer's request.

There is a fixed field for comments made by the sales department and an open field for free comments.

If an addendum was made in for the F.A.T. and updated, it will also appear here.

Installation / Start-Up / Training / Site Acceptance Test (S.A.T.)

Each of these four services displays the:

- **Scheduled Date:** taken from the system
- **Personnel Table:** a table portraying the personnel quoted for the activity, as well as the total days they will be away

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- **Comments (sales department):** displays any comment the sales department may have entered
- **Comments (own):** text field to introduce comments
- **Addendum:** if an addendum was made, it will be displayed here

Appendix B: Mapping of Technical Specifications

WASHING MACHINES

Machine type selection	(Rotating or Linear Washing Machines)
Model selection	(suggest the smallest admissible model for all types, for RA and RC based on size and capacity; for AW and VW based on max diameter, checking height...allow for override)
Size Selection	(only for AW and VW, based on model and capacity)
Main glassware	(Select the Main glassware for which the machine will be designed, from supported formats)

Number ID	Description	Condition	Input	Qty
BASIC FEATURES				
1	WFI System circuit		Yes	n/a
2	Compressed air circuit		Yes	n/a
3	Recycled water circuit	display only for RC, AW, VW series	Yes	n/a
4	Infeed Rotary Table	display only for RA and RC, when only vials are in the line	Yes	n/a
5	Infeed Conveyor and Screw	display only for RA and RC, when Ampoules of Cartridges are in the line	Yes	n/a
6	Automatic drainage		Yes	n/a
7	Automatic drying		Yes	n/a
8	Accident Prevention Hood		Yes	n/a
9a	Embedded control cabinet in SS	display only for RA and RC and if there is no tunnel in line	Yes	n/a
9b	Control Cabinet in painted steel	display only for AW and VW and if there's no tunnel in line	Yes	n/a
9c	Shared control cabinet with depyrogenating tunnel	display if there is a tunnel in line	Yes	n/a
10	Human Machine interface at the machine	display only for RA and RC and if there is no tunnel in line	Yes	n/a
ADDITIONAL STATIONS				
11	Recycled Water	only for RA	Yes / No	n/a
12	Additional water (purified or demineralized)		Yes / No	n/a
13	Silicone Emulsion		Yes / No	n/a
ADDITIONAL FORMATS				
14	Set of parts for additional format	One item for each glassware format in line	Yes / No	X
WASHING STATIONS				
16a	1 Internal Rcy + External New W.	Number of stations according to each machine's default (6 for RA and RC, 7+ if it's an AW or VW). The selections are not available if a system is not quoted. Each steps allows also to choose between Recycled Water, Water for Injection, Purified Water, Compressed Air and Silicon.	Yes / No	n/a
16b	2 Air + Air		Yes / No	n/a
16c	3 Rcy + Rcy		Yes / No	n/a
16d	4 Air +		Yes / No	n/a
16e	5 WFI + WFI		Yes / No	n/a
16f	6 Air + Air		Yes / No	n/a
16g	7 def/cho + def/cho		Yes / No	n/a
ADDITIONAL FEATURES				
17	Automatic Steam Sterilization		Yes / No	n/a
18	- WFI System circuit	grayed out if appropriate circuite is not quoted	Yes / No	n/a
19	- Recycled Water circuit	grayed out if appropriate circuite is not quoted	Yes / No	n/a
20	- Additional New Water circuit	grayed out if appropriate circuite is not quoted	Yes / No	n/a
20a	- Silicone Emulsion circuit	grayed out if appropriate circuite is not quoted	Yes / No	n/a
20a	Separate Control Cabinet, for stand-alone machine,	display for RA and RC series and if there's no tunnel in the line	Yes / No	n/a
21	- In painted steel		choose between	n/a
22	- In stainless steel			n/a
23	- Human Machine Interface at the machine		Yes / No	n/a
24	Control Cabinet in Stainless Steel	display for AW and VW series and if there's no tunnel in the line	Yes / No	n/a
25	Human Machine Interface at the machine	display for AW and VW series and if there's no tunnel in the line	Yes / No	n/a
26	Automatic adjustment of needle insert, according to format change	only available for RA	Yes / No	n/a
27	Exhaust fan		Yes / No	n/a
28	Needle obstruction control	only available for AW and VW series	Yes / No	n/a
28	Exit Mechanism (if Tray Loader is not desired)		Yes / No	n/a
29	- Unloading device on single tray (displayed when vials, cartridges and ampoules are in the line)		Yes / No	n/a
29a	- Set of parts for additional formats		Yes / No	X
30	- Unloading device on double tray (displayed when vials, cartridges and ampoules are in the line)		Yes / No	n/a
30a	- Set of parts for additional formats		Yes / No	X
31	VP, L-Shape Vial Pusher	only available for RA and RC series	Yes / No	n/a
32	- Exit laminar flow, for "L" connection with tunnel		Yes / No	n/a
33	Water sample trap		Yes / No	X
34	Vials Hot Air drying unit		Yes / No	n/a
35	Manual spray gun, for recycled water, compressed air and WFI	only available for RA and RC series	Yes / No	n/a
36	Machine utilities set on a skid at ground level		Yes / No	n/a
37	Output production counter	only available for RA and RC series	Yes / No	n/a
38	Ultrasonic bath		Yes / No	n/a
39	Mirrored (destorsora) operation		Yes / No	n/a
40	Ethernet Card		Yes / No	n/a
41	PLC Upgrade for connection with customer's SCADA		Yes / No	n/a
OTHERS				
42	Spare part kit, for two years operation, without filters		Yes / No	n/a
43	IQ/OQ Protocols		Yes / No	n/a
44	UL NEMA Electrical Components & Certification (US & CANADA)		Yes / No	n/a
45	Packing with Crate		Yes / No	n/a
46	Packing with Sea Crate		Yes / No	n/a
ADDITIONAL INFO				
47	Standard Working Height (900 mm +/- 25 mm)		Yes / No	n/a
48	- Custom Working Height		alphanumeric input	n/a
49	Loading tray dimensions		alphanumeric input	n/a
50	Standard Exhaust duct length		Yes / No	n/a
50a	- Custom Exhaust duct length		alphanumeric input	n/a
51	Downstream machine		alphanumeric input	n/a
51	Water sample trap in:	grayed out if water trap is not checked		
52	- WFI circuit		Yes / No	n/a
53	- Recycled water circuit		Yes / No	n/a
54	- Additional new water circuit		Yes / No	n/a
55	Dipping needles, instead of fixed	only available for AW and VW series	Yes / No	n/a

WASHING MACHINES

FROM	TECHNICAL SPECS	LOGIC	VALUE
machine type	MODEL & SIZE	= model + size	alphanumeric
DESIGN SPECS			
47, 48	Working height	if 47 = yes, then "Standard, 900mm +/- 25mm" / if 47 = no, then = 48	Standard, 900mm +/- 25mm /
49, 50	Loading Tray size	= 49	alphanumeric
39	Operation form Left to Right (Sinistrorsa)	if 39 = yes, then no	Yes / No
51	Downstream machine	= 51	alphanumeric
4	Infeed by rotary table	if 4 = yes, then yes	Yes / No
5	Infeed by conveyor and screw	if 5 = yes, then yes	Yes / No
6	Automatic pipe drainage system	if 6 = yes, then yes	Yes / No
7	Automatic pipe drying system	if 7 = yes, then yes	Yes / No
8	Accident prevention hood	if 8 = yes, then yes	Yes / No
55	Fixed needles	if 55 = yes, then no	Yes / No
BASIC STATIONS			
1	WFI	if 1 = yes, then yes	Yes / No
2	Compressed Air	if 2 = yes, then yes	Yes / No
3	Recycled Water	if 3 = yes, then yes	Yes / No
ADDITIONAL STATIONS			
11	Recycled Water	if 3 or 11 = yes, then yes	Yes / No
12	Additional water (purified or demineralized)	if 12 = yes, then yes	Yes / No
13	Silicone Emulsion	if 13 = yes, then yes	Yes / No
WASHING STATIONS			
	Internal	External	
16a	1 Rcy +	New W.	from 16a
16b	2 Air +	Air	from 16b
16c	3 Rcy +	Rcy	from 16c
16d	4 Air +	0	from 16d
16e	5 WFI +	WFI	from 16e
16f	6 Air +	Air	from 16f
16g	7 def/cho +	def/cho	from 16g
			Yes / No
			Yes / No
			Yes / No
			Yes / No
			Yes / No
			Yes / No
			Yes / No
			Yes / No
ADDITIONAL FORMATS			
14	Additional formats	= 14	number
ADDITIONAL FEATURES			
17	Automatic Steam Sterilization		
	- For WFI System circuit	if 17 = yes, then yes	Yes / No
18	- For Recycled Water circuit	if 18 = yes, then yes	Yes / No
19	- For Demineralized Water circuit	if 19 = yes, then yes	Yes / No
20	- For Silicone Emulsion circuit	if 20 = yes, then yes	Yes / No
	Control Cabinet		
9c	- With Tunnel	if 9c = yes, then yes	Yes / No
20a	- Stand Alone separated	if 20a = yes, then yes	Yes / No
9c, 10, 23, 25	- Human Machine Interface at the machine	if 9c = yes, then "with tunnel", if not: if 10 and 23 = yes, then yes / if 25 = yes, then yes / if 25 = no, then no / if 10 = yes and 23 = no, then no	Yes / No / with tunnel
9a, 9c, 20a, 21, 22, 24	- Made in SS	if 9c = yes, then "with tunnel", if not: if 9a = yes and 20a = no, then yes / if 9a, 20a and 21 = yes, then no / if 9a, 20a and 22 = yes, then yes / if 24 = yes, then yes	Yes / No / with tunnel
26	Automatic adjustment of needle insert, according to format change	if 26 = yes, then yes	Yes / No
27	Exhaust fan	if 27 = yes, then yes	Yes / No
50, 50a	Exhaust duct length	if 50 = yes, then "Standard, 300 mm - 500 mm" / if 50 = no, then = 50a	Yes / No
28	Needle obstruction control	if 28 = yes, then yes	Yes / No
29	Unloading one tray system	if 29 = yes, then yes	Yes / No
29a, 14	- Parts to unload additional formats	if 29a and 14 = yes, then yes	Yes / No
30	Unloading two trays system	if 30 = yes, then yes	Yes / No
30a, 14	- Parts to unload additional formats	if 30a and 14 = yes, then yes	Yes / No
31	VP, L-Shape Vial Pusher	if 31 = yes, then yes	Yes / No
32	Exit laminar flow, for "L" connection with tunnel	if 32 = yes, then yes	Yes / No
33, 52	Water sample trap in WFI circuit	if 33 and 52 = yes, then yes	Yes / No
33, 53	Water sample trap in recycled water circuit	if 33 and 53 = yes, then yes	Yes / No
33, 54	Water sample trap in additional new water circuit	if 33 and 54 = yes, then yes	Yes / No
34	Vials Hot Air drying unit	if 34 = yes, then yes	Yes / No
35	Manual spray gun, for recycled water, compressed air and WFI (only available for RA and RC series)	if 35 = yes, then yes	Yes / No
36	Machine utilities set on a skid at ground level	if 36 = yes, then yes	Yes / No
37	Output production counter	if 37 = yes, then yes	Yes / No
38	Ultrasonic bath	if 38 = yes, then yes	Yes / No
40	Ethernet Card	if 40 = yes, then yes	Yes / No
41	PLC Upgrade for connection with customer's SCADA	if 41 = yes, then yes	Yes / No
OTHERS			
42	Spare part kit, for two years operation, without filters	if 42 = yes, then yes	Yes / No
43	IQ/OQ Protocols	if 43 = yes, then yes	Yes / No
44	UL NEMA Electrical Components & Certification (US & CANADA)	if 44 = yes, then yes	Yes / No
45	Packing with Crate	if 45 = yes, then yes	Yes / No
46	Packing with Sea Crate	if 46 = yes, then yes	Yes / No

DEPYROGENATING TUNNEL

Machine type selection	(tunnel)
Model selection	(suggest the smallest admissible model for all types...allow for override)

Number ID	Description	Condition	Input	Qty
BASIC FEATURES				
1	Automatic air balance with exhaust fan in the cooling chamber		Yes	n/a
2	Automatic pressure balance		Yes	n/a
3	Air speed monitoring and automatic adjustment		Yes	n/a
4	Doors positioning and automatic adjustment		Yes	n/a
5	Pipes for DOP/DEHS test		Yes	n/a
6	Paperless recorder (6 channels)		Yes	n/a
7	Control board, made of painted steel	display if there is no washing machine in the line	Yes	n/a
8	Control board for Washing Machine & Tunnel, made of painted steel	display if there is a washing machine in the line	Yes	n/a
ADDITIONAL FEATURES				
9	Automatic door at the entrance of the tunnel		Yes / No	n/a
10	Closed Tunnel		Yes / No	n/a
11	Pipes for particles test		Yes / No	n/a
12	Cooling Chamber Dry Heat Sterilization		Yes / No	n/a
13	- Automatic Tight door for Cooling Chamber sterilization		Yes / No	n/a
Condensation free cooling systems:				
14	- Cooling System for tunnels without Cooling Chamber Sterilization		Yes / No	n/a
15	- Cooling System for tunnels with Cooling Chamber Sterilization	display only for models ST0 - ST9	Yes	n/a
16	- Cooling System for tunnels with Cooling Chamber Sterilization	display only for models ST12 - ST20	Yes	n/a
- Cooling System for tunnels with Cooling Chamber Sterilization and water with Glycole (Mandatory when glycole is present)				
17			Yes	n/a
18	Automatic discharge of final vials (MANDATORY FOR CCS)		Yes / No	n/a
20	Conveyor Belt in AISI 316 execution		Yes / No	n/a
22	Control board made of AISI 304		Yes / No	n/a
23	Human Machine Interface at the machine		Yes / No	n/a
24	Infrared emitters		Yes / No	n/a
25	Δp pressure transmitter between tunnel and sterile room		Yes / No	n/a
26	Stainless steel fans, for non sterilizable chambers		Yes / No	n/a
55	Magnehelic at prefilter		Yes / No	n/a
27	Cladding on top, up to the ceiling, in SS		Yes / No	n/a
28	Substitute standard filters for special Filters (Nippon Muki)		Yes / No	n/a
29	Extra Cooling, for exit temperature of glassware < 25°C		Yes / No	n/a
30	Double Door for Hot Chamber	display for models =< ST17	Yes / No	n/a
31	VP, L-Shape Vial Pusher	when tunnel is linked with third party rotary washers	Yes / No	n/a
32	Extra height of the doors, for large vials (250 - 1.000 ml)		Yes / No	n/a
33	Mirrored (destructors) operation		Yes / No	n/a
34	Paperless recorder (12 channels),		Yes / No	n/a
35	Ethernet card		Yes / No	n/a
36	PLC Upgrade for connection with customer's SCADA		Yes / No	n/a
OTHERS				
37	Spare part kit for two years operation - without filters		Yes / No	n/a
38	Spare part kit for two years operation - with filters		Yes / No	n/a
39	IQ-OQ Protocols & execution during FAT		Yes / No	n/a
40	UL NEMA Electrical Components & Certification (US & CANADA)		Yes / No	n/a
41	Rigid Bars for transport	display for models ST12 - ST15, automatically checked for models ST18 - ST20	Yes / No	n/a
42	Packing with crate		Yes / No	n/a
43	Packing with sea crate		Yes / No	n/a
ADDITIONAL INFO				
44	Standard Working Height (900 mm +/- 25 mm)		Yes / No	n/a
44a	- Custom Working Height		alphanumeric input	n/a
45	Standard Exit Flange (for walls under 800mm)		Yes / No	n/a
45a	- Custom Exit Flange		alphanumeric input	n/a
46	Standard Production Speed		Yes / No	n/a
47	Standard filters (CI-ERGS, CC-FRK, CR-ERGS)		Yes / No	n/a
47a	- Custom filter on inlet chamber		alphanumeric input	n/a
47b	- Custom filter on heating chamber		alphanumeric input	n/a
47c	- Custom filter on cooling chamber		alphanumeric input	n/a
48	Standard Reduction Motor		Yes / No	n/a
48a	Standard Condensation free cooling system		Yes / No	n/a
49	Upstream Machine		alphanumeric input	n/a
50	Downstream Machine		alphanumeric input	n/a
51	Electrical box required on top of tunnel		Yes / No	n/a
59	Inlet of utilities from the top		Yes / No	n/a
52	Standard height of entry doors		Yes / No	n/a
53	- Custom door height		alphanumeric input	n/a
54	Synchronization with washing machine	required if preceded by rotary washing machine	Yes / No	n/a
56	Power input of 380/400v @50Hz		Yes / No	n/a
57	Discharge on metallic strips instead that on sheet, to compensate stability		Yes / No	n/a
58	Presence of a third party pusher at the entrance of the tunnel		Yes / No	n/a
59	Water for cooling system below 6°C	display only for models <= ST09	Yes / No	n/a
60	Water for cooling system mixed with glycole	display only for models <= ST09	Yes / No	n/a

DEPYROGENATING TUNNEL

FROM	TECHNICAL SPECS	LOGIC	VALUE
machine type, 12	MODEL & SIZE	= model + size + CCS	alphanumeric
DESIGN SPECS			
44, 44a	Working height	if 44 = yes, then "Standard, 900mm +/- 25mm" / if 44 = no, then = 44a	Standard, 900mm +/- 25mm / alphanumeric
33	Mirrored (destrorsa) operation	if 33 = yes, then yes	yes/no
54	Sincronismo all'ingresso	if 54 = yes, then yes	yes/no
51	Scatola PLC a lato camera calda	if 51 = yes, then yes	yes/no
45, 45a	Flangia uscita standard	if 45 = yes, then "800mm" / if 45 = no, then = 45a	alphanumeric
machine type, 52, 53	Altezza serrande	if 32 and 52 = yes, then if model from ST0 - ST9, then 125mm, if =>ST12, then 190 / if 52 = no, then 53	alphanumeric
10	Ventilatore aggiunto in camera raffreddamento soffiante	if 10 = yes, then no	yes/no
10	Closed Tunnel	if 10 = yes, then yes	yes/no
9	Automatic door at the entrance of the tunnel	if 9 = yes, then yes	yes/no
56	Voltaggio 380/400V 50Hz	if 56 = yes, then yes	yes/no
57	Pianetto uscita con lamelle	if 57 = yes, then yes	yes/no
line glassware	Nastro standard con H-alette-Tappeto 20 mm (produzione di Flaconi o Fiale)	if ampoule is a selected glassware, then = 40mm, if not, then = 20mm	alphanumeric
48	Motore riduttore standard	if 48 = yes, then yes	yes/no
46	Velocità di produzione STD (per definizione riduttore)	if 46 = yes, then yes	yes/no
59	Entrata utilities dall'alto	if 59 = yes, then yes	yes/no
58	Presenza di un pusher/scarico automatico all'ingresso camera ingresso	if 58 = yes, then yes	yes/no
49	Upstream Machine	= 49	alphanumeric
50	Downstream Machine	= 50	alphanumeric
ADDITIONAL FEATURES			
12	Cooling chamber sterilization	if 12 = yes, then yes	yes/no
13	Tight door automatica	if 13 = yes, then yes	yes/no
14, 15, 16, 17	Condensation free cooling system	if 14 or 15 or 16 or 17 = yes, then yes	
machine type, 12, 14, 59	- no CCS tunnel (3 way valves + pump) (small)	if 12 = no and 14 = yes and model <= ST09 and 59 = no, then yes	yes/no
machine type, 12, 14, 59	- no CCS tunnel with water below 6°C (small)	if 12 = no and 14 = yes and model <= ST09 and 59 = yes, then yes	yes/no
machine type, 12, 15	- CCS tunnel (small), no glycole	if 12 = yes and 15 = yes and model <= ST09, then yes	yes/no
machine type, 12, 17	- CCS tunnel (small), with glycole	if 12 = yes and 17 = yes and model <= ST09, then yes	yes/no
machine type, 12, 16	- no CCS tunnel (large)	if 12 = no and 16 = yes and model >= ST12, then yes	yes/no
machine type, 12, 16	- CCS tunnel (large)	if 12 = yes and 16 = yes and model >= ST12, then yes	yes/no
48a	- Condensation free cooling system, SPECIAL	if 48a = no, then yes	yes/no
machine type, 18	Automatic discharge of final vials	if 18 = yes and model <= ST5, then "carramatino", if 18 = yes and Model >= ST6, then pignone	alphanumeric
27	Pannelli a soffitto	if 27 = yes, then yes	yes/no
55	Magnehelic su prefiltro (PDI10)	if 55 = yes, then yes	yes/no
26	Richiesta di ventilatori inox in camere non sterilizzabili	if 26 = yes, then yes	yes/no
11	Pipes for Particle test	if 11 = yes, then yes	yes/no
24	Lampade IR	if 24 = yes, then yes	yes/no
47, 47a, 47b, 47c	Filtri delle camere	if 47 = yes, then = "standard" / if 47 = no, then concatenate " IC, 47a; HC, 47b; CC, 47c" yes	alphanumeric
29	Temperatura flaconi uscita < 25°C (per definizione batteria)	if 29 = yes, then yes	yes/no
machine type, 30	Portellone camera calda doppio	if 30 = yes and/or machine model >18, then yes	yes/no
28	Presenza dei filtri tipo MUKI da 290 in camera calda	if 28 = yes, then yes	yes/no
25	Transducer between tunnel exit and filling room	if 25 = yes, then yes	yes/no
31	VP, L-Shape Vial Entry Pusher	if 31 = yes, then yes	yes/no
20	Tappeto e pianetti AISI 316	if 20 = yes, then yes	yes/no
22	Control board made of AISI 304	if 22 = yes, then yes	yes/no
23	HMI posizionato sul tunnel	if 23 = yes, then yes	yes/no
40	Marcatura componenti UL/CSA	if 40 = yes, then yes	yes/no
6, 12, 34	Number of channels on Paperless recorder	if 34 = yes, then = 12, if 34 = no, then = 6	alphanumeric
35	Ethernet card, for connection with customer's SCADA	if 35 = yes, then yes	yes/no
36	PLC upgrade and communication protocols for connection with customer's SCADA	if 36 = yes, then yes	yes/no
OTHERS			
37	Spare part kit for two years operation - without filters	if 37 = yes, then yes	yes/no
38	Spare part kit for two years operation - with filters	if 38 = yes, then yes	yes/no
39	IQ-OQ Protocols & execution during FAT	if 39 = yes, then yes	yes/no
40	UL NEMA Electrical Components & Certification (US & CANADA)	if 40 = yes, then yes	yes/no
41	Rigid Bars for transport	if 41 = yes, then yes	yes/no
42	Packing with crate	if 42 = yes, then yes	yes/no
43	Packing with sea crate	if 43 = yes, then yes	yes/no

FILLING AND CAPPING MACHINES

Machine type selection	(Filling Machines, Capping Machines, Filling and Capping Machines)
Model selection	(suggest the smallest admissible model...allow override)
Main glassware	(Select the Main glassware for which the machine will be designed)

Number ID	Description	Condition	Input	Qty
BASIC FEATURES				
Dosing System				
1	Stainless steel volumetric piston pump, for one filling station	display only when filling function is selected display only when model is 50	Yes	1
2	Stainless steel volumetric piston pumps, for one filling station	display only when model is 100	Yes	2
3	Stainless steel volumetric piston pumps, for one filling station	display only when model is 200	Yes	4
4	Stainless steel volumetric piston pumps, for one filling station	display only when model is 300	Yes	6
5	Stainless steel volumetric piston pumps, for one filling station	display only when model is 400	Yes	8
6	Plugging station for cartridges	display only if cartridges are in the line	Yes	n/a
7	Available connections for one additional filling station	pumps and needles are purchased separately	Yes	n/a
Closing Systems				
8	Pick & Place Stoppering Station (incl. one size of rubber stopper)	display when vials are in the line, there are no syringes, stoppering function is selected and model is <200	Yes	n/a
9	Disc Stoppering Station (incl. one size of rubber stopper)	display when vials and syringes are in the line and/or if model is >=200 and stoppering function is selected	Yes	n/a
10	Plugging station for syringes	display when syringes are in the line	Yes	n/a
11	Ampoule Closing Station	display when ampoules are in the line	Yes	n/a
12	Sealing roller capping station for alum. caps (one cap format size)	display when vials are in the line, no cartridges are in the line and capping function is selected	Yes	n/a
13	Crimping head capping station for alum. caps (one cap format size)	display when cartridges are in the line and capping function is selected	Yes	n/a
General				
14	Set of format parts for transport mechanism		Yes	1
15	Infeed Rotating Table	display when vials are in the line and no ampoules and/or cartridges are in the line	Yes	n/a
16	Infeed Conveyor	display when ampoules and/or cartridges are in the line	Yes	n/a
17	Infeed Syringe Chute	display when syringes are in the line	Yes	n/a
18	Intermediate Product Vessel	display if Filling is selected as a function	Yes	n/a
19	No vial - No filling function	display if Filling is selected as a function	Yes	n/a
20	Filling Needles Holder Unit	display if Filling is selected as a function	Yes	n/a
21	Adjustment of the dosing volume from operator panel	display if Filling is selected as a function	Yes	n/a
22	Accident Prevention Hood	gray out and invalidate if RABS or Isolator is selected	Yes	n/a
23	Control Cabinet, made of painted steel		Yes	n/a
ALTERNATIVES FOR DOSING SYSTEMS				
24	Alternative pumping systems, replacing the stainless steel volumetric piston pumps		Yes / No	n/a
25	- Masterflex Peristaltic pumps		Yes / No	n/a
26	- Flexicon - Watson Marlow Peristaltic pumps		Yes / No	n/a
27	- Mass Flow meters filling system		Yes / No	n/a
ADDITIONAL FORMATS (other than FO)				
28	Additional Formats for containers		Yes / No	
ADDITIONAL FEATURES				
Dosing System				
33a	Additional connections for pumping station after the 2nd	display only when filling	Yes / No	X
33	Additional pumps (after the first station)		Yes / No	n/a
	- Volumetric piston pumps		Yes / No	n/a
34	- Stainless Steel, 1 - 5 ml		Yes / No	X
35	- Stainless Steel, 5 - 20 ml		Yes / No	X
36	- Stainless Steel, 20 - 50 ml		Yes / No	X
37	- Stainless Steel, 100 ml		Yes / No	X
34a	- Ceramic, 1 - 5 ml		Yes / No	X
35a	- Ceramic, 5 - 20 ml		Yes / No	X
36a	- Ceramic, 20 - 50 ml		Yes / No	X
37a	- Ceramic, 100 ml		Yes / No	X
38	- Masterflex Peristaltic pump		Yes / No	X
39	- Flexicon - Watson Marlow Peristaltic pump		Yes / No	X
40	- Mass Flow meters filling system		Yes / No	X
41	IPC, Check Weighing System, 100%	gray out until transport by walking beam is selected	Yes / No	n/a
42	IPC, Statistical Check Weighing System	gray out until transport by transport chain is selected	Yes / No	n/a
43	De-ionizer at weighing points, to eliminate static charges		Yes / No	n/a
44	Gas Flushing Unit (Before - After Filling)		Yes / No	n/a
45	Gas Flushing Unit (During Filling)		Yes / No	n/a
45a	Recirculating system for product		Yes / No	n/a
46	Bottom-Up filling		Yes / No	n/a
47	Cartridge crystal agitation sphere inserting unit	display only when cartridges are on the line	Yes / No	n/a
48	Set of parts for additional cartridge plug size	display only when cartridges are on the line	Yes / No	X
49	Extra buffer with minimum load sensor, for cartridge plug vibrating bowl		Yes / No	n/a
50	- Laminar Flow Unit to cover the extra buffer for cartridge plug loading		Yes / No	n/a
Stoppering System				
51	Set of parts for additional rubber stopper size	display only when stoppering display when vials are in the line	Yes / No	X
52	Set of parts for additional syringe plug size	display when syringes are in the line	Yes / No	X
53	Extra buffer with minimum load sensor, for rubber stopper vibrating bowl		Yes / No	n/a
54	- Laminar Flow Unit to cover the extra buffer for rubber stopper loading		Yes / No	n/a
55	Vacuum assisted stoppering station		Yes / No	n/a
Capping System				
59	Set of parts for additional aluminum cap size	display only when capping	Yes / No	X
60	Closing station for screw caps		Yes / No	n/a
61	- Set of parts for additional aluminum screw cap size		Yes / No	X
62	Extra buffer with minimum load sensor, for aluminium caps vibrating bowl		Yes / No	n/a
63	- Laminar Flow Unit to cover the extra buffer for alu caps loading		Yes / No	n/a
64	Ink Jet printer, in order to print bar code on the alu cap, integrated in the capping machine		Yes / No	n/a
65	Camera to detect raised stopper before capping, software included		Yes / No	n/a
Syringe filling options				
66	Laminar Flow Hood for nest opening	display only when syringes are in the line	Yes / No	n/a
67	Automatic De-nesting station, supports one syringe format		Yes / No	n/a
68	- Set of parts for de-nesting of additional formats		Yes / No	X
69	Automatic Re-nesting station, supports one syringe format		Yes / No	n/a
70	- Set of parts for re-nesting of additional formats		Yes / No	X

Ampoule filling options		displayed only when ampoules are in the line		
71	Burner GAS filter		Yes / No	n/a
72	Additional inlet for closed ampoules		Yes / No	n/a
73	Opening station for closed ampoules		Yes / No	n/a
Exit Mechanisms		displayed when vials, cartridges and ampoules are in the line		
74	Unloading device on single tray		Yes / No	n/a
75	- Set of parts for additional formats		Yes / No	X
76	Unloading device on double tray		Yes / No	n/a
77	- Set of parts for additional formats		Yes / No	X

Number ID	Description	Condition	Input	Qty
General				
78	Additional rotating table entrance for vials	display when cartridges and/or ampoules are in the line	Yes / No	n/a
78a	Additional conveyor entrance		Yes / No	n/a
79	Laminar Flow hood	gray out and invalidate if RABS or Isolator is selected	Yes / No	n/a
81	Reject station for incomplete vials (includes parts for one format)		Yes / No	n/a
82	- Set of parts for additional formats		Yes / No	X
83	Pair of gloves, including flange Ø200 Piercan, hand & sleeve; and light barrier	gray out and invalidate if C-RAB or Isolator is selected	Yes / No	X
84	Non viable sampling port for instrument, with TC connection	gray out and invalidate if C-RAB or Isolator is selected	Yes / No	n/a
85	Viable sampling port for Petri Dish, with TC connection	gray out and invalidate if RABS or Isolator is selected	Yes / No	n/a
86	Output production counter		Yes / No	n/a
87	Control board made of AISI 304		Yes / No	n/a
88	Human Machine Interface at the machine		Yes / No	n/a
89	Mirrored (destrors) operation		Yes / No	n/a
90	Ethernet card, for connection with customer's SCADA		Yes / No	n/a
91	PLC upgrade and communication protocols for connection with customer's SCADA		Yes / No	n/a

CIP- SIP Equipment				
92	CIP- SIP Function, including the special movement of the pumps in overstroke position	display if Filling is selected as a function	Yes / No	n/a
93	- Stainless steel product vessel, instead of the glass standard, suitable for CIP- SIP			n/a
	- Substitute all regular volumetric pumps for ones suitable for CIP - SIP			n/a
97	- Special connection for product inlet, suitable for CIP-SIP, including draining point			n/a
98	Additional documentation for CIP-SIP (IQ-OQ)	display if Filling is selected as a function	Yes / No	n/a

OTHERS				
99	Spare parts kit, for two years of operation		Yes / No	n/a
100	IQ-OQ Protocols & execution during FAT		Yes / No	n/a
101	UL NEMA Electrical Components & Certification (US & CANADA)		Yes / No	n/a
102	Packing with crate		Yes / No	n/a
103	Packing with sea crate		Yes / No	n/a

ADDITIONAL INFO				
104	Standard Working Height (900 mm +/- 25 mm)		Yes / No	n/a
105	- Custom Working Height		alphanumeric input	n/a
Transportation Mechanism		when cartridges are in the line, the transport chain is the only mechanism		
107	- Walking beam		Yes / No	n/a
108	- Transport chain		Yes / No	n/a
109	- Conveyor belt	display only when Capping is the only function	Yes / No	n/a
Filling Information:				
109a	- for F0	type	fill vol.	fill temp.
109b	- for F1	from		Pump
109c	- for F2	selected		Type
109d	- for F3	glass		fill steps
		ware		
Plastic formats review:				
110a	- for F0	transport	unload	rejects
110b	- for F1	yes	74, 75	81
110c	- for F2	28	75, 77	82
110d	- for F3	29	75, 77	82
		30	75, 77	82
				de nest
				re nest
				material
110a	- for F0			69
110b	- for F1			68
110c	- for F2			70
110d	- for F3			70
				32a
				32b
				32c
				32d
117	RABS / Isolator quoted separately?		Yes / No	
118	Upstream machine		alphanumeric input	n/a
119	Downstream machine		alphanumeric input	n/a
120	Individual HMI		Yes / No	
121	- Shared HMI		alphanumeric input	

FILLING AND CAPPING MACHINES

FROM		TECHNICAL SPECS	LOGIC	VALUE																																			
machine type		MODEL & SIZE	= model + size	alphanumeric																																			
DESIGN SPECS																																							
104, 105		Working height	if 104 = yes, then "Standard, 900mm +/- 25mm" / if 104 = no, then = 105	alphanumeric																																			
89		Operation from left to right (sinistrorsa)	if 89 = yes, then "Right to Left", if not, "Left to Right"	Yes / No																																			
machine type		Main glassware	= Main glassware	alphanumeric																																			
117		RABS / Isolator quoted separately?	= 117	alphanumeric																																			
118		Upstream machine	= 118	alphanumeric																																			
119		Downstream machine	= 119	alphanumeric																																			
ENTRANCE AND MOTION SYSTEMS																																							
15, 78		Rotary Table at the entrance	if 15 or 78 = yes, then yes	Yes / No																																			
16		Conveyor Belt at the entrance	if 16 = yes, then yes	Yes / No																																			
107, 108, 109		Transportation mechanism	if 107 = yes, then = 107 / if 108 = yes, then = 108 / if 109 = yes, then = 109	alphanumeric																																			
OPERATIONS																																							
6		Cartridge plugging	if 6 = yes, then yes	Yes / No																																			
47		Crystal sphere insertion	if 47 = yes, then yes	Yes / No																																			
machine type		Filling	if machine function "filling" is selected, then yes	Yes / No																																			
machine type		Vial stoppering	if machine function "stoppering" is selected, then yes	Yes / No																																			
10		Syringe plugging	if 10 = yes, then yes	Yes / No																																			
machine type		cap sealing / crimping	if machine function "capping" is selected, then yes	Yes / No																																			
81		Rejects	if 81 = yes, then yes	Yes / No																																			
FORMATS																																							
Information of Formats																																							
		<table border="1" style="font-size: small;"> <thead> <tr> <th>type</th> <th>transport</th> <th>unload</th> <th>rejects</th> <th>de nest</th> <th>re nest</th> <th>material</th> </tr> </thead> <tbody> <tr> <td>- for F0</td> <td>yes</td> <td>74. 76</td> <td>81</td> <td>67</td> <td>69</td> <td>32a</td> </tr> <tr> <td>- for F1</td> <td>selected</td> <td>28</td> <td>75. 77</td> <td>82</td> <td>68</td> <td>70</td> </tr> <tr> <td>- for F2</td> <td>glass</td> <td>29</td> <td>75. 77</td> <td>82</td> <td>68</td> <td>70</td> </tr> <tr> <td>- for F3</td> <td>ware</td> <td>30</td> <td>75. 77</td> <td>82</td> <td>68</td> <td>70</td> </tr> </tbody> </table>	type	transport	unload	rejects	de nest	re nest	material	- for F0	yes	74. 76	81	67	69	32a	- for F1	selected	28	75. 77	82	68	70	- for F2	glass	29	75. 77	82	68	70	- for F3	ware	30	75. 77	82	68	70		
type	transport	unload	rejects	de nest	re nest	material																																	
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110a						taken from 110a																																	
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110c						taken from 110c																																	
110d						taken from 110d																																	
Additional formats for containers																																							
Additional formats for stoppers																																							
Additional formats for caps																																							
DOSING SYSTEM																																							
33a		Total number of filling stations	if 33a = yes, then = 33a	number																																			
Installed Pumps																																							
- Volumetric piston pumps																																							
34, 92, 95		- Stainless Steel, 1 - 5 ml	if 92 = no and 95 = SS, then if 34 > 0, then = qty	number																																			
35, 92, 95		- Stainless Steel, 5 - 20 ml	if 92 = no and 95 = SS, then if 35 > 0, then = qty	number																																			
36, 92, 95		- Stainless Steel, 20 - 50 ml	if 92 = no and 95 = SS, then if 36 > 0, then = qty	number																																			
37, 92, 95		- Stainless Steel, 100 ml	if 92 = no and 95 = SS, then if 37 > 0, then = qty	number																																			
34a, 92, 95		- Ceramic, 1 - 5 ml	if 92 = no and 95 = Ceramic, then if 34 > 0, then = qty	number																																			
35a, 92, 95		- Ceramic, 5 - 20 ml	if 92 = no and 95 = Ceramic, then if 35 > 0, then = qty	number																																			
36a, 92, 95		- Ceramic, 20 - 50 ml	if 92 = no and 95 = Ceramic, then if 36 > 0, then = qty	number																																			
37a, 92, 95		- Ceramic, 100 ml	if 92 = no and 95 = Ceramic, then if 37 > 0, then = qty	number																																			
34, 92, 95		- CIP-SIP, Stainless Steel, 1 - 5 ml	if 92 = yes and 95 = SS, then if 34 > 0, then = qty	number																																			
35, 92, 95		- CIP-SIP, Stainless Steel, 5 - 20 ml	if 92 = yes and 95 = SS, then if 35 > 0, then = qty	number																																			
36, 92, 95		- CIP-SIP, Stainless Steel, 20 - 50 ml	if 92 = yes and 95 = SS, then if 36 > 0, then = qty	number																																			
37, 92, 95		- CIP-SIP, Stainless Steel, 100 ml	if 92 = yes and 95 = SS, then if 37 > 0, then = qty	number																																			
34a, 92, 95		- CIP-SIP, Ceramic, 1 - 5 ml	if 92 = yes and 95 = Ceramic, then if 34 > 0, then = qty	number																																			
35a, 92, 95		- CIP-SIP, Ceramic, 5 - 20 ml	if 92 = yes and 95 = Ceramic, then if 35 > 0, then = qty	number																																			
36a, 92, 95		- CIP-SIP, Ceramic, 20 - 50 ml	if 92 = yes and 95 = Ceramic, then if 36 > 0, then = qty	number																																			
37a, 92, 95		- CIP-SIP, Ceramic, 100 ml	if 92 = yes and 95 = Ceramic, then if 37 > 0, then = qty	number																																			
38		- Masterflex Peristaltic pump	if 38 > 0, then = qty	number																																			
39		- Flexicon - Watson Marlow Peristaltic pump	if 39 > 0, then = qty	number																																			
40		- Mass Flow meters filling system	if 40 > 0, then = qty	number																																			
6			if 6 = yes, then yes	Yes / No																																			
Plugging station for cartridges																																							
Filling information according to formats:																																							
		<table border="1" style="font-size: small;"> <thead> <tr> <th>type</th> <th>fill vol.</th> <th>fill temp.</th> <th>Pump</th> <th>Type</th> <th>fill steps</th> </tr> </thead> <tbody> <tr> <td>- for F0</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>- for F1</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>- for F2</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>- for F3</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	type	fill vol.	fill temp.	Pump	Type	fill steps	- for F0						- for F1						- for F2						- for F3												
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- for F0																																							
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- for F3																																							
					taken from 109a																																		
					taken from 109b																																		
					taken from 109c																																		
					taken from 109d																																		
Additional Equipment																																							
41		IPC, Check Weighing System, 100%	if 41 = yes, then yes	Yes / No																																			
42		IPC, Statistical Check Weighing System	if 42 = yes, then yes	Yes / No																																			
43		De-ionizer at weighing points, to eliminate static charges	if 43 = yes, then yes	Yes / No																																			
44		Gas Flushing Unit (Before - After Filling)	if 44 = yes, then yes	Yes / No																																			
45		Gas Flushing Unit (During Filling)	if 45 = yes, then yes	Yes / No																																			
45a		Recirculating system for product	if 45a = yes, then yes	Yes / No																																			
46		Bottom-Up filling	if 46 = yes, then yes	Yes / No																																			
92		CIP-SIP function	if 92 = yes, then yes	Yes / No																																			
93		Stainless steel manifold, instead of the standard of glass, suitable for CIP-SIP	if 93 = yes, then yes	Yes / No																																			
95		Special connection for product inlet, suitable for CIP-SIP, including draining point	if 95 = yes, then yes	Yes / No																																			
STOPPERING SYSTEM																																							
8		Pick & Place stoppering device	if 8 = yes, then yes	Yes / No																																			
9		Disc stoppering device	if 9 = yes, then yes	Yes / No																																			
10		Plugging station for syringes	if 10 = yes, then yes	Yes / No																																			
Additional Equipment																																							
55		Vacuum assisted stoppering station	if 55 = yes, then yes	Yes / No																																			
CAPPING SYSTEM																																							
12		Sealing roller capping station	if 12 = yes, then yes	Yes / No																																			
13		Crimping head capping station	if 13 = yes, then yes	Yes / No																																			
11		Ampoule Closing Station	if 11 = yes, then yes	Yes / No																																			
Additional Equipment																																							
60		Closing station for screw caps	if 60 = yes, then yes	Yes / No																																			
64		Ink Jet printer, in order to print bar code on the alu cap, integrated in the capping machine	if 64 = yes, then yes	Yes / No																																			
65		Camera to detect raised stopper before capping, software included	if 65 = yes, then yes	Yes / No																																			

Exit Mechanisms (If Tray Loader is not desired)			
29	Unloading one tray system	if 29 = yes, then yes	Yes / No
30	Unloading two trays system	if 30 = yes, then yes	Yes / No
General			
81	Reject station	if 81 = yes, then yes	Yes / No
83	Pair of gloves, including flange Ø200 Piercan, hand & sleeve; and light barrier	if 83 = yes, then yes	Yes / No
84	Non viable sampling port for instrument, with TC connection	if 84 = yes, then yes	Yes / No
85	Viable sampling port for Petri Dish, with TC connection	if 85 = yes, then yes	Yes / No
86	Output production counter	if 86 = yes, then yes	Yes / No
87	Control board made of AISI 304	if 87 = yes, then yes	Yes / No
88	Human Machine Interface at the machine	if 88 = yes, then yes	Yes / No
120	Individual HMI	if 120 = yes, then yes	Yes / No
121	Shared HMI with:	if 120 = no, then = 121	alphanumeric
90	Ethernet card, for connection with customer's SCADA	if 90 = yes, then yes	Yes / No
91	PLC upgrade and communication protocols for connection with customer's SCADA	if 91 = yes, then yes	Yes / No
EXTRA BUFFERS			
49, 50	Buffer for cartridge plugging station	if 49 = yes, then yes	Yes / No
53, 54	Buffer for vial stopper station / syringe plug	if 53 = yes, then yes	Yes / No
62, 63	Buffer for aluminum cap station	if 62 = yes, then yes	Yes / No
LAFs			
79	LAF for main machine	if 79 = yes, then yes	Yes / No
50	LAF for Buffer for cartridge plugging station	if 50 = yes, then yes	Yes / No
54	LAF for Buffer for syringe plug / vial stopper station	if 54 = yes, then yes	Yes / No
63	LAF for Buffer for aluminum cap station	if 63 = yes, then yes	Yes / No
66	LAF for nest opening	if 66 = yes, then yes	Yes / No
SPECIAL EQUIPMENT FOR SPECIAL FORMATS			
Syringes			
17	Infeed Syringe Chute (display when syringes are in the line)	if 17 = yes, then yes	Yes / No
10	Plugging station for syringes (display when syringes are in the line)	if 10 = yes, then yes	Yes / No
67	Automatic De-nesting station, supports one syringe format	if 67 = yes, then yes	Yes / No
69	Automatic Re-nesting station, supports one syringe format	if 69 = yes, then yes	Yes / No
Ampoules			
71	Burner GAS filter	if 71 = yes, then yes	Yes / No
72	Additional inlet for closed ampoules	if 72 = yes, then yes	Yes / No
73	Opening station for closed ampoules	if 73 = yes, then yes	Yes / No
OTHERS			
99	Spare parts kit, for two years of operation	if 99 = yes, then yes	Yes / No
100	IQ-OQ Protocols & execution during FAT	if 100 = yes, then yes	Yes / No
98	Additional documentation for CIP-SIP (IQ-OQ)	if 98 = yes, then yes	Yes / No
101	UL NEMA Electrical Components & Certification (US & CANADA)	if 101 = yes, then yes	Yes / No
102	Packing with crate	if 102 = yes, then yes	Yes / No
103	Packing with sea crate	if 103 = yes, then yes	Yes / No

EXTERNAL DECONTAMINATING MACHINE

Machine type selection	(decontaminating machines)
Model selection	(suggest the smallest admissible model for all types...allow for override)
Main glassware	(Select the Main glassware for which the machine will be designed)

Number ID	Description	Condition	Input	Qty
Basic Features				
1	WFI System circuit		Yes	n/a
2	Compressed air circuit		Yes	n/a
3	Recycled water circuit	display only for EMD 3	Yes	n/a
4	Infeed Rotary Table	display only when vials are in the line and model is EDM C, EDM 1 or EDM 2	Yes	n/a
5	Infeed Conveyor and Screw	display only when Ampoules of Cartridges are in the line and/or if model EDM 3 is selected	Yes	n/a
6	Automatic drainage		Yes	n/a
7	Automatic drying		Yes	n/a
8	Accident Prevention Hood		Yes	n/a
9	Control Cabinet on top, made in SS		Yes	n/a
10	Human Machine interfase at the machine		Yes	n/a
Additional Circuits				
11	Recycled Water	display only for EMD C, EMD 1, EMD 2	Yes / No	n/a
12	Additional New Water		Yes / No	n/a
13	Detergent		Yes / No	n/a
Additional format (other than F0):				
14	Set of parts for additional format		Yes / No	X
16	Parts set in PEEK, instead of in Delrin		Yes / No	X
Stages (according to machine) (the selections are not available if a system is not quoted)				
	TOP BOTTOM			
17a	1 choose + choose	The number of stations depends on the model. For each station the systems shows the default for the machine model and the user is free to change it. The selections are not available if a system is not quoted. Each steps allows also to choose between Recycled Water, Water for injection, Additional New Water, Compressed Air and Detergent.		
17b	2 choose + choose			
17c	3 choose + choose			
17d	4 choose + choose			
17e	5 choose + choose			
17f	6 choose + choose			
17g	7 choose + choose			
	number of stations depends on the model			
Additional features				
18	Cabin Enhancements		Yes / No	n/a
	- Noise reduction hood		Yes / No	n/a
19	- Negative Pressure RABS		Yes / No	n/a
20	Exhaust fan		Yes / No	n/a
20a	Exhaust duct extension up to _____		Yes / No	n/a
	Exit Mechanism (if Tray Loader is not desired)		Yes / No	n/a
21	- Unloading device on single tray	displayed when vials, cartridges and ampoules are in the line	Yes / No	n/a
21a	- Set of parts for additional formats		Yes / No	n/a
22	- Unloading device on double tray	displayed when vials, cartridges and ampoules are in the line	Yes / No	n/a
22a	- Set of parts for additional formats		Yes / No	n/a
23	Water sample trap		Yes / No	X
24	Conductivity Sensor for drain point		Yes / No	n/a
25	Manual spray gun, for recycled water, compressed air and WFI		Yes / No	n/a
26	Output production counter		Yes / No	n/a
27	Mirrored (destrorsa) operation		Yes / No	n/a
28	Ethernet card, for connection with customer's SCADA		Yes / No	n/a
29	PLC upgrade and communication protocols for connection with customer's SCADA		Yes / No	n/a
OTHERS				
30	Spare part kit, for two years operation, without filters		Yes / No	n/a
31	IQ/OQ Protocols		Yes / No	n/a
32	UL NEMA Electrical Components & Certification (US & CANADA)		Yes / No	n/a
33	Packing with Crate		Yes / No	n/a
34	Packing with Sea Crate		Yes / No	n/a
ADDITIONAL INFO				
35	Standard Working Height (900 mm +/- 25 mm)		Yes / No	n/a
36	- Custom Working Height		alphanumeric input	n/a
37	Upstream machine		alphanumeric input	n/a
38	Downstream machine		alphanumeric input	n/a
	Water sample trap in:	gray out if water sample trap "23" was not selected	Yes / No	n/a
39	- WFI circuit		Yes / No	n/a
40	- Recycled water circuit		Yes / No	n/a
41	- Demineralized water circuit		Yes / No	n/a
42	Individual HMI		Yes / No	n/a
43	- Shared HMI		alphanumeric input	n/a

EXTERNAL DECONTAMINATING MACHINE

FROM	TECHNICAL SPECS	LOGIC	VALUE
machine type	MODEL & SIZE	= model + size	alphanumeric
DESIGN SPECS			
35, 36	Working height	If 35 = yes, then "Standard, 900mm +/- 25mm" / if 35 = no, then = 36	Standard, 900mm +/- 25mm / alphanumeric
27	Operation from left to right (sinistrorsa)	if 27 = yes, then yes	Yes / No
37	Upstream machine	= 37	alphanumeric
38	Downstream machine	= 38	alphanumeric
machine type	Main glassware (FO)	= Main glassware	alphanumeric
4	Infeed by rotary table	if 4 = yes, then yes	Yes / No
5	Infeed by conveyor and screw	if 5 = yes, then yes	Yes / No
6	Automatic pipe drainage system	if 6 = yes, then yes	Yes / No
7	Automatic pipe drying system	if 7 = yes, then yes	Yes / No
8	Accident prevention hood	if 18 and 19 = no, then yes	Yes / No
ADDITIONAL CIRCUITS			
11	Recycled Water	if 3 or 11 = yes, then yes	Yes / No
12	Additional New Water	if 12 = yes, then yes	Yes / No
13	Detergent	if 13 = yes, then yes	Yes / No
STAGES			
17a	Internal choose + External choose	from 17a	
17b	2 choose + choose	from 17b	
17c	3 choose + choose	from 17c	
17d	4 choose + choose	from 17d	
17e	5 choose + choose	from 17e	
17f	6 choose + choose	from 17f	
17g	7 choose + choose	from 17g	
ADDITIONAL FORMATS			
14	Set of parts for additional format	= 14	number
16	Parts set in PEEK, instead of in Delrin	= 16	number
ADDITIONAL FEATURES			
18	Noise reduction hood	if 18 = yes, then yes	Yes / No
19	Negative Pressure RABS	if 19 = yes, then yes	Yes / No
20	Exhaust fan	if 20 = yes, then yes	Yes / No
20a	Standard exhaust duct	if 20a = yes, then no	Yes / No
21	Unloading one tray system	if 21 = yes, then yes	Yes / No
21a, 14	Parts to unload additional formats	if 21a and 14 = yes, then yes	Yes / No
22	Unloading two trays system	if 22 = yes, then yes	Yes / No
22a, 14	Parts to unload additional formats	if 22a and 14 = yes, then yes	Yes / No
23, 39	Water sample trap in WFI circuit	if 23 and 39 = yes, then yes	Yes / No
23, 40	Water sample trap in additional new water	if 23 and 40 = yes, then yes	Yes / No
23, 41	Water sample trap in detergent	if 23 and 41 = yes, then yes	Yes / No
24	Conductivity Sensor for drain point	if 24 = yes, then yes	Yes / No
25	Manual spray gun, for recycled water, compressed air and WFI	if 25 = yes, then yes	Yes / No
26	Output production counter	if 26 = yes, then yes	Yes / No
42	Individual HMI	if 42 = yes, then yes	Yes / No
43	Shared HMI with:	if 43 = no, then = 121	Yes / No
28	Ethernet card, for connection with customer's SCADA	if 28 = yes, then yes	Yes / No
29	PLC upgrade and communication protocols for connection with customer's SCADA	if 29 = yes, then yes	Yes / No
OTHERS			
30	Spare part kit, for two years operation, without filters	if 30 = yes, then yes	Yes / No
31	IQ/OQ Protocols	if 31 = yes, then yes	Yes / No
32	UL NEMA Electrical Components & Certification (US & CANADA)	if 32 = yes, then yes	Yes / No
33	Packing with Crate	if 33 = yes, then yes	Yes / No
34	Packing with Sea Crate	if 34 = yes, then yes	Yes / No

RABS / ISOLATORS

Machine type selection	(RABS/Isolators)
Model selection	(O-RABS, C-RABS or Isolator)
Machine to install to	(Filling Machine, PDS, Tray Loader, Capping Machine, Freeze Dryer, Rotating Table, Belt, Stand Alone, free text input)
Size	(up to 1m3, from 1m3 to 2m3, from 2m3 to 3m3, from 3m3 to 4m3, over 4m3)

Number ID	Description	Condition	Input	Qty
AUTOMATIC PRESSURE CONTROL				
		display only for C-RABS and Isolators		
	Automatic air pressure control		Yes	n/a
1a	Internal volume under 1m3	display if size is "up to 1m3"	Yes / No	n/a
1b	Internal volume between 1m3 and 2m3	display if size is "from 1m3 to 2m3"	Yes / No	n/a
1c	Internal volume between 2m3 and 3m3	display if size is "from 2m3 to 3m3"	Yes / No	n/a
1d	Internal volume over 3m3	display if size is "over 3m3"	Yes / No	n/a
1e	Each additional m3	display if size is "over 3m3"	Yes / No	X
2	Air speed indication with venturi system & pressure transmitter		Yes	n/a
RETURN AIR DUCT AND BIBO HOUSING				
		display only for C-RABS and Isolators		
3	Return air duct up to room ceiling and BIBO housing		Yes	X
3a	Internal volume under 1m3	display if size is "up to 1m3"	Yes / No	n/a
3b	Internal volume between 1m3 and 2m3	display if size is "from 1m3 to 2m3"	Yes / No	n/a
3c	Internal volume between 2m3 and 3m3	display if size is "from 2m3 to 3m3"	Yes / No	n/a
3d	Internal volume over 3m3	display if size is "over 3m3"	Yes / No	n/a
3e	Each additional m3	display if size is "over 3m3"	Yes / No	X
GLOVES AND PHOTOCELLS				
4	Pair, Piercan, including hand, sleeve and Ø200 flange		Yes	X
5	Pair, Piercan, including hand, sleeve and Ø178 flange		Yes / No	X
6	Pair, La Calhene, including hand, sleeve and RGI Ø300 flange		Yes / No	X
7	Pair, La Calhene, including hand, sleeve and RGI Ø186 flange		Yes / No	X
14	Couple of photocells as light barriers, including support		Yes	X
DOORS				
15	Under 1m2, vertical opening, including inflatable gasket		Yes / No	X
16	Over 1m2, vertical opening, including inflatable gasket		Yes / No	X
17	Under 1m2, horizontal opening, including inflatable gasket		Yes / No	X
18	Over 1m2, horizontal opening, including inflatable gasket		Yes / No	X
19	Fixed windows		Yes / No	X
RTP (ALPHA PART)				
20	RTP (alpha part) Ø105, installed on the isolator wall		Yes / No	X
21	RTP (alpha part) Ø190, installed on the isolator wall		Yes / No	X
22	RTP (alpha part) Ø270, installed on the isolator wall		Yes / No	X
23	RTP (alpha part) Ø350, installed on the isolator wall		Yes / No	X
SENSORS				
		display only for C-RABS and Isolators		
24	RH & Temperature sensor		Yes	n/a
25	Pressure Transmitter 0 - 250 Pa, for isolator pressure indication and tightness test		Yes / No	n/a
26	Pressure Transmitter +100 -100 Pa, for isolator pressure indication		Yes / No	n/a
27	Differential pressure indication with 0 - 500 Pa for inlet HEPA filter pressure drop		Yes	n/a
28	Differential pressure indication with 0 - 500 Pa for exhaust air HEPA filter pressure drop		Yes	n/a
AIR MONITORING				
29	Non viable sampling port for instrument, with Tri-clamp connection		Yes / No	X
31	Viable sampling port for Petri Dish, with Tri-clamp connection		Yes / No	X
AIR FLOW				
34	Laminar flow with diffusion membrane		Yes	n/a
35	Tri-clamp ports for DOP/DEHS test aerosol infeed, before the fans		Yes	X
36	Tri-clamp ports for DOP/DEHS test aerosol concentration after the fans, before the filters		Yes	X
PNEUMATIC TIGHT VALVES, Double effect				
		display only for C-RABS and Isolators		
37	DN100		Yes / No	X
38	DN150		Yes / No	X
39	DN250		Yes / No	X
40	DN300		Yes / No	X
41	DN450		Yes / No	X
42	DN600		Yes / No	X
ISOLATOR WASHDOWN				
		display only for C-RABS and Isolators		
43	Manual Spray gun, located in isolator wall		Yes / No	X
44	Washing ball CD17A, 1/4"G 360° washing, including support		Yes / No	n/a
45	Washing ball CD17C holes in the bottom - 1/4"G, including support		Yes / No	n/a
46	Manual drain valve, located on the benches of the machine		Yes / No	n/a
OTHERS				
79	Mock Up model		Yes	n/a
80	600 LUX lighting		Yes / No	n/a
81	Predisposition for VHP, including tri-clamp connection for VHP in-out	display only for C-RABS and Isolators	Yes / No	n/a
82	Additional enclosure of stopper/capping bowl into the volume		Yes / No	n/a
83	IQ/OQ Protocols		Yes / No	n/a
84	Additional documentation for EEX execution	display only for C-RABS and Isolators	Yes / No	n/a
85	ATEX certification (upon request)	display only for C-RABS and Isolators	Yes / No	n/a
86	Packing with crate		Yes / No	n/a
87	Packing with sea crate		Yes / No	n/a

RABS / ISOLATORS

FROM	TECHNICAL SPECS	LOGIC	VALUE
Machine type	ORABS / CRABS / Isolator		alphanumeric
Machine type	Size (m3)		number
Machine type	Machine to be installed on		alphanumeric
AUTOMATIC PRESSURE CONTROL			
	Automatic air pressure control	if 1 = yes, then yes	Yes / No
1a	Internal volume under 1m3	if 1a = yes, then yes	Yes / No
1b	Internal volume between 1m3 and 2m3	if 1b = yes, then yes	Yes / No
1c	Internal volume between 2m3 and 3m3	if 1c = yes, then yes	Yes / No
1d	Internal volume over 3m3	if 1d = yes, then yes	Yes / No
1e	Each additional m3	if 1e = yes, then 1e	number
2	Air speed indication with venturi system & pressure transmitter	if 2 = yes, then yes	Yes / No
RETURN AIR DUCT AND BIBO HOUSING			
3	Return air duct up to room ceiling and BIBO housing	if 3 = yes, then 3	number
3a	Internal volume under 1m3	if 3a = yes, then yes	Yes / No
3b	Internal volume between 1m3 and 2m3	if 3b = yes, then yes	Yes / No
3c	Internal volume between 2m3 and 3m3	if 3c = yes, then yes	Yes / No
3d	Internal volume over 3m3	if 3d = yes, then yes	Yes / No
3e	Each additional m3	if 3e = yes, then 3e	number
GLOVES AND PHOTOCELLS			
4	Pair, Piercan, including hand, sleeve and Ø200 flange	if 4 = yes, then 4	number
5	Pair, Piercan, including hand, sleeve and Ø178 flange	if 5 = yes, then 5	number
6	Pair, La Calhene, including hand, sleeve and RGI Ø300 flange	if 6 = yes, then 6	number
7	Pair, La Calhene, including hand, sleeve and RGI Ø186 flange	if 7 = yes, then 7	number
14	Couple of photocells as light barriers, including support	if 14 = yes, then 14	number
DOORS			
15	Under 1m2, vertical opening, including inflatable gasket	if 15 = yes, then 15	number
16	Over 1m2, vertical opening, including inflatable gasket	if 16 = yes, then 16	number
17	Under 1m2, horizontal opening, including inflatable gasket	if 17 = yes, then 17	number
18	Over 1m2, horizontal opening, including inflatable gasket	if 18 = yes, then 18	number
19	Fixed windows	if 19 = yes, then 19	number
RTP (ALPHA PART)			
20	RTP (alpha part) Ø105, installed on the isolator wall	if 20 = yes, then 20	number
21	RTP (alpha part) Ø190, installed on the isolator wall	if 21 = yes, then 21	number
22	RTP (alpha part) Ø270, installed on the isolator wall	if 22 = yes, then 22	number
23	RTP (alpha part) Ø350, installed on the isolator wall	if 23 = yes, then 23	number
SENSORS			
24	RH & Temperature sensor	if 24 = yes, then yes	Yes / No
25	Pressure Transmitter 0 - 250 Pa, for isolator pressure indication and tightness test	if 25 = yes, then yes	Yes / No
26	Pressure Transmitter +100 -100 Pa, for isolator pressure indication	if 26 = yes, then yes	Yes / No
27	Differential pressure indication with 0 - 500 Pa for inlet HEPA filter pressure drop	if 27 = yes, then yes	Yes / No
28	Differential pressure indication with 0 - 500 Pa for exhaust air HEPA filter pressure drop	if 28 = yes, then yes	Yes / No
AIR MONITORING			
29	Non viable sampling port for instrument, with Tri-clamp connection	if 29 = yes, then yes	number
31	Viable sampling port for Petri Dish, with Tri-clamp connection	if 31 = yes, then yes	number
AIR FLOW			
34	Laminar flow with diffusion membrane	if 34 = yes, then yes	Yes / No
35	Tri-clamp ports for DOP/DEHS test aerosol infeed, before the fans	if 35 = yes, then 35	number
36	Tri-clamp ports for DOP/DEHS test aerosol concentration after the fans, before the filters	if 36 = yes, then 36	number
PNEUMATIC TIGHT VALVES, Double effect			
37	DN100	if 37 = yes, then 37	number
38	DN150	if 38 = yes, then 38	number
39	DN250	if 39 = yes, then 39	number
40	DN300	if 40 = yes, then 40	number
41	DN450	if 41 = yes, then 41	number
42	DN600	if 42 = yes, then 42	number
ISOLATOR WASHDOWN			
43	Manual Spray gun, located in isolator wall	if 43 = yes, then 43	number
44	Washing ball CD17A, 1/4"G 360° washing, including support	if 44 = yes, then yes	Yes / No
45	Washing ball CD17C holes in the bottom - 1/4"G, including support	if 45 = yes, then yes	Yes / No
46	Manual drain valve, located on the benches of the machine	if 46 = yes, then yes	Yes / No
OTHERS			
79	Mock Up model	if 79 = yes, then yes	Yes / No
80	600 LUX lighting	if 80 = yes, then yes	Yes / No
81	Predisposition for VHP, including tri-clamp connection for VHP in-out	if 81 = yes, then yes	Yes / No
82	Additional enclosure of stopper/capping bowl into the volume	if 82 = yes, then yes	Yes / No
83	IQ/OQ Protocols	if 83 = yes, then yes	Yes / No
84	Additional documentation for EEX execution	if 84 = yes, then yes	Yes / No
85	ATEX certification (upon request)	if 85 = yes, then yes	Yes / No
86	Packing with crate	if 86 = yes, then yes	Yes / No
87	Packing with sea crate	if 87 = yes, then yes	Yes / No

RABS / ISOLATORS Accessories

Accessory type selection	(VHP Generators, HVAC Systems, Air Monitoring Systems, Glove Testing Systems and Control Cabinets)
Manufacturer	(if "VHP Generator" is selected, Bioquell, Steris and TBM)

Number ID	Description	Condition	Input	Qty
AIR TREATMENT UNIT (HVAC)				
1	Size	display only when Accessory Type is HVAC Systems	Yes	S / M / L
4	Additional ventilation ducts (other than standard design)	display only when Accessory Type is HVAC Systems	Yes / No	n/a
5	Additional EEX components for HVAC	display only when Accessory Type is HVAC Systems	Yes / No	n/a
6	Additional EEX components for Isolator and Filling line	display only when Accessory Type is HVAC Systems	Yes / No	n/a
7	Packing with crate for HVAC	display only when Accessory Type is HVAC Systems	Yes / No	n/a
8	Packing with sea crate for HVAC	display only when Accessory Type is HVAC Systems	Yes / No	n/a
VHP GENERATION				
From Bioquell:				
9	- Stand Alone VHP generator, model CLAUROS C	display only if "Bioquell" is selected	Yes / No	n/a
10	- Integration and testing	display only if "Bioquell" is selected	Yes / No	n/a
11	- Dedicated VHP generator, model IG1	display only if "Bioquell" is selected	Yes / No	n/a
12	- Integration and testing	display only if "Bioquell" is selected	Yes / No	n/a
13	- VHP concentration sensors (HI-LOW)	display only if "Bioquell" is selected	Yes / No	n/a
14	- VHP diffuser	display only if "Bioquell" is selected	Yes / No	n/a
15	- VHP cycle development	display only if "Bioquell" is selected	Yes / No	n/a
16	- Insulated distribution piping	display only if "Bioquell" is selected	Yes / No	n/a
17	- IQ-OQ Protocols for BIOQUELL equipment	display only if "Bioquell" is selected	Yes / No	n/a
From Steris:				
18	- Stand Alone VHP generator, model XX	display only if "Steris" is selected	Yes / No	n/a
19	- Integration and testing	display only if "Steris" is selected	Yes / No	n/a
20	- Dedicated VHP generator, model YY	display only if "Steris" is selected	Yes / No	n/a
21	- Integration and testing	display only if "Steris" is selected	Yes / No	n/a
22	- VHP concentration sensors (HI-LOW)	display only if "Steris" is selected	Yes / No	n/a
23	- VHP diffuser	display only if "Steris" is selected	Yes / No	n/a
24	- VHP cycle development	display only if "Steris" is selected	Yes / No	n/a
25	- Insulated distribution piping	display only if "Steris" is selected	Yes / No	n/a
26	- IQ-OQ Protocols for STERIS equipment	display only if "Steris" is selected	Yes / No	n/a
From TBM:				
27	- Stand Alone VHP generator	display only if "TBM" is selected	Yes / No	n/a
28	- Integration and testing	display only if "TBM" is selected	Yes / No	n/a
29	- Dedicated VHP generator	display only if "TBM" is selected	Yes / No	n/a
30	- Integration and testing of VHP generator	display only if "TBM" is selected	Yes / No	n/a
31	- VHP concentration sensors (HI-LOW)	display only if "TBM" is selected	Yes / No	n/a
32	- VHP cycle development	display only if "TBM" is selected	Yes / No	n/a
33	- IQ-OQ Protocols for TBM equipment	display only if "TBM" is selected	Yes / No	n/a
CONTROL CABINET				
Control Cabinet				
34	- Control Cabinet, when installed on Steriline machine	display only when Accessory Type is Control Cabinets	Yes / No	n/a
35	- Control Cabinet, when installed on third party machine	display only when Accessory Type is Control Cabinets	Yes / No	n/a
36	Over price for Control Cabinet in St. St.	display only when Accessory Type is Control Cabinets	Yes / No	n/a
37	Ethernet card, for connection with customer's SCADA	display only when Accessory Type is Control Cabinets	Yes / No	n/a
38	PLC upgrade and communication protocols for connection with customer's SCADA	display only when Accessory Type is Control Cabinets	Yes / No	n/a
AIR MONITORING				
39	In Line Particle Counter for one sampling point	display only when Accessory Type is Air Monitoring Systems	Yes / No	n/a
40	- Additional sampling points	display only when Accessory Type is Air Monitoring Systems	Yes / No	X
41	Integration of Particle counter into 21CFR Part11	display only when Accessory Type is Air Monitoring Systems	Yes / No	n/a
GLOVE TESTING DEVICE				
42	Manual Glove Testing Device	display only when Accessory Type is Glove Testing Device	Yes / No	X
43	Automatic WLAN Glove Leak Testing Device WGTD	display only when Accessory Type is Glove Testing Device	Yes / No	n/a
44	- Additional Test Disc	display only when Accessory Type is Glove Testing Device	Yes / No	X
45	- Docking Station for Glove Testing Devices	display only when Accessory Type is Glove Testing Device	Yes / No	n/a
46	- Service Station Storage including Docking Station	display only when Accessory Type is Glove Testing Device	Yes / No	n/a
47	Glove suspenders, in st. st	display only when Accessory Type is Glove Testing Device	Yes / No	X
48	Flange for liner, for waste / sample out	display only when Accessory Type is Glove Testing Device	Yes / No	n/a

RABS / ISOLATORS Accessories

FROM	TECHNICAL SPECS	LOGIC	VALUE
Air treatment unit (HVAC)			
1	Size	= "S", "M" or "L"	alphanumeric
4	Additional ventilation ducts (other than standard design)	if 4 = yes, then yes / if 4 = no, do not display	n/a
5	Additional EEX components for HVAC	if 5 = yes, then yes / if 5 = no, do not display	n/a
6	Additional EEX components for CRABS/Isolator and Filling line	if 6 = yes, then yes / if 6 = no, do not display	n/a
7	Packing with crate for HVAC	if 7 = yes, then yes / if 7 = no, do not display	n/a
8	Packing with sea crate for HVAC	if 8 = yes, then yes / if 8 = no, do not display	n/a
VHP GENERATION			
manufacturer	Supplier	= manufacturer	alphanumeric
9	- Stand Alone VHP generator, model CLAUROS C	if 9 = yes, then yes / if 9 = no, do not display	n/a
10	- Integration and testing	if 10 = yes, then yes / if 10 = no, do not display	n/a
11	- Dedicated VHP generator, model IG1	if 11 = yes, then yes / if 11 = no, do not display	n/a
12	- Integration and testing	if 12 = yes, then yes / if 12 = no, do not display	n/a
13	- VHP concentration sensors (HI-LOW)	if 13 = yes, then yes / if 13 = no, do not display	n/a
14	- VHP diffuser	if 14 = yes, then yes / if 14 = no, do not display	n/a
15	- VHP cycle development	if 15 = yes, then yes / if 15 = no, do not display	n/a
16	- Insulated distribution piping	if 16 = yes, then yes / if 16 = no, do not display	n/a
17	- IQ-OQ Protocols for BIOQUELL equipment	if 17 = yes, then yes / if 17 = no, do not display	n/a
18	- Stand Alone VHP generator, model XX	if 18 = yes, then yes / if 18 = no, do not display	n/a
19	- Integration and testing	if 19 = yes, then yes / if 19 = no, do not display	n/a
20	- Dedicated VHP generator, model YY	if 20 = yes, then yes / if 20 = no, do not display	n/a
21	- Integration and testing	if 21 = yes, then yes / if 21 = no, do not display	n/a
22	- VHP concentration sensors (HI-LOW)	if 22 = yes, then yes / if 22 = no, do not display	n/a
23	- VHP diffuser	if 23 = yes, then yes / if 23 = no, do not display	n/a
24	- VHP cycle development	if 24 = yes, then yes / if 24 = no, do not display	n/a
25	- Insulated distribution piping	if 25 = yes, then yes / if 25 = no, do not display	n/a
26	- IQ-OQ Protocols for STERIS equipment	if 26 = yes, then yes / if 26 = no, do not display	n/a
27	- Stand Alone VHP generator	if 27 = yes, then yes / if 27 = no, do not display	n/a
28	- Integration and testing	if 28 = yes, then yes / if 28 = no, do not display	n/a
29	- Dedicated VHP generator	if 29 = yes, then yes / if 29 = no, do not display	n/a
30	- Integration and testing of VHP generator	if 30 = yes, then yes / if 30 = no, do not display	n/a
31	- VHP concentration sensors (HI-LOW)	if 31 = yes, then yes / if 31 = no, do not display	n/a
32	- VHP cycle development	if 32 = yes, then yes / if 32 = no, do not display	n/a
33	- IQ-OQ Protocols for TBM equipment	if 33 = yes, then yes / if 33 = no, do not display	n/a
CONTROL CABINET			
34	Control board included in the filling line	if 34 = yes, then yes / if 34 = no, do not display	n/a
35	Control board separated from the filling line (only option if the isolated machine is not from Steriline)	if 35 = yes, then yes / if 35 = no, do not display	n/a
36	Cabinet made in Stainless Steel	if 36 = yes, then yes / if 36 = no, do not display	n/a
37	Ethernet card, for connection with customer's SCADA	if 37 = yes, then yes / if 37 = no, do not display	n/a
38	PLC upgrade and communication protocols for connection with customer's SCADA	if 38 = yes, then yes / if 38 = no, do not display	n/a
AIR MONITORING			
39	Particle Counter instrumentation	if 39 = yes and 40 = no, then 1 / if 39 and 40 = yes, then X+1	number
41	Integration of Particle counter into 21CFR Part11	if 41 = yes, then yes / if 41 = no, do not display	n/a
GLOVE TESTING DEVICE			
42	Manual Glove Testing Device	if 42 = yes, then X / if 42 = no, do not display	number
43	Automatic WLAN Glove Leak Testing Device WGTD	if 43 = yes, then yes / if 43 = no, do not display	n/a
44	- Additional Test Disc	if 44 = yes, then X / if 44 = no, do not display	number
45	- Docking Station for Glove Testing Devices	if 45 = yes, then yes / if 45 = no, do not display	n/a
46	- Service Station Storage including Docking Station	if 46 = yes, then yes / if 46 = no, do not display	n/a
47	Glove suspenders, in st. st	if 47 = yes, then X / if 47 = no, do not display	number
48	Flange for liner, for waste / sample out	if 48 = yes, then yes / if 48 = no, do not display	n/a

Auxiliary Machines

Machine type selection	(Tray Loader, Transport Belt, Rotating Table, PDS)
Machine Model	(TL 1, TL 2, TL 1-S, TL 2-S, LBT 300, LBT 600, LBT 900, SBW 300 RT 600, RT 900, RT 1200, PDS)
RABS / Isolator quoted separately?	Yes, No

Number ID	Description	Condition	Input	Qty
FEATURES				
1	Set of parts for additional formats		Yes / No	X
2	Extra charge for making the format parts in PEEK, per set		Yes / No	X
3	Laminar Flow	display only if "RABS / Isolator" is NOT "quoted separately"	Yes / No	n/a
4	Accident Protection Hood	display only if "RABS / Isolator" is NOT "quoted separately"	Yes / No	n/a
5	Additional 300 mm	display only for LBT 900	Yes / No	X
GENERAL ADDITIONALS				
8	Packing with crate		Yes / No	n/a
9	Packing with sea crate		Yes / No	n/a

Auxiliary Machines

FROM	TECHNICAL SPECS	LOGIC	VALUE
FEATURES			
1	Set of parts for additional format	if 1 = yes, then X	number
2	Parts set in PEEK, instead of in Delrin	if 2 = yes, then X	number
3	Laminar Flow	if "RABS / Isolator" IS quoted separately, then "within RABS / Isolator" / if not, if 3 = yes, then yes / if not, then no	Yes / No
4	Accident Protection Hood	if "RABS / Isolator" IS quoted separately, then "within RABS / Isolator" / if not, if 4 = yes, then yes / if not, then no	Yes / No
5	Additional 300 mm segments	if 5 = yes, then yes / if 5 = no, do not display	number
GENERAL ADDITIONALS			
8	Packing with crate	if 8 = yes, then yes	Yes / No
9	Packing with sea crate	if 9 = yes, then yes	Yes / No