SYNTEGON
PROCESSING & PACKAGING

Quotation

08.05.24

FLT 1020 Filling and Closing Machine with RTU Infeed
ITP 4002-TO Isolator
ITP 4002-FS Isolator

Stock Machine Formal Quotation

Quotation Overview

Based on our terms and conditions and on the enclosed supplementary General Conditions for the Supply of Machinery we submit the following quote:

Executive Summary			COMMENTS
FLT 1020 Filling and Closing Machine Total			
ITP 4002 Isolator Modules for FLT Filling and Closing Machine with Options Total			
Glove Testing Options Total			
Controls Options Total			
SVC Services Total			
Training Total			Q03 Update-See SLA
Installation and Start-up			
SUB-TOTAL PRICE			
Travel estimate for SVC onsite activities, billed at actual			
Travel estimate For install and start-up, billed at actual			
Travel estimate for onsite training activities, billed at actual			Q03 Update-See SLA
Freight			
SUB-TOTAL PRICE WITH TRAVEL ESTIMATES			
DISCOUNT			Q03 Update
Post SAT Service Level Agreement SLA			Q03 Update-Free of Charge
TOTAL PRICE WITH TRAVEL ESTIMATES			

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1 Customer Requirements

Ambient Conditions/Operating conditions

The following conditions need to be warranted at the place of installation and operation of the machine correct functioning of the machine/s.

Height of the installation site relative to NHN:

- As a rule, a height of < 1000 m (3300 ft) above NHN is presumed for the place of installation.

Operating Environment:

- In the case of active RABS applications, the machine is intended for operation in a temperature and humidity controlled environment of ISO Class 7 (EU Grade B).
- In case of isolator applications. the machine is intended for operation in a temperature and humidity controlled environment of ISO Class 8 (EU Grade C).

Ambient temperature:

- The ambient temperature at the place of operation must be within the range of 10°C and 30°C degrees.
- In case of isolator applications the ambient temperature must be 21°C±2°C at the place of operation.

Air humidity:

- The absolute air humidity in the ambient environment of the line may not exceed 14 g/kg.
- The relative humidity may not exceed 70%.
- In case of isolator applications, the relative humidity may not exceed 60% at the place of installation.
- condensate formation on the exterior surface and inside the machine is to be eliminated

Power supply:

- By default our machines are designed for the US mains standard (voltage 480 V with fluctuations +/- 10% and mains frequency 60 Hz with fluctuations of +/- 1%).

Ionizing radiation:

- If the machine is exposed to an ionizing / non-ionizing radiation (e.g. micro-waves, X-rays, UV or Laser radiation) to an extent that a function impairment can be expected, additional measures must be taken as needed. The reference requirement rests with the customer.

Vibration, shock, impact, air currents, ambient pressure fluctuations:

- The customer must ensure that vibrations, fluctuations and shocks due to environmental causes must not impair the function of the machine.

- Room pressure to be at 25 +/-5 Pa. Air currents and ambient pressure fluctuations may lead to function problems of the machine/n. These influences must therefore be reduced to a minimum.

Compressed air quality:

Compressed air is to be of the following quality:

- Max. solids content: 5mg/m³
- Max. particle size: 5µm
- Max. residual water content: 5.953 g/m³ at +3 °C pressure dew point (DTP)
- Max. total oil content: 5mg/m³.

Risk of explosion:

- The installation and the operation of the machine/s is performed in a no explosion risk range as per ATEX product guideline 94/9/EG.

Processed product:

- As a rule, no products will be processed that might lead to an atmosphere with explosion capability as per ATEX-product guideline 94/9/EG.
- As a rule, no toxic and highly potent products will be processed, neither products containing any live virus.

Customer building:

- It must be ensured that the statically admissible floor loads as well as point loads will not be exceeded.
- A customer supplied structural engineer is to check whether the existing machine loads can be accommodated by the building and/or the ceiling/floor. Floorings must be engineered so that surface pressures can be accommodated. This applies particularly when using devices equipped with mobile casters.
- If the machine/s are desired or required to be bolted to the floor, the floor characteristics must allow for this procedure.

- Building constructions that have vibration tendencies can have detrimental effects on the function of the machine/s.

Further information for the customer:

- The length of the low-pressure lines between low-pressure generators (vacuum pumps, ...) supplied by Syntegon and the customer may not exceed 20 m as otherwise functional problems can be expected . In

case an on-site low-pressure source is used, it must be checked whether the height of the low pressure and the volume flow are sufficient.

Ambient conditions/Transportation and storage

Ambient temperature:

- The ambient temperature must range between -25 °C and +55 °C.

Air humidity:

- At ambient temperatures of -25 °C to 0 °C the relative humidity may not exceed 90%.
- At ambient temperatures of 0 °C to 55 °C the relative humidity may not exceed 70%.
- The formation of condensation must be excluded in each case.
- The time for transportation/storage of the machine under the above listed conditions should not exceed a period of 3 months. Otherwise damage occurring thereby cannot be excluded.

Ionizing radiation:

- The machine may not be exposed to an ionizing / non-ionizing radiation (such as micro-waves, UV or Laser radiation, X-rays) to an extend that might cause damage to the machine.

Vibration, shock, impact:

- The customer must ensure that vibrations, oscillations, shocks and impacts caused by its ambient environment such as transportation will not cause damage to the machine.

Rigging and placement at customer site:

- Routes for riggers are to be calculated so as to ensure that the installation is possible (corners in passage ways, width / heights of doors, ...). Rigging of the equipment to the place of operation is the responsibility of the customer. Syntegon can provide rigging supervision.

- See FLT-ITP Installation Attachment

TECHNICAL INFORMATION:

Technical Data: See FLT-ITP Technical Data Attachment

Filling Product Characteristics:

- liquid solutions water-like, non foamy, non viscous, not crystallizing

Commodities and Rate: TBD upon review of commodities and fill volume. Below are estimates based on glass tubing:

Filling Volume	FLT 1020 with 100%IPC
2ml	30/min | 1800/hr
5ml	30/min | 1800/hr
10ml	25/min | 1500/hr
20ml	15/min | 900/hr
30ml	11/min | 660/hr
50ml	7/min | 420/hr
100ml	3/min | 180/hr

Output data according to filling test number:
If no filling tests agreed between the customer and Syntegon we refer to the following:
The values entered comply with the adjusted output per DIN 8743. The output depends on the characteristics of the packaging material and product, subject to tests to be performed.
If output values without associated filling volumes are specified in the offer, the outputs with liquid products are always related to the rated volume of the associated containers (for example 20 ml with a 20R vial). If the container is filled beyond the rated volume, the specified output values can no longer be reached.

Syntegon tests the filling machines with demineralized water (for filling liquids) if no other agreement has been made.

General Line layout: according to

Working height: 900mm ± 15 mm

Design Language: English

Size part coding:

- The coding of the size parts for identification is carried out according to Syntegon Guideline Typically Syntegon part number, vial diameter, and vial height. Customer can request specific coding at start of design.

Design Guidelines: GAMP5, OSHA CFR29-1910, ANSI/PMMI B155.1, cGMP, NFPA 79

Interface with other works/machines:

- Utility (e.g. electrical, water, compressed air…) interface locations are identified on the General Arrangement drawing. The customer is responsible for utility chases, piping and connections to the points noted in the drawing.

- Electrical interfaces (e.g. potential-free contacts, profibus or Ethernet connection): In case of sold signal exchange (see separate item in the quotation), the interface is placed at the corresponding clamp in the Syntegon electrical cabinet. The cables to the other machines or works are not in Syntegon scope of supply.

Room height recommendation/requirement for the suspended/false ceiling:

- washing room approx. 3000mm for tunnel type 2000/3000/4000/6000/7000/8000 and approx. 3300mm for tunnel type 5000
- if possible, with an access option from the top
- filling and capping room (also for RABS applications) depending on the execution and position of the UDAF system (onsite or Syntegon scope of supply) pending between 2300 and 3300mm
- filling and capping room with isolator, depending on the execution and position of the air handling unit approx. 3045mm recommended with ceiling integration, 3600mm recommended without ceiling integration

Wall thickness recommendation/requirement:

- washing room approx. 60mm
- filling and capping room approx. 60mm

2 Scope of Supply

2.1 FLT 1020 Filling and Closing Machine with RTU Infeed

Description	Base Machine /Option
A high-performance, versatile, intermittently operating machine with a single head filling station for the GMP-compliant filling of liquid pharmaceuticals	Base Machine
General Features • Processing range: o Vial dia: 14-52mm o Vial height: 30-95mm • Machine direction: left to right • Preparatory measures for the integration of a Syntegon isolator with regard to the mechanical and control systems. These include: o Seam-less integration of base table to the structure of the isolator o The sealing off of the entire operating range toward the drive section to achieve the lowest leakage rates o Orienting devices to be isolator-compatible standard with regard to seal integrity and ergonomic layout o Ergonomic working position with gloves and RTP's within the isolator o Compatible cleaning and VHP materials o Slowed motion of the filling and closing machine during the decontamination process o Virtual mock-up design review with project team	Base Machine
Base structure • Welded stainless steel frame with anodized aluminum table top and stainless steel skin (See MOC appendix for specific material types) • Stainless steel feet with ±25mm adjustment	Base Machine
RTU Vial Preparation and Unpacking • Located in IM1 (Isolator Module 1) to aid in the storage and unpacking of RTU (ready to use) vial trays. • Storage of up to ten RTU object trays with maximum size of 400mm x 300mm by means of stainless steel hangers. • The staging area stainless steel perforated base plates which provides an ergonomic position for the unpacking of vials. • (1) Stainless steel pusher tool	Base Machine

• (2) Wire mesh baskets for packing waster	
Rotary vial pack inverter with (1) pack fixture to aid in removing vials with the finish facing towards the bottom of the tray. Tray inverter can be interchanged with the standard deadplate.	Option
Vial pack fixture for additional pack configuration	Option
Filler Infeed • Located in IM2 (Isolator module 2) • Stainless steel accumulation disk with DC motor and speed settings from the HMI • Sweep arm to singularize vials • Infeed guide path with fallen vial chute for vials ≤24mm diameter • Removable fallen vial container • Sensor to detect fallen vials and for minimum accumulation	Base Machine
Transport • Proven servo driven intermittent walking beam made of anti-static UHMW-PE material • Back rail is manually adjustable with mechanical counter settings • Object presence sensor detects vials at the infeed cradle	Base Machine
In-Process Checkweigh • Fully automatic system for 100% in-process control with (1) Wipotec scale • Vials are weighed (tare), filled and weighed again (gross) on the scale platform • Display of the weight values on the HMI • Batch-related storage of the IPC data in the central SQL database • Reject of vials that are outside the adjusted filling tolerance limits • Possibility of adjusting filling parameters while in production • The machine should be installed on a low-vibration floor. Low-frequency vibrations or oscillations (< 5 Hz) can cause false weighing result. • The total tolerance to be considered is calculated on a statistical basis. The total tolerance is calculated from the scale tolerance and the fill tolerance. These values are taken as a basis for establishing the warning and alarm limits. All tolerance limits refer to ± 2 Sigma range. • Static reduction bar prior to weight platform	Base Machine
Filling System • (1) Servo driven peristaltic pump (small 0.5-100ml) • The filling volume settings configurable via the HMI • Servo driven bottom-up vertical filling needle movement configurable via the HMI • Stainless steel needle holder with tubing bracket	Base Machine
Single-use components for the peristaltic pump station for one specific filling volume range	Option

Includes (2) non-sterile technical filling sets for filling one defined filling volume range: • 1 set for commissioning and factory acceptance test (FAT) • 1 set for acceptance on-site (SAT) Technical set consisting of: • Product bag and one connection • Suction and filling hoses • Y-pieces and other connectors • Syntegon pump hoses • Syntegon disposable filling needle • Filters (for product i.e. ventilation/gassing) are not included. These sets are not sterile and are therefore only used for technical runs of the filling machine. For aseptic fillings (Media fill, stability batches, production, ...), sterile sets must be used.	
Product Bag Scale • Mount for Single Use product bag with level sensing via weigh cell (20kg range) • For level-controlled product supply flow into the product bag, an over-pressure must be present at the onsite product tank. • If overpressure cannot be applied to the customer-provided product tank (e.g. with complete single-use version), an additional transfer peristaltic pump with pinch valve can be offered.	Option
Dose-In/Dose-Out Product loss during startup and running empty of the filling system is reduced to a minimum, consisting of: • Product supply and filling system are optimized for minimized product loss Precondition: • 100% IPC • Bag weigh scale option Mode of operation Dose-In (venting of the filling system):	Option

• The filling needle is purged into the container placed on the scale until the target weight is reached • The Dose-In process is executed until the filling system is completely de-aerated and a defined stability criterion is achieved • By means of the Dose-In function, fillings within the tolerance limits can be reached from the beginning, the correction values depending on the filling positions are calculated automatically and are adjusted to the target weight Mode of operation Dose-Out (running empty of the filling system): • After reaching the min. level in the product bag, the filling position is purged into the container placed on the scale in “Dose-Out“ mode until the target weight is reached • The Dose-Out process is executed until filling position is below target weight.	
Gassing at stopper closing • Gassing of vials immediately before stoppering, via (1) 316L stainless steel gassing needle • Base gas supply system including valve bank mounted below machine table, monitoring of gas flow and adjustable gassing needle mount. Test tubing and disposable in-line filter are supplied for machine testing only. • Residual O2 levels are approx. ≤3% depending on size of the vial, fill volume and machine output.	Option
1 year of suggested spare parts for FLT filler: Given as a budget. Project Manager and customer will decide on parts after Spare Parts List is created. Delivery of parts timeline TBD by Project Manager.	Option
Stoppering • For siliconized liquid and lyo stoppers up to 20 mm, with automatic stopper sorting and infeed from the supply hopper into the sorting bowl. • Stopper supply consists of a 316L stainless steel supply hopper which holds approx. 9 liters and rotary metering 316L stainless steel disk. A sensor monitors the level of stoppers in the bowl. • The orienting device consists of a 316L stainless steel tapered feed bowl with sealed base drive and 316L SS track. • The stopper insertion station is a single rotary pick and place system utilizing vacuum tooling and post. • Stopper insertion vertical motion is servo driven and adjustable from the HMI • A dual sensor located immediately after placement check for missing and high stoppers. This is a pure height measurement of the central axis of the stopper barrel. The possible tilting of a stopper and/or vial can result in the stopper not being detected	Base Machine

as faulty. Detection limit of high stoppers are dependent on vial and stopper tolerance and permissible gap. • "Safe stoppering" functionality is included by means of a sensor at the point of vial insertion and, if a stopper is not placed, would trigger another pick and place motion. Machine will stop and alarm after a programmable amount of consecutive re-stoppering attempts. Total calculated machine output may be affected by this functionality.	
Crimp Capping • For low particle over-seal capping up to 20 mm, with automatic cap sorting and infeed from the supply hopper into the sorting bowl. • Cap supply consists of a 316L stainless steel supply hopper which holds approx. 8 liters and rotary metering 316L stainless steel disk. A sensor monitors the level of caps in the bowl. • The orienting device consists of a 316L stainless steel tapered feed bowl with sealed base drive with manual height adjust. Caps then transfer into a 316L stainless steel track and chute. Caps are stripped onto a moving vial. Vials without stoppers do not receive a cap are verified with a cap sensor. • "Cap confirmation" minimum cap track sensor is used to verify a cap is stripped onto a vial • The cap crimp is accomplished by using a free-rolling crimp roller that is rotated in place by a servo motor. Motion on the roller is adjusted via the HMI. A plunger above the vial and cap is lowered via a servo motor to provide a crimping force. Crimping force is manually adjustable. A motorized rotating platform below the vial engages when the plunger is lowered to spin the vial to complete the crimp. • A cap sensor verifies a cap is on the vial after crimping is completed	Base Machine
Outfeed and Reject Station • Vials proceed from the transport and into a dual lane pneumatic divert guide that directs them to either a good-vial tray or reject tray. Vials are assumed to be reject until proven good by machine controls. • A reject verify sensor verifies that a vial in the sift register that is to be rejected goes to the reject guide path. • The outfeed and reject station is equipped with a fixed deadplate, in which, a stainless steel tray is slid underneath. When a tray is removed, an operator uses a paddle to pull the vials from the deadplate and into the stainless steel tray for removal. Sensors are included on each tray station to indicate if a removable tray is present or if a tray is	Base Machine

full. The machine will stop after a determined count if a removable tray is not present or if the tray is full. Standard 3 sided reject tray size is 107mm wide x 368mm long. Standard good vial 3-sided tray size is 302mm wide x 456mm long. Quantity of (1) tray each is provided.	
Size Parts • Vial diameter size parts for (1) vial size. Includes RTU deadplate, infeed, checkweigh, and reject station. • Stoppering size parts for (1) stopper size including: (1) 316L stainless steel hopper, (1) 316L stainless steel metering disk, (1) 316L stainless steel vibratory feeder bowl, (1) 316L stainless steel track, (1) 316L stainless steel vacuum pick and place tooling, and (1) 316L stainless steel stopper post. Product contact certificates are provided. • Cap crimping size parts for (1) cap size including: (1) 316L stainless steel hopper, (1) 316L stainless steel metering disk, (1) 316L stainless steel vibratory feeder bowl, (1) 316L stainless steel track, (1) 316L stainless steel feed chute, (1) 316L stainless steel cap plunger. Product contact certificates are provided.	Base Machine
Additional set of stoppering size parts • Additional stoppering size parts for (1) stopper size including: (1) 316L stainless steel hopper, (1) 316L stainless steel metering disk, (1) 316L stainless steel vibratory feeder bowl, (1) 316L stainless steel track, (1) 316L stainless steel vacuum pick and place tooling, and (1) 316L stainless steel stopper post	Option
Additional set of cap crimping size parts • Additional cap crimping size parts for (1) cap size including: (1) 316L stainless steel hopper, (1) 316L stainless steel metering disk, (1) 316L stainless steel feeder bowl, (1) 316L stainless steel track, (1) 316L stainless steel feed chute, (1) 316L cap plunger	Option
Machine system testing for additional vial diameter	Option
Vial pack inverter fixture size part for additional vial pack configuration	Option
Un-packing module deadplate guides and rake for additional RTU tray size	Option

Size parts for additional vial diameter range. Includes infeed, checkweigh and reject parts	Option
Additional transport walking beam cleat for vial diameter range TBD	Option
Environmental Monitoring • Active Viable Monitoring Microbial air sampler system MAS-100 Iso NT (manufacturer: MBV) for use in isolator systems (aseptic). Installed completely with a vacuum pump and a sampling head, including: o 3 measuring points (one in IM1, two in IM2) o Process parameters are specified directly by the MAS100 system o Monitoring of the critical parameters during microbial sampling of the MAS100 o Connection to the machine control system via Ethernet interface o Microbial sampling started from the Machine HMI o Display of device faults at the Machine HMI o Display "Microbial sampling ended" at the machine HMI o No recording of the volume flow o Compatible with 90-100mm diameter petri dishes • Non-viable Particle Monitoring Measuring device for the particle sensor system Airnet II-510 XR (manufacturer: PMS) for use in isolator systems (aseptic). Installed completely with a vacuum pump, and isokinetic connection funnel, including o 3 sampling positions (one in IM1, two in IM2) o Connection to the machine control system via ModBus TCP o Monitoring of the operating status of the particle counter o Machine stop when the particle limit has been exceeded o Display and trending of the 2 particle sizes (0.5 µm and 5 µm) on the HMI o Analysis is made using ft^3, summation of the individual values in m^3 with display on the HMI o Low flow sensor on vacuum pumps • Passive Viable Monitoring (3) Settling plate mounts, made of stainless steel, for positioning petri dish. Includes mounting area for covers.	Base Machine

2.2 ITP 4002-TO and ITP 4002-FS Isolator Modules

Description	Base Machine /Option
Basic configuration for isolators: Consisting of a single or multiple clean/overpressure zones, suitable for the aseptic filling of pharmaceutical products compliant with Cleanroom Class 5 according to ISO 14644-1. The pressure zone concept provides an effective protection to the operator, and the surrounding room, from highly active substances. The isolator and the isolator specific units are cGMP (FDA) and PICS compliant. Conditions in the isolator: • Air velocity: 0.45 m/s +/- 20% (Measurement point is according to DIN EN ISO 14644-3 300mm below the sterile air distributor) • Temperature: Set point: 22 - 24° C Overpressure relative to the ambient space in the process zones: depending on production mode, aseptic 25 Pa +/- 5 Pa Relative humidity in production: dependent on the air humidity in the surrounding cleanroom Leakage rate for the overall system of the machine combined with isolator: 2% of the isolator volume per hour by means of the pressure decay principle. Ambient conditions at the place of operation: • Temperature: 21° C +/- 2° C • Relative humidity: 60% max Isolator housing: • Housing made of stainless steel 1.4404 (316 L) with windows made of single-pane tempered glass • Stainless steel surfaces on the inside (Ra < 0.5), brushed on the outside (Ra < 1.2). • Easy to clean corners and edges with a corner radius of 10 mm. • Safety doors with inflatable and individual pressure monitored seals • Air recirculation from the processing zone to the UDAF-unit via single- sided stainless steel air return ducts. Ducts are located on the back-side of each module. • Additional integrated air ducts in the base-machine for optimized air guidance within the processing zone of each Isolator module. • Oval glove ports with one-piece sterile gloves (length of 920mm) made of CSM/Tosoh. (5) in TO module, (7) in FS module.	Base Machine

- Corresponding compact glove holders. The design of the glove holders ensures active monitoring of the glove ports during bio-decontamination.
- Light grids for monitoring the glove ports. The light grids are mounted inside the isolator (protection class IP65).
- Lighting through flow-optimized encapsulated LED-lighting. The lighting is designed to be dimmable. Luminous intensity in the Isolator at through- conveyance level at least 600 lux; light color white
- Static mouse holes between two processing zones or to the surrounding room. Quantity and position of the transfer systems (RTP) is defined project specific and quoted as separate options.

Integrated UDAF unit:

- Filter Fan Units (FFU's) with high-efficiency particulate air filters of HEPA U15 as well as energy-efficient EC fans for air recirculation to maintain the cleanroom classification.
- Housing of the air UDAF unit made of stainless steel 1.4301 (304)
- Air distribution via a CG panel made of a stainless steel frame (1.4301) applied, double-covered textile fabric (PET)
- Maintenance access for the purpose of filter and fan exchange is performed from the processing zone
- Connection points for filter integrity testing for each FFU via centralized aerosol ports located on the outside (TC connection 3/4 inch)
- The filter integrity testing can be performed from the surrounding cleanroom

Operating modes of the isolator system:

Service mode:

- The barrier system is not sterile in this operating mode. The operating mode allows manual control of the most important actuators. The statuses set are not retained upon changeover to other operating modes

Operating mode Off:

- The barrier system is not sterile in this operating mode. In this operating mode all fans are inactive and all flaps are closed.

LF mode:

- The barrier system is not sterile in this operating mode. In ventilation terms the barrier system operates with the settings of production mode. The temperature control is active.

Decontamination mode:

- Decontamination of the barrier system is performed in this operating mode. Decontamination consists of the following four phases:
    - A leakage test (performance of the leakage test to check the leak tightness of the barrier system
    - Drying (preparation of the air in the barrier system for decontamination)

o Decontamination (injection and distribution of H2O2 inside the isolator chamber) o Aeration (the air with hydrogen peroxide is flushed by usage of catalytic converters.) Standby mode: • Standby mode is selected automatically after a successful decontamination run. The production conditions are created or maintained. Production mode • The production of the machine on which the barrier system is installed is enabled in this operating mode. All process-related parameters are monitored. Centralized basic module as supply for multiple isolator modules with H2O2. The basic module compromises the following items: • Module consisting of stainless steel housing (1.4301) with integrated loading unit. • Loading unit for the hydrogen peroxide supply bottle (up to 5 kg) with a scale for determination of the total peroxide discharge. Automatic lowering and lifting of the dosing needle for delivery of the hydrogen peroxide to the evaporator • Centralized compressed air supply for different isolator module functions. • Piping between the centralized basic module and the individual FFP isolator as part of Syntegon scope of supply.	Base Machine
Isolator for the TO module consisting of the specific components: • Number of doors: 2 • Number of glove ports: 5 • Number of filter fan units: 1 • Number of catalytic converter units: 4	Base Machine
Isolator for the FS module consisting of the specific components: • Number of doors: 2 • Number of glove ports: 7 • Number of filter fan units: 2 • Number of catalytic converter units: 4 • (1) 110mm Sartorius Biosafe® Rapid Transfer Port (RTP) for transfer of stoppers • (1) 110mm Sartorius BioSafe® Rapid Transfer Port (RTP) for transfer of caps • (1) 110mm Sartorius Biosafe® Rapid Transfer Port (RTP) for transfer of fluid components	Base Machine
The aseptic TO and FS modules consist of the following integrated UDAF units: Exhaust air unit: • Consisting of (HEPA) H13 exhaust filter, a gas-tight flap and an exhaust fan for pressure control of the barrier system. The exhaust air is transferred back to the	Base Machine

cleanroom. Includes exhaust bypass with H2O2 catalytic converter for pressure control during operating mode bio-decontamination . Supply air unit: • Consisting of (HEPA) H13 Supply air filter, a gas-tight flap and an air flow measuring device for the supply air to the barrier system. Recirculation Unit: • Consisting of H2O2 catalytic converters for the decomposition of H2O2 integrated into the recirculation path and a cooling coil for the temperature regulation of the process zone. The following items must be provided as the scope of supply of the customer: • Connection to heat exchanger piping • Provision of all media required (cold water 6 °C/12 °C, and compressed air 6 bar)	
H2O2 Evaporator unit Ultra SafeVAP: A fully integrated system for high-efficiency bio-decontamination of all isolator and machine surfaces with the aid of hydrogen peroxide vapor for reduction of at least 6log inside the isolator chamber. The system architecture comprises the following components: A patented evaporator unit consisting of: • Safe vacuum delivery of the liquid hydrogen peroxide between the central basic module and the integrated SafeVAP evaporation units • Measurement and regulation of the dosing rate are performed for each processing zone by means of a mass flowmeter • The actual evaporation process takes place in the evaporator elements as atomization process of the liquid hydrogen peroxide by means of a venturi tube • The evaporator is connected by means of tri-clamps for easy removal for maintenance and cleaning purposes. • Additional H2O2 gas filtration (0,22µm) before the H2O2 is entering the process zone between filter and sterile air distributor (CG panel) • Sterile compressed air (class 6-3-1 in accordance with ISO 8573-1:2010) provided by the customer is used to guide the mixture of dry carrier air and hydrogen peroxide vapor to the isolator's injection points. Treatment of the compressed air is performed by means of a compressed air maintenance unit. • PT100 sensors for the monitoring of the evaporator temperature • Control system of the bio-decontamination system is fully integrated into the machine/isolator controls • Operator control and visualization is fully integrated into the isolator control panel.	Base Machine

• Logging of all process-critical data of the decontamination cycle, such as start/end, recipe, alarms, cycle log with duration, temperatures, air humidity and dosing rates, in all phases. • Function check with process-technological characterization within the framework of the internal factory acceptance test at Syntegon. • The drying is performed by means of sterile compressed air provided by the customer.	
Sensors and monitoring: The following process parameters are monitored by default and displayed on the HMI: • Air velocity inside each isolator module • Temperature inside each isolator module • Humidity monitoring, via Vaisala H2O2, inside each isolator module • Filter differential pressure sensor for each filter fan unit • Differential pressure sensor between the isolator and the surrounding cleanroom. • "High/low level sensor" (mfg. Vaisala)for the monitoring of the hydrogen peroxide concentration in each isolator module during the bio-decontamination cycle • "Low level sensor" (mfg. Draeger) hydrogen peroxide monitoring for the determination of low peroxide concentrations in each isolator module exhaust • "Low level sensor" (mfg. Draeger) for monitoring the peroxide content in the ambient air on the outside of the isolator	Base Machine
Mock-Up Mock-up allowance includes (1) day 3D virtual review of system prior to release of isolator modules	Base Machine
Integration of the gas flushing station into the bio-decontamination loop	Option
Additional set of one piece sterile gloves CSM/Tosoh with a length of 920mm	Option
Mock-up with a wooden model for isolator Ergonomics study and process simulation at the model structure to determine the number and position of glove ports, transfer doors and particle and germ count monitoring. The machine will be reproduced as a wooden model. Note: Additional lead-time required for design, build and to perform study. See preliminary project schedule for impact.	Option
Spare set of ULPA filters for recirculation FFU's: Qty 3	Option
1 year of suggested spare parts: Given as a budget. Project Manager and customer will decide on parts after Spare Parts List is created. Delivery of parts timeline TBD by Project Manager.	Option

2.4 Glove Testing Options

Description	Base Machine /Option
KHD 3000 Integrated Glove Testing System A flexible, wireless system for the reproducible leakage testing of gloves on a Isolator system. The testing system is fully integrated into the Syntegon machine controls and can be operated conveniently via the filler HMI. Mode of operation: The pressure required for the test is built up by a pump that is integrated into the test lid and measuring is performed on the pressure-drop principle. Accuracy of the system: • A test leak with a diameter of 100 µm can be safely detected if a standard glove is used. The basic configuration includes the following components: • Software package for the wireless communication between glove testing lid/s and machine PC • Communication module/control unit for glove testing (is integrated into the control cabinet) • 1 Cleanroom-capable W-Lan Access Point for the wireless communication between glove test lid/s and machine PC (PLC). • Test specification for a pressure test of standard gloves (CSM/Tosoh for isolators) • Calibration and function check at the factory • Standard Documentation	Option
Wireless Isolator glove testing lid, with RFID communication, for Syntegon standard glove port Consisting of: • an integrated pump • a pneumatic seal • an exchangeable rechargeable battery • a differential pressure sensor	Option

• an integrated display indication of the status of the test disc and charge status of the battery	
Wireless Isolator) glove testing lid, without RFID communication, for Syntegon standard glove port Consisting of: • an integrated pump • a pneumatic seal • an exchangeable rechargeable battery • a differential pressure sensor • an integrated display indication of the status of the test disc and charge status of the battery	Option
Single port-charging station for battery (battery not included)	Option
5-port charging station (batteries not included)	Option
Additional i.e. spare re-chargeable battery for the glove test lid	Option
Transport cart for up to 10 isolator test lids and storage for a 5 point charging system	Option
Adapter plate for recalibration of test lid Option to fit the test lid and to connect a reference pressure gauge (not included in scope of supply) to recalibrate the test disk.	Option

2.5 Controls

Description	Base Machine /Option
Controls • The machine controls standard includes the follow design features: o HMI-Shared by FLT and ITP: 21.5" Beckhoff stainless steel IP65 multi-touch control panel ▪ HMI Software: Wonderware Intouch o Industrial PC: Beckhoff, mounted in control cabinet o FLT PLC: Allen Bradley (AB) 5069 Compact GuardLogix (additional features - dual IP networks, machine control, integrated safety performance up to SIL2/PLd, and integrated motion control) o ITP PLC Allen Bradley (AB) 5069 CompactLogix (additional features - dual IP networks and machine control) o All servo motion via AB Servo Motors with Integrated Motion within the FLT PLC o AB PowerFlex AC Drives which support seamless integration into the Logix environment and EtherNet/IP networks o Light Stack - AB three color stack with Amber, Red, and Green with audible horn, Mounted at/near HMI o Emergency stop buttons at HMI and rear of the machine minimum o Jogging of machine done from HMI only which is allowed in SemiAuto or Manual mode o Ethernet Lightly Managed Switch in main enclosure with spare port o Individual wire numbering according to Syntegon standard (Polyester non-smear wrap labels) o UL of the main control cabinets ▪ Control cabinet built according UL508A ▪ Machine executed according NFPA79 o FLT Control cabinet: Stainless steel NEMA 12 with galvanized sub-panel o IPT Control Cabinet: Stainless steel NEMA 12 with galvanized sub-panel o Interconnect: 20m max length provided as standard o Connection to on-site UPS for supply of control units and operation of process related LF fans • Controls Architecture: o Ethernet IP designed with lightly managed switches. o Completely integrated architecture including machine control, safety and motion o ISO 13849 SIL2/PLd safety o Extensive PLC code annotation.	Base Machine

- 21 CFR Part 11 on PC HMI
    - Windows Based Security
    - This satisfies the requirement for users to have user ID and password combinations so that no two individuals can have the same combination, password aging and password complexity.)
    - Electronic Signatures
    - The system allows for an additional step to digitally sign the actions related to Recipe and Batch (Optional) handling. This step is defined as an electronic signature.
    - Three types of electronic signatures are available:
    - Comment Only (Comment)
    - Single Signature (Done By)
    - Dual Signature (Done By, Verified By)
    - Either type of signature can be applied to virtually any action including, but not limited to:
    - Modifying Recipe Parameters
    - Creating/Loading/Deleting/Activating a Recipe
    - Starting/Stopping Batches
    - Signatures are securely stored in the SQL Database for future retrieval and reporting
    - Reporting
        - Along with the additional requirements of Electronic Signatures, Events, and Batch Control - Reporting is a necessity
        - The system permits the following reports:
        - Alarm Report (Timed range)
        - Recipe List Report
        - Recipe Parameters Report
        - Audit Trail (Timed range)
        - Events Report (Timed range)
        - Batch Report (Optional with Addition of Batch Management)
    - Database Level Recipe Handling
        - Recipes are securely stored in the SQL Database.
        - All recipes feature a version number that cannot be altered by the user. Version control is handled by the system. In addition to this number, the format also includes a letter that indicates the working revision prior to the release.
        - “Released” recipes are “locked down” meaning they are not modifiable. Only working revisions may be modified.

Options	
Remote connection to the PLC and HMI/SCADA system	Option
Batch data on the HMI. This system includes historian software, programming and data output to customer supplied network for formatting, data storage or printing. Data is overwritten or deleted after x months For Batch reporting we can offer the following: • This is implemented on the Touch Screen Industrial PC HMI running Wonderware • Batch report number • Start and stop times • Alarms • Machine counters (if included on the machine) • Recipe parameter list at the start of the batch • OEE information For Batch reporting the data collected is stored in a SQL database on an industrial PC in the electrical cabinet. The data can be viewed on the HMI screen based on Batch ID or operator entered start and end times (goal posts) The selected data can be output via Ethernet Hub connection in the main electrical enclosure to a customer supplied printer or to a customer network storage location. The data is stored until allocated storage space is full. The data can be cleared after x period of time. This option provides a means to capture the process data information and send it to a paper copy or offline storage.	Option

2.6 Documentation PH Liquid

Description	Base Machine /Option
Syntegon Turn-Over Package (TOP) The Syntegon Turn-Over Package provides the essential documentation needed to aid in the qualification and operation of your Syntegon equipment. The TOP is designed to give you the head start you need for your qualification preparation, shortening your time to market. It is also specifically designed to assist you in your submissions to regulatory agencies Syntegon uses GAMP 5 guidelines to assist in defining and documenting the design process of our controls and equipment. Documents are customized to the customer supplied User Requirements Specification (URS) and Purchase Order. The standard TOP includes one (1) hard copy and (1) electronic copy of all the documentation that is supplied for each machine. All documentation is provided in English with the exception of some cut sheets and spare parts documentation. Documentation life cycle: • Drafts are written by engineering and documentation departments • Documents are under change control starting with first version (1.0) • Customer review of first version (1.0) documents are issued prior to design or development • Customers are allowed two weeks to alter documentation. After two weeks, the documents are considered approved and the design proceeds • Any customer updates to the documentation after the first version (1.0) is approved may result in a charge to the customer	
Syntegon TOP includes: Original Instruction Manual: • Instructions with all pertinent information regarding installation, operation, troubleshooting, safety, size parts and maintenance • Safety measures: Information on max/min values, handling hazardous materials, information regarding electrical equipment, machine operation (cleaning, upkeep, maintenance) • Information with regard to transportation and installation of the machines	Base Machine

- The description of the machine includes information on the ambient environment conditions, supplied format sizes, structure and operating method of the machine

Component Cut Sheets:

- Original instructions for the operator control, operation and maintenance of the relevant bought-in parts for components on the P&ID
- The respective manufacturers or suppliers are responsible for the content

General Arrangement Drawing includes:

- Layout of the machine / Line in customer's environment
- Information to the machine-related sizes of utility/media connections, supply of all utilities/media (e. g. water, sterile air, power supply), estimated weight, heat load, noise level
- AutoCAD file available upon request

Process and Instrumentation Diagram (P&ID) includes:

- for each machine, graphic diagram of technical equipment showing process flow and critical instruments
- Complete listing of process components with identification of critical instruments (with Syntegon part #), and calibration recommendation
- AutoCAD file available upon request

Product Contact Material Certification per PANP QMM 4.12 includes:

- Material certificates for applicable product contact parts
- Welding certificates for applicable product contact parts
- Finish certificates for applicable product contact parts

Electrical Schematics include:

- Wiring diagrams of electrical and controls
- Interconnect cable description
- Panel Layouts
- AutoCAD file available upon request

As shipped programs:

- PLC, HMI, servo drive, etc.
- All downloadable programs for disaster recovery
- Delivered as downloadable software

Spare Parts Catalogue includes: • Instructions with all pertinent information regarding spare parts, BOM's, drawings, and ordering • Easy and efficient identification of spare parts by way of assembly drawings and BOM's. SolidWorks eDrawings are provided for easy access to spare part locations on the machine. • Machine spare parts identified per individual BOM Spare Parts List includes: • List of all recommended spare parts per machine Component Cut Sheets: • Original instructions for the operator control, operation and maintenance of the relevant bought-in parts for components on the P&ID • The respective manufacturers or suppliers are responsible for the content All documents are provided in the form of an electronic copy (PDF file) unless otherwise noted.	
Standard Factory Acceptance Test (FAT)	
Prior to leaving the Syntegon facility, the system will have a standard X days, single shift, FAT with the assistance of Syntegon Technician(s). For the standard FAT, the customer may choose one of the following options. • The customer may provide FAT documentation to be executed during this time o All customer provided documentation must be sent to Syntegon at least 6 weeks prior to the Syntegon Internal Testing (SIT) o All acceptance criteria is to be agreed upon at least 4 weeks prior to SIT • The customer may execute the Syntegon Internal Testing (SIT) form for Test of Performance and Interfaces and review the remainder of the completed SIT during this time o All acceptance criteria is to be agreed upon at least 4 weeks prior to SIT Duration of standard FAT to be provided by the Project Manager.	Base Machine
Specifications	
Functional Specification (FS)	Base Machine

This is a *Design Document*. It defines verbally the basic and GMP-critical functionality of the machine. It describes what the system should do, and what functions and facilities are to be provided.
 	
Contents:
 	
• System overview
• Design criteria including standards and regulations
• Operational, control and safety description
• Functions of the machine
  o Device names with function, dependency and other information
  o Reference to designation numbers in the P&ID
• Appendices:
  o Commodity specification and rates
  o Materials of Construction
 	
Version in language: English	

Software Design Specification (SDS)
This is a *Design Document*. It defines the hardware and software structure, gives details on software functions, system data, system interfaces and alarms.
 	
It describes what the system should do and which functions are to be provided.
 	
Content:
 	
• System Overview
• System Specification: Software, Firmware, HMI, Interfaces (PLC)
• Software Architecture
• Security
• Electronic signatures
• Audit trail
• Parameter Management
• Alarms and alarm categories
• Batch operation
• SCADA (if purchased)
• Operation Specification
• Functions of the machine
• Power loss
• Appendices:
  o Alarm condition and recoveries
  o Interface data input and output tables
	Base Machine

o Security access table o Control system including power requirements o Interconnect o Control Hardware o I/O Type, designation, name, range Note: A separate SCADA SDS will be provided if purchased Version in language: English	

2.7 Initial Qualifications of New Machinery

Description	Base Machine /Option
Commissioning, Qualification, and Validation Services	
Commissioning	
Customized Factory Acceptance Test (cFAT) Customized Factory Acceptance Test (cFAT) is a tailored period of testing according to customer specific requirements with Syntegon management, preparation and execution. cFAT plan, execution, and test results documentation are GMP compliant. cFAT plan consists of test philosophy, detailed test plan, and acceptance criteria. Acceptance criteria agreed upon with the customer. Scope and details of testing clarified during the commissioning workshop (if purchased) at Syntegon prior cFAT plan approval. cFAT test results are documented in GMP-compliant format, compiled in the cFAT report and summary. Test execution is at Syntegon by trained personnel, according to Syntegon standard operating procedures (SOPs) where applicable. Duration can be adjusted to match the requirement (quotation will be provided for additional scope). Service includes: • Test support and time management by dedicated validation engineer • Writing of a draft of the cFAT plan • Release final revision of the cFAT plan after the commissioning workshop (if purchased)	Option

• Approval of the cFAT plan by customer prior to execution • Labor for machine preparation, test preparation, test execution, meetings, wrap-up, etc. up to a maximum of 10 hours per day • Support of relevant SME(s): validation engineers, technicians, programmers, designers or as required • Documentation of observations in an open point list / punch list • cFAT test approval by the customer	
Customized Site Acceptance Test (cSAT) Customized Site Acceptance Test (cSAT) is a tailored period of testing according to customer specific requirements with Syntegon management, preparation and execution. cSAT plan, execution, and test results documentation are GMP compliant. cSAT plan consists of test philosophy, detailed test plan, and acceptance criteria. Acceptance criteria agreed upon with the customer. Scope and details of testing clarified during the commissioning workshop (if purchased) at Syntegon prior cSAT plan approval. cSAT test results are documented in GMP-compliant format, compiled in the cSAT report and summary. Test execution is at customer location by Syntegon trained personnel, according to Syntegon standard operating procedures (SOPs) where applicable. Duration can be adjusted to match the requirement (quotation will be provided for additional scope). Service includes: • Test support and time management by dedicated validation engineer • Writing a draft of the cSAT plan • Release final revision of the cSAT plan after the commissioning workshop (if purchased) • Approval of the cSAT plan by the customer prior to execution • Labor for machine preparation, test preparation, test execution, meetings, wrap-up, etc. up to a maximum of 10 hours per day • Support of relevant SME(s): validation engineers, technicians, programmers, designers or as required • Documentation of observations in an open item list / punch list • cSAT test approval by the customer	Option
Disaster Recovery Procedure (tested at Syntegon) Project-specific disaster recovery procedure for PLC systems, PC systems, servo drives and frequency drives with specific application software.	Option

Description of the steps required to backup and rebuild the system after a breakdown using the backed up software (backup) and, if necessary, a system image (for PC applications). The procedure includes a description of how to make a backup or image, software (partly also hardware) recovery, suitable for people with the necessary PC system knowledge (e.g. working with different data carriers, formatting, partitioning, creating boot media, installing drivers, etc.). The procedure applies only to control hardware for Syntegon systems. The reliability of the procedure verified by a documented test (one test for each type of system) at Syntegon prior to delivery of the machine. Service includes: • Disaster recovery procedure (final revision), approved by Syntegon after testing • Procedure test execution	
Qualification	
Syntegon qualification service is engineered to achieve the following: • Establish documented evidence that machine(s) comply with GMP-requirements • Establish documented evidence that machine(s) fit for intended use • Deliver documentation that can be used for audits and inspections by regulatory authorities and third party • Provide modular and flexible structure for qualification documents and activities to allow to focus on what is required • Do it right the first time by elimination of non-value adding activities by planning and executing testing at appropriate time(s) and location(S0 • By default the execution of IQ, Calibration and OQ takes place after final installation at customers site • Management of time and activities by a dedicated Syntegon qualification project leader based on a project schedule • Qualified Syntegon personnel trained on theory and application of Syntegon SOPs • Transparency and collaboration between Syntegon and customer through workshops (if purchased) • Syntegon SOPs are proven to in all major markets(applied worldwide) • Qualification test plans and reports include: o Test objective o Scope of the test o Test procedure o Acceptance criteria o Summary of results • GMP-compliant change control and deviation procedures during qualification execution. • Formal test result documentation in a GMP-compliant format using individual test sheets, along with qualification report and summary • Use of NIST traceable calibrated measuring devices for relevant activities included o NOTE: Specific details of service and support depends on the scope of order.	Option

Project Quality Plan (PQP) Project Quality Plan describes project specific quality, qualification and validation activities carried out by Syntegon that take place during development, manufacturing, commissioning, testing and qualification of the machine(s). The PQP is divided into: • Supplier qualification section with details about Syntegon engineering, project management, quality principles and procedures • Specification and execution section with activities in planning, specification and testing phases • Project plan section with information about the Syntegon organization, technical documentation to be delivered with machine(s) and project schedule • Commissioning and qualification activity matrix section that describes individual verification phases, tests, and acceptance criteria This PQP also • Describes typical qualification / validation principles, e.g. deviation procedures, change control, good documentation practice and training of personnel involved. • Outlines responsibilities and interfaces between Syntegon and the customer • Provides detailed content for a smooth project management Service includes: • Draft version of the PQP for customer review and approval • Approval of the released version by Syntegon and customer	Option
Qualification Workshop Workshop(s) provide an opportunity for a detailed presentation and an intensive discussion regarding the activities, responsibilities and interfaces during development, manufacturing, commissioning, testing and qualification of the machines. Workshop(s) are based on draft versions of design and/or qualification documentation. Service includes: • Workshop at Syntegon (or on-line) • Update of design and/or qualification documentation based on workshop results • SME level discussions between Syntegon and customer experts	Option
Installation Qualification (IQ) (at customer site) This GMP-compliant qualification activity establishes documented evidence that as-built equipment installed on-site matches the design. The IQ plan consists of a test philosophy and a detailed test plan agreed with the customer. Qualification details discussed during a qualification workshop at Syntegon prior to IQ plan approval (if purchased).	Option

IQ execution will be at customers' location by trained Syntegon personnel according to established Syntegon standard operating procedures (SOPs). Test documentation will be in a GMP-compliant format on single test sheets, compiled in report with a summary. IQ execution also includes the use of GMP-compliant change control and deviation procedures during the qualification execution. The scope of supply includes: • Activity and time management by a dedicated qualification / validation engineer, using a mutually agreed project schedule • Writing draft of the IQ plan • Release of final revision of the IQ plan • Approval of the IQ plan by the customer prior to execution • IQ execution at customers' location by trained personnel / validation experts • GMP-compliant test documentation • Approval of the IQ plan by the customer after execution • Use of calibrated reference devices for relevant activities The scope of supply is based on the number of days in the contract.	
Hardware Loop Check Testing (at customer site) This GMP-compliant hardware loop check establishes documented evidence that wiring of the digital and analogue inputs / outputs of the PLC are connected to the correct machine sensor / actuator (according to the electrical wiring diagram). Testing covers the complete loop from sensor / actor to PLC input / output control module. The input / output test plan comprises a test philosophy and a test plan. The input / output testing execution at the customers' location by trained personnel according to Syntegon standard operating procedures (SOPs). Results will be documented in a GMP-compliant format and compiled in input / output report summary. The test execution includes GMP-compliant change control and deviation procedures during the test execution. Service includes: • Activity and time management by a dedicated validation engineer, using an agreed project schedule • Release of final revision of the input / output plan • Approval of the input / output plan by Syntegon prior to execution • Input / output testing execution at the customers' location by trained personnel / validation experts and GMP-compliant test documentation Input / output plan approval by Syntegon after execution	Option
Calibration (at customer site)	Option

This GMP-compliant calibration establishes documented evidence that the installed process critical analogue sensors work properly and within the required accuracy. The calibration comprises: • A full loop calibration, including values displayed on the HMI, local displays and recording equipment • The use of calibrated reference devices with traceability to a national measurement standard (NIST). • A 3-point calibration, typically at 10%, 50% and 90% of the working range (some exceptions apply) The calibration plan is comprised of a test philosophy and a test plan. The calibration certificates to be completed will contain the acceptance criteria. The calibration execution will be at the customers' location on the completed machine by trained personnel / validation experts according to Syntegon standard operating procedures (SOPs). Test documentation will be in GMP-compliant format on individual test sheets and compiled in the calibration report as a summary. Calibration execution includes the use of GMP-compliant change control and deviation procedures. NOTE: Some instruments, such as flow meters, particle counters, hydrogen peroxide concentration, oxygen and TOC sensors are not included in the scope of Syntegon calibration. Factory (OEM) calibration certificates for can be purchased through Syntegon, but it must be specified in the URS. Customer will be responsible for the further calibration of such sensors. The scope of supply includes: • Activity and time management by a dedicated qualification/validation engineer, using a mutually agreed project schedule • Writing final revision of the calibration plan • Calibration execution at the customers' location by trained personnel / validation experts and GMP-compliant calibration documentation • Calibration approval by the customer. • The calibration certificates of the reference devices used will also be submitted • Shipment & use of calibrated Syntegon measuring devices (NIST traceable)	
Operational Qualification (OQ) (at customer site) This GMP-compliant qualification establishes documented evidence that the installed machine operates correctly at customers' site according to GMP or customer specific requirements.	Option

The OQ plan comprises a test philosophy and a detailed test plan agreed upon with the customer. Qualification details clarified during a qualification workshop at Syntegon before OQ plan approval.(if purchased) The OQ execution will be at customers' location by trained personnel / validation experts according to established Syntegon standard operating procedures (SOPs). The execution includes also the use of GMP-compliant change control and deviation procedures during the qualification execution. The test execution includes also the use of GMP-compliant change control and deviation procedures during the qualification execution. Service includes: • Activity and time management by a dedicated qualification / validation engineer, using a mutually agreed project schedule • Writing draft of the OQ plan • Release of final revision of the OQ plan • Approval of the OQ plan by the customer prior to execution • OQ execution at the customer site by trained personnel / validation experts and GMP-compliant test documentation • OQ test approval by the customer • Calibrated reference devices for relevant activities (NIST traceable) The scope of supply is based on the number of days in the contract.	
Alarm and Function Testing (AFT) (at Syntegon) The Alarm and Function Testing represents the OQ of the software. This GMP-compliant qualification establishes documented evidence that control system functions of the installed machine or system work properly according to the specifications. The AFT plan consists of a test philosophy and a detailed test plan. AFT execution will be at Syntegon by trained personnel / validation experts according to established Syntegon standard operating procedures (SOPs) and various AFT test procedures. Test documentation will be in a GMP-compliant format on single test sheets, compiled in report with a summary. The test execution includes also the use of GMP-compliant change control and deviation procedures during the qualification execution. Service includes: • Activity and time management by a dedicated validation engineer • Issuing the AFT plan	Option

• Approval of the AFT plan by Syntegon prior to execution • AFT execution by trained personnel / validation experts and GMP-compliant test documentation at Syntegon • AFT test approval by Syntegon The scope of supply is based on the number of days in the contract.	
Process Development of Bio-Decontamination (at customer site) A process development plan describes activities during development of the bio-decontamination cycle to attain the required reduction of the microbiological load. The test methodology explains how individual tests result in determination of valid cycle parameters for validation and production. For process development, the physical, chemical and biological testing has significant importance. Such testing discovers positions inside the isolator system that are regarded as “worst case locations” for the bio-decontamination cycle. A process development report lists activities and their results, justifies decisions, and formally defines parameters for process validation and production setting. Evaluation of an entire process development is covered in a one-day process development / validation workshop at Syntegon. The scope of supply includes: • Activities and time management by a dedicated validation expert, using a mutually agreed project schedule • Writing draft of the process development plan • Release of final revision of the process development plan after review by the customer • Approval of the process development plan by the customer prior to execution • Process development plan execution and GMP-compliant test documentation by trained validation experts at the customer site • Evaluation and documentation of the test results and documentation of the determined ”worst case locations” • The approval of the completed tests by customer. • Creation of a process development report by a validation expert • Approval of the process development report by the customer • Use of calibrated Syntegon test devices (NIST traceable) Number of isolators: 2 Note: PQP and Qualification Workshop required	Option
Process Validation of Bio-Decontamination (at customer site)	Option

A process validation plan describes activities during the validation of the bio-decontamination cycle. Three validation runs will be performed and observed. During these runs, it will be demonstrated that the developed cycle, using the determined parameters in all determined “worst case” positions, produces the required kill. A process validation report lists activities and their results, justifies decisions, and formally defines (includes customer feedback) the parameters for production. The scope of supply includes: • Activities and time management by a dedicated validation expert, using a mutually agreed project schedule • Writing draft of the process validation plan • Release of final revision of the process validation plan after review by the customer • Approval of the process validation plan by the customer prior to execution • Execution of process validation plan and GMP-compliant test documentation completion performed by trained validation experts at the customer site. • The evaluation and documentation of the test results. • The approval of the completed tests by the customer. • The creation of a process validation report. • The approval of the process validation report by the customer • Transport & use of calibrated Syntegon test devices (NIST traceable) Number of isolators: 2	
Materials, Tools and Services for Cycle Development / Cycle Validation for 2 isolators The scope of supply includes: • Certified Biological Indicators (BI) Geobacillus stearothermophilus ATCC 12980 on stainless steel carriers sealed in TyvekTM bags for the cycle development and validation - only one lot of Biological Indicators will be used which have passed the Syntegon inspection of incoming goods • Certified Chemical Indicators (CI) with lot number and expiration date for the estimation of the Peroxide distribution during the Cycle Development. • Draeger tubes (H2O2) for determination of the residual concentration of Peroxide during the Cycle Development and Cycle Validation • Equipment for online measurement of the Peroxide concentration during the cycle development and validation • Smoke generator and video camera for the documentation of the airflow during the cycle development • Calibrated data logger system with thermocouples for temperature mapping during the cycle development Inspection of the incoming goods (material and hours) of this lot of BIs with:	Option

• Spore identification • Spore count • Reference D-Value at the Syntegon test isolator Materials and tools for the execution of the cycle development must be provided by the customer: • Microbiological laboratory with necessary equipment for handling of Biological Indicators • Caseinpeptone-Soybeanpeptone-Bouillon as the culture media for the spores • Incubators with an incubation temperature of 55 °C • Hydrogen Peroxide (relevant quality)	
Optional Additional cFAT, cSAT and OQ tests for other formats	Option
General terms and traveling conditions	
General terms and conditions for commissioning & qualification / validation activities Documents will be in English language. Some plans & reports will be delivered in draft form for review. Comments must then be supplied within 2 weeks and then the final revision for approval is issued. If no comments are supplied within 2 weeks, it will be taken as agreement to the draft version, and the final revision will be issued. Further revisions of documents is not included and will be invoiced separately by the Project Manager. Workshops are usually held in Minneapolis, MN as in-person meetings; alternatively, other options (e.g. Teams virtual call) can be arranged. The documents will be supplied in PDF or paper copy only. For the on-site activities, the customer shall provide: • Machines / systems necessary for the qualification execution, ready for use, according to the agreed time schedule. The machines / systems have to be in a clean condition ,complying to GMP, and with the operators required. There shall be no restrictions because of a simultaneous production, installation, or retrofit of equipment. • The product to be processed, the necessary packaging material, and all required consumables for the qualification execution (e.g. vials, stoppers, caps, etc.) as well as utilities especially power, water, steam and air in the required amount and quality.	

• Offices and test rooms necessary for the execution as well as computer and communication facilities (telephone, printer, copying machine, internet access) on site free of charge. All accruing costs because of delays due to lack of these items will be charged to the customer. The regular working day at Syntegon and at customer site is 8 hours (exceptionally up to a maximum of 10 hours) from Monday to Friday between 6:00 am and 7:00 pm. Working outside the regular working day - from 7:00 pm to 6:00 am; working on Saturday, Sunday & holidays - will be charged separately according to applicable service rates.	
Travel Estimate: Travel time as well as expenses for food, car rental and lodging in combination with the qualification activities are billed at actual (additional waiting times which may accrue for our personnel that are outside our area of responsibility are not included in this price).	Option

2.8 Training

Description	Base Machine /Option
Essential Training The essential training is focusing on the operator group. The trainer(s) is coaching the operators in order to enforce the operational sequences, so that the customer team can take over the commitment for their line. Recommended training execution is at your site before media-fills. Training language is English. The training on the job includes: • Preparation • 4 days execution Training in groups of 4-5 persons is recommended to ensure the best knowledge transfer.	Option
Automation Training This training package focuses on the implemented automation systems of the line and is designed for mechanical and electrical engineers, electricians, automation technicians and engineers. The training course is designed to describe the hard- and software structure of the systems, revealing the links and interfaces within the built up automation system architecture. The course enables the participants to understand the in depth principles and programs needed to execute a complex troubleshooting of the line. The training includes: • Preparation • 3 days execution Training in groups of 3-4 persons is recommended to ensure the best knowledge transfer.	Option
Process Training This training package focuses on the process qualification and validation systems of the line and is designed for quality and validation technicians and engineers. The course enables the participants to understand the in depth principles and troubleshooting of the cycle development and validation process. The training includes:	Option

- Preparation
- 3 days execution

Training in groups of 3-4 persons is recommended to ensure the best knowledge transfer.

2.9 Packaging, Freight, Installation, and Start-up

Description	Base Machine /Option
Shipping crate and transport frame for ground transport within the US	Base Machine
Installation and commissioning are carried out by our qualified technicians. Please request the installation personnel early on - at the latest, the time delivery. Definite details with regard to the assembly procedure will be reconciled with you prior to delivery of the machines. Scope of installation/start-up: • Erecting the machines • Electrical connection of machines • Function test with all sizes Costs for installation are only applicable for an uninterrupted schedule. Should additional travel expenses or waiting times occur for reasons not by Syntegon (due to missing on-site preparations or in case of additional requests), the Project Manager will notify the customer and a change order will be provided.	Option
Travel Estimate: Travel time as well as expenses for food, car rental and lodging in combination with the installation are billed at actual (additional waiting times which may accrue for our personnel that are outside our area of responsibility are not included in this price).	Option

Wire Pull Supervision*	EQUIPMENT	ON SITE LABOR	TRAVEL ESTIMATE
	FLT ITP		(INC TRAVEL TIME)
Electrical Assembler	2		
sub-total install man days	2		
Wire Pull Supervision total			
Rigging Supervision	**EQUIPMENT**	**ON SITE LABOR**	**TRAVEL ESTIMATE**
	FLT ITP		
Mechanical Assembler	3		
sub-total install man days	3		
Rigging Supervision total			
Install Man Weeks / Cost	**EQUIPMENT**	**ON SITE LABOR**	**TRAVEL ESTIMATE**
	FLT ITP		
Mechanical Assembler	2		
Electrical Assembler	1		
sub-total install man weeks	3		
Install Costs			
Start-up Support Man Weeks / Costs	**EQUIPMENT**	**ON SITE LABOR**	**TRAVEL ESTIMATE**
	FLT ITP		
Mechanical Assembler	2		
Programmer	1		
PC Communciation to network	1		
sub-total start-up man weeks	4		
Start-up Costs			
TOTAL:	EQUIPMENT	ON SITE LABOR	TRAVEL ESTIMATE
	FLT ITP		
Total for Install & Start-up			

Assumptions
40 hour work week
Customer met requirements listed below

Customer Requirements for Installation
*Wire pull supervision is highly recommended to ensure cable runs are not damaged during cable installation
Contracting licensed electrician to terminate cables if required by state or local codes
Equipment onsite, uncrated (if possible), inspected for damage, and prepared for rigging (prior to arrival of personnel).
Preliminary verification of packing list (crates and boxes).
Final placement all electrical/control cabinets.
Provide all electrical enclosure cutouts and all cables pulled.
High voltage and low voltage cables in separate wire ways.
Bolt down of all equipment following final placement.

Customer Requirements for Start-up
All utilities (power, air, water, etc,) run to all pieces of equipment.
Fill media supply complete.
Fresh, production-grade commodities available.
Vendors for other equipment present. Syntegon will not be responsible for other vendor's products in the line.

2.10 Post SAT Service Level Agreement-Level 4

Description	Base Machine /Option
To ensure an efficient start-up and maintain high reliability of your new equipment throughout the machine life cycle, we are happy to offer you our Service Agreement Level 4, covering all aspects of preventive maintenance: Contract Fulfilment Manager: The Contract Fulfilment Manager is the first point of contact for the planning and execution of the maintenance activities, parts delivery and other services included in the Service Agreement. Helpline: Helpline refers to all activities that serve to identify, analyze and rectify reported breakdown incidents and machines errors as well as to answer machine-related technical questions, through email, telephone and audiovisual support or provided the machines in scope meet the technical requirements – through establishing a remote communication and transmission channel to the machines. Scheduled inspections: Inspection interventions are done regularly and for which the date for execution and completion is defined. Activities will include machine and process evaluation, identification and brush up training for operation. 2 Days, 2 Technicians – (3 visits) Scheduled maintenance: Maintenance interventions that are carried out at regular intervals and for which the date for execution and completion is defined. Activities will include replacements of wear parts necessary during the first year of operation and any other man, machine, method center-lining activities. 5 Days, 2 Technicians – (1 visit) Operator Training: • Essential Training: 4 Days, 2 Technicians • Automation Training: 3 Days 1 Technicians • Process Training: 4 Days. 2 Technicians	Option

3 Price Summary

FLT 1020 Filling and Closing Machine	Item	QTY	Extended Price	Comments
General Features	Included			
Filling and stoppering machine for GMP-compliant filling of liquid pharmaceuticals into injection vials up to 100ml	Included			
Machine in a left to right configuration	Included			
Preparatory measures for the integration of a Syntegon isolator with regard to the mechanical and control systems	Included			
900mm (+/- 25mm) vial transfer height from the floor	Included			
RTU Vial Preparation and Un-packing Module	Included			
Stainless steel hangers for up to (10) 300mm x 400mm RTU vial tray packs	Included			
Stainless steel perforated staging deadplate	Included			
Stainless steel perforated deaplate interface to filler infeed accumulation disk	Included			
(1) Stainless steel vial pusher tool with hanger	Included			
(2) Stainless steel wire waste bins	Included			
Filler Infeed	Included			
Infeed stainless steel accumulation disk interface to perforated deadplate. Includes sweep arm	Included			
Infeed guide with fallen vial chute and removable tray (up to 24mm dia vial)	Included			
Infeed fallen vial and minimum accumulation sensor prior to transport	Included			
Transport	Included			
Walking beam with v-cleat servo driven transport, anti-static UHMW PE material	Included			
Manually adjustable back guide rail	Included			
Vial in transport pocket sensor prior to filling	Included			
Checkweigh	Included			
100% In-process checkweigh, includes (1) Wipotec scale and stainless steel mounting platform	Included			
Static reduction bar prior to checkweigh platform	Included			
Fill System	Included			
Bottom-up servo driven filling station with needle and tubing holder	Included			
(1) Syntegon peristaltic pump (small 0.5-100ml) with standoff and servo drive	Included			

Stoppering	Included			
Rotary disk stopper feeder bowl loading system including disk stand-off and drive	Included			
Stopper feeding including sealed vibratory base drive and mount	Included			
Rotary stopper pick and place system with servo height control	Included			
Low stopper in feeder bowl sensor	Included			
Dual sensor for high and present/missing stoppers	Included			
"Safe stoppering" functionality to sense a mis-placed stopper and trigger another stopper pick and place motion	Included			
Crimp Capping	Included			
Rotary disk cap feeder bowl loading system including disk stand-off and drive	Included			
Cap feeding and placement including sealed base drive with manual height adjust mount	Included			
Crimping station including servo driven single roller crimping with manual height adjust and motorized rotary vial platform	Included			
Low cap in feeder bowl sensor	Included			
"Cap confirmation" minimum cap in track sensor to verify cap is stripped on to vial	Included			
Cap present on vial sensor prior to crimping	Included			
Cap present on vial sensor after crimping	Included			
Outfeed/Reject	Included			
Outfeed/Reject station with pneumatic diverter mechanism. Outfeed and reject path to single tray deaplates outside of the isolator.	Included			
Reject verify sensor	Included			
Tray position/full sensors on both outfeed and reject trays	Included			
Size Parts	Included			
Vial diameter size parts for (1) vial size. Includes RTU deadplate, infeed, checkweigh, and reject station.	Included			Base vial diameter format: 2R
Stoppering size parts for (1) stopper size including: (1) 316L stainless steel hopper, (1) 316L stainless steel metering disk, (1) 316L stainless steel vibratory feeder bowl, (1) 316L stainless steel track, (1) 316L stainless steel vacuum pick and place tooling, and (1) 316L stainless steel stopper post	Included			Base stopper format: 13mm
Cap crimping size parts for (1) cap size including: (1) 316L stainless steel hopper, (1) 316L stainless steel metering disk, (1) 316L stainless steel vibratory feeder bowl, (1) 316L stainless steel track, (1) 316L stainless steel	Included			Base cap format: 13mm

feed chute, (1) 316L stainless steel cap plunger				
Particle Monitoring	Included			
MAS-100 Iso NT multi-head sampling unit with Ethernet communication; including 3 sampling heads including 300 hole perforated lids	Included			
(3) Airnet II 510 XR non-viable particulate sensors; including vacuum pumps and flow sensors, standoffs, funnels, lids and tubing	Included			
Syntegon interface of active viable and non-viable units into the mechanical space below the machine, into the bio-decontamination unit of the isolator modules and electrical interface with PLC/HMI. Includes data preparations for batch report	Included			
(3) Passive viable settling plate mounts	Included			
Utilities	Included			
Vacuum pump with low vacuum sensor mounted under the machine baseplate	Included			
Instrument air pressure control valve to filter and regulate customer supplied air. Includes low air pressure sensor	Included			
Controls	Included			
Allen Bradley PLC controls and servo motion. Industrial PC with interface to 21" HMI touchscreen on swivel mount. HMI software is Wonderware. HMI in English language.	Included			
3-Color LED light stack with horn	Included			
NEMA 12 separate main electrical cabinet constructed of stainless steel	Included			
20 meters of interconnect cable	Included			
Single Wire Numbering according to Syntegon standard	Included			
UL certificate for main electrical cabinet-FLT Filler	Included			
Standard Testing, Documentation and Crating	Included			
SIT (Syntegon Internal Testing) machine testing for (1) vial diameter, (1) fill volume and (1) stopper/cap size	Included			
Syntegon Turn Over Package (TOP), standard documentation package in English	Included			
Shipping crate and skid for transport	Included			
FLT 1020 Filling and Closing Machine Total		1		Stock Machine

FLT Dosing System Options	Price	QTY	Extended Price	Comments
Peristaltic Fill System Non-Sterile Technical Set for FAT and SAT: Includes needle, tubing, 8L bag for one fill volume, dosing test for one fill volume		1		Estimate of 2 total sets for 2ml-10ml fill range
Dose-in/Dose Out: product loss during startup and run empty of the filling system is reduced to a minimum. Options that must also be chosen: Product bag scale w/controls on HMI		1		Stock Machine
Product bag scale w/controls on HMI, 20 kg range. Includes stainless steel exterior mount.		1		Stock Machine
FLT General Machine Options	Price	QTY	Extended Price	Comments
Rotary vial pack inverter mounted at infeed un-packing module. Includes (1) vial pack fixture.		1		Stock Machine
Machine level tool holders for tweezers or scissors		3		
Gassing station at stopper closing: Includes valve bank, monitoring of gas flow, adjustable gassing needle mount, (1) 316L gassing needle, and silicone tubing/ disposable sterile filter for testing.		0		
Zone 4 seismic analysis (earthquake region)		0		N/A
Stainless steel coving around base of the machine		0		
1 year of suggested spare parts for FLT filler		1		Budget amount with specific components TBD upon review of spare parts list
FLT Stoppering and Capping Size Parts Options	Price	QTY		Comments
Additional stoppering size parts for (1) stopper size including: (1) 316L stainless steel hopper, (1) 316L stainless steel metering disk, (1) 316L stainless steel vibratory feeder bowl, (1) 316L stainless steel track, (1) 316L stainless steel vacuum pick and place tooling, and (1) 316L stainless steel stopper post		1		TBD: Additional 20mm stopper and /or redundant sets
Additional cap crimping size parts for (1) cap size including: (1) 316L stainless steel hopper, (1) 316L stainless steel metering disk, (1) 316L stainless steel feeder bowl, (1) 316L stainless steel track, (1) 316L stainless steel feed chute, (1) 316L cap plunger		1		TBD: Additional 20mm stopper and /or redundant sets

FLT Vial Diameter Size Parts	Price	QTY	Extended Price	Comments
Machine system testing for additional vial diameter		2		2R included in base price: Additional 6R, 10R
Vial pack inverter fixture size part for additional vial pack configuration		2		2R included in base price: Additional 6R, 10R
Un-packing module deadplate guides and rake for additional RTU tray size		2		2R included in base price: Additional 6R, 10R
Size parts for additional vial diameter range. Includes infeed, checkweigh and reject parts		2		2R included in base price: Additional 6R, 10R
Additional transport walking beam cleat for vial diameter range TBD		0		
FLT Filling and Closing Machine Total with Options				
ITP 4002 Isolator Modules for FLT Filling and Closing Machine	Price	QTY	Extended Price	Comments
General Features Isolator	Included			
Isolator ITP 4002-TO module for un-packing of RTU vials-1.5m in length	Included			
Isolator ITP 4002-FS module for filling, stoppering and capping-2.0m in length	Included			
Isolator housings made of 316L stainless steel with single pane tempered glass	Included			
Doors with inflatable seals with individual pressure monitoring	Included			
Air recirculation to the UDAF unit via single side stainless steel air return ducts located on back side of machine	Included			
LED lighting, 600 lux at transport level , color white and dimmable	Included			
Mouse hole with inflatable seal between the isolator modules	Included			
Static mouse hole at the filling module outfeed	Included			
ITP 4002-TO Transfer Isolator Module	Included			
Qty 2 doors	Included			
Qty 5 Oval glove ports with one piece gloves made of CSM/Tosoh with a length of 920mm. Includes stainless steel glove extenders.	Included			
ITP 4002-FS Fill, Stopper and Cap Isolator Module	Included			

Qty 2 doors	Included			
Qty 7 Oval glove ports with one piece gloves made of CSM/Tosoh with a length of 920m. Includes stainless steel glove extenders.	Included			
Qty 2 light curtain pairs for monitoring glove ports mounted inside isolator	Included			
Tempered glass panel between stoppering and capping	Included			
110mm Sartorius Biosafe Rapid Transfer Port (RTP) for transfer of stoppers	Included			
110mm Sartorius Biosafe Rapid Transfer Port (RTP) for transfer of caps	Included			
110mm Sartorius Biosafe Rapid Transfer Port (RTP) for transfer of fluid components	Included			
Integrated Supply Air Unit For Each Isolator Module	Included			
H13 HEPA intake filter with air supplied from cleanroom	Included			
Gas-tight damper with air velocity monitoring	Included			
Integrated UDAF Unit For Each Isolator Module	Included			
Fan filter units with HEPA U15 filters and EC fan(s) for air recirculation	Included			
UDAF housing made from 304SS	Included			
Air distribution via CG membranes (PET) with stainless steel frame	Included			
Connection points for filter integrity testing via 3/4 in TC connections	Included			
Air velocity monitoring per isolator module	Included			
Filter differential pressure monitoring per fan filter unit	Included			
Integrated Exhaust Air Unit For Each Isolator Module	Included			
H13 Exhaust filter with air returning to cleanroom	Included			
Exhaust fan for pressure control with gas-tight valve	Included			
Overpressure monitoring to the surrounding room per isolator module	Included			
Integrated Catalytic Converters For Each Isolator Module	Included			
H202 catalyzers in recirculation air path of the process zones and prior to room exhaust with gas tight valves	Included			
Integrated Temperature Control For Each Isolator Module	Included			
Cooling coil with regulating valve and pump for temperature control	Included			
Temperature monitoring inside the isolator	Included			

Relative humidity monitoring inside the isolator-RH is not controlled	Included			
H2O2 Integrated Evaporator System Ultra SafeVAP	Included			
Centralized H2O2 supply module for multiple isolators	Included			
High efficiency bio-decontamination system with hydrogen peroxide vapor	Included			
H2O2 evaporator system	Included			
Measurement and regulation via mass flowmeter	Included			
Injection below the UDAF filters and before the CG membranes	Included			
"High/low level sensor" (mfg. Vaisala)for the monitoring of the hydrogen peroxide concentration in each isolator module during the bio-decontamination cycle	Included			
"Low level sensor" (mfg. Draeger) hydrogen peroxide monitoring for the determination of low peroxide concentrations in each isolator module exhaust	Included			
"Low level sensor" (mfg. Draeger) for monitoring the peroxide content in the ambient air on the outside of the isolator	Included			
Operation and visualization integrated into isolator HMI with loggng of all process critical data	Included			
Ability to decontaminate isolator modules individually, sequentially or both at the same time	Included			
Mock-up	Included			
Mock-up allowance includes (1) day 3D virtual review of system prior to release of isolator modules	Included			
Controls	Included			
Allen Bradley PLC controls. Industrial PC interface to 21" HMI touchscreen mounted in NEMA 4X stainless steel enclosure on swivel Strongarm (shared with filler). HMI software is Wonderware. HMI in English language.	Included			
NEMA 12 separate main electrical cabinet constructed of stainless steel	Included			
20 meters of interconnect cable	Included			
Single Wire Numbering according to Syntegon standard	Included			
UL certificate for main electrical cabinet-Isolator	Included			
Connection to on-site UPS for supply of control units and operation of process related LF fans	Included			

Standard Testing, Documentation and Crating	Included			
SIT (Syntegon Internal Testing) machine testing for one vial diameter, fill volume and stopper size	Included			
Syntegon Turn Over Package (TOP), standard documentation package in English	Included			
Seaworthy shipping crate and skid for transport	Included			
ITP 1002 A Isolator Modules for FLT Filling and Closing Machine Total		1		
ITP 1002 A Isolator Options	Price	QTY	Extended Price	Comments
Integration of the gas flushing station into the bio-decontamination loop		0		
Additional set of one piece sterile gloves CSM/Tosoh with a length of 920mm		0		TBD
Mock-up with a wooden model for isolator		0		See lead-time implications in proposal
Spare set of ULPA filters: Qty 3		1		
1 Year of suggested spare parts		1		Budget amount with specific components TBD upon review of spare parts list
ITP 4002 Isolator Modules for FLT Filling and Closing Machine with Options Total				
Glove Testing Options	Price	QTY	Extended Price	Comments
KHD 3000 Glove Testing System - wireless W-Lan with operation via the isolator HMI. Includes RFID for glove ports.		1		Stock Machine
(1) KHD 3000 Wireless glove testing lid with RFID communication and re-chargeable battery. Does not include charging station.		3		Stock Machine
Glove test lid-without wireless LAN and RFID of glove ports. Includes re-chargeable battery. Does not include charging station.		0		
Single port-charging station for battery (battery not included)		2		Stock Machine
5-port charging station (batteries not included)		0		
(1) Additional re-chargeable battery		3		
Transport cart for up to 10 isolator test lids and storage for a 5 point charging system		0		
Adapter plate for re-calibration of test lids		1		Stock Machine
Glove Testing Options Total				

Controls Options	Price	QTY	Extended Price	Comments
Batch data for the filler and isolator on the filler HMI. This system includes historian software, programming and data output to customer supplied network for formatting, data storage or printing.		1		Stock Machine
Remote connection to the PLC's-FLT and Isolator		1		Stock Machine
Controls Options Total				
Commissioning, Qualification and Validation Services for the following machines: FLT 1020 ITP 4002 TO and FS	PRICE	QTY	EXTENDED PRICE	COMMENTS
Activities at Syntegon				
Project Quality Plan (PQP)		1		
Qualification Workshop: 1 Day		1		
Customized Factory Acceptance Test (cFAT) Protocol and Execution: 5 Days		1		
cFAT Execution- Additional Vial Formats: 1 Day		2		2R included in base price: Additional 6R, 10R
Alarm and Function Testing (AFT) Protocol and Execution: 10 Days		1		
Disaster Recovery Procedure		1		
Activities at customer site				
Hardware Loop Check Protocol and Execution: 4 Days, 2 Technicians		1		
Calibration Protocol and Execution: 5 Days, 2 Technicians		1		
Customized Site Acceptance Test (cSAT) Protocol and Execution: 5 Days, 2 Technicians.		1		
cSAT Execution Additional Vial Format: 1 Day		2		2R included in base price: Additional 6R, 10R
Installation Qualification (IQ) Protocol and Execution: 5 Days, 2 Technicians		1		
Operational Qualification (OQ) Protocol and Execution: 6 Days, 2 Technicians		1		
OQ Execution-Additional Vial Format: 1 Day		2		2R included in base price: Additional 6R, 10R
Process Development: 20 Days, 2 Technicians		1		

Process Validation: 10 Days, 2 Technicians		1		
Materials, Tools and Services for Process Development / Process Validation		1		
Travel estimate for onsite SVC activities, billed at actual				
SVC Services Total				
Training	PRICE	QTY	EXTENDED PRICE	COMMENTS
Essential Training: 4 Days, 2 Technicians		0		Q03 Update- See Service Level Agreement (SLA)
Automation Training: 3 Days 1 Technicians		0		Q03 Update- See SLA
Process Training: 4 Days. 2 Technicians		0		Q03 Update- See SLA
Travel estimate for SVC onsite training activities, billed at actual	-			Q03 Update- See SLA
Training Total				
Installation and Start-up	PRICE	QTY	EXTENDED PRICE	COMMENTS
Installation and Start-up		1		
Travel estimate for install and start-up, billed at actual				
Freight	Price	QTY	Extended Price	Comments
Ground Freight Estimate. Billed at actual		1		
Post SAT Service Level Agreement SLA	Price	QTY	Extended Price	Comments
Level 4 Service Level Agreement		1		Q03 Update

4 Specification Response

A User Requirements Specification (URS) has not been provided at the time of this proposal. Machine requirements and testing are per this proposal and/or Syntegon standard testing protocols unless otherwise agreed upon.

5 Terms and Conditions

Price Adjustment:

Prices are valid for 60 days

The information concerning scope of delivery, delivery times and prices provided in this quote is valid subject to a check of the specific applicable local regulations. It has been created based on the regulations referenced in the quote

This quotation is valid for the following target markets and use: North America, Pharmaceutical

Payment Terms:

- 30% Upon contract conclusion, Due net 15
- 30% After completion of Mechanical Engineering, latest within 90 days after contract conclusion. Due net 30
- 30% After Factory Acceptance Test (FAT) at Syntegon site, latest at the scheduled FAT date in the event of delay due to circumstances not attributable to CONTRACTOR, receipt of payment prior to shipping. Invoiced 30 days prior to scheduled shipment
- 10% After Site Acceptance Test (SAT), latest within 90 days after FAT in the event of SAT delay due to circumstances not attributable to CONTRACTOR. Due net 30

Commodity Requirements:

Commodities will also be needed by specific dates to ensure no delays in shipment. Commodities are required for both machine set-up and FAT and must be representative of production quality.

At the time of purchase order Syntegon will send out a data sheet to the customer with the exact needed number of components and the related dates when these will be needed.

Shipment:

Delivery is performed on the basis of Incoterm CPT dispatch plant according to Incoterms® 2020 (version enforced at the conclusion of the contract.) The place of delivery may still change after the conclusion of the contract. Delivery and prices will include appropriate packing, freight paid to named place of delivery, and will exclude unloading, installation and commissioning.

All prices are net prices in USD. Costs will be paid by Syntegon and invoiced to the buyer after the completion of the shipment (pre-pay & add).

Delivery

Please refer to attached schedule. Additional options that are not already included on the pricelist configuration or other changes to the machine could increase the lead-time to FAT depending on scope and engineering capacity at the time of order.

Due to the current critical supply situation, compliance with agreed delivery dates is subject to timely self-delivery to the Contractor by its suppliers and subcontractors. Both parties are aware that the Contractor is experiencing procurement difficulties with regard to raw materials / parts / components due to a current worldwide supply chain crisis. The Parties, therefore, agree that the Contractor shall

not be at fault and that there shall be no delay attributable to him insofar as contractual deadlines cannot be met because he is not supplied on time by his suppliers.

The Contractor can only initiate the procurement process with regard to the required raw materials, parts and components after completion of the design process (i. e., after conclusion of this contract), which is why there are no delivery date commitments on the part of the Contractor's suppliers at the time of conclusion of this contract. The Contractor shall inform the Customer if the agreed dates have to be postponed due to raw materials / parts / components that cannot be procured in time. For the purpose of continuous review of the delivery situation, the parties agree on a regular exchange.

Start of Schedule Impacts:

After receipt of purchase order the start of the delivery schedule will be dependent on Syntegon having finalized documentation including, but not limited to:

- Hard copy of purchase order along with clear scope of line-item total
- URS with final exceptions and clarifications
- Proposal drawing with room layout
- Commodity drawings and samples for each container(s), stopper(s), cap(s), tray(s) or other relevant commodities to be processed on the line according to the schedule below.

Commodity Requirements:

Commodities will also be needed by specific dates to ensure no delays to shipment. Commodities are required for both machine set-up and FAT and must be representative of production quality. The quantities listed below are typical and will be adjusted based on specific job requirements by the Project Manager.

- Typical requirements upon placement of order
  - containers – 10 to 20 for each size
  - stoppers & caps – 10 to 15 liters for each size
  - trays – 2 of each size
  - required no later than 2 weeks after placement of order

- Typical requirements for sorting system manufacturing
  - stopper & caps – 2 hour run time for each size
  - required no later than 2 months after PO

- Typical machine set-up requirements
  - containers – 2 hour run time for each size
  - stoppers & caps – 2.5 hour run time for each size
  - trays – specified by Syntegon project manager
  - required 12 weeks prior to FAT date

- Typical FAT requirements (dependent on customer requirements)
  - containers – 2 hour run time for each size
  - stoppers & caps – 2.5 hour run time for each
  - Required 4 weeks prior to FAT date

Warranty:

Please reference the attached "Terms and Conditions" for period and conditions of warranty.

Sales and Use Tax Resale/Exemption Certificate

By law, we are required to collect sales and/or use taxes on your purchases unless you provide us with a current resale/exemption certificate applicable for the state in which your purchases are shipped. If your purchases are exempt from these taxes, please provide a current resale/exemption certificate to Syntegon.

6 Attachments

1. Syntegon Terms and Conditions
2. General Arrangement Drawing with Utilities
3. FLT ITP Installation Data Sheet
4. Draft schedule

SYNTEGON

SYNTEGON GROUP

(Syntegon Packaging Technology, LLC, Syntegon Technology Services LLC, Osgood Industries, LLC, Kliklok LLC and Syntegon Pharma Technology, LLC)

NORTH AMERICAN TERMS AND CONDITIONS OF SALE FOR EQUIPMENT, SPARE PARTS AND SERVICES
January 30, 2023

1. **ORDERS/ACCEPTANCE:** Customer may order Supplier's machines or components (collectively "Equipment"), spare parts ("Spare Parts") and/or modernization or repair services collectively ("Services") either by signing Supplier's proposal/quotation to Customer or submitting a purchase order. In either case, Customer's order will be subject to these terms and conditions, and any and all additional or different terms in a purchase order or other document sent by Customer will not be part of this agreement unless Supplier agrees in writing to those additional or different terms. Customer's orders are valid only when accepted by Supplier. Supplier's acceptance of Customer's order, and Customer's obligations under the order, will be effective upon (i) Supplier's transmittal of a written acceptance/acknowledgment, or (ii) Supplier's commencement of performance of Customer's order, whichever occurs first.

2. **CHANGES:** At any time prior to ninety (90) days before the scheduled shipping date, Customer shall have the right at any time to make changes in Specifications, materials, packaging, time and place of delivery, method of transportation or other changes. If changes required by Customer or proposed by Supplier result in a change in the price or a change in the amount of time required for performance, Supplier will provide Customer with a written quotation for such changes and Customer will issue a new Purchase Order or issue an addendum or supplement to the existing Purchase Order. Supplier shall incorporate such changes in revised plans, drawings and/or Specifications which shall be subject to Customer's approval.

3. **SOFTWARE:** The Equipment purchased may include software owned by Supplier or licensed to Supplier. When Customer pays the purchase price for the Equipment in full, Customer will have a single, perpetual, royalty-free, nonexclusive license to use the software in connection with the operation of the Equipment. Customer agrees not to modify, adapt, translate, reverse engineer, decompile or otherwise attempt to discover the source code of the software.

4. **PRICE/OTHER CHARGES:** Stated pricing and performance criteria for the Equipment, Spare Parts and Services quoted herein are based only on the information, parts, product samples and work descriptions available to Supplier at the time this Quotation was issued and apply only to the specifications, delivery schedule and materials specified in the Quotation. Customer understands that any changes to these terms after the date of the Quotation may increase the pricing or result in additional charges. Unless otherwise stated in Supplier's Quotation all pricing is F.C.A., Supplier's facility, and does not include freight/shipping costs, packaging, local, state and federal taxes, duties and/or assessments. Charges will also include travel expenses, including reasonable transportation charges, meals and lodging for service personnel, and any additional work authorized by Customer at the time of the performance of Services will be an additional charge at Supplier's usual and customary service rates. If Supplier's technicians respond to an order for Services placed by Customer and are delayed or prevented from performing the services contemplated thereunder by Customer, all waiting time and any return Services so necessitated, shall be an additional charge to Customer at Supplier's established service rates then in effect. Unless otherwise stated in Supplier's quotation all pricing contained herein shall be in U.S. currency. Pricing for equipment manufactured in Europe is based upon Euro/US dollar exchange rate in effect at the time the quotation issued. Customer hereby assumes the risk of fluctuations in the exchange rate between the date of this quotation and the date of Customer's acceptance hereof for equipment manufactured in Europe. The prices for components that comprise the Equipment was determined at the time of the quotation based on the current applicable indices. Should these indices deviate by more than 3% from the initial value on the final invoice date, the parties will discuss negotiating a corresponding appropriate price adjustment.

5. **DELIVERY OF GOODS:** Supplier will deliver the goods to customer as stated in this order acknowledgement under Incoterms 2020, unless otherwise agreed to in this document. All damages must be denoted on the delivery receipt by the consignee.

6. **INSTALLATION:** Supplier will not install the equipment, unless Supplier agrees to do so in the proposal provided to Customer. In the event Supplier has agreed to install the equipment, Customer will, at its expense, ensure that the site is prepared in accordance with Supplier's site planning instructions prior to the proposed shipping date stated in Supplier's proposal to Customer. Customer will, at its expense, uncrate and locate the equipment prior to start-up. Supplier may, at its discretion, inspect the site prior to shipment and supervise the movement of the equipment at the site. Customer will, at its expense, provide all utility requirements for the equipment at the site. Supplier's technicians shall have reasonable and free access to all equipment to provide service thereon and Customer will provide a safe place in which to perform such service, including working space, heat

light, ventilation, electric current and outlets for the use of Supplier's technicians. In the event the Equipment is to be used in conjunction with other equipment not manufactured by Supplier, Customer will be solely responsible for the integration of the Equipment with any other equipment.

7. **PAYMENT TERMS:** Except as agreed to in writing otherwise, payments shall be made in United States currency as specified in the quotation. Notwithstanding anything to the contrary contained in the Quotation, Customer understands that the Equipment shall not be shipped until 90% of the contract price has been paid, and that the final 10% is net thirty (30) days from shipment.

   Spare Parts are normally invoiced at time of shipment to Customer and due within (30) days of the date of invoice. Services are normally invoiced weekly and payment is due within thirty (30) days of the date of invoice. Modernization is normally invoiced in progress billings and is due according to the terms specified in the proposal. Payments are considered made when good funds in United States Dollars are received in the account specified on the invoice.

   No discount is allowed for earlier payments. Past due payment amounts will be subject to an interest charge of the lesser of eighteen percent (18) or the maximum legal rate permitted under law, from the date payment is due. Any costs and expenses incurred by Supplier as a result of non-payment or delinquent payment by Buyer, including collection costs, interest, and reasonable attorney's fees shall be paid by Customer.

   Supplier reserves the right to grant, deny, suspend or terminate credit terms, require cash or advance payment in its sole discretion. Customer authorizes Supplier to conduct a credit investigation for the purposes of determining whether to extend credit, and agrees to provide any documents or consents reasonably necessary to permit Supplier to do so. Should Customer become delinquent in payment or refuse to accept a C.O.D. shipment, Supplier shall have the right, in addition to any other right it may have under law, to cancel any order of Customer, to withhold future deliveries, declare all unpaid amounts immediately due and payable, and/or condition shipment, installation, or other assistance on receipt of payments due by Customer.

8. **AGENT'S AUTHORITY:** Customer understands and agrees that none of Supplier's agents, employees or representatives have the authority to make any promise, representation or warranty related to the equipment other than those warranties contained in this agreement or in the proposal Supplier provided to Customer.

9. **WARRANTY:** Supplier warrants the Equipment and Spare Parts manufactured by Supplier shall conform to the specifications contained in the proposal provided to Customer and be free from defects in workmanship and material under conditions of normal use and service for a period of one year from the earlier of the date of installation or thirty (30) days from the date of delivery, single shift operation or for a period of twenty-one hundred (2100) accumulated hours of use, whichever occurs first. Within the stated warranty period, Supplier, at Supplier's option, shall repair or replace the Equipment, components or Spare Parts thereof that prove defective under conditions of normal use, or shall refund the purchase price subject to Customer paying a fair market value for usage. Supplier will pay all shipping charges to return repaired or replaced equipment, but equipment which does not prove to be under warranty will be returned to Customer at its expense. All repaired and replaced parts shall assume the identity of the original for purposes of this warranty and this warranty shall not be extended with respect to such parts or the Equipment. Customer shall notify Supplier promptly in writing of any claims under this warranty and, upon request, will return the Equipment or components thereof to Supplier, on conditions to be agreed upon. Specifically excluded from this warranty are failures caused by abuse, misuse, neglect, improper installation, unauthorized service work, failure to follow maintenance and operating manuals, the use of unauthorized parts, ordinary wear and tear, failures due to external forces or compliance with Customer's design specifications. The warranty will be voided if modifications are made or non-Supplier parts are installed. Repairs or alterations performed by someone other than Supplier will not be covered by warranty and may void warranty. Customer agrees to indemnify and hold harmless Seller, its affiliated companies, officers, directors and employees with respect to any claims arising out of such failures.

   These warranties does not cover (i) equipment not manufactured and supplied by Supplier, (ii) wrapper materials, bags, containers, labels, glues films or any other materials or accessories purchased from other parties for use with the Equipment, (iii) consumable, wearable, or disposable items included in the Equipment, including, without limitation, heat elements, cutting knives and sealing bands, and (iv) routine maintenance, such as lubrication, adjustments and replacement of expendable items and production consumable.

   Supplier further warrants that the Services provided by Supplier will be performed in a timely and workmanlike manner, using only qualified technicians familiar with the Equipment and Spare Parts and their operation.

   THESE WARRANTIES ARE THE SOLE AND EXCLUSIVE WARRANTIES PROVIDED BY SUPPLIER AND ALL OTHER WARRANTIES, EXPRESS AND IMPLIED, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE, ARE HEREBY EXPRESSLY DISCLAIMED AND EXCLUDED BY SUPPLIER. THE REMEDIES SET FORTH IN THIS SECTION ARE THE SOLE AND EXCLUSIVE REMEDIES

PROVIDED BY SUPPLIER IN THE EVENT THE EQUIPMENT IS DETERMINED TO NOT BE IN CONFORMITY WITH THE WARRANTY PROVIDED BY SUPPLIER.

10. **DISCLAIMER AND LIMITATION OF DAMAGES:** SUPPLIER WILL HAVE NO LIABILITY TO CUSTOMER OR ANY OTHER PERSON FOR ANY BUSINESS INTERRUPTION, LOSS OF PROFIT, REVENUE, MATERIALS, ANTICIPATED SAVINGS, DATA, CONTRACT, GOODWILL, DOWNTIME, OVERTIME COSTS, (WHETHER DIRECT OR INDIRECT IN NATURE), OR FOR ANY OTHER FORM OF INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES OF ANY KIND, WHETHER ARISING OUT OF BREACH OF WARRANTY OR BREACH OF ANY OTHER PROVISION HEREOF, NEGLIGENCE OR OTHER SORT, OR OTHERWISE, EVEN IF SUPPLIER HAS BEEN ADVISED OF THE POSSIBILITY OR LIKELIHOOD OF POTENTIAL LOSS OR DAMAGE. In addition, Supplier shall not be liable for any damages, regardless of type or the allegations supporting such damages, in excess of the total purchase price for the Equipment.

11. **TITLE AND SECURITY INTEREST:** Title to the equipment will pass to Customer upon delivery to the carrier for shipment to Customer. Customer will not sell the equipment or encumber its title until the purchase price has been paid in full to Supplier, and Prior to moving the Equipment, shall notify Seller of the new location. Customer grants to Supplier a purchase money security interest in the Equipment and components thereof. Failure of Customer to make any payment when due shall entitle Supplier, in its sole discretion, to declare all obligations of Customer immediately due and payable and Supplier shall have all the rights and remedies of a secured party under applicable law. Customer agrees to execute upon request such documents, which may be deemed necessary or appropriate by Supplier to create, perfect and maintain the perfection of its security interest under applicable law. Customer hereby appoints Supplier as its attorney-in-fact to sign and file a financing statement and such other documents as Supplier deems necessary to create, file, perfect and maintain the protection of its security interest.

12. **TIME OF DELIVERY SUBJECT TO INTERNATIONAL EXPORT CONTROL REGULATIONS:** Deliveries and services (fulfillment of contract) will only be executed under the proviso that their fulfillment complies with national or international export control regulations and does not violate any embargoes or other sanctions. The Customer commits to supply all necessary information and documents necessary for the export or transfer to other EU member states. Delays due to export control assessments or export control licensing procedures invalidate terms and dates of delivery. When licenses are not granted, or the delivery and service is not licensable, this contract becomes void in respect of the affected parts.

    When re-exporting the Customer is responsible for applying for the required licenses. Customer commits to compliance with applicable export control regulations. The Customer is specifically advised to check the applicability of the US re-export control legislation.

13. **INFRINGEMENT:** Supplier warrants that the Equipment delivered hereunder shall be delivered free of rightful claims for infringement of any United States patent or trademark, provided, however, that this warranty shall not apply to claims for patent infringement to the extent that any Equipment is (1) manufactured to Customer's specifications, (2) altered by Customer without the consent of Supplier, (3) used in combination with products not purchased from Supplier in a manner which infringes a patent covering the combination, of (4) used in a manner not reasonably anticipated by Supplier. Supplier's obligation hereunder is conditioned upon Customer giving Supplier prompt written notice of any infringement claim and cooperating fully with respect to the defense of such claim. In addition, upon Supplier's request, Customer shall turn over to Supplier control of the defense including settlement and/or litigation of such claim. Supplier shall be entitled, at its option, to obtain a license on Customer's behalf for the Equipment which (allegedly) infringes an intellectual property right, or alter the Equipment in a way or replace it by similar Equipment which does not infringe the intellectual property right.

14. **FORCE MAJEURE; ALLOCATIONS:** In the event either party is unable to fully perform its obligations hereunder (except for Customer's obligation to pay for Equipment ordered) due to events beyond its reasonable control including but not limited to acts of God, action by any governmental authority (whether valid or invalid), fires, floods, windstorms, explosions, riots, natural disasters, wars, sabotage, supranational supply chain disruptions and defective or delayed deliveries by subcontractors on account of such disruptions, labor problems (including lockouts, strikes, slowdowns), inability to obtain power, material, labor, equipment or transportation, or court injunction or order, that party shall be relieved of its obligations to the extent it is unable to perform. Timely notice of such inability to perform shall be given to the other party. Supplier may, at its discretion and without liability to Customer, allocate any and all available equipment or parts thereof among Customer and any other persons or entities with which Supplier is obligated to provide such equipment and parts.

15. **CANCELLATION:** Equipment - Customer may cancel its order by giving Supplier written notice delivered at least sixty (60) days before the scheduled shipping date. Upon receipt of a written cancellation notice by Supplier, Supplier will cease work on the equipment as promptly as reasonably possible. Customer agrees to pay Supplier either the full purchase price shown on Supplier's proposal to Customer or order for equipment if completed prior to receipt of the written cancellation notice, or Supplier's full cost, including but not limited to materials, parts labor, and overhead, plus 20% for equipment which had not been completed

prior to receipt of the written cancellation notice. Supplier reserves the right to complete and ship equipment if written cancellation is received less than sixty (60) days prior to the scheduled shipping date.

Spare Parts – in the event Customer cancels an order for Spare Part after shipment, Customer agrees to pay a restocking fee equal to 35% of the proposal. Modernization - in the event Customer cancels an order for Modernization after work has begun, Customer agrees to pay for all costs incurred to date plus an additional 25%. Services - in the event Customer cancels an order for Services less than four (4) business days prior the scheduled work date, Customer agrees to pay a cancellation fee of $1,000.00. Additionally, in the event Supplier's proposal entails specially manufactured goods or equipment, cancellation by Customer at any time after Supplier has commenced construction of the specially manufactured goods or equipment will not release Customer from liability for any loss Supplier incurs.

16. **TRAVEL ASSISTANCE:** In the event Supplier is to provide any technical services at Customer's site located outside of the United States, Customer agrees to provide all reasonable assistance necessary for Supplier's technician to obtain the travel documents required for such a visit by the authorities in the location of Customer's site.

17. **NOTICE:** All notices in connection with Customer's order shall be in writing and shall be given by (i) Federal Express or other reputable next day courier service, or (ii) U.S. mail, postage prepaid, certified or registered, return receipt requested, or (iii) in person. Each notice shall be addressed to the party at the address set forth on the face of this Agreement or at such other address as a party shall provide by notice to the other party. Notice shall be deemed effective upon delivery.

18. **WAIVERS:** No waiver shall be effective unless it is in writing. The failure of either party to require performance under any provision of this Agreement shall in no way affect the right of such party to require full performance at any subsequent time, nor shall the waiver by either party of a breach of any provision of this Agreement constitute a waiver of any succeeding breach of the same or any other provision.

19. **SEVERABILITY:** These Terms and Conditions shall be deemed severable and if any portion hereof shall be held to be invalid for any reason, the remainder shall not be deemed invalid but shall remain in full force and effect.

20. **GOVERNING LAW/DISPUTE RESOLUTION:** These Terms and Conditions shall be governed and construed in accordance with the laws of the State in which the Supplier's facility is located, except for its choice of law provisions. The United Nations Convention of the International Sale of Goods shall not apply. The parties shall attempt in good faith to resolve promptly any dispute arising out of or relating to this Agreement by negotiation. If the matter cannot be resolved in the normal course of business either party shall give the other party written notice of any such dispute not resolved, after which the dispute shall be referred to senior executives of both parties, who shall likewise attempt to resolve the dispute.

    If the dispute has not been resolved by negotiation within forty-five (45) days of the party's written notice or of the parties fail to meet within twenty (20) days from such notice, either party may submitted the dispute to arbitration in accordance with the CPR Arbitration Rules and Commentary. A single, impartial arbitrator mutually acceptable to the parties shall conduct the arbitration. In the event the parties cannot agree on an arbitrator within twenty-one (21) days after the end of the aforesaid sixty (60) days, either party may have an arbitrator appointed by the CPR. The location of the arbitration will be in Atlanta, Georgia, unless the parties agree otherwise. As a condition of appointment of the arbitrator, said arbitrator shall agree to use her/his best efforts to conclude the proceeding within sixty (60) days. Said arbitrator shall further have the authority to limit the volume of evidence and documents to be submitted by the parties. Any court having jurisdiction thereof may enter judgment upon the award rendered by the arbitrator.

    This section shall, however, not be construed to limit or to preclude either party from bringing any action in any court of competent jurisdiction for injunctive or other provisional relief as necessary or appropriate.

21. **ANTI-CORRUPTION**: Each party represents that it will not, directly or indirectly, pay, olffer, grant, promise or give, or authorize the payment or grant of, any money or thing of value to any person or entity for the purpose of unlawfully or improperly effecting any decision or obtaining or retaining any business or benefit in connection with these Terms and Conditions. Customer agrees to promptly notify Supplier in writing if at any time Customer becomes aware that its aforementioned representation is no longer accurate. Customer shall promptly notify Supplier of any known or suspected breach of the foregoing representation. Supplier may terminate the Purchase Order without notice if it is proven that Customer has breached any of its obligations under this Section, and in such event Customer is excluded from raising a claim for any damage or other rights on account of such termination.

22. **MODIFICATION:** These Terms and Conditions may not be amended, modified or supplemented at any time except by a written document signed by the parties.

23. **ENTIRE AGREEMENT:** This is the complete and final agreement between the parties related to the subject matter of these Terms and Conditions and supersedes all prior writings, conversations, understandings or agreements.

24. **PARTIES IN INTEREST:** These Terms and Conditions shall be binding upon and inure to the benefit of the parties and their respective successors and assigns.

25. **ASSIGNMENT:** Customer shall not assign Customer's order without the prior written consent of Supplier, which consent may be granted or withheld in the sole discretion of Supplier'

26. **ENFORCEMENT:** Customer shall reimburse Supplier for all costs and expenses (including attorney fees) reasonably incurred in the enforcement of Customer's order and these Terms and Conditions.

27. **BREXIT CLAUSE:**

The Parties acknowledge and agree that due to the United Kingdom's (regardless of which countries comprise the UK at such date) exit from the European Union/ceasing to be a:

(i) member state of the European Union,
(ii) member of the European Economic Area and/or
(iii) member of the EU customs union;
and/or
(iv) the end of any transition period agreed with the European Union (together "Brexit") there may be delays and disruptions due to any Brexit-related change to (or new application of existing) taxes, customs, duties, tariffs, levies, charges or fees, licences or consents or any restriction to trade (not involving a tax or duty) whether foreseen or unforeseen at the date of the Agreement (together, or separately, the "Brexit-related Delay(s)").

The Parties agree that in the event of any delays in delivery of goods or services resulting from a Brexit-related Delay, the respective Party first aware of the Brexit-related Delay shall promptly confirm by notice in writing, by recorded first class post, that such Brexit-related Delay has taken effect (the "Brexit Delay Notice"). From the confirmed date of receipt of the Brexit Delay Notice by the recipient Party, which may be issued by email but on confirmed receipt by the sender Party of the Brexit Delay Notice shall be deemed to have occurred on a date no later than two (2) Business Days from the date of posting, the agreed delivery date shall automatically be extended by: the continued period of the Brexit-related Delay.

28. **QUARANTINE COSTS:**

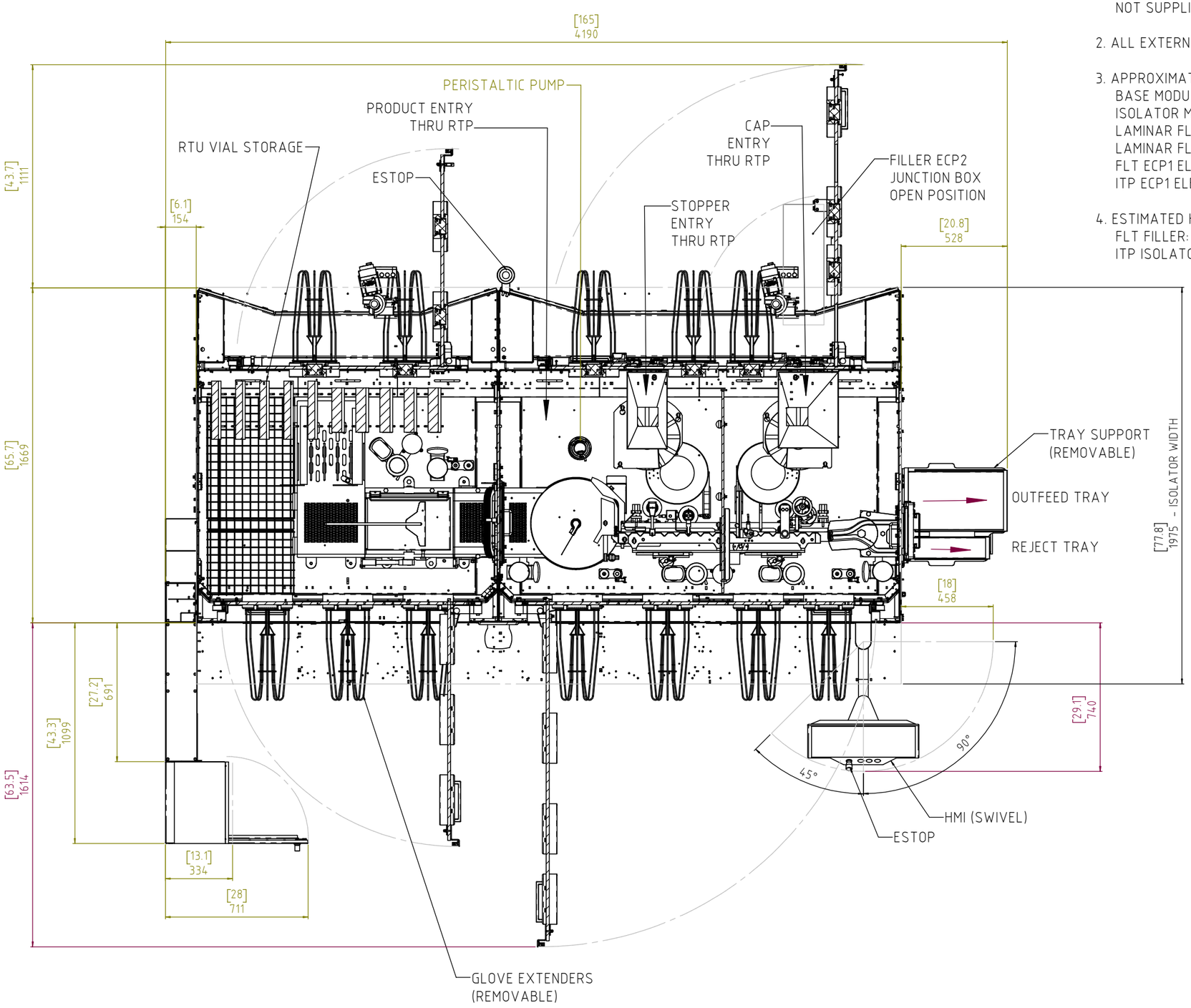
Any additional costs incurred by the Supplier due to the entry regulations in the respective target country for the execution of the works on the subject matter of the contract as well as in the home country upon the return of the Supplier's employees due to the Covid-19 pandemic, in particular increased travel and accommodation costs, loss of earnings during the quarantine, etc. (hereinafter referred to as "Quarantine Costs") are not included in the price calculation of the quotation or the order confirmation. Any and all Quarantine Costs incurred by the Supplier and/or its subcontractor's during the execution of the order shall be for the account of the Customer and reimbursed by the Customer to the Supplier.

29. **FAT and DELIVERY DATES:**

Due to the current critical supply situation, compliance with the agreed dates is subject to timely self-delivery to the Supplier by its sub-suppliers and subcontractors. Both parties are aware that the Supplier is experiencing procurement difficulties with regard to raw materials / parts / components due to a current worldwide supply chain crisis. The parties, therefore, agree that the Supplier shall not be at fault and that there shall be no delay attributable to it insofar as contractual deadlines cannot be met because it is not supplied on time by its suppliers.

The Supplier can only initiate the procurement process with regard to the required raw materials, parts and components after completion of the design process (i. e., after conclusion of this contract), which is why there are no delivery date commitments on the part of the Supplier's sub-suppliers at the time of conclusion of this order. The Supplier shall inform the Customer if the agreed dates have to be postponed due to raw materials / parts / components that cannot be procured in time. For the purpose of continuous review of the delivery situation, the parties agree on a regular exchange.

PLAN VIEW
TOP OF ITP REMOVED TO SHOW DETAIL



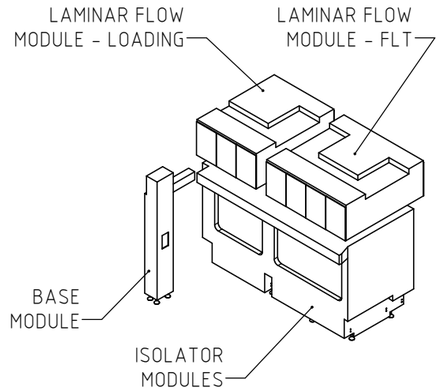
NOTES:
1. UNLESS SPECIFIED OTHERWISE ALL UN-TOLERANCED DIMENSIONS ARE ±25MM (±1.0 IN). ALL DIMENSIONS TO STRUCTURES OR UTILITIES NOT SUPPLIED BY SYNTEGON ARE FOR REFERENCE ONLY.

2. ALL EXTERNAL CONDUITS AND CUTOUTS BY CUSTOMER.

3. APPROXIMATE WEIGHTS:
   BASE MODULE: 200 KG (440 LBS)
   ISOLATOR MODULES: 3900 KG (8600 LBS)
   LAMINAR FLOW MODULE - LOADING: 650 KG (1400 LBS)
   LAMINAR FLOW MODULE - FLT: 800 KG (1800 LBS)
   FLT ECP1 ELEC CABINET: 1000 KG (2200 LBS)
   ITP ECP1 ELEC CABINET: 1600 KG (3500 LBS)

4. ESTIMATED HEAT LOSS DURING OPERATION:
   FLT FILLER: 8850 KJ/HR
   ITP ISOLATOR: 0 KJ/HR

① ACTIVE VIABLE SAMPLING PORT
② NON-VIABLE SAMPLING PORT
③ PASSIVE VIABLE SAMPLING POSITION



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Rev	Change/Aend.	DDMMYYYY	Drawn/Gez.	BWN	DDMMYYYY	Checked/Gepr.	Releas./Freig.	
1_B	CEC	27.10.2022		5770	Updated ITP Model			
1_A	CEC	10.06.2022		5770	Updated Utility Table			
01		22.03.2022		5770	RELEASED			
00		22.03.2022		5770	29.09.2021			see PA Norm 00164 PA Norm 00164 beachten

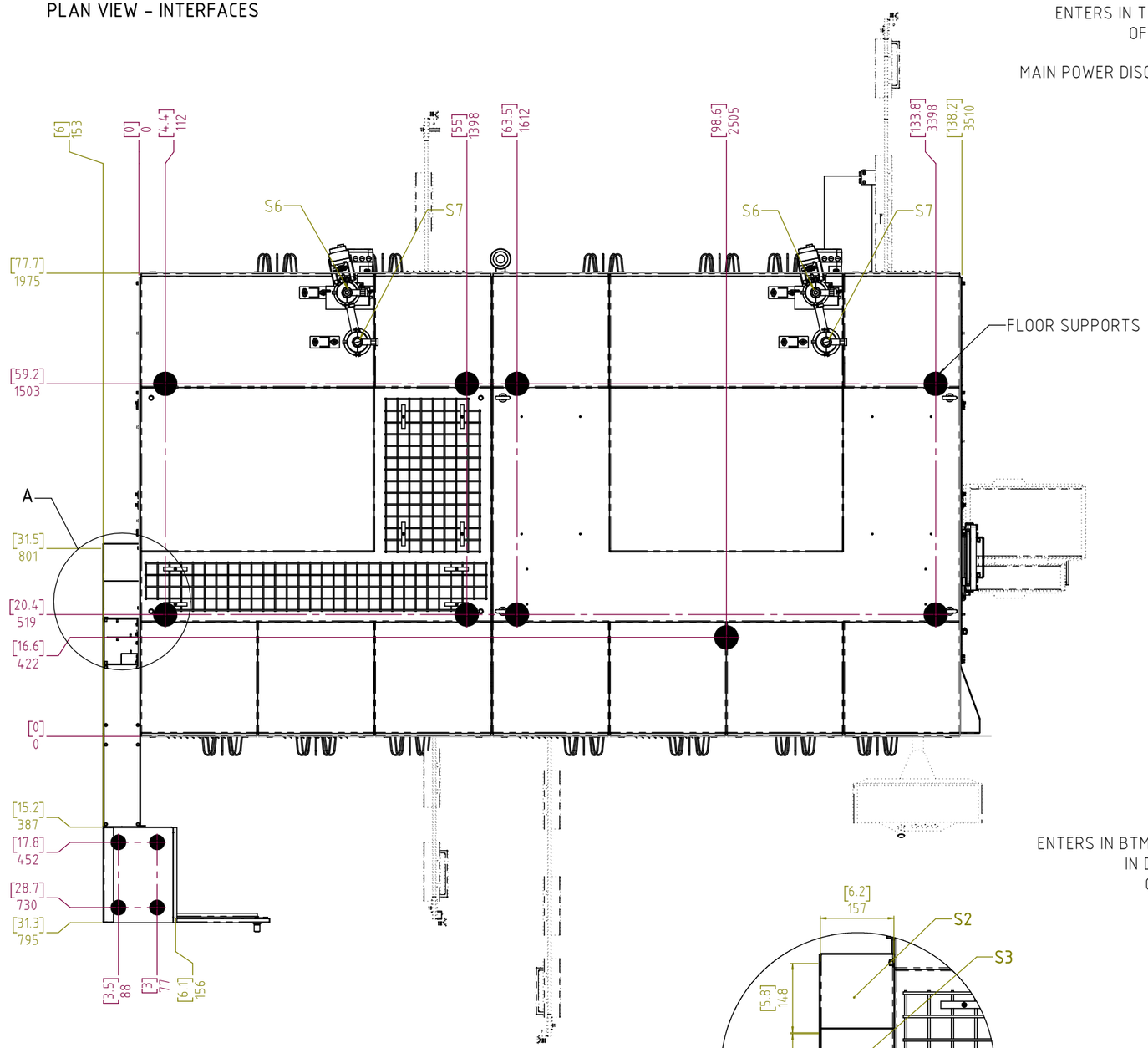
Treatment/ Behandlung: ----------
Material Werkstoff: ----------
Origin/Ursprung
Machine type/Maschinentyp: FLT 1020
Lang./Spr: en/de
Wght/Gew.: 8731.26kg
Scale/M.stab: 1:10
SYNTEGON
Project GA FLT 1020 ITP 4000
Syst.: SW
Doc.type: DRW
Material class
Sheet/Blatt: 1 / 3
DP/TD
Rev.: 1_B
Format: A1

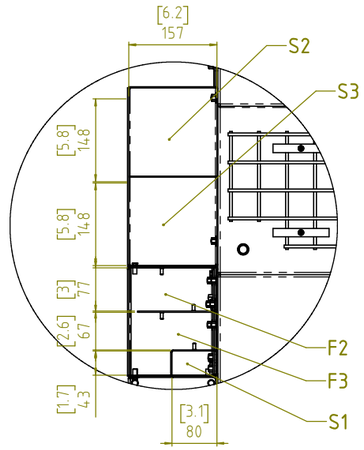
Allgemeintoleranzen für Maße, Form und Lage
General tolerances according to DIN ISO 2768-mH

Nominalm. über / Bereich mm bis	1 6	6 30	30 120	120 400	400 1000	1000 2000	2000 4000
Abmaße in mm	± 0.1	± 0.2	± 0.3	± 0.5	± 0.8	± 1.2	± 2

DIN ISO 13715
Bleche bis 1.5 mm Dicke: +0.3 -0.3
Bleche > 1.5 mm Dicke und alle übrigen Teile: +0.2 -0.5

PLAN VIEW - INTERFACES

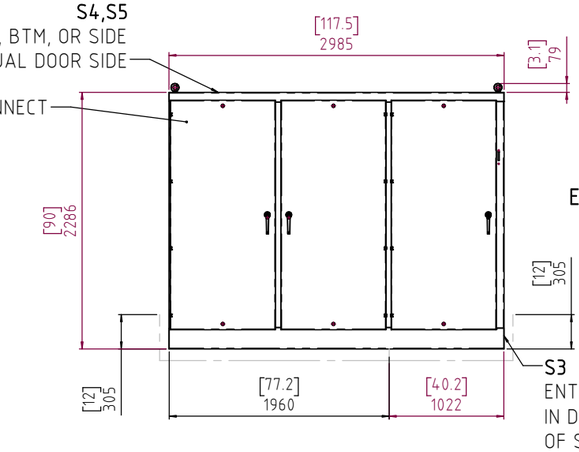




A 1 : 5

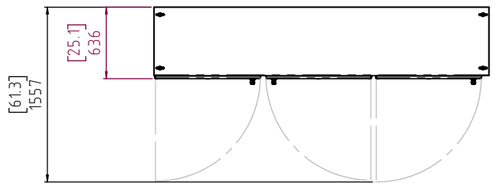
S4,S5
ENTERS IN TOP, BTM, OR SIDE
OF DUAL DOOR SIDE

MAIN POWER DISCONNECT



S3
ENTERS IN BTM OR BTM SIDE
IN DASHED AREA
OF SINGLE DOOR SIDE

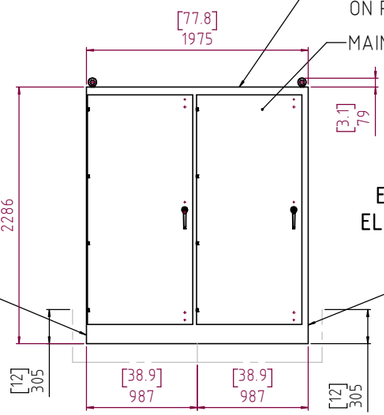
ITP ECP1
ELEC CABINET
ELEVATION VIEW
SCALE 1:25



ITP ECP1
ELEC CABINET
PLAN VIEW
SCALE 1:25

F4
ENTERS IN TOP, BTM, OR SIDE
ON RIGHT HALF

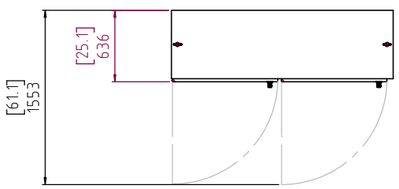
MAIN POWER DISCONNECT



F3
ENTERS IN BTM OR BTM SIDE
IN DASHED AREA
ON LEFT HALF

F2
ENTERS IN BTM OR BTM SIDE
IN DASHED AREA
ON RIGHT HALF

FLT ECP1
ELEC CABINET
ELEVATION VIEW
SCALE 1:25



FLT ECP1
ELEC CABINET
PLAN VIEW
SCALE 1:25

ISOLATOR ITP 4000						
ITEM	DESCRIPTION	CONNECTION SIZE	ELEVATION	PARAMETER 1	PARAMETER 2	PARAMETER 3
S1	PROCESS AIR	1" NPT-M	3098MM (122.0IN)	5.5-10 BAR (80-145 PSI)	100 M^3/HR (60 CFM)	N/A
S2	HIGH VOLTAGE INTERCONNECT	148 X 157MM (5.8 X 6.2IN)	3098MM (122.0IN)	>50V	20M MAX LENGTH	N/A
S3	LOW VOLTAGE INTERCONNECT	148 X 157MM (5.8 X 6.2IN)	3098MM (122.0IN)	<50V	20M MAX LENGTH	N/A
S4	MAIN POWER SUPPLY	DETERMINED BY CUSTOMER	SEE DRWG	480VAC, 3/PE, 60HZ	35A	N/A
S5	UPS	DETERMINED BY CUSTOMER	SEE DRWG	480VAC, 3/PE, 60HZ	25A	N/A
S6	COOLING WATER INLET	1" NPT-F	3940MM (155.0IN)	1 BAR (14.5 PSI)	25 L/MIN (6.6 GPM)	6-12 °C (43-54°F)
S7	COOLING WATER OUTLET	1" NPT-F	3940MM (155.0IN)	1 BAR (14.5 PSI)	25 L/MIN (6.6 GPM)	10-16 °C (50-61°F)
FILLER FLT 1020						
F2	HIGH VOLTAGE INTERCONNECT	77 X 157MM (3.0 X 6.2IN)	3098MM (122.0IN)	>50V	20M MAX LENGTH	N/A
F3	LOW VOLTAGE INTERCONNECT	67 X 157MM (2.6 X 6.2IN)	3098MM (122.0IN)	<50V	20M MAX LENGTH	N/A
F4	MAIN POWER SUPPLY	DETERMINED BY CUSTOMER	SEE DRWG	480VAC, 3/PE, 60HZ	60 A	N/A

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01		22.03.2022		5770	RELEASED			
00		22.03.2022		5770	29.09.2021			see PA Norm 00164 PA Norm 00164 beachten

Treatment/ Behandlung
Material/ Werkstoff
Origin/Ursprung
Machine type/Maschinentyp
Lang./Spr. en/de
Wght./Gew. kg
Scale/M.stab 1:20
Material class
Sheet/Blatt 2 / 3
Syst SW
Doc type DRW
DP/TD
Rev. 1_B
Format A1

SYNTEGON

Encl 90H77.75W24D NE4X SS 2D w/GvPnl

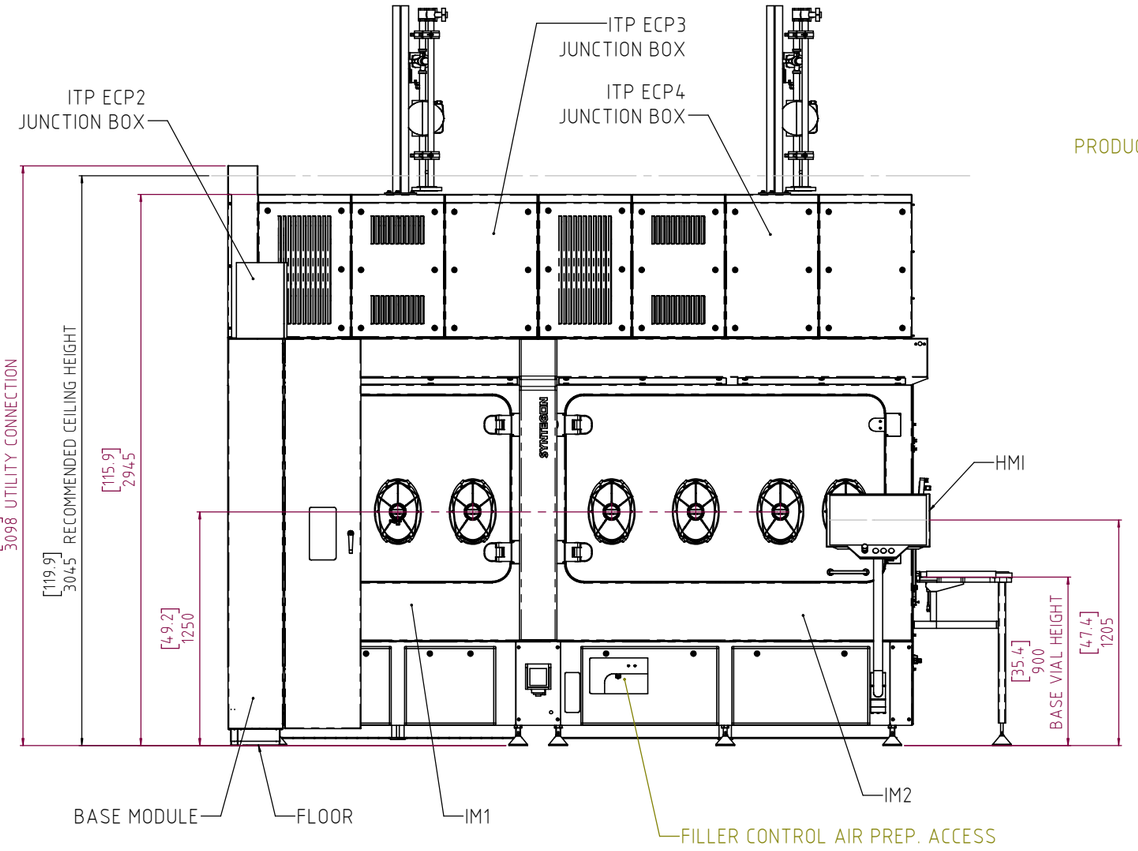
Allgemeintoleranzen für Maße, Form und Lage
General tolerances according to
DIN ISO 2768-mH

Nennmaß	über	1	6	30	120	400	1000	2000
Bereich mm	bis	6	30	120	400	1000	2000	4000
Abmaße in mm		± 0.1	± 0.2	± 0.3	± 0.5	± 0.8	± 1.2	± *

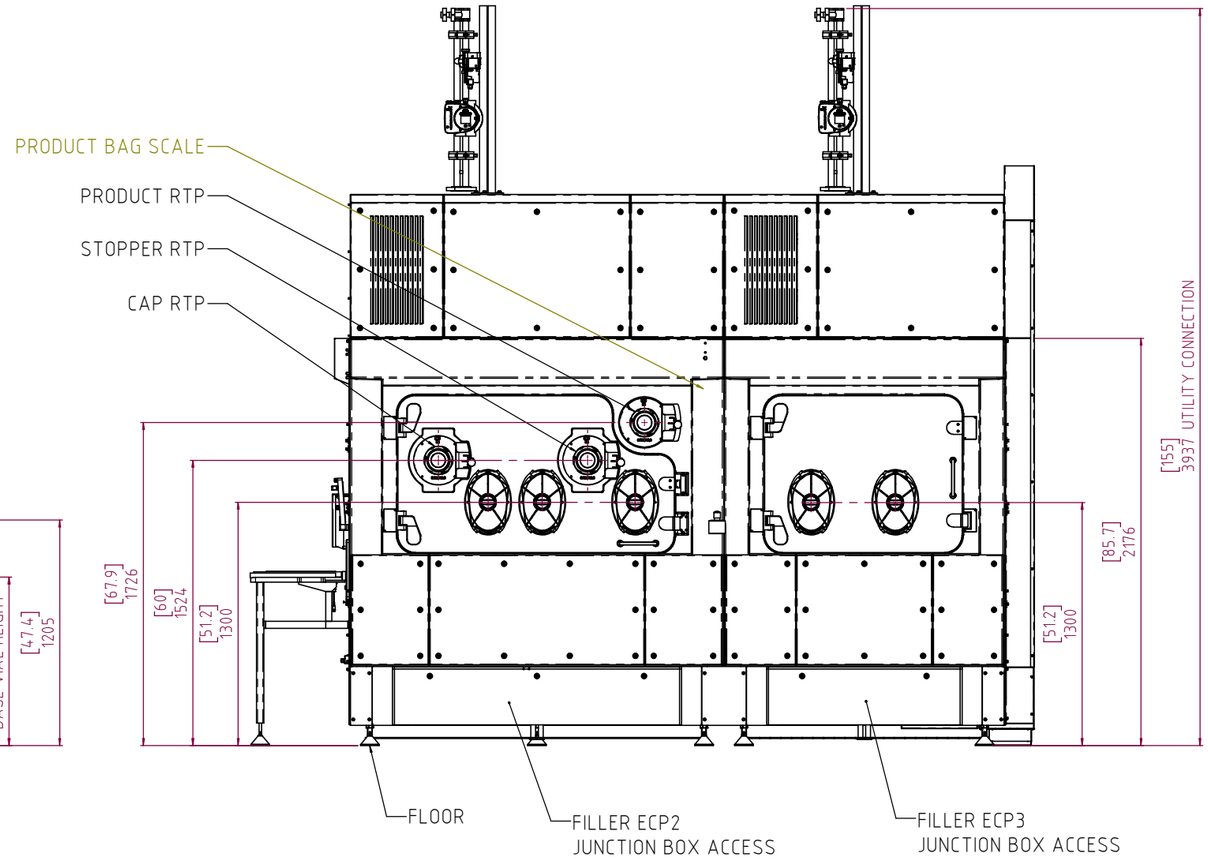
DIN ISO 13715

Bleche bis 1.5 mm Dicke	Bleche > 1.5 mm Dicke und alle übrigen Teile
+0.3 −0.3	+0.2 −0.5

ELEVATION VIEW FRONT



ELEVATION VIEW REAR



NOTES:

1. MACHINE FEET VERTICAL ADJUSTMENT OF +60MM /-20MM IS INCLUDED.

1_B	CEC	27.10.2022		5770	Updated ITP Model
1_A	CEC	10.06.2022		5770	Updated Utility Table
01		22.03.2022		5770	RELEASED
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Rev.	Change/Aend.	DDMMYYYY	Drawn/Gez.	BWN	DDMMYYYY Checked/Gepr. Releas./Freig.

see PA Norm 00164
PA Norm 00164 beachten

Treatment/
Behandlung: ----------

Material
Werkstoff: ----------

Origin/Ursprung

Machine type/Maschinentyp: **FLT 1020**

Lang./Spr.: en/de

Wght./Gew.: **8470.88kg**

Scale/Maßstab: **1:15**

SYNTEGON

Project GA FLT 1020 ITP 4000

Syst.: **SW**

Doc type: **DRW**

DP/TD

Material class

Sheet/Blatt: **3 / 3**

Rev. / Format: **1_B A1**

Allgemeintoleranzen für Maße, Form und Lage
General tolerances according to
DIN ISO 2768-mH

Nennmaß- Bereich mm	über	1	6	30	120	400	1000	2000
	bis	6	30	120	400	1000	2000	4000
Abmaße in mm		± 0.1	± 0.2	± 0.3	± 0.5	± 0.8	± 1.2	± 2

DIN ISO 13715

Bleche bis 1.5 mm Dicke: -0.3 / -0.3

Bleche > 15 mm Dicke und alle übrigen Teile: -0.2 / -0.5

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FLT 1020 + ITP 4000

Installation
Filling and Closing Machine with Isolator

SYNTEGON
PROCESSING & PACKAGING

1. Room Requirements

Environment

ISO Grade 8 or better
Temperature: 21 +/-2 °C
Pressure: Positive to surrounding rooms +/- 5 Pa
Relative Humidity: <60%

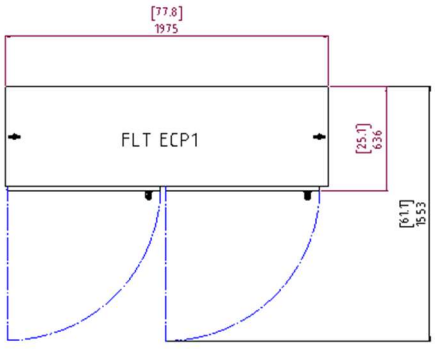
Room conditions (temp, pressure, Rh) must be stable, unaffected by operator activity or activity in surrounding rooms.

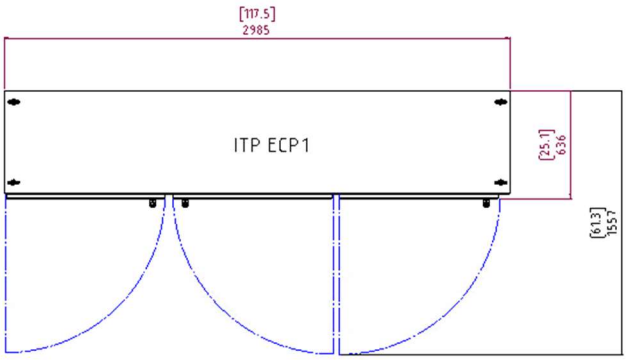
Utilities

Description	Connection Size	Elevation	Parameter 1	Parameter 2	Parameter 3
Process Air	1" NPT-M	3098mm/122in	5.5-10 Bar (80-145 PSI)	100 M^3/Hr (60 CFM)	N/A
Cooling Water Inlet	1" NPT-F	4110mm/162in	1 Bar (14.5 PSI)	25 l/min (6.6 GPM)	6-12 °C (43-54 °F)
Cooling Water Outlet	1" NPT-F	4110mm/162in	1 Bar (14.5 PSI)	25 l/min (6.6 GPM)	10-16 °C (50-61 °F)
Main Power Supply-ITP	By Customer	3098mm/122in	480V 3/PE 60Hz	35A	N/A
Main Power Supply-FLT	By Customer	3098mm/122in	480V 3/PE 60Hz	60A	N/A
UPS-ITP	By Customer	3098mm/122in	480V 3/PE 60Hz	25A	N/A

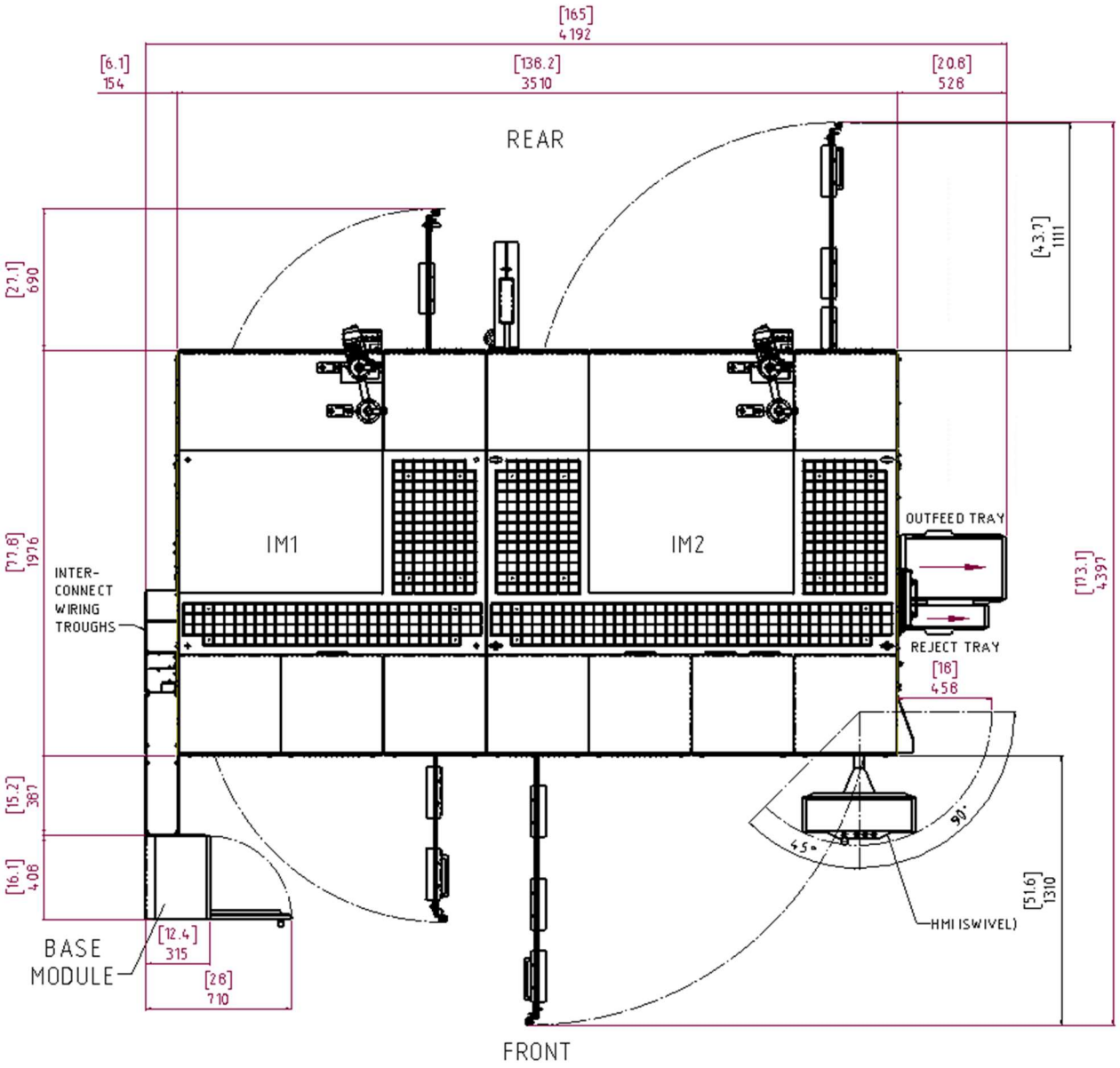
Area

Footprint In Interstitial Space	Electrical Control Panels: FLT 1020 + ITP 4000



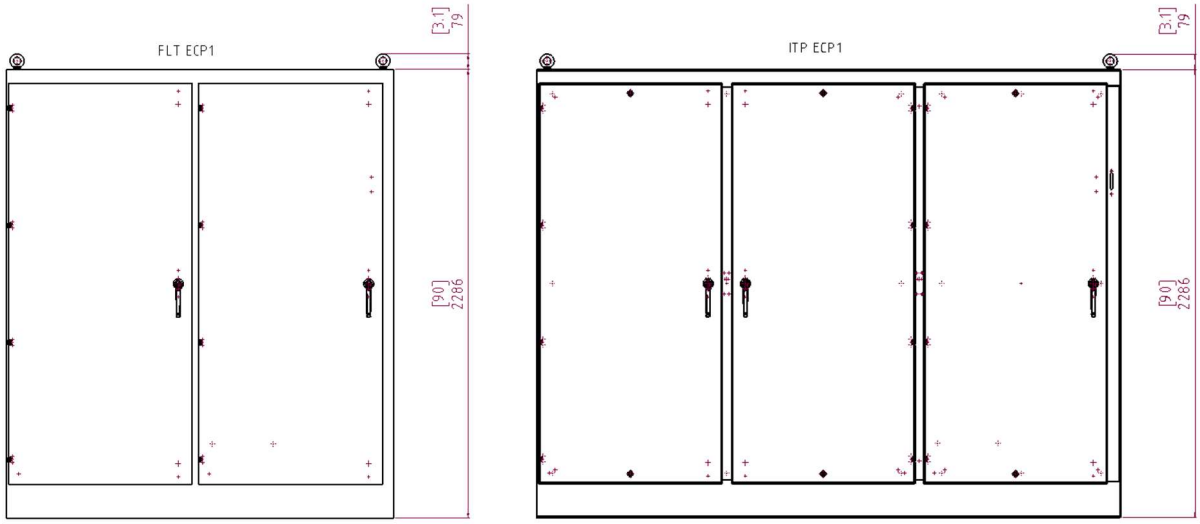


Footprint In Room	FLT 1020 + ITP 4000

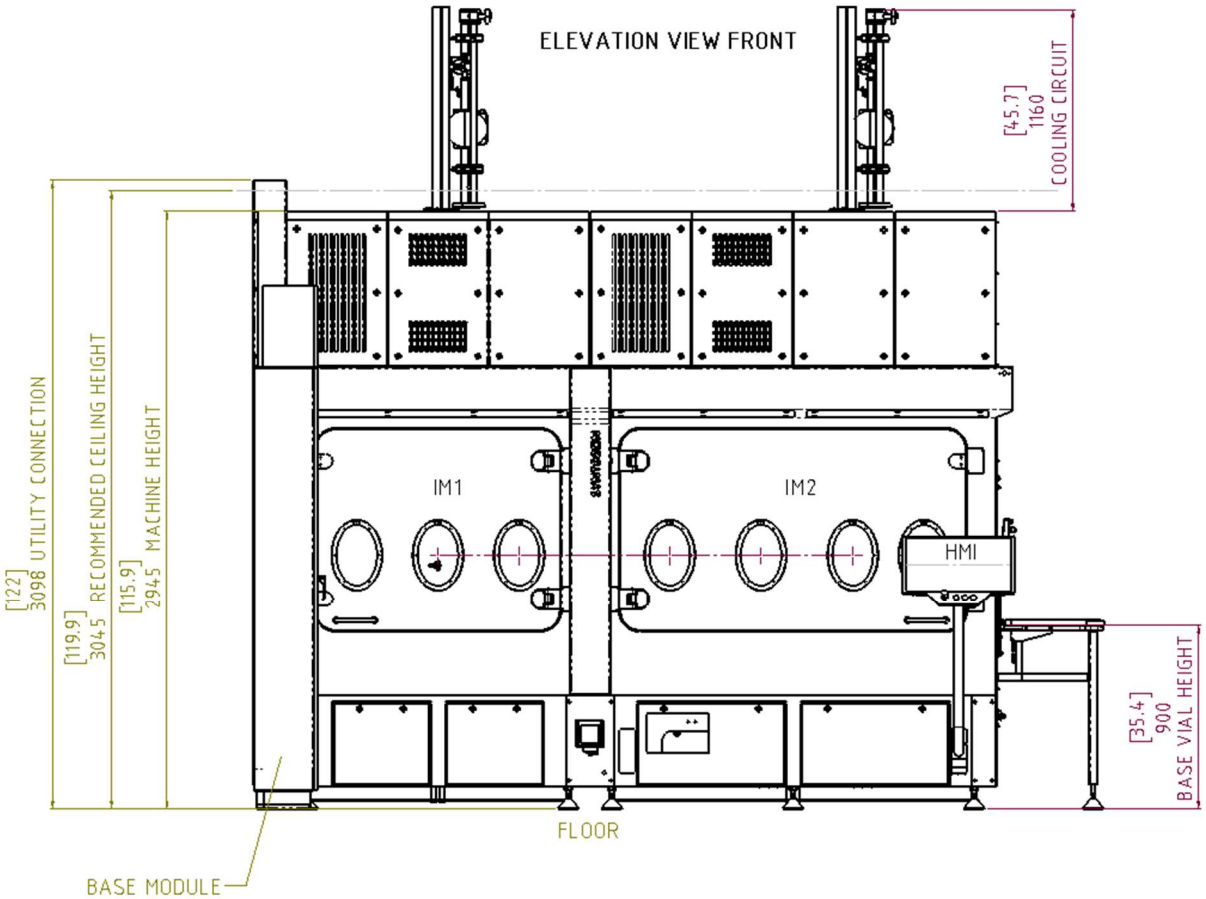


SYNTEGON
PROCESSING & PACKAGING

Ceiling Heights	Electrical Control Panels: FLT 1020 + ITP 4000



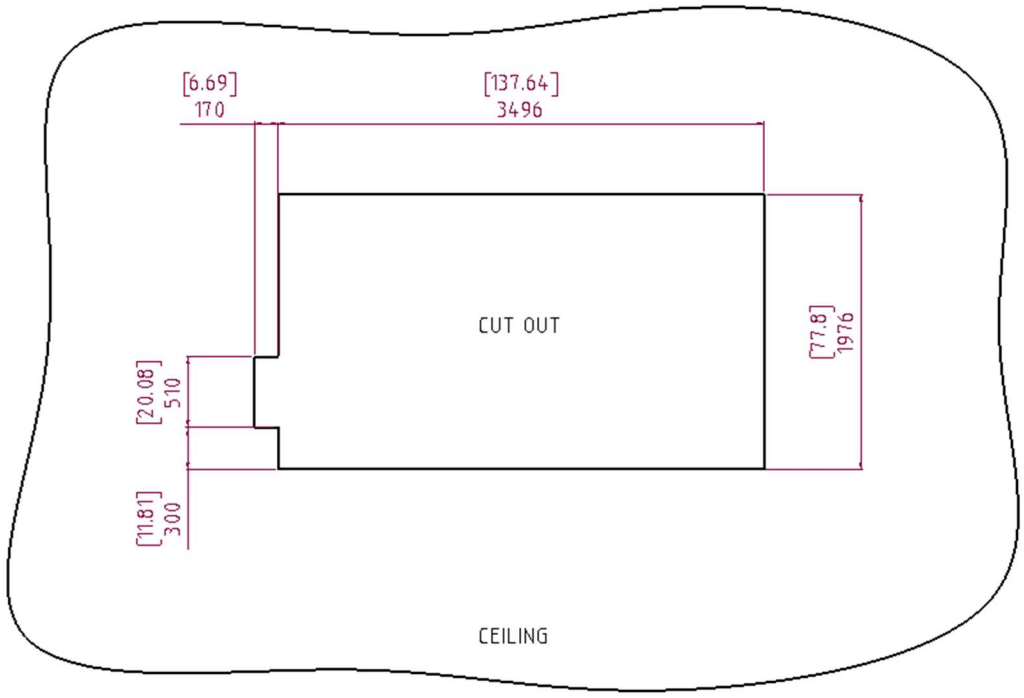
Ceiling Heights	FLT 1020 + ITP 4000

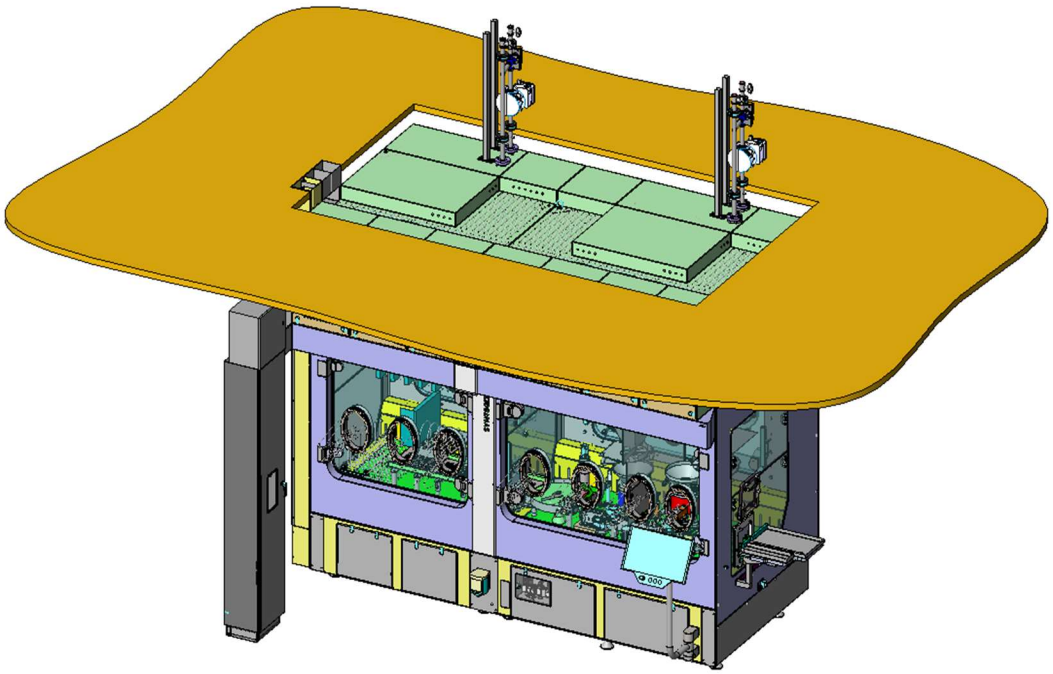


2. Room Preparation

Ceiling Cutout	FLT 1020 + ITP 4000

For ease of installation and for future access to the LF module wiring, it is recommended to make the below cutout in the ceiling above the isolator in preparation for installation:



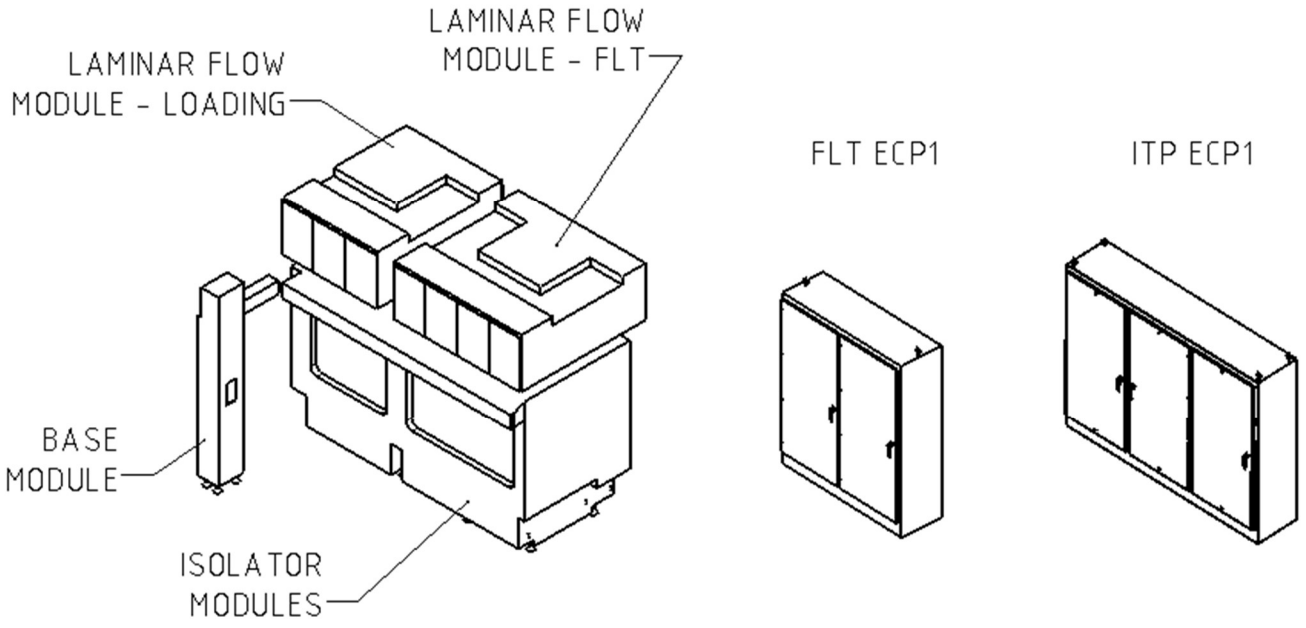


3. Installation

Shipping	

The equipment will be shipped from Syntegon in six pieces, each on its own wooden shipping pallet:

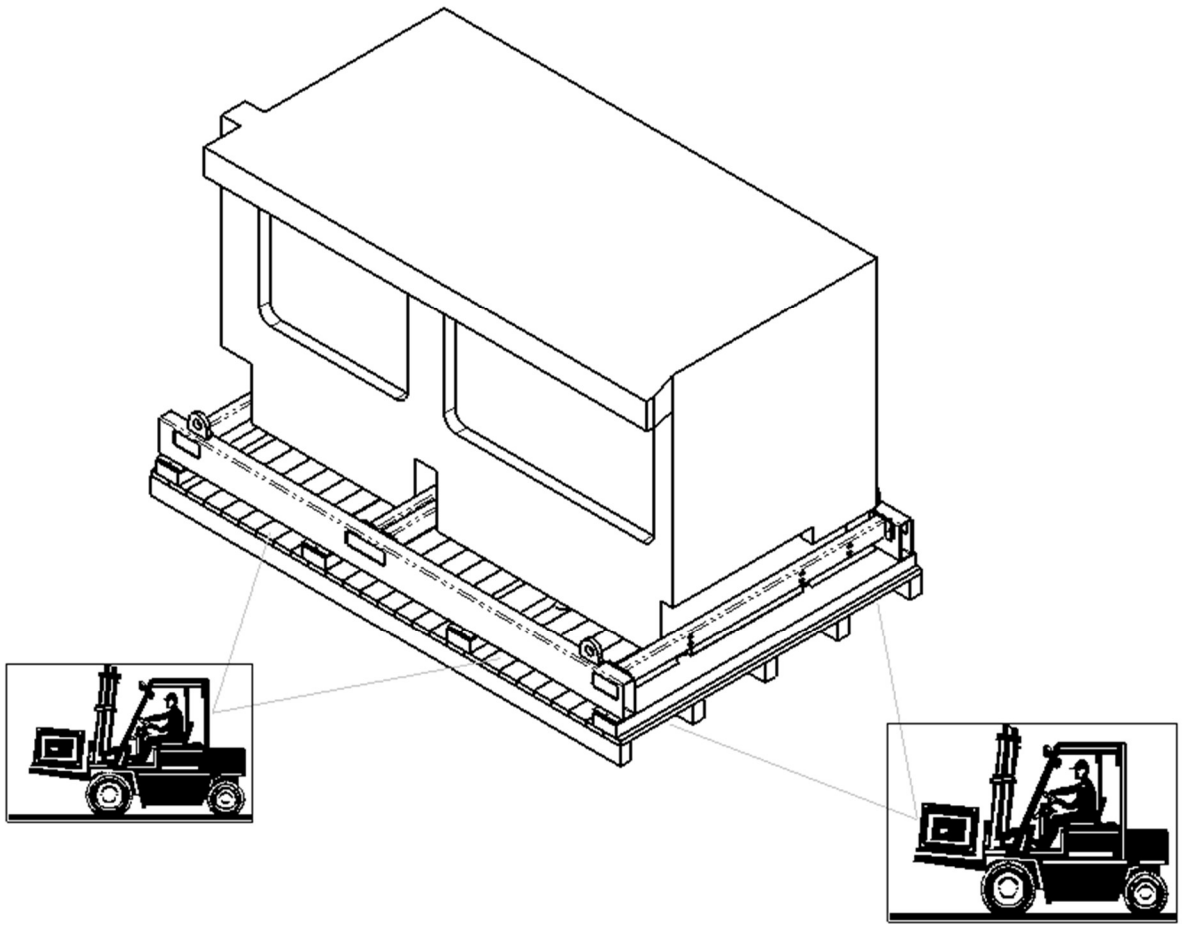
- Base Module
- Isolator Modules
- Laminar Flow Module - Loading
- Laminar Flow Module - FLT
- FLT ECP1
- ITP ECP1



Dimensions, Weight of shipping skids (L x W x H)	FLT 1020 + ITP 4000
Base Module	2800 mm x 1200 mm x 440 mm (110 in x 47 in x 17 in) 200 kg (440 lbs)
Isolator Modules (w transport frame)	3860 mm x 2490 mm x 2565 mm (152 in x 98 in x 101 in) 5400 kg (12000 lbs)
Laminar Flow Module - Loading	2290 mm x 1910 mm x 1170 mm (90 in x 75 in x 46 in) 650 kg (1400 lbs)
Laminar Flow Module - FLT	2290 mm x 2290 mm x 1170 mm (90 in x 90 in x 46 in) 800 kg (1800 lbs)
FLT ECP1	2260 mm x 990 mm x 2656 mm (89 in x 39 in x 101 in) 1000 kg (2200 lbs)
ITP ECP1	3280 mm x 990 mm x 2656 mm (129 in x 39 in x 101 in) 1600 kg (3500 lbs)

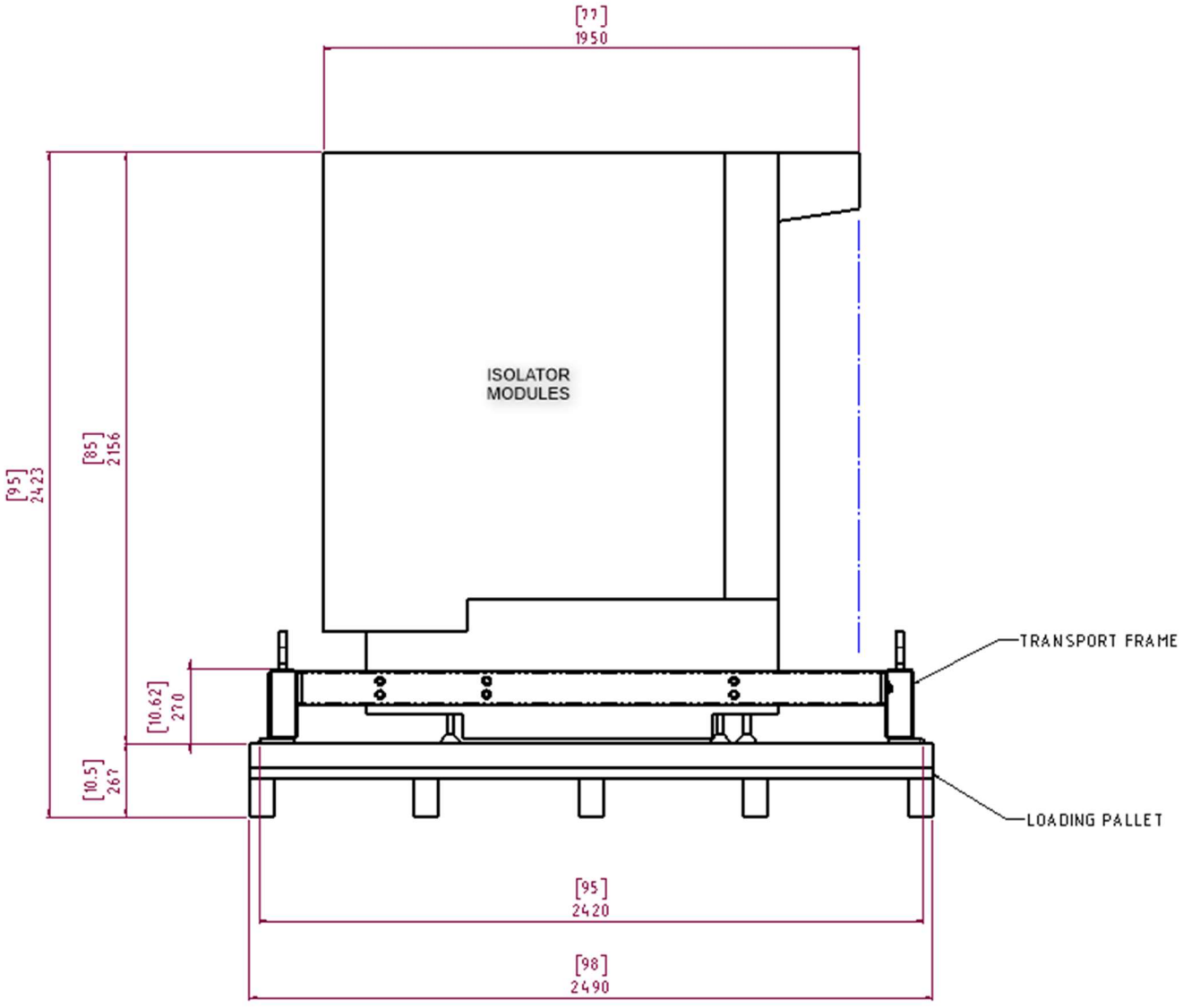
Rigging

It is recommended to use fork trucks and/or skates and toe jacks to lift and move the palletized equipment

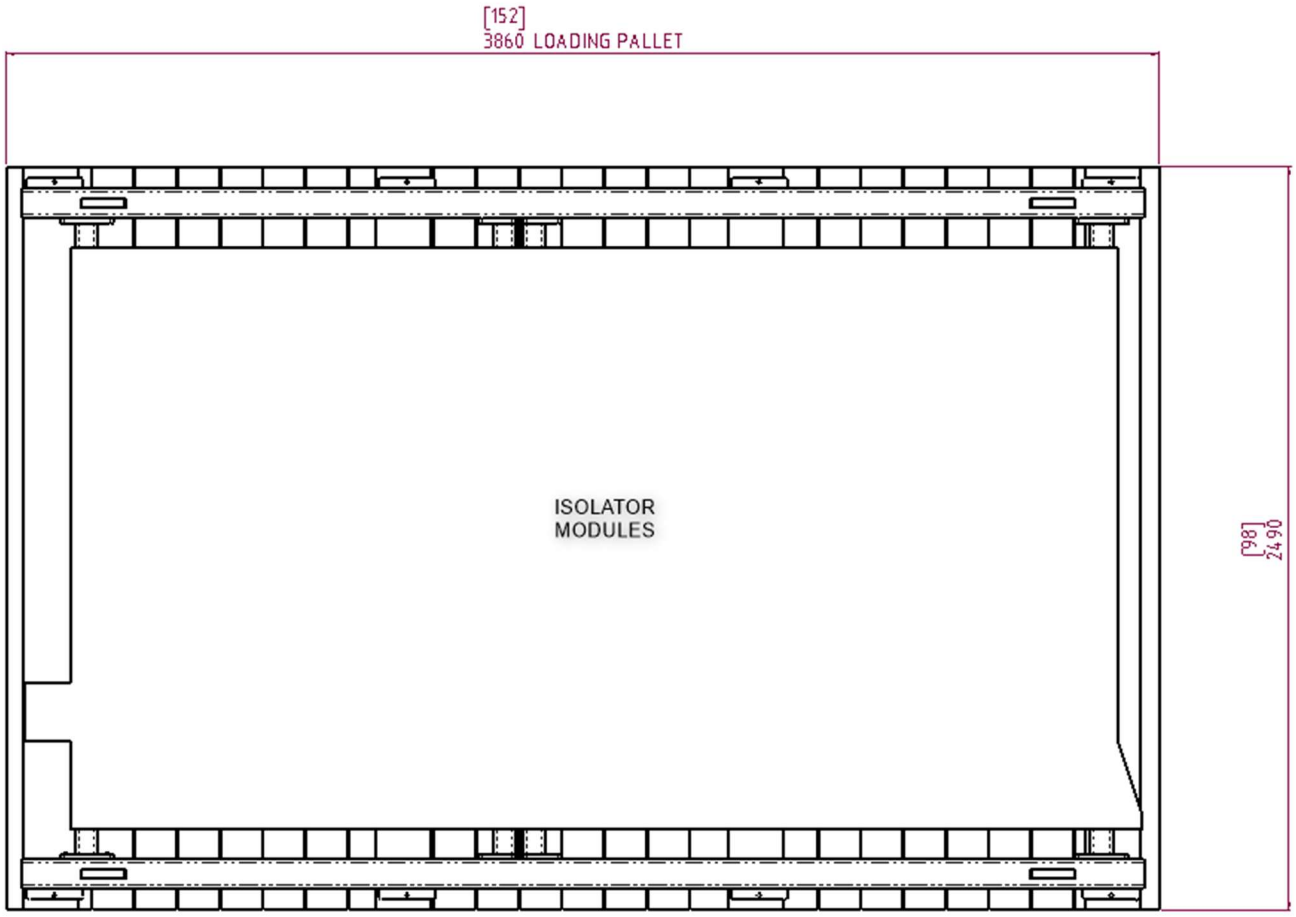


The largest pallet would need to be considered when it comes to determining doorway sizes and hallway access from the receiving point to the final location of the equipment.

Doorway size, minimum (L x H): 2490 mm x 2423 mm (98 in x 95 in) PLUS APPLICABLE CLEARANCE

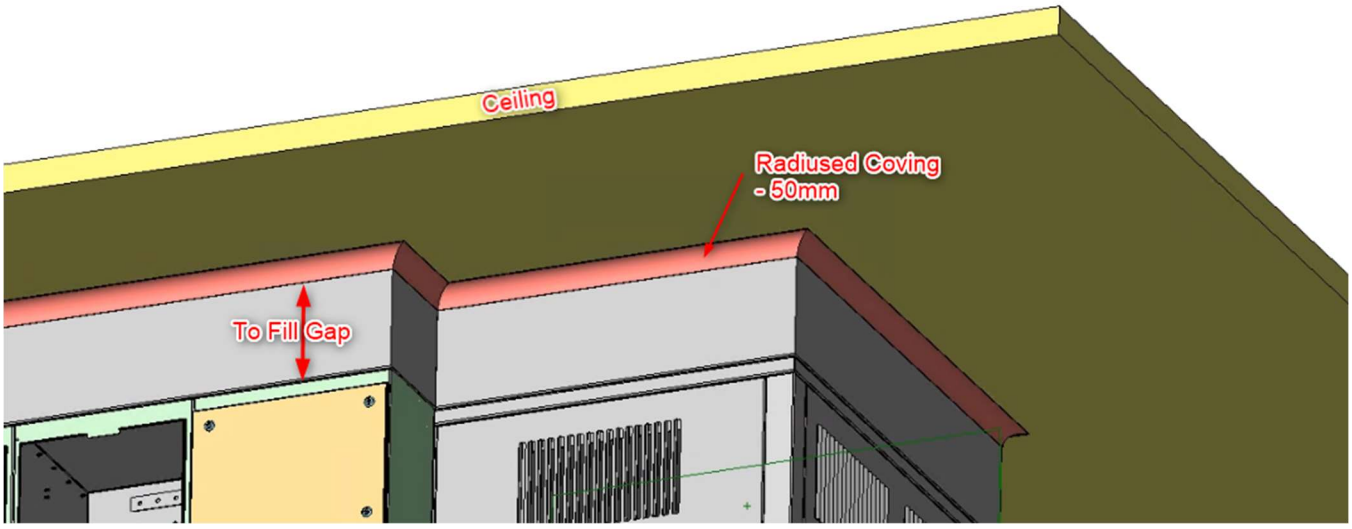


Hallway width (L x W): 2490 mm x 3860 mm (98 in x 152 in) PLUS APPLICABLE CLEARANCE
Particularly consider corners when it comes to determining adequate clearance to move equipment through hallways

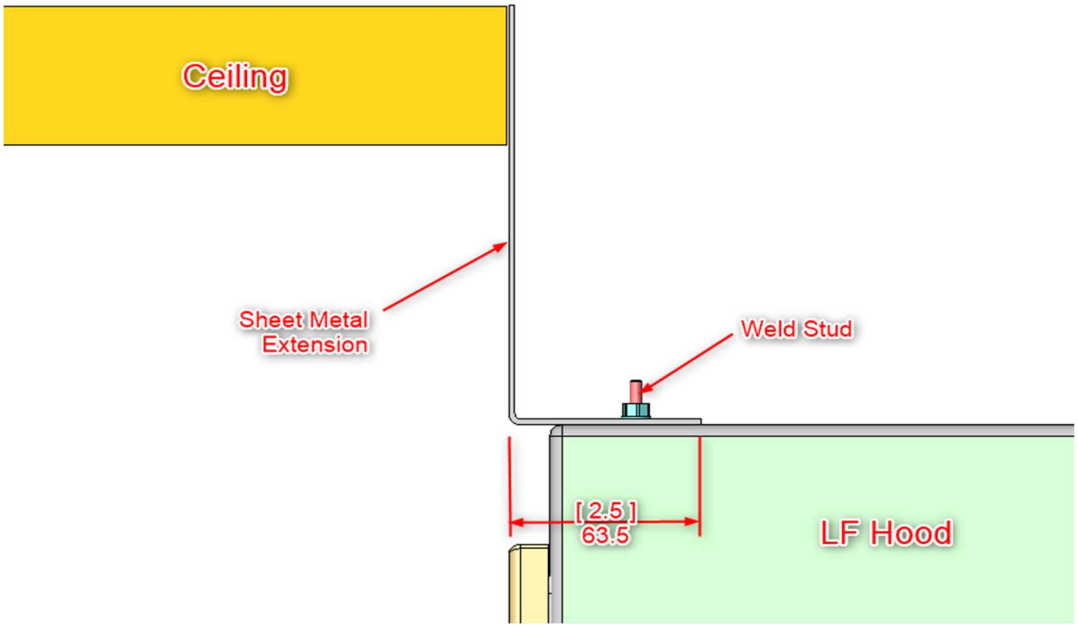


Ceiling Coving	

Once installed, customer is responsible to construct sheet metal extensions to fill the gap between the top of the LF hood and the ceiling using 50mm radiused coving for cleanability or other applicable design:



We suggest constructing the sheet metal extensions with a sufficient flange length and mounting the sheet metal extensions by attaching weld studs to the top of the LF Hood so no penetrations are made into the LF Hood:



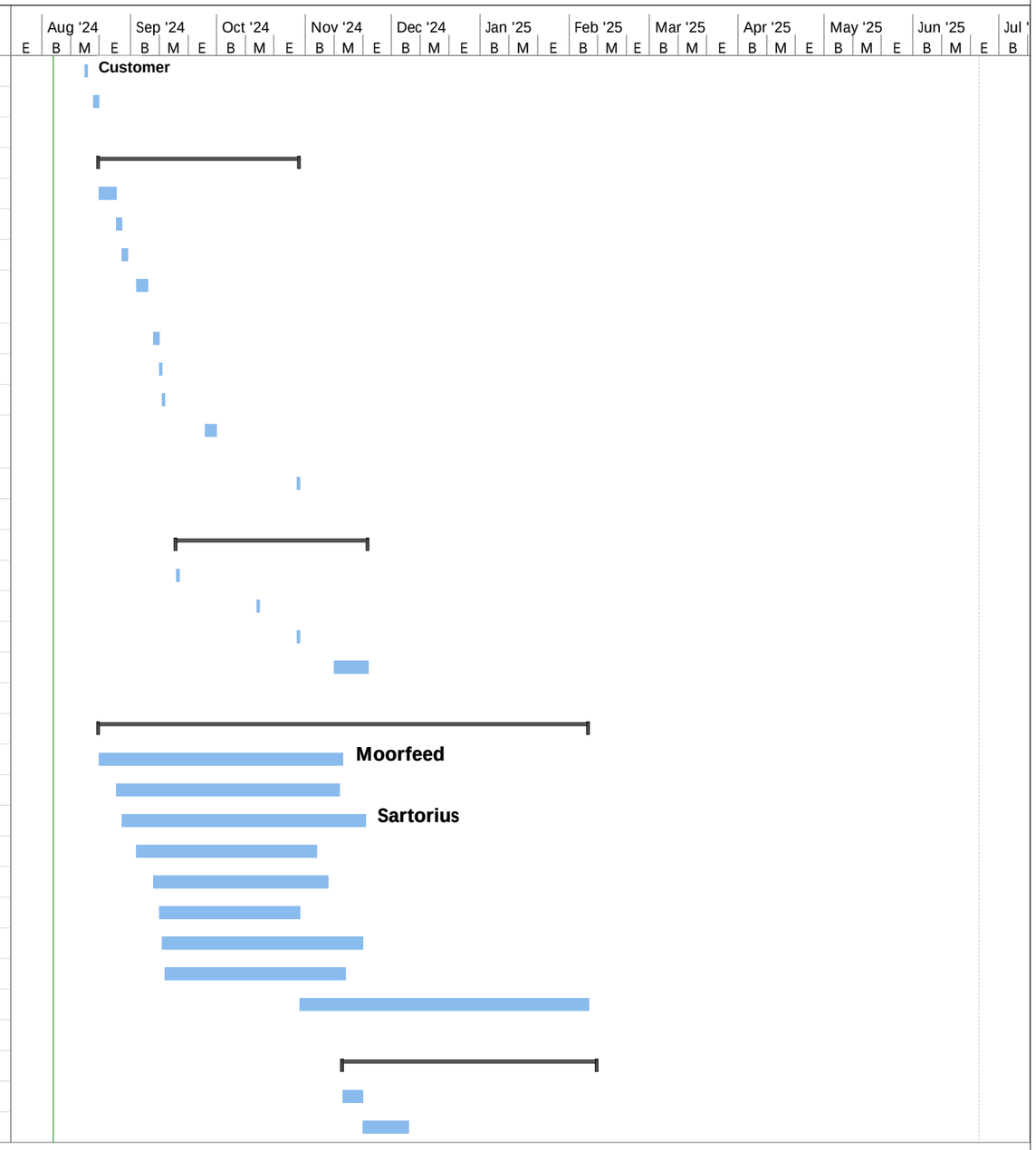
Syntegon Technology Inc.

United States

www.syntegon.com

Preliminary Project Schedule - 2ml, 5ml, 10ml

ID	Task Mode	Task Name	Duration	Start	Finish
1		Receipt of PO & 20mm Commodity Drawings	1 day	Fri 8/16/24	Fri 8/16/24
2		Order Prep / COHO	2 days	Mon 8/19/24	Tue 8/20/24
3					
4		**Mechanical Engineering Tasks**	**49 days**	**Wed 8/21/24**	**Tue 10/29/24**
5		Design 20mm Format Parts	4 days	Wed 8/21/24	Mon 8/26/24
6		Design Technical Sets (need fill volumes)	2 days	Tue 8/27/24	Wed 8/28/24
7		Design 5ml & 10ml Sizeparts (need vial drawings)	2 days	Thu 8/29/24	Fri 8/30/24
8		Design Vial Pack Fixture & Deadplate Guides (need vial pack sizes)	4 days	Tue 9/3/24	Fri 9/6/24
9		Design Tool Holders	2 days	Mon 9/9/24	Tue 9/10/24
10		Release Isolator Spare Filters	1 day	Wed 9/11/24	Wed 9/11/24
11		Release (3) KHD Batteries	1 day	Thu 9/12/24	Thu 9/12/24
12		Update Documentation - FS, PID, SSPL, IM, SPC, Change Part Matrix	2 days	Fri 9/27/24	Mon 9/30/24
13		Release Mechanical Spare Parts	1 day	Tue 10/29/24	Tue 10/29/24
14					
15		**Electrical Engineering Tasks**	**49 days**	**Tue 9/17/24**	**Fri 11/22/24**
16		Set-up New Recipes	1 day	Tue 9/17/24	Tue 9/17/24
17		Update Documentation - Schematics, SDS, IM Screen Shots	1 day	Tue 10/15/24	Tue 10/15/24
18		Release Electrical Spare Parts	1 day	Tue 10/29/24	Tue 10/29/24
19		Disaster Recovery Procedure	10 days	Mon 11/11/24	Fri 11/22/24
20					
21		**Fabrication / Procurement**	**114 days**	**Wed 8/21/24**	**Fri 2/7/25**
22		Fabricate 20mm Bowls	12 wks	Wed 8/21/24	Wed 11/13/24
23		Fabricate 20mm Format Parts	11 wks	Tue 8/27/24	Tue 11/12/24
24		Procure Technical Sets	12 wks	Thu 8/29/24	Thu 11/21/24
25		Fabricate 5ml & 10ml Sizeparts	9 wks	Tue 9/3/24	Mon 11/4/24
26		Fabricate Vial Pack Fixture & Deadplate Guides	9 wks	Mon 9/9/24	Fri 11/8/24
27		Procure Tool Holders	7 wks	Wed 9/11/24	Tue 10/29/24
28		Procure Isolator Spare Filters	10 wks	Thu 9/12/24	Wed 11/20/24
29		Procure (3) KHD Batteries	9 wks	Fri 9/13/24	Thu 11/14/24
30		Procure Mechanical & Electrical Spare Parts	13 wks	Wed 10/30/24	Fri 2/7/25
31					
32		**Assembly / Debug / Test / Ship**	**55 days**	**Thu 11/14/24**	**Mon 2/10/25**
33		Receive / Assemble Parts	5 days	Thu 11/14/24	Wed 11/20/24
34		Debug 2ml, 5ml, 10ml Vials / 13mm & 20mm Stoppers Caps	10 days	Thu 11/21/24	Fri 12/6/24

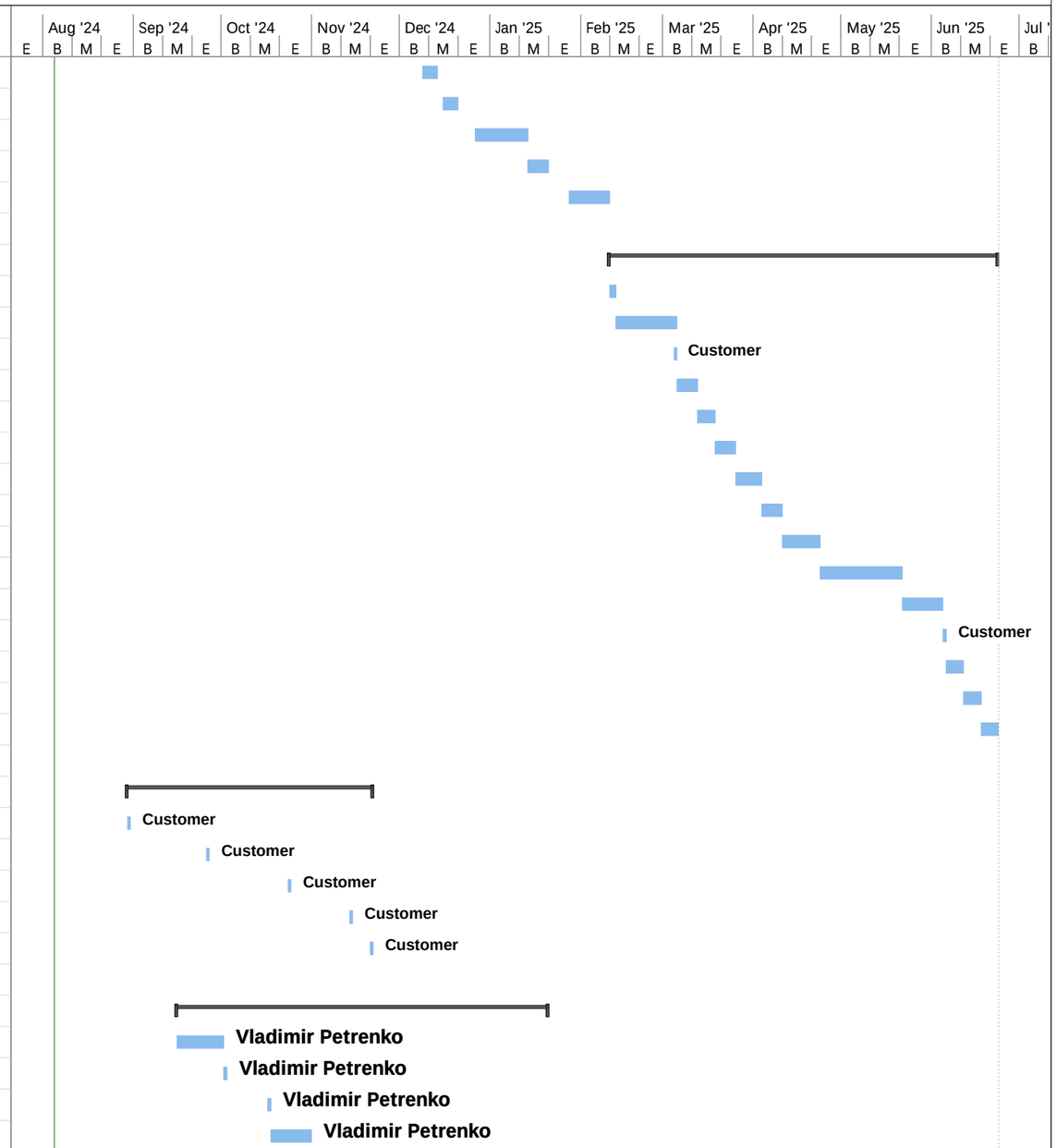


Date: 8/5/2024

Task
Split
Milestone
Summary
Project Summary
Inactive Task
Inactive Milestone
Inactive Summary
Manual Task
Duration-only
Manual Summary Rollup
Manual Summary
Start-only
Finish-only
External Tasks
External Milestone
Deadline
Progress
Manual Progress

Preliminary Project Schedule - 2ml, 5ml, 10ml

ID	Task Mode	Task Name	Duration	Start	Finish
35		Syntegon Internal Testing (SIT) - Execution & Punchlist	5 days	Mon 12/9/24	Fri 12/13/24
36		Customer FAT	5 days	Mon 12/16/24	Fri 12/20/24
37		Alarm / Function Testing (AFT)	10 days	Fri 12/27/24	Mon 1/13/25
38		FAT / AFT Punchlists	5 days	Tue 1/14/25	Mon 1/20/25
39		Teardown / Ship	10 days	Tue 1/28/25	Mon 2/10/25
40					
41		**Onsite Activities**	**93 days**	**Tue 2/11/25**	**Mon 6/23/25**
42		Transit Time to **Customer**	2 days	Tue 2/11/25	Wed 2/12/25
43		Installation - Mechanical & Electrical	15 days	Thu 2/13/25	Wed 3/5/25
44		All Utilities Installed / Functional	1 day	Wed 3/5/25	Wed 3/5/25
45		Start-up	5 days	Thu 3/6/25	Wed 3/12/25
46		Hardware Loop Check Execution (2 technicians)	4 days	Thu 3/13/25	Tue 3/18/25
47		Calibration Execution (2 technicians)	5 days	Wed 3/19/25	Tue 3/25/25
48		SAT (2 technicians)	7 days	Wed 3/26/25	Thu 4/3/25
49		IQ Execution (2 technicians)	5 days	Fri 4/4/25	Thu 4/10/25
50		OQ Execution (2 technicians)	8 days	Fri 4/11/25	Wed 4/23/25
51		Process Development (2 technicians)	20 days	Thu 4/24/25	Wed 5/21/25
52		Process Validation (2 technicians)	10 days	Thu 5/22/25	Wed 6/4/25
53		Media Fill Start	1 day	Thu 6/5/25	Thu 6/5/25
54		Essential Training (2 technicians)	4 days	Fri 6/6/25	Wed 6/11/25
55		Automation Training (1 technician)	3 days	Thu 6/12/25	Tue 6/17/25
56		Process Training (2 technicians)	4 days	Wed 6/18/25	Mon 6/23/25
57					
58		**Commodity Due Dates**	**59 days**	**Fri 8/30/24**	**Thu 11/21/24**
59		Engineering Samples Including Stoppers & Caps	1 day	Fri 8/30/24	Fri 8/30/24
60		Stopper & Cap Debug Commodities for Bowl Supplier	1 day	Thu 9/26/24	Thu 9/26/24
61		Debug Commodities	1 day	Thu 10/24/24	Thu 10/24/24
62		SIT Commodities	1 day	Thu 11/14/24	Thu 11/14/24
63		FAT Commodities	1 day	Thu 11/21/24	Thu 11/21/24
64					
65		**Validation Documents**	**83 days**	**Mon 9/16/24**	**Mon 1/20/25**
66		Project Quality Plan (PQP)	12 days	Mon 9/16/24	Tue 10/1/24
67		Submit PQP to **Customer**	1 day	Wed 10/2/24	Wed 10/2/24
68		Qualification Workshop in Mpls with **Customer**	1 day	Thu 10/17/24	Thu 10/17/24
69		FAT Protocol	10 days	Fri 10/18/24	Thu 10/31/24

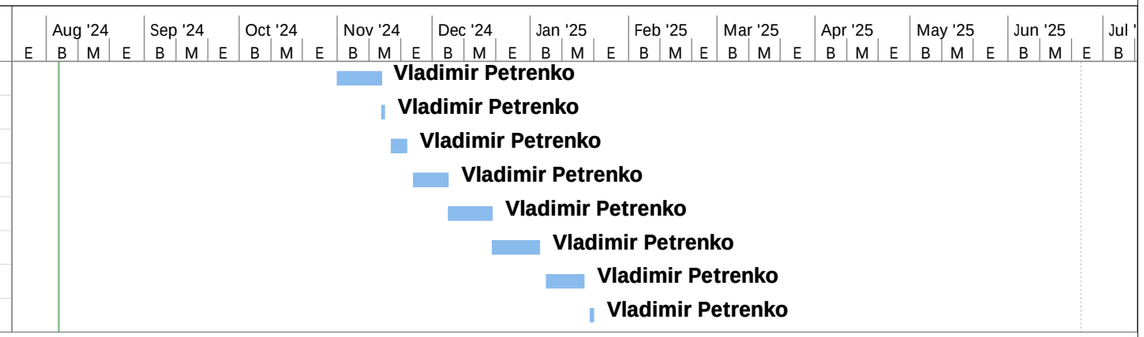


Date: 8/5/2024

Task	Project Summary	Manual Task	Start-only	Deadline
Split	Inactive Task	Duration-only	Finish-only	Progress
Milestone	Inactive Milestone	Manual Summary Rollup	External Tasks	Manual Progress
Summary	Inactive Summary	Manual Summary	External Milestone	

Preliminary Project Schedule - 2ml, 5ml, 10ml

ID	Task Mode	Task Name	Duration	Start	Finish
70		AFT Protocol	10 days	Fri 11/1/24	Thu 11/14/24
71		Submit FAT & AFT Protocols to **Customer**	1 day	Fri 11/15/24	Fri 11/15/24
72		Hardware Loop Check Protocol	5 days	Mon 11/18/24	Fri 11/22/24
73		Calibration Protocol	7 days	Mon 11/25/24	Thu 12/5/24
74		SAT Protocol	10 days	Fri 12/6/24	Thu 12/19/24
75		IQ Protocol	5 days	Fri 12/20/24	Fri 1/3/25
76		OQ Protocol	10 days	Mon 1/6/25	Fri 1/17/25
77		Submit HWL, CAL, SAT, IQ & OQ Protocols to **Customer**	1 day	Mon 1/20/25	Mon 1/20/25



Date: 8/5/2024

Task	Project Summary	Manual Task	Start-only	Deadline
Split	Inactive Task	Duration-only	Finish-only	Progress
Milestone	Inactive Milestone	Manual Summary Rollup	External Tasks	Manual Progress
Summary	Inactive Summary	Manual Summary	External Milestone	