Document Type	Functional Specification (FS)
Equipment	Collection Kit Packaging Line

Approvals

	Name	Title
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Revision Author:		N/A (initial release)

Version	Author	Description
A.0.0	S Bennett	ORIGIN
A.1.1	S Bennett	Issued

Contents

COMPANY CONFIDENTIAL

1. Purpose

This Functional Design Specification (FDS) document was generated for the purpose of specifying the user requirements for collection kit packaging line.

Suitable equipment and systems will be provided for the collection kit packaging line within this document. This URS will describe the equipment and interfaces necessary for the required integration of the associated system.

2. Objective

The objective of this document is to describe what the collection kit packaging line must do and the specifications to which the automated system must conform. This Functional Design Specification document will serve as the basis for final design of the manufacturing system as well as a guide for system qualification and validation.

3. Scope

This document is for the design of the collection kit packaging line detailed in this document.

4. Acronym List and Definitions

4.1. Acronyms

AC	Air Changes
AHU	Air Handling Unit
ANSI	American National Standards Institute
BS EN	British Standard European Norm
C	Centigrade
CE	Conformité Européenne
CFM	Cubic Feet per Minute
CTF	Critical to Function
E-Stop	Emergency Stop
EU	European Union
FAT	Factory Acceptance Test
FD	Fabrication Drawing
FDS	Functional Design Specification
ft^3	Cubic Feet
HDPE	High Density Polyethylene
HEPA	High Efficiency Particulate Air
HMI	Human Machine Interface
IO	Input Output
IQ	Installation Qualification
ISO	International Standards Organisation
L	Litre
LBLD	Labelled
M	Metre
Mm	Millimetres
MMF	Manchester Manufacturing Facility
NIST	National Institute of Standards and Technology
NPT	National Pipe Thread

OCV	Optical Character Verification
OEE	Overall Equipment Efficiency
OIT	Operator Interface Terminal
OQ	Operational Qualification
Pa	Pascal
PLC	Programmable Logic Controller
PQ	Performance Qualification
PSI	Pounds per Square Inch
QCS	Quality Control Specification
PPM	Parts Per Minute
RFID	Radio Frequency Identification
RH	Relative Humidity
SAT	Site Acceptance Test
TBD	To Be Determined. Information will be updated in future document revision.
TFZ	Template Free Zone
UK	United Kingdom
URS	Functional Design Specification
V	Volts

5. Product Description

The system will consist of a complete turn-key system that will be used to feed, flow wrap, print, inspect and check weigh various product configurations. It will also erect kit boxes, print, inspect, and load them with corresponding wrapped products. Finished kit boxes will be check weighed.

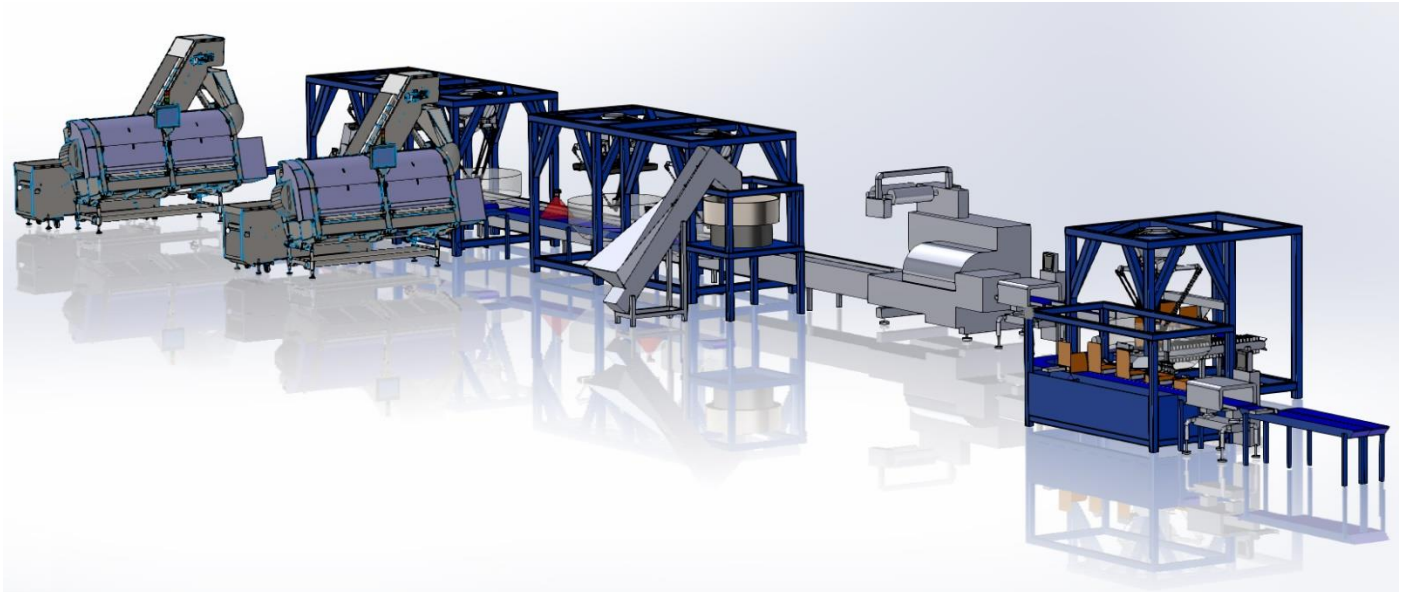
NOTE: (Processes noted above may not necessarily reflect final system configuration). The planned location for this unit is Manchester Manufacturing.

6. Reference Documentation

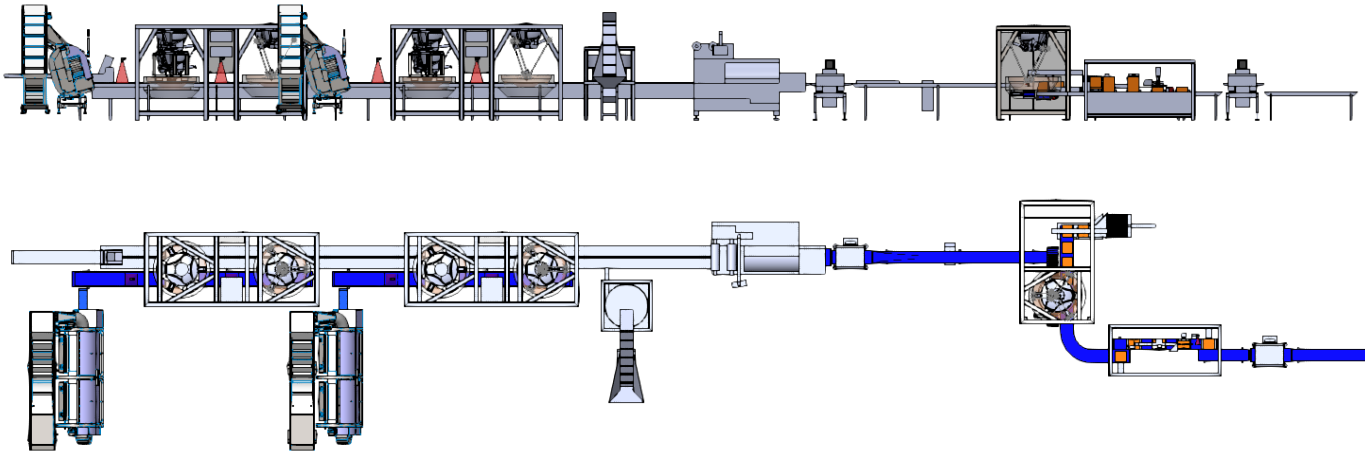
Note: Refer to Appendices for pertinent sections of actual documents.

Document Type	Title	Appendices No.	Document Number
URS	User Requirement Specification for Collection Kit Packaging at Hologic UK	Appendix 1	DRD-07241_001_01

7. System Overview



Overall dimensions of each line:



Length	31500mm
Width	5700mm
Overall Height	2600mm
Working Height	650mm

The system will consist of a complete turn-key system that will be used to feed, flow wrap, print, inspect and check weigh various product configurations. It will also erect kit boxes, print, inspect, and load them with corresponding wrapped products. Finished kit boxes will be check weighed.

The line will consist of bespoke equipment designed and manufactured specifically for this application integrated with generic equipment where required. The different sections will be integrated into a seamless control architecture as to allow global control.

This Functional Design Specification will describe the operation of each section as it is positioned in the logical operation of the line. For convenience, the Relevant references of the URS are included in this document and unless stated otherwise this FDS complies with those references.

NOTE: (Processes noted above may not necessarily reflect final system configuration). The planned location for this unit is Manchester Manufacturing.

8. User Requirements

Process Requirements

UR Category	UR#	User Requirement
Process	**10.1**	There shall be a means to flow wrap each pack configuration (ref. Sec. 6) at a rate of 100 - 150 ppm. NOTE: There shall be one universal pack size that all part configurations fit in. * Final pack size now confirmed as being nominal size: 2” W x 9.75” L
Process	**10.2**	Swabs, Backing cards, pipettes, pre-filled tubes and Brushes will be automatically loaded onto the infeed conveyor.

UR Category	UR#	User Requirement
Process	**10.3**	There shall be a means to automatically feed a Backer Card, Transport Tube and Pipette into the flow wrapper to support the product output speed of the flow wrapper (Ref. item 10.1). Every flight /position on the flow wrapper infeed conveyor must have a complete component group to be flow wrapped. (See pack configurations Sec. 6). NOTES: All components must be oriented lengthwise in flow wrap pack and, can be oriented 0° or 180°. (i.e.: Transport tube can have the cap leading or trailing in the pack). Backer card must be on the inside bottom against the fin seal side of the pack. Other components can be placed on top of the backer card. Final backer card dim's (TBD). Tentative nominal size: ~.01" x ~1.5" x ~8" (~2.54 x ~38.1 x ~203.2 mm)
Process	**10.4**	There shall be a means to safely, easily and efficiently load components into the feeders.
Process	**10.5**	Feeders must be able to accept components loaded in a bulk non-oriented format.
Process	**10.6**	Packs shall not be formed in the absence of components. (i.e.: empty infeed conveyor position/flight)
Process	**10.7**	The flow wrapper shall be able to run the specified film: 120 gauge OPP.
Process	**10.8**	There shall be a print registration feature on the flow wrapper machine.
Process	**10.9**	Packs must be devoid of excessive air by implementing pinhole venting. Pinhole vents are preferred to be near the fin seal.
Process	**10.10**	All seals on packs must be complete, consistent and without wrinkles or bunching. Pack seals do not need to be Hermetic.
Process	**10.11**	End seals on packs shall be "zig-zag" cut. (No tear notch required).
Process	**10.12**	There shall be a means to automatically print text (via Thermal Transfer) on every pack including, Lot, Date, 2D barcode & Human readable text. (2D barcodes are not serialized). *Print layout to be determined by Hologic.

UR Category	UR#	User Requirement
Process	**10.13**	Printer must be compatible with easy label software.
Process	**10.14**	Print must be abrasion resistant, clear and legible to the naked eye.
Process	**10.15**	Print to be black in colour.
Process	**10.16**	Inspection frequency for production: 100% There shall be a barcode verifier to automatically inspect the 2D barcode on every pack. Pass & Fail limits must be consistent with ISO/IEC 15415 & GS1 standards. Verifier must also have the ability to store inspection data logs that can be downloaded by an operator. **NOTE:** No vision inspection required for human readable text or symbols.
Process	**10.17**	There shall be a means to automatically reject packs with failed or missing 2D barcodes.
Process	**10.18**	There shall be a means to automatically check weigh every pack at a rate to support the product output speed of the flow wrapper (as determined from item 10.1).
Process	**10.19**	Checkweigher must have a program for each product configuration. **NOTE:** Liquid fill in Transport Tubes can vary +/- 7% but is more consistent within each lot. Checkweigher must be able to be easily calibrated to the specific liquid fill amount in a particular lot so as not to mask the presence or absence of other components in the pack. We suggest operator's tare or calibrate the checkweigher with a filled tube from the lot to be packaged. The pass/fail tolerances should be a fixed percentage (in the software program) of the tared weight. Variation of weights from the other components are expected to remain consistent enough to enter as a fixed value in each product program configuration.
Process	**10.20**	System must automatically reject packages where component quantity is not correct for its specific configuration.
Process	**10.21**	The system must include a means to automatically erect flat folded kit boxes at a rate to support the product output speed of the flow wrapper (as determined from item 10.1).
Process	**10.22**	There shall be a means to safely, easily and efficiently load flat folded kit boxes into the box erector machine in a bulk format.

UR Category	UR#	User Requirement
Process	**10.23**	There shall be a means to automatically load (50) flow wrapped packs into each erected kit box. **NOTES:** Careful consideration must be taken when designing the loading methodology of packs into the kit box. They could pyramid or pile up in such a fashion where they could be prone to falling out during loading or conveyance. Depending how they are loaded, it may be necessary to include a means to contain packs within the box throughout the line. If needed, containment devices must be included on the system. A device to evenly settle and/or gently press the group of packs down in the box after loading might be acceptable but, must be presented and approved by Hologic before build phase.
Process	**10.24**	All wrapped packs must be oriented inside the kit box parallel to each other laying lengthwise side to side (Ref. photo Sec. 6) with all the pack texts facing up and in the same orientation. No criss-crossed packs or packs sticking out of the kit box are acceptable.
Process	**10.25**	There shall be a reserved location and integration means on the system for an automatic feeder to insert (1) pre-folded business card information leaflet (IN0143) (ref. sec. 6) into every kit box on top of the flow wrapped packs. The business card information leaflet is nominally 2" x 3 ½" (50.8 x 88.9mm). Hologic requests an option in the system quote for a machine to automatically feed inserts into every kit box. Should Hologic choose not to include the feeder at time of order but rather request the feeder be retro-fit at a later date, the reserved location and integration means will be available to integrate it into the system.
Process	**10.26**	The machine shall have the capability to produce completed kit boxes at a rate to support the product output speed of the flow wrapper (as determined from item 10.1). **NOTE:** Completed means erected kit box, loaded w/ 50 flow wrapped packs in the correct orientation.
Process	**10.27**	There shall be a means to automatically print Lot, Date, 2D barcode and Human readable text on the back of every kit box. Printer must be self- cleaning so the print head does not dry out or clog. *Print layout to be determined by Hologic.
Process	**10.28**	Print to be black in colour.
Process	**10.29**	Print must be fast dry (within 2 seconds), abrasion resistant, clear and legible to the naked eye.

UR Category	UR#	User Requirement
Process	**10.30**	Inspection frequency for production: 100% There shall be a barcode verifier to automatically inspect the 2D barcode on every kit box. Pass & Fail limits must be consistent with ISO/IEC 15415 & GS1 standards. Verifier must also have the ability to store inspection data logs that can be downloaded by an operator. **Note:** No vision inspection required for human readable text or symbols.
Process	**10.31**	There shall be a means to automatically reject kit boxes with failed or missing 2D barcodes.
Process	**10.32**	There shall be a means to automatically check weigh every kit box to verify the proper quantity of components (50 flow wrapped packs) and automatically reject any kit boxes that fail to meet weigh criteria for that particular product. This must be done at a rate to support the product output speed of the flow wrapper (as determined from item 10.1).
Process	**10.33**	Checkweigher must have a program for each kit configuration (Ref. Sec. 6).
Process	**10.34**	Operators will have the ability to manually load a package insert booklet (LBL-05298)

8.1. Operational Requirements

UR Category	UR#	User Requirement
Operational	**11.1**	Flow Wrapper & Checkweighers must display number of completed & rejected packages.
Operational	**11.2**	All interconnected machines must be linked such that a fault condition, power off or, not ready status prevents the equipment from running. (i.e.: feeders and checkweigher interconnected to flow wrapper).
Operational	**11.3**	Each hopper should have at a minimum 30 minutes run time at full speed without the need to replenish.

8.2. Construction Requirements

UR Category	UR#	User Requirement
Construction	**12.1**	System layout and all designs relating to items within this URS must be approved by Hologic prior to build.
Construction	**12.2**	All electrical enclosures and components must be clearly labelled and include the nominal voltage & amperage of the circuit or device.
Construction	**12.3**	Systems must not contaminate, mark, bend, kink, fold, warp, gall, gouge, cut, tear, indent, deface or otherwise damage Hologic components, kit boxes and inserts.
Construction	**12.4**	Equipment must fit in the available floor space. It is the responsibility of the vendor to confirm acceptable final dimensions of the system with Hologic. As well as fitting into the space the vendor must allow ergonomic space around the machine for operators access.
Construction	**12.5**	All inspection equipment (sensors, cameras and lighting) are to be rigidly mounted so operator/mechanic movements do not bump or move them out of position.
Construction	**12.6**	Product contact surfaces must be non-porous and durable enough to be cleaned with both 70% IPA or 10% Bleach solution.
Construction	**12.7**	Any pneumatic systems shall not require lubrication and operate in a dry state.
Construction	**12.8**	All product contact surfaces must be made from any of these materials: PTFE, Delrin, UHMW, Polypropylene, Polyethylene, Anodized Aluminium and Stainless steel. *Other materials must be assessed and approved by Hologic on a case by case basis.

UR Category	UR#	User Requirement
Construction	**12.9**	All non-product contact surfaces must be made from any of these materials: Stainless Steel, *Epoxy coated or *Powder coated Steel, Anodized Aluminium, PTFE, Delrin, UHMW, Polypropylene, Polyethylene and Phenolics. (No raw metal surfaces are acceptable unless specifically approved by Hologic). *Epoxy and powder coat colour(s) must be approved by Hologic. **Other materials must be assessed and approved by Hologic on a case by case basis.
Construction	**12.10**	Conveyance systems must be safe to touch, quiet and smooth operating. It's preferred (but not mandatory) to have variable speed controllers on conveyors. (VFD's must reside inside an electrical enclosure or box). Conveyors must have E-stops that are interconnected to machines they are feeding or exiting product from.
Construction	**12.11**	All interconnected machines must have linked E-stops. (i.e.: Feeder or checkweigher e-stop will stop flow wrapper).
Electrical, Grounding	**12.12**	All doors shall be grounded to the cabinet ground with a green insulated 14AWG stranded copper wire or a copper braid.
Electrical, Grounding	**12.13**	All components shall be grounded per component manufacturer's recommendations and enclosure grounding must meet applicable code requirements.
General Electrical	**12.14**	All wires shall be contained in wiring duct with snap type covers, where applicable.
Electrical Cabinet	**12.15**	Electrical enclosures and wire-ways should be designed such that, when practical, the high & low voltage lines are uniquely separated.
Electrical Cabinet	**12.16**	Main electrical enclosure is to be equipped with mechanical means of disconnect and easily accessible by an operator of 4'7" (140cm).
Electrical, Component Labelling	**12.17**	Component identification shall be permanent both in type and adhesion.
Electrical, Component Labelling	**12.18**	Label all electrical panels and components with identification corresponding with the technical documentation.
Electrical, Device Labels	**12.19**	Terminal bricks shall be identified using nameplates affixed to the top of each group of terminals. Individual terminals shall be numbered.
Electrical, Wire Marking	**12.20**	All wires shall be labelled at each termination point by number, letter, etc. corresponding with the technical documentation.
General Electrical	**12.21**	Vendor to provide adequate power protection to the PLC and it is preferable to include line filters (Isolator or similar) for all noise sensitive equipment such as: Computers, Instrumentation, PLC's, Power supplies, etc.

UR Category	UR#	User Requirement
Control System	**12.22**	Colour touch-screen operator interface (HMI) is to be mounted on a swivel-arm and accessible from several convenient operational locations.
Control System	**12.23**	The touch-screen button orientation, screen designs and any momentary button delays will be agreed upon before final design approval.
Control System	**12.24**	The operator, maintenance and engineering personnel will have the ability to view all respective password protected pertinent operational parameters and conditions through the HMI, SCADA systems, and programming PCs.
Controls	**12.26**	Vendor shall submit alarm lists for approval as soon as available
Controls	**12.27**	The PLC and ancillary controls (e.g. vision system) will be configured such that remote access is possible.

Utility Requirements

UR Category	UR#	User Requirement
Utility	**13.1**	The equipment shall be able to operate between 0 - 50°C and 5 - 80% RH.

Health and Safety Requirements

UR Category	UR#	User Requirement
Health, Safety & Environment	**14.1**	All equipment shall be equipped with emergency stop buttons. Once activated, all movement will immediately cease.
Health, Safety & Environment	**14.2**	The equipment shall incorporate good ergonomic design principles (e.g. minimize poor posture, excessive vibration, excessive stretching/ reaching, and twisting, heavy, repetitive lifting, etc.) All feed systems must be accessible for loading at ground level. Any materials (such as film rolls for flow wrap) exceeding 50lbs. must have a mechanical means provided to easily and safely load them onto the machine.
Health, Safety & Environment	**14.3**	The equipment shall have safety guarding where required as stated in the machinery directive. All conveyors, chains, gears, pulleys, etc. must be guarded or located to prevent accidental contact with operators. Moving parts of equipment, pinch points and sharp edges must be guarded or mitigated to prevent unintentional contact with operators. All guard doors must be safety interlocked. Fixed panels fastened in a manner requiring hand tools to remove them do not need interlocks.
Health, Safety & Environment	**14.4**	All safety features must be enabled before the process can be started.
Health, Safety & Environment	**14.5**	All individual machines must have a means to Lock Out Tag Out.
Health, Safety & Environment	**14.6**	All equipment shall be provided with LOTO De-energizing and Re-energizing instructions, especially for equipment with latent energy. Format to be provided by Hologic.
Health, Safety & Environment	**14.7**	Equipment must be provided with all required safety warning signage in English .
Health, Safety & Environment	**14.8**	The design must adhere to the requirements under the Supply of Machinery (Safety) Regulations 2008. Particularly relating to Schedule 2, Part 1, Annex 1: Essential health and safety requirements relating to the design and construction of machinery, and also conform to CE standards

Control System Hardware and Electrical Requirements

UR Category	UR#	User Requirement
Control System Hardware and HMI	**15.1**	The manufacturer will provide a means for user to interface and edit parameters for the equipment as necessary.

Monitoring Requirements

UR Category	UR#	User Requirement
Monitoring	**16.1**	Alarms shall be classified into categories for equipment diagnostics. Machine Alarms, Status Messages & Informational Messages.
Monitoring	**16.2**	The reason for rejection must be identifiable for each rejected part.
Monitoring	**16.3**	Open safety doors and guards must be individually identified.
Monitoring	**16.4**	The operator shall be notified of the operational status of the equipment with stack lights as well as any available HMI screens. Stack light must include Red (E-stop, Fault, Stop, Guarding safety switch, Not ready, etc), Yellow (low material in feeders and other pending fault conditions), Green (system ready or running). Yellow typically does not yield a stop condition. It serves as an early warning. Yellow light can flash to alert operator while system is running and green light is still on.
Monitoring	**16.5**	The process shall have diagnostics to identify and enunciate faults, machine alarms, critical alarms, machine status, and general information.

Computer System Logical & Physical Requirements

UR Category	UR#	User Requirement
Computer System Logical & Physical Security Requirements	**17.1**	All logical security settings (passwords, assigning roles and levels of access, password expiration durations) shall be configurable by an authorized individual.
Computer System Logical & Physical Security Requirements	**17.2**	Control systems must have a minimum of three levels of access, Operator, Engineering and Admin.
Computer System Logical & Physical Security Requirements	**17.3**	The system shall not display or print passwords when entered.
Computer System Logical & Physical Security Requirements	**17.4**	Operating modes other than Production Mode must be selected by the use of user authorization level (i.e. passwords).
Computer System Logical & Physical Security Requirements	**17.5**	The control system must prevent duplication, reuse, and reassignment of User ID and passwords.
Computer System Logical & Physical Security Requirements	**17.6**	Control systems shall disable the User's account after an extended period of inactivity, requiring re-entry of password.
Computer System Logical & Physical Security Requirements	**17.7**	The electronic raw data will not be used for product release or investigations. Therefore, 21 CFR Part 11 compliance is not required.

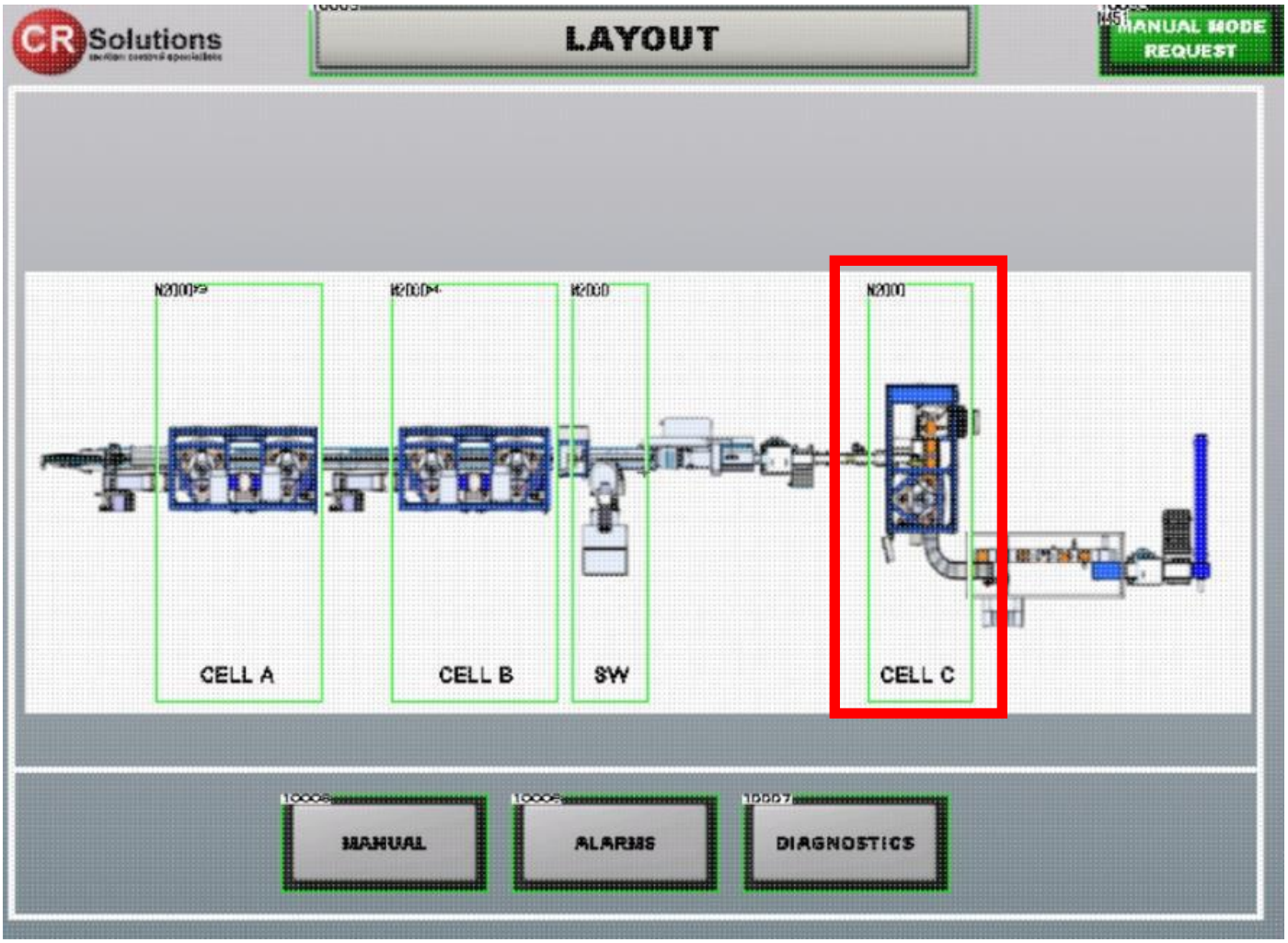
Maintenance Requirements

UR Category	UR#	User Requirement
Maintenance	**18.1**	All instruments and devices requiring calibration must be in a state of calibration during the factory acceptance test (FAT).
Maintenance	**18.2**	All calibrated instruments and devices must have documentation showing that they are in calibration during the FAT.
Maintenance	**18.3**	Preventative maintenance plan must provide all key component inspections/adjustments/replacements and interval for each.

Documentation Requirements

UR Category	UR#	User Requirement
Documentation	**19.1**	All calibrated instruments and devices must have documentation showing that they are in calibration during the FAT.
Documentation	**19.2**	Recommended spares list (including part #, price & lead time) complete upon receipt of delivery.
Documentation	**19.3**	Operator manuals complete upon receipt of delivery.
Documentation	**19.4**	Preventative maintenance procedure complete upon receipt of delivery.
Documentation	**19.5**	Digital copies of software program configurations for all equipment as applicable.
Documentation	**19.6**	Utility requirements for each piece of equipment. (Air pressure, CFM, Voltage, Amps, Hz, etc.)
Documentation	**19.7**	Complete wiring diagrams and schematics.
Documentation	**19.9**	Complete Mechanical Diagrams including assembly drawings and part numbers.

9. CELL C



9.1.1 Operation

Cell C performs box assembly , delivery and packing and has two modes of operation.
AUTO Functions as an in-line component of the complete line.
MAN Can be run as a stand-alone cell for maintenance and setup.

There are two HMI screens. The large HMI Screen provides overall line information and local setup and diagnostics CELL C

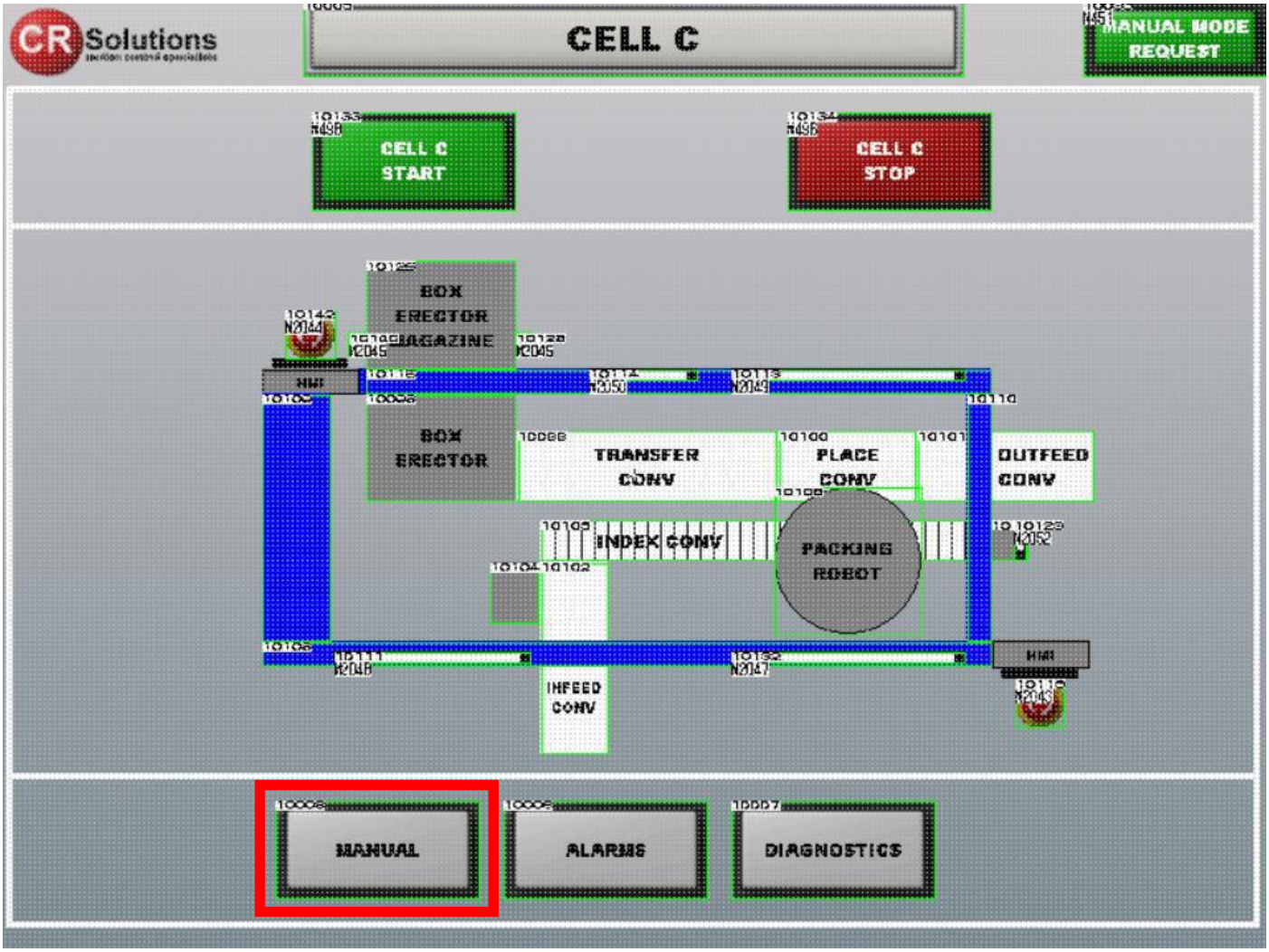
A smaller HMI located next to the box erector provides monitoring, setup, and diagnostics for the box erector.

CELL C default state of operation is AUTO and will start operation when the main line is started without any direct operator intervention.

The handheld programmer for the robot is located under the emergency stop button. The programmer is not

required for normal operation and is locked out with a password. Care must be taken not to have the black two position switch in Teach mode. This will prevent the cell from running in auto.

The polycarbonate doors are magnetically locked to prevent access during operation. When any door is open the cell will not allow the line to operate in AUTO. The HMI screen indicates the status of all guard and interlocks.



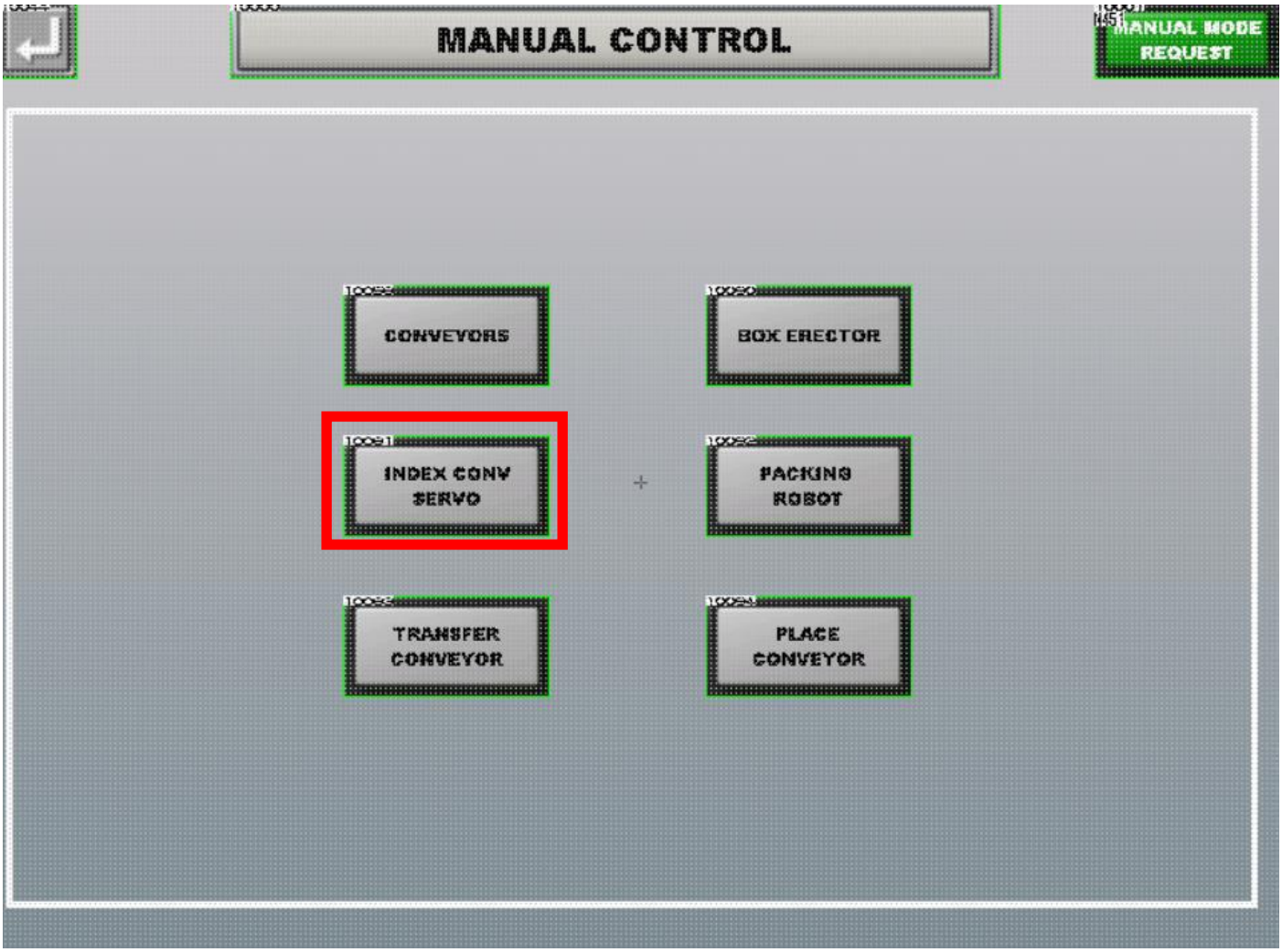
9.1.2 Main Screen

CELL C START
Starts the Cell sequence in automatic mode. The cell will continue to operate until CELL C STOP is pressed, or product is no longer available.

CELL C STOP
Stops the cell at the start of the cycle and allows the guards to be unlocked. NOTE: Stopping the cell whilst the line is in operation will cause upstream cells to pause. When in STOP the MAG LOCKS are disabled and

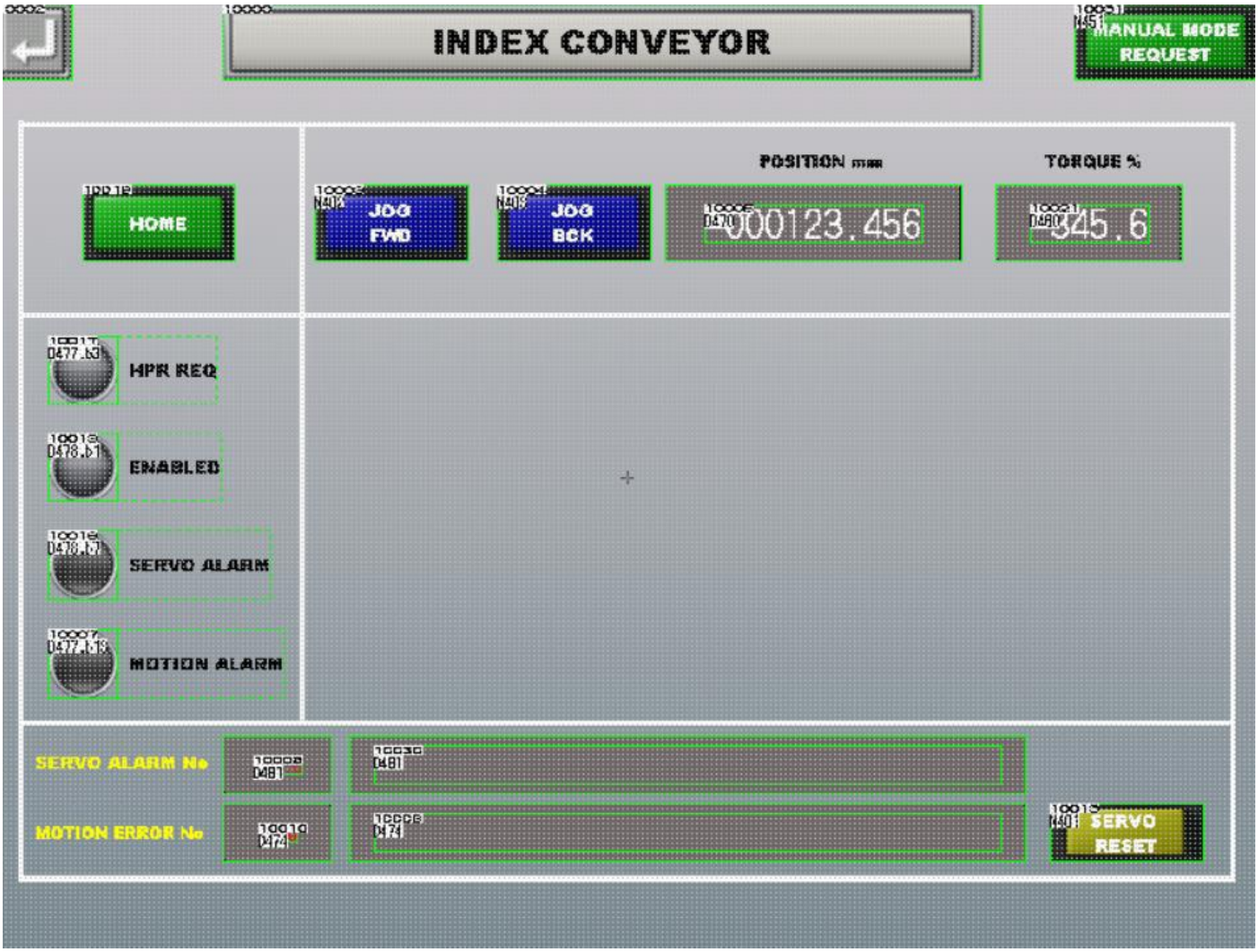
access to the cell is permitted. If the START is pressed with the Guards open the cell will not start and issue an alarm.

Manual Mode Request (maintenance Only)
Allows the cell sequence to be stepped through manually. A password is required to access this function.



MANUAL CONTROL ALLOWS SUPERVISOR ACCESS TO CELL C PROCESSES. THE REURN KEY WILL TAKE THE USER
BACK TO THE PREVIOUSE SCREEN.

9.1.3 Index Conveyor

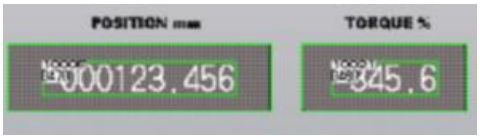


When Pressed

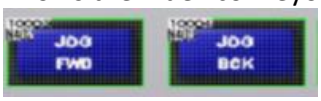
Will Illuminate and the index conveyor to find its datum. The index conveyer will move to a sensor and zero the position counter.

WARNING: Tools or objects left on the conveyor may result in damage!

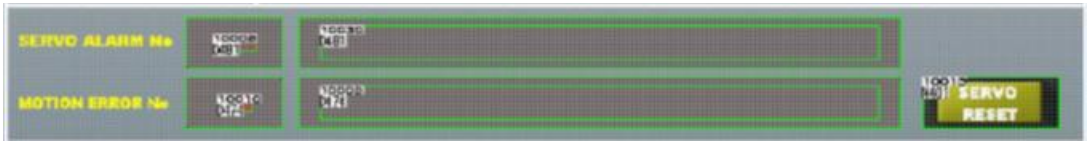
Indicates the belt position relative to the zero point for each index and the motor torque.



Allows the index conveyor to be continuously jogged in either direction.

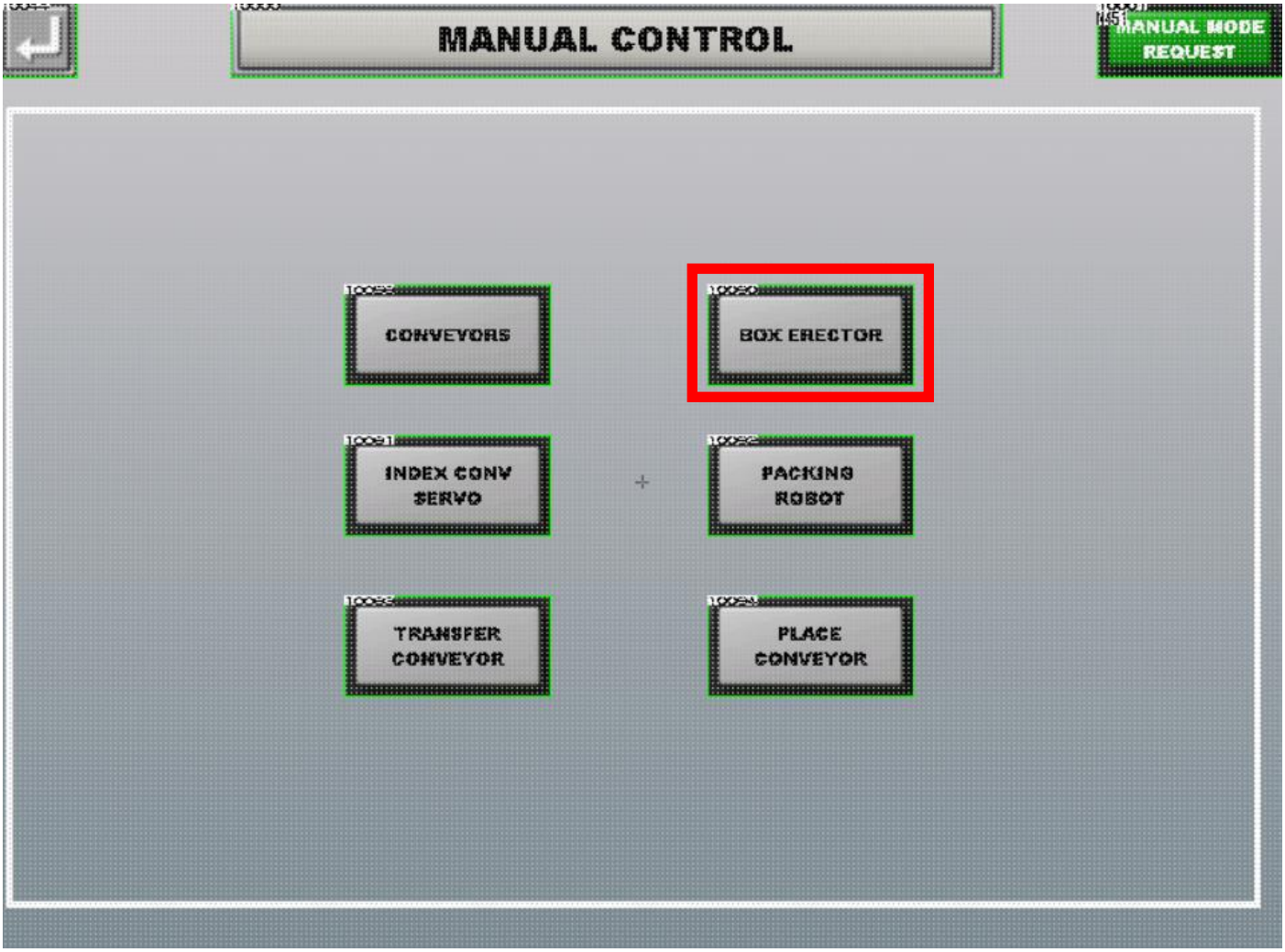


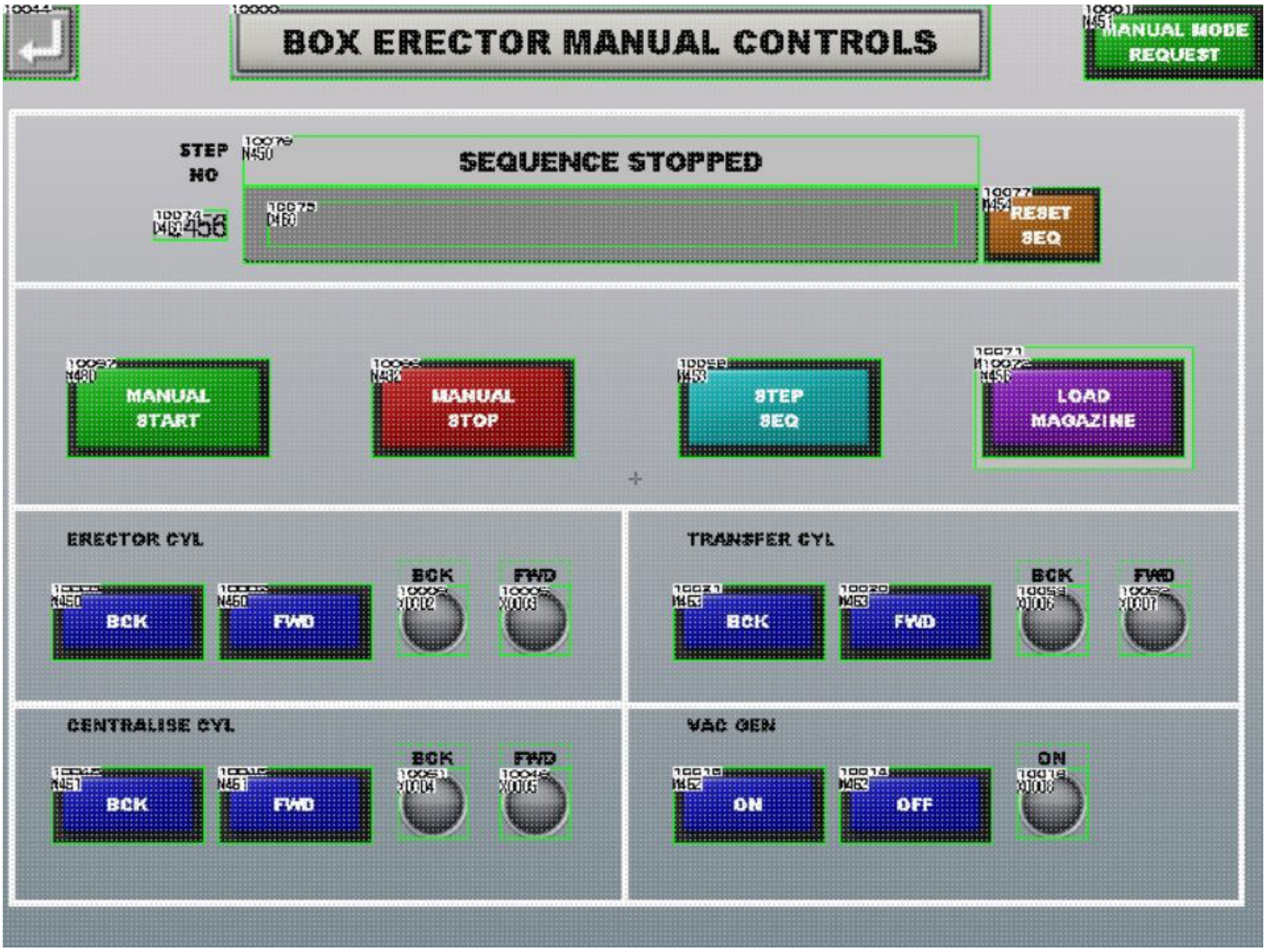
Displays errors related to the indexing servo and allows a direct reset.



9.1.4 Box Erector (Small HMI)

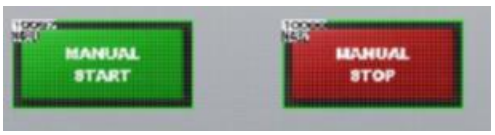
This page is used by a supervisor when setting the case erector up for a new product or making adjustments.





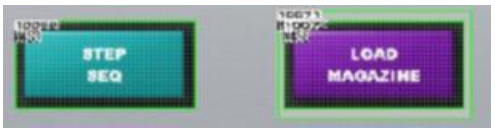
Describes the stage the sequence has stopped and allows the operator to reset the sequence.

Allows the case erector to start and stop whilst the line is not running in automatic. When stop is pressed the erector will complete its sequence before stopping.



STEP SQ
Allows an operator to step through each stage of the case erector

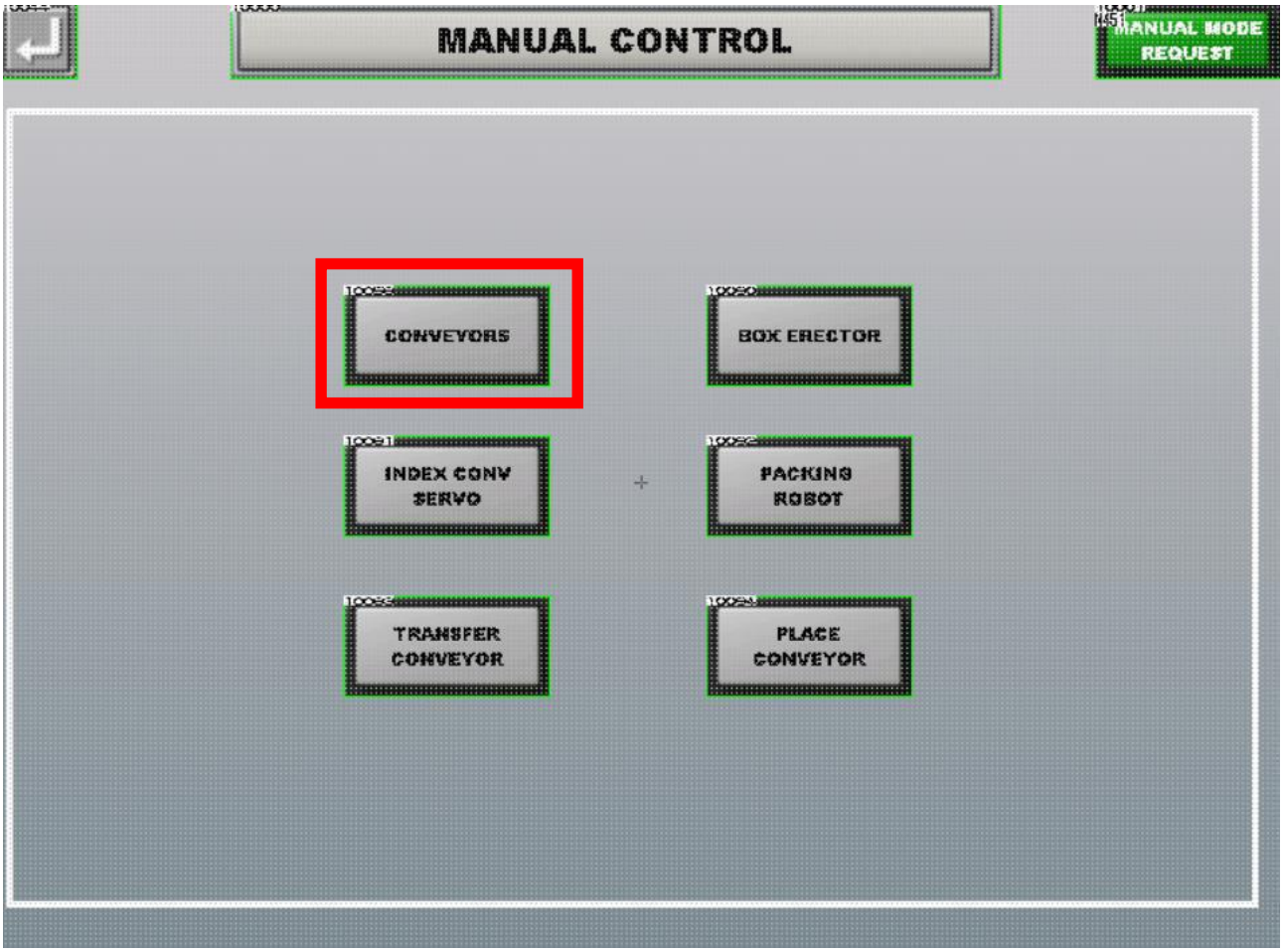
LOAD MAGAZINE
Prepares the magazine allowing an operator to load new product.



MANUAL OPERATION
Allows an operator to manually cycle the actuators. The actuators are automatically returned to default when the operator exits the page.

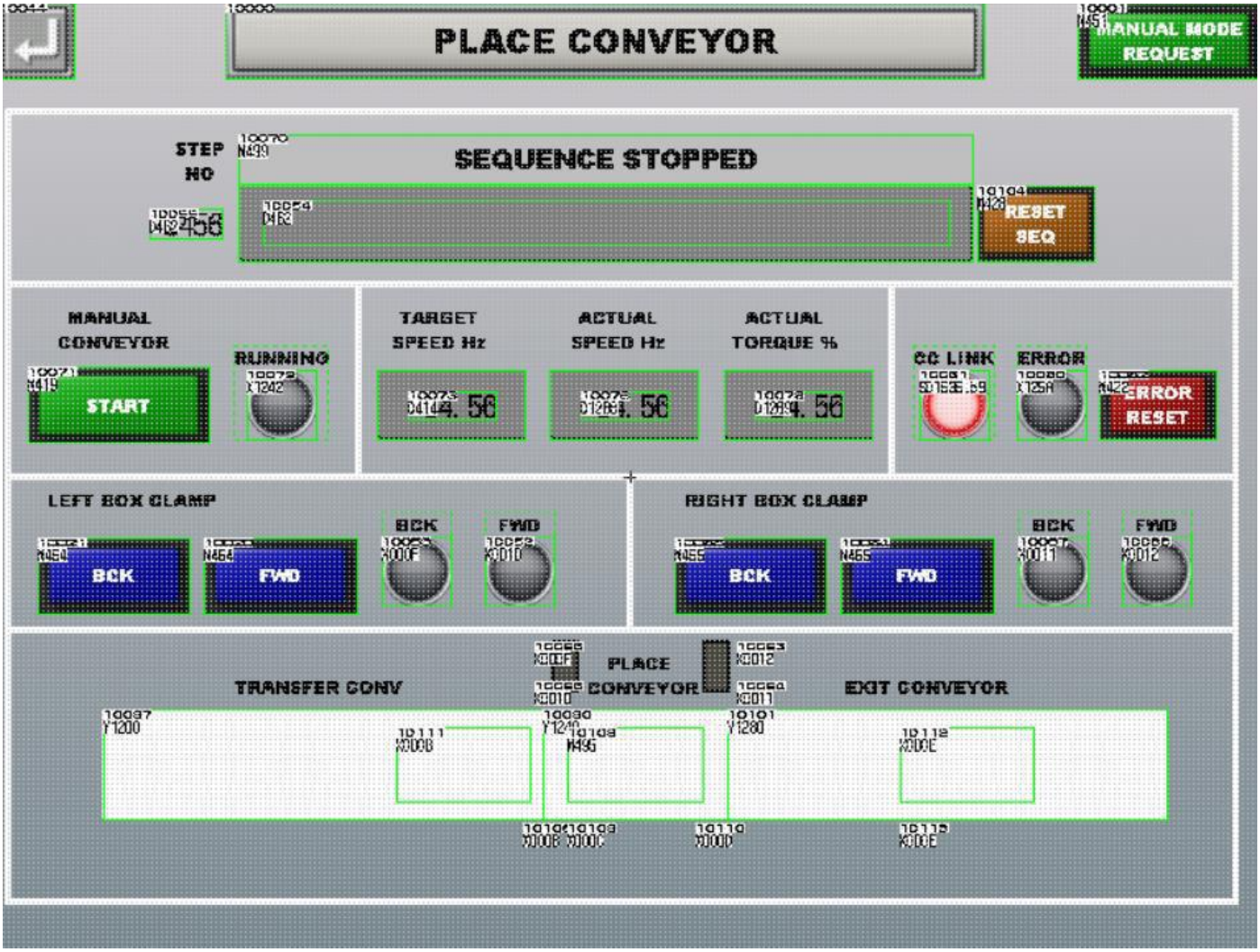
WARNING: Tools or objects left in may result in damage!
WARNING: If operating in Maintenance with guards open trap and nip Hazards are present!

9.1.5 Conveyors



Conveyors

Operator/Maintenance to test and reset errors relating to the place conveyors.



Displays the point at which the sequence has stopped and allows an operator to reset.

Allows the conveyor to be operated manually and monitors the drive and network status.

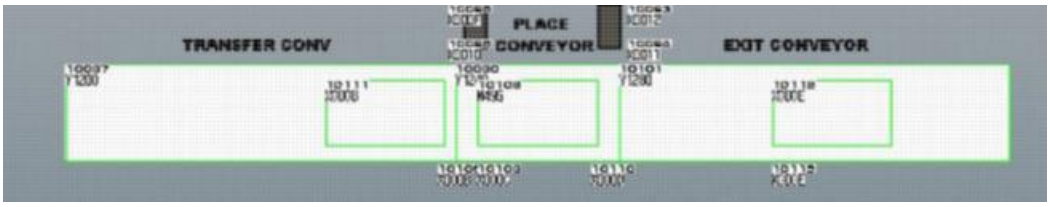
Allows the box clamps to be operated manually when setting up a new product.

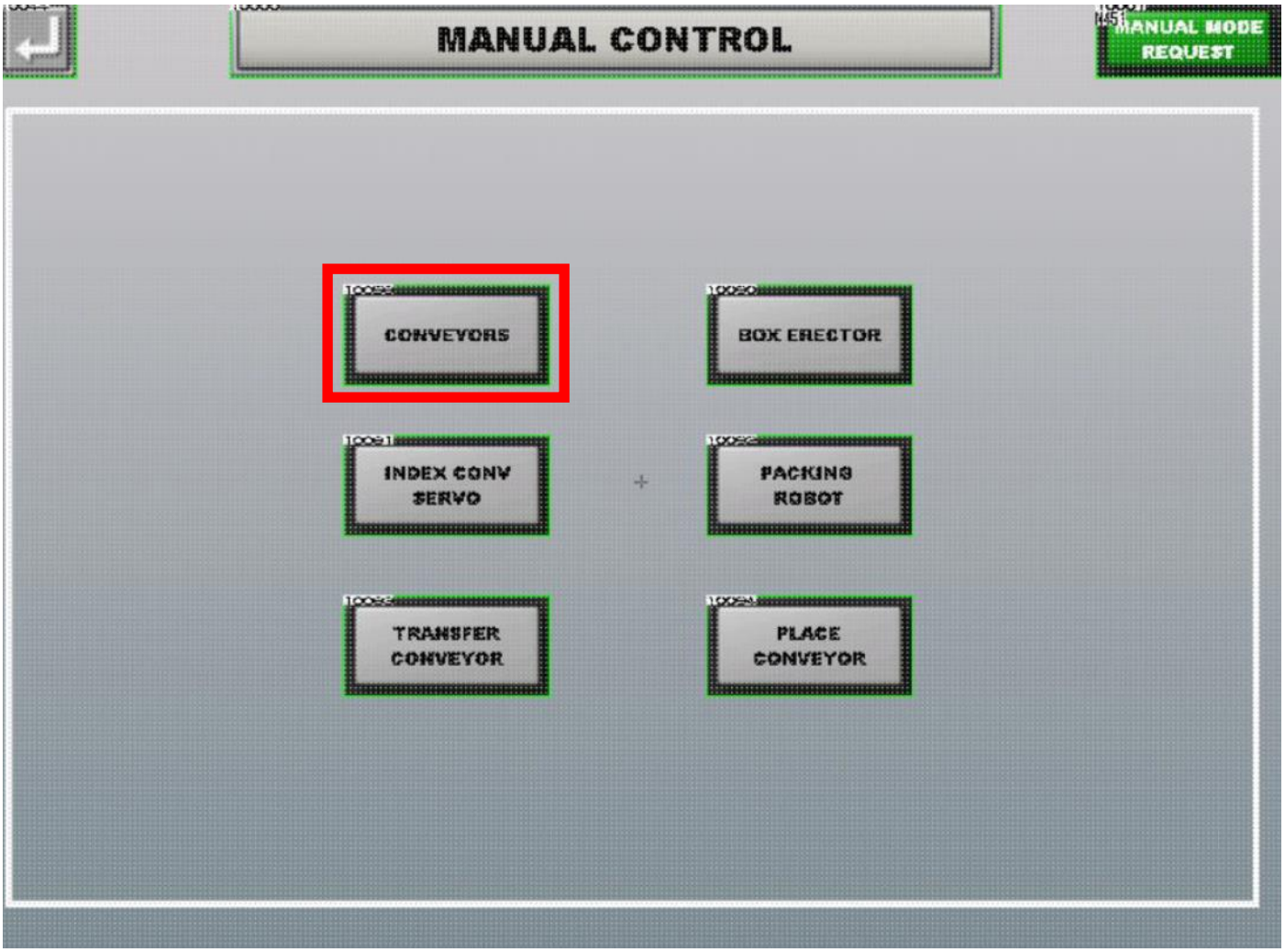
Actuators will reset to default when an operator exits the page.

WARNING: Tools or objects left in may result in damage!

WARNING: If operating in Maintenance wit guards open trap and nip Hazards are present!

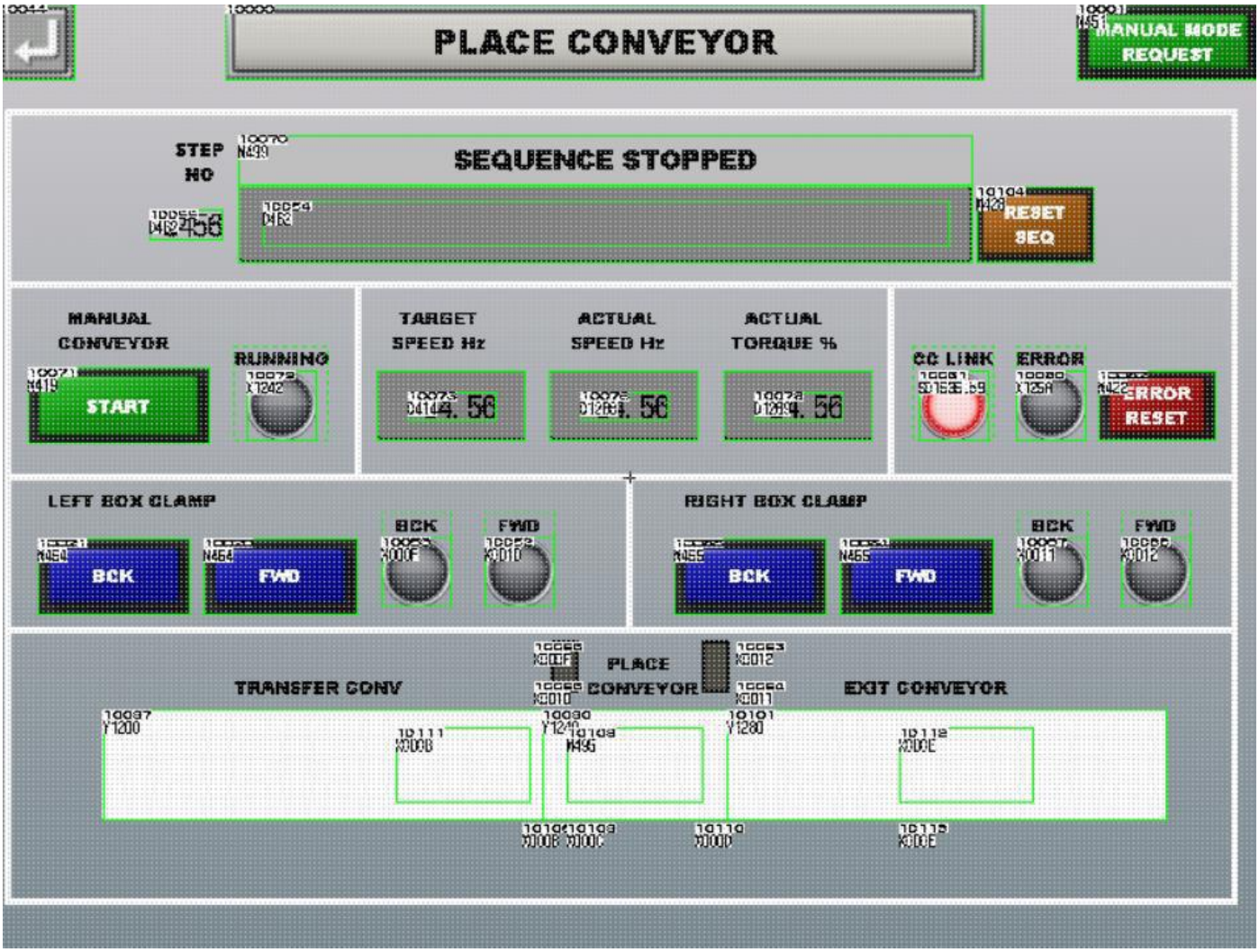
Displays the condition and status of the conveyer.





Conveyors

Operator/Maintenance to test and reset errors relating to the place conveyors.



Displays the point at which the sequence has stopped and allows an operator to reset.

Allows the conveyor to be operated manually and monitors the drive and network status.

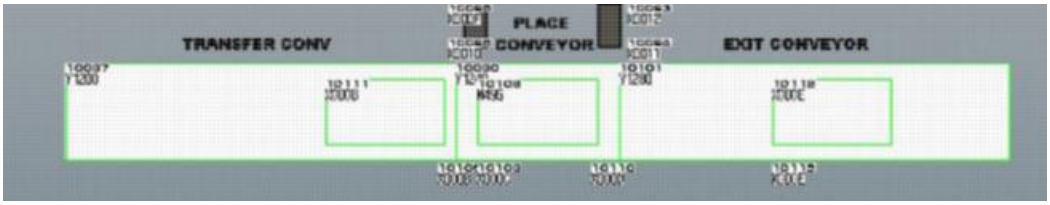
Allows the box clamps to be operated manually when setting up a new product.

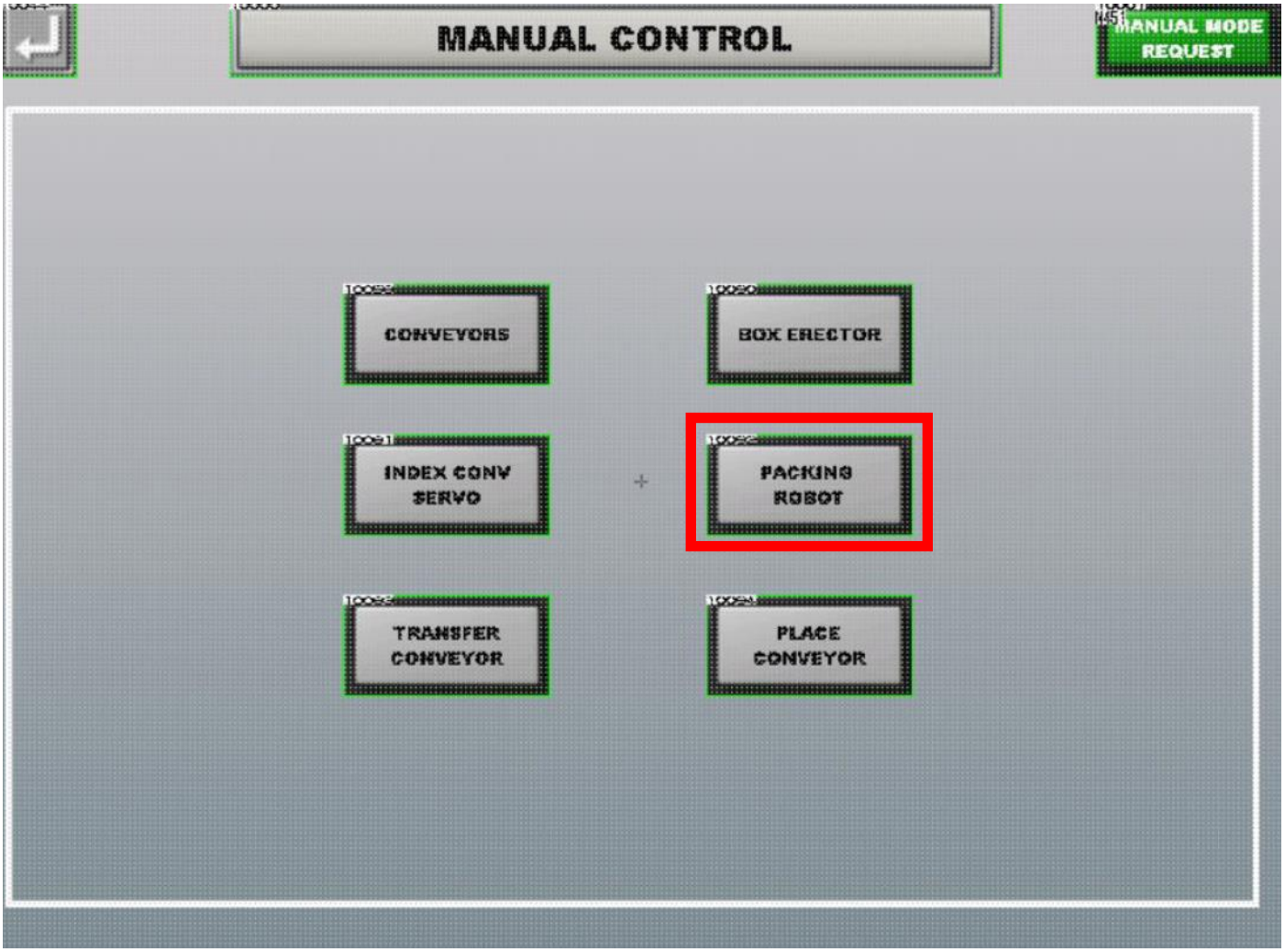
Actuators will reset to default when an operator exits the page.

WARNING: Tools or objects left in may result in damage!

WARNING: If operating in Maintenance wit guards open trap and nip Hazards are present!

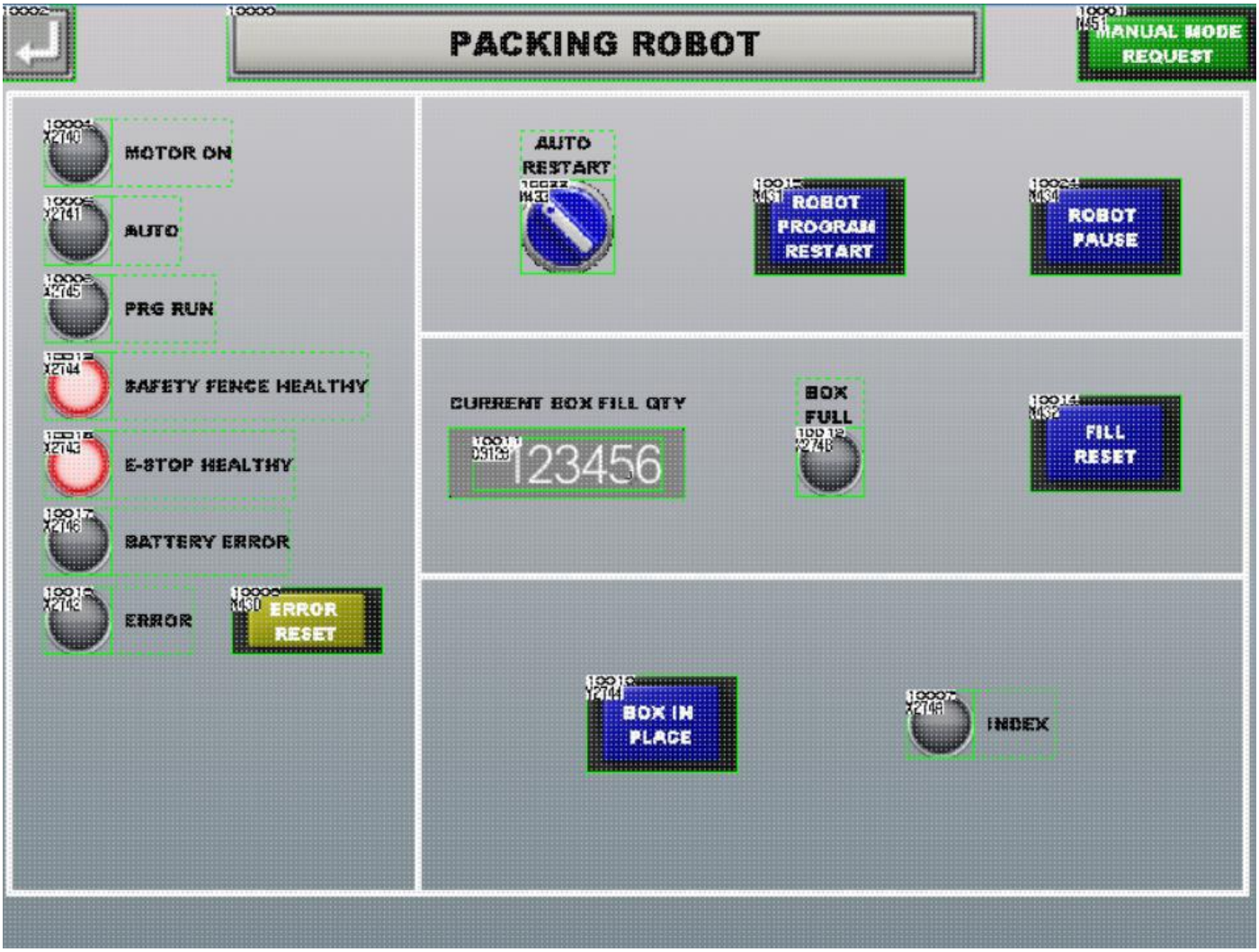
Displays the condition and status of the conveyer.





9.1.6 Packing Robot

Allows the packing robot to be reset and operated manually.



AUTO RESTART

Allows the robot to automatically pick up from where it left off after a pause

ROBOT PROGAM RESTART

Causes the robot to begin from zero count (new box).

ROBOT PAUSE

Causes the robot to pause mid cycle.

FILL RESET

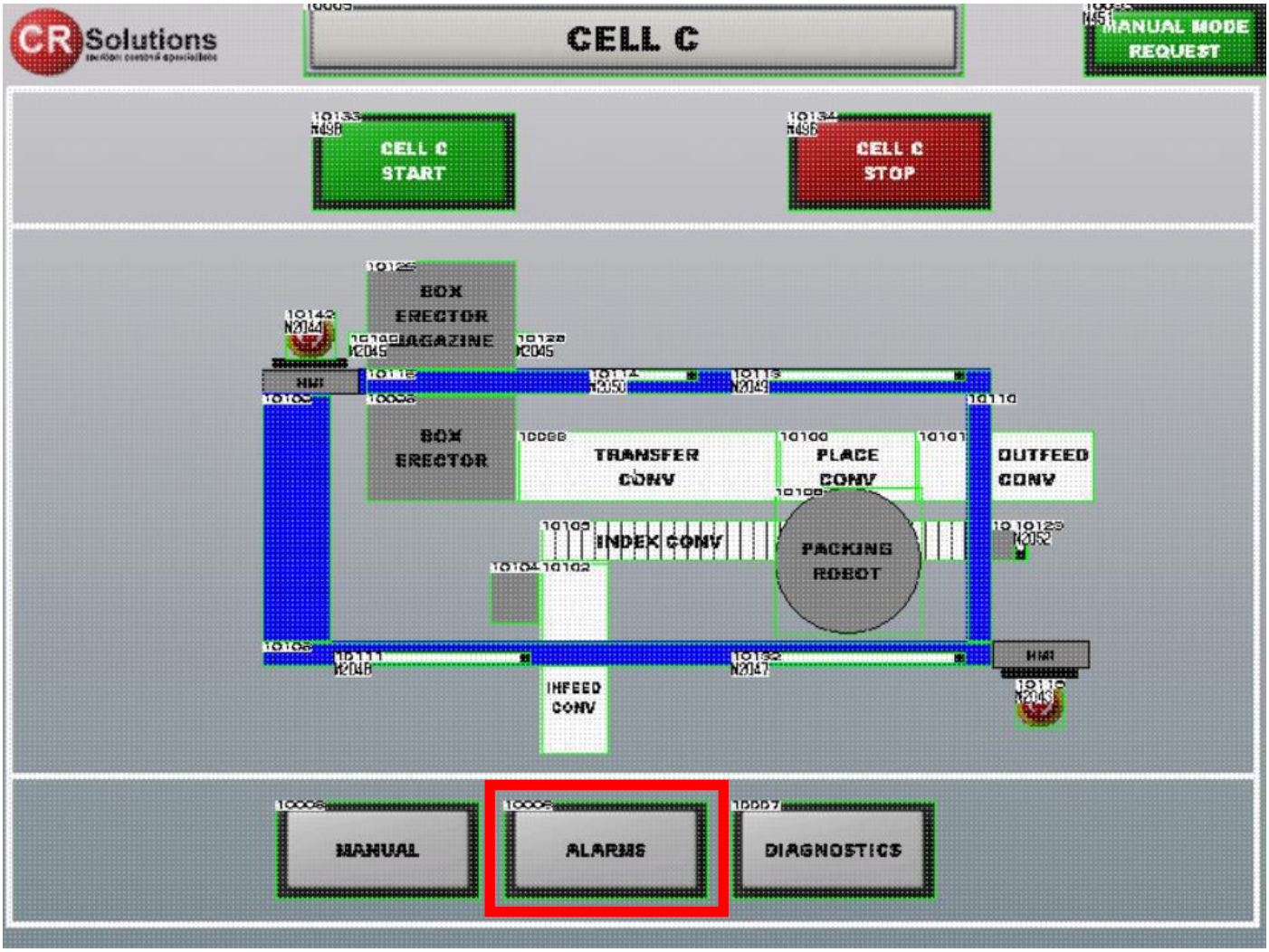
Resets the fill counter allows a part filled box to be completed.

BOX IN PLACE

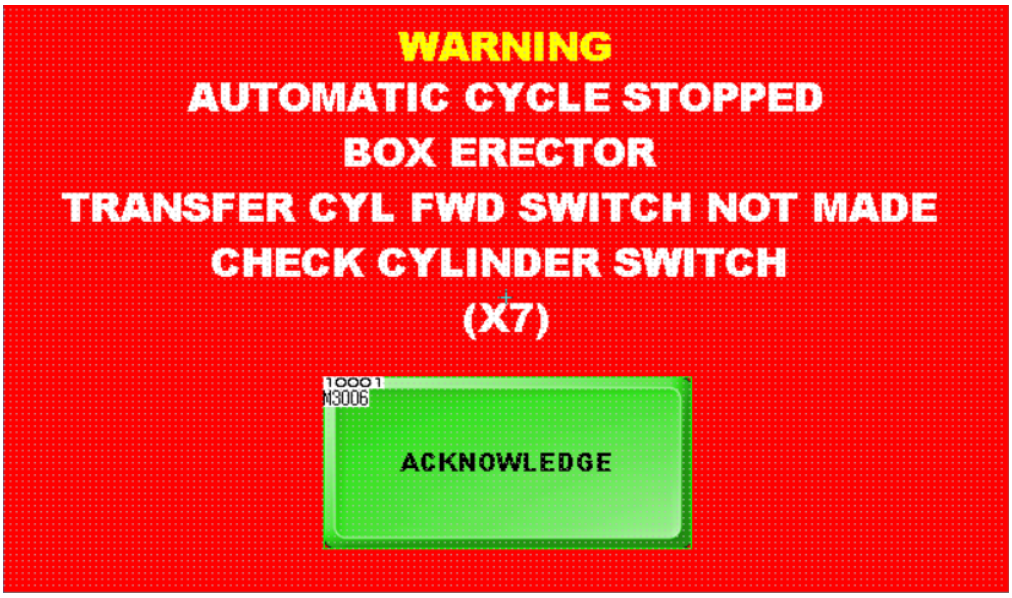
Allows a manually placed box to be indexed once filled.

Provides error monitoring and local reset functions for the robot.

9.1.7 ALARMS

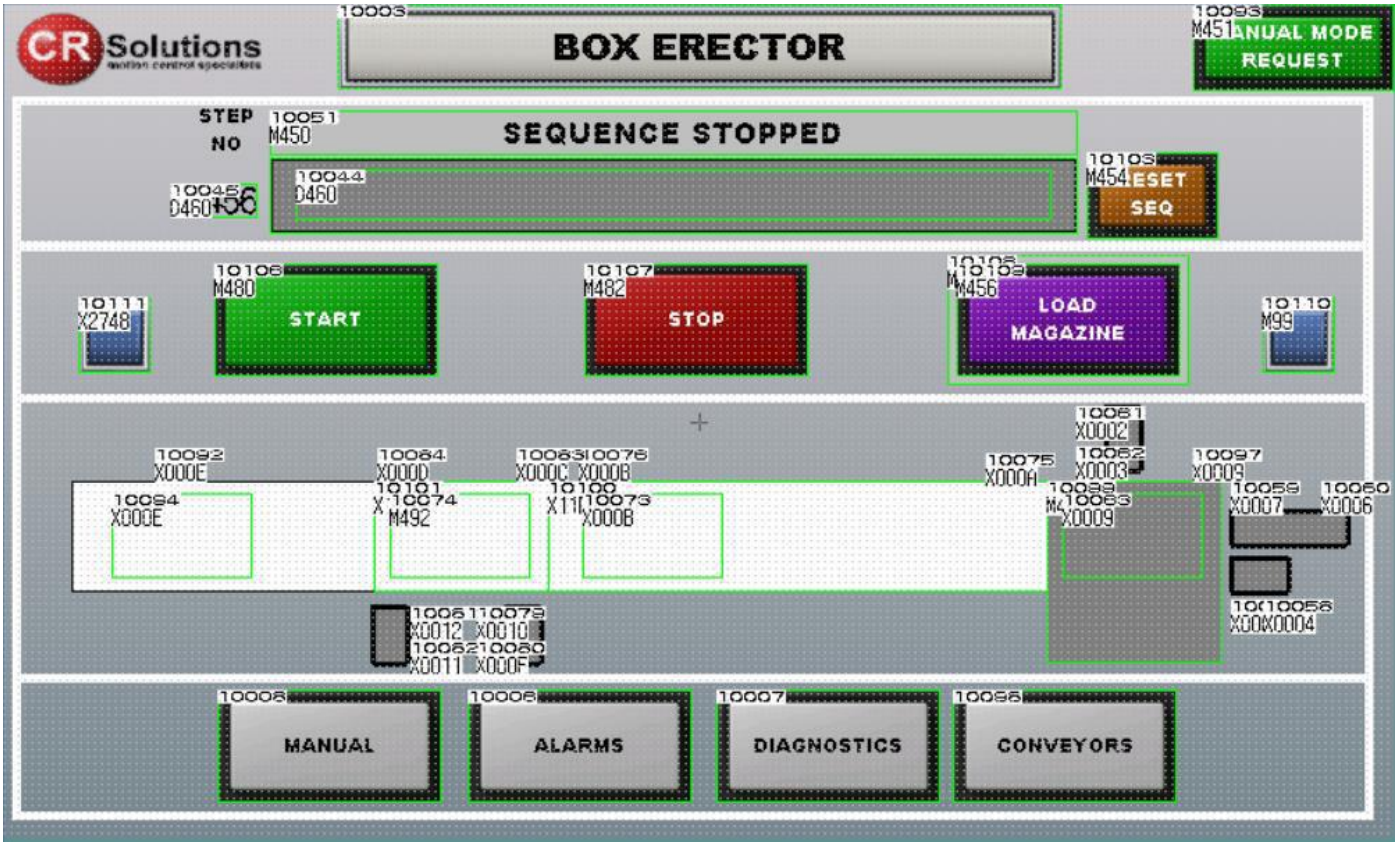

CR Solutions
CELL C
MANUAL MODE REQUEST
CELL C START
CELL C STOP
BOX ERECTOR MAGAZINE
BOX ERECTOR
TRANSFER CONV
PLACE CONV
OUTFEED CONV
INDEX CONV
PACKING ROBOT
INFEED CONV
HMI
MANUAL
ALARMS
DIAGNOSTICS


WARNING
AUTOMATIC CYCLE STOPPED
CELL C INFEED CONVEYOR
NOT RUNNING
ACKNOWLEDGE


WARNING
AUTOMATIC CYCLE STOPPED
BOX ERECTOR
TRANSFER CYL FWD SWITCH NOT MADE
CHECK CYLINDER SWITCH
(X7)
ACKNOWLEDGE


WARNING
AUTOMATIC CYCLE STOPPED
BOX NOT ERECTED
(X9)
ACKNOWLEDGE

9.1.8 Box Erector HMI



9.1.9 BOX ERECTOR OPERATION SCREEN

Monitors the erector sequence and allows local operator to reset.

START

STOP

Allows local control of the box erector allowing an operator to stop the erector and reload the magazine

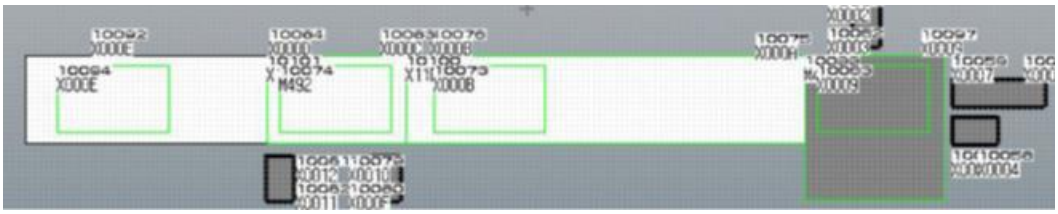
without affecting the machine.

LOAD MAGAZINE

The SpaceFeeder is equipped with a 2-channel safety circuit control. E-stop buttons are placed at several locations. A volt free safety contact will allow the safety circuit to be connected to the main line.

Prepares the box erector and allows access for an operator to fill the magazine. Once pressed the following screen will be displayed.

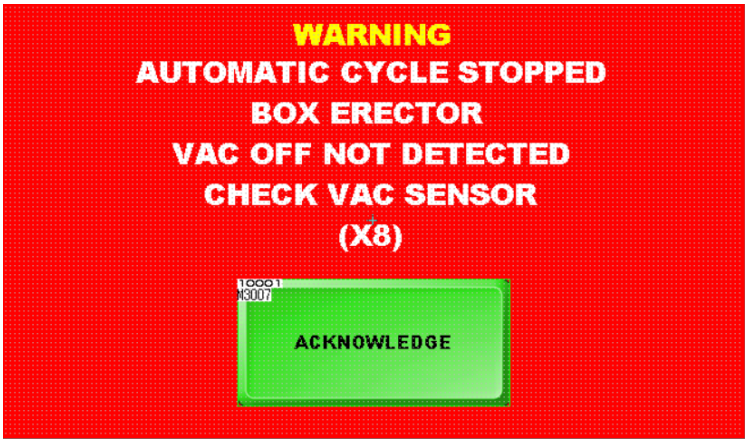
MIMIC Shows the status of the box erector and the transfer conveyors.

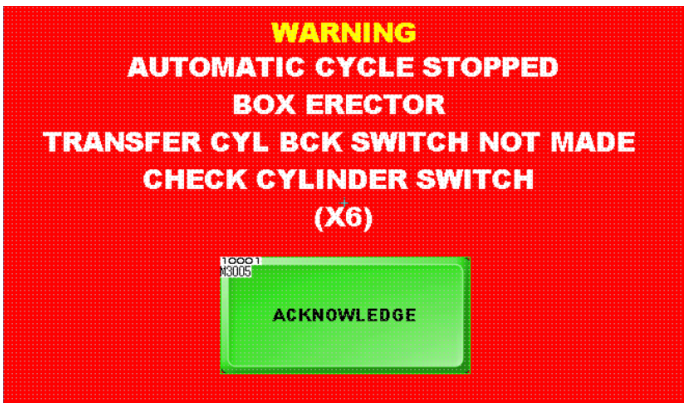


9.2.0 ALARMS


WARNING
AUTOMATIC CYCLE STOPPED
BOX NOT ERECTED
(X9)
ACKNOWLEDGE


WARNING
AUTOMATIC CYCLE STOPPED
OUTFEED BACK UP SENSOR COVERED
(XE)
ACKNOWLEDGE


WARNING
AUTOMATIC CYCLE STOPPED
BOX ERECTOR
VAC OFF NOT DETECTED
CHECK VAC SENSOR
(X8)
ACKNOWLEDGE



10. STAR WHEEL/BOWL FEEDER

10.Specification

The tubes will be presented to the bowl feeder outlet, selected in a single line orientated all one way hanging from their cap ready for discharge down a proposed vibratory linear feeder.

15.1.1 Feed rate

150 PPM

15.1.2 Capacity

30 minutes between re-fill

15.1.3 Bowl Material

Mild Steel with Interior bowl coating of pharmaceutical polyurethane

15.1.4 Bowl diameter

800mm

15.1.5 Electrical

Transport Tube Bowl Feeder	
Rated Voltage	230V
Frequency	50HZ
Variable Speed Control	MAN
Rated Current	13A
Inputs	2
Outputs	2
Network	NA

The tube delivery system consists of a bowl feeder and a rotating star wheel. Tubes are fed from the bowl feeder to the star wheel chute and deposited into each of the shrink wrap pocked by the synchronised wheel.

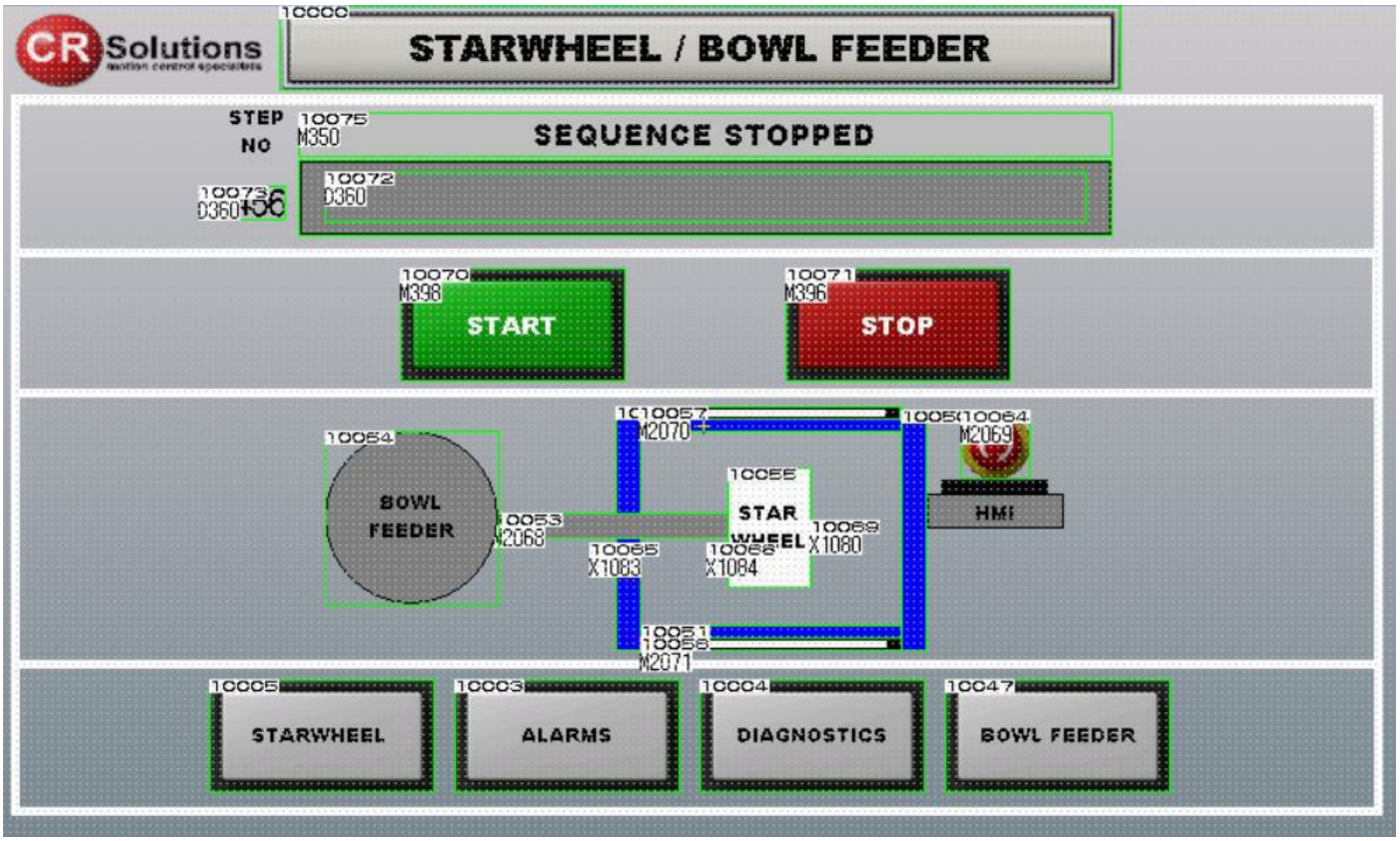
No operator intervention is required during normal running. A local HMI provides setup, monitoring and diagnostics.

The bowl feeder and elevator are controlled locally. Elevator speed and Bowl frequency can be adjusted from the control panel mounted on the frame.

Tube Hopper can be filled by an operator by lifting the lid and emptying the tubes into the hopper.

A low product sensor will alert an operator by flashing amber on the light stack and showing a warning banner on the HMI which must be acknowledged before it can be cleared.

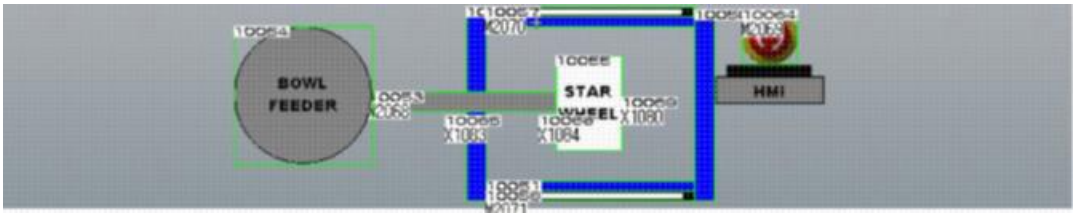
10.1.1 Star Wheel Main Screen



Allows local control over the star wheel and bowl feeder

Monitors the star wheel sequence step number.

MIMIC The Bow feeder and star wheel status.

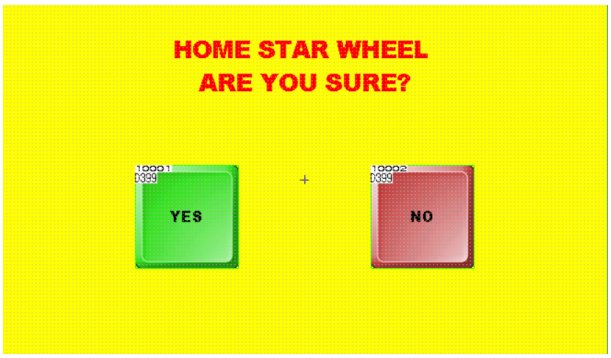


10.1.2 Datum the Star Wheel

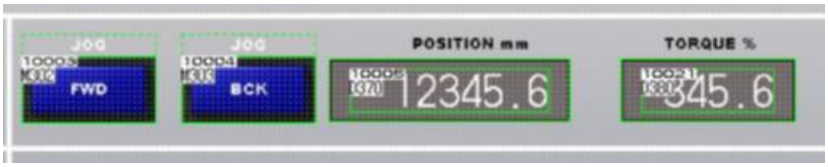
WARNING: Tools or objects left in may result in damage!

WARNING: If operating in Maintenance wit guards open trap and nip Hazards are present!

WARNING: Remove product from star wheel before performing HOME

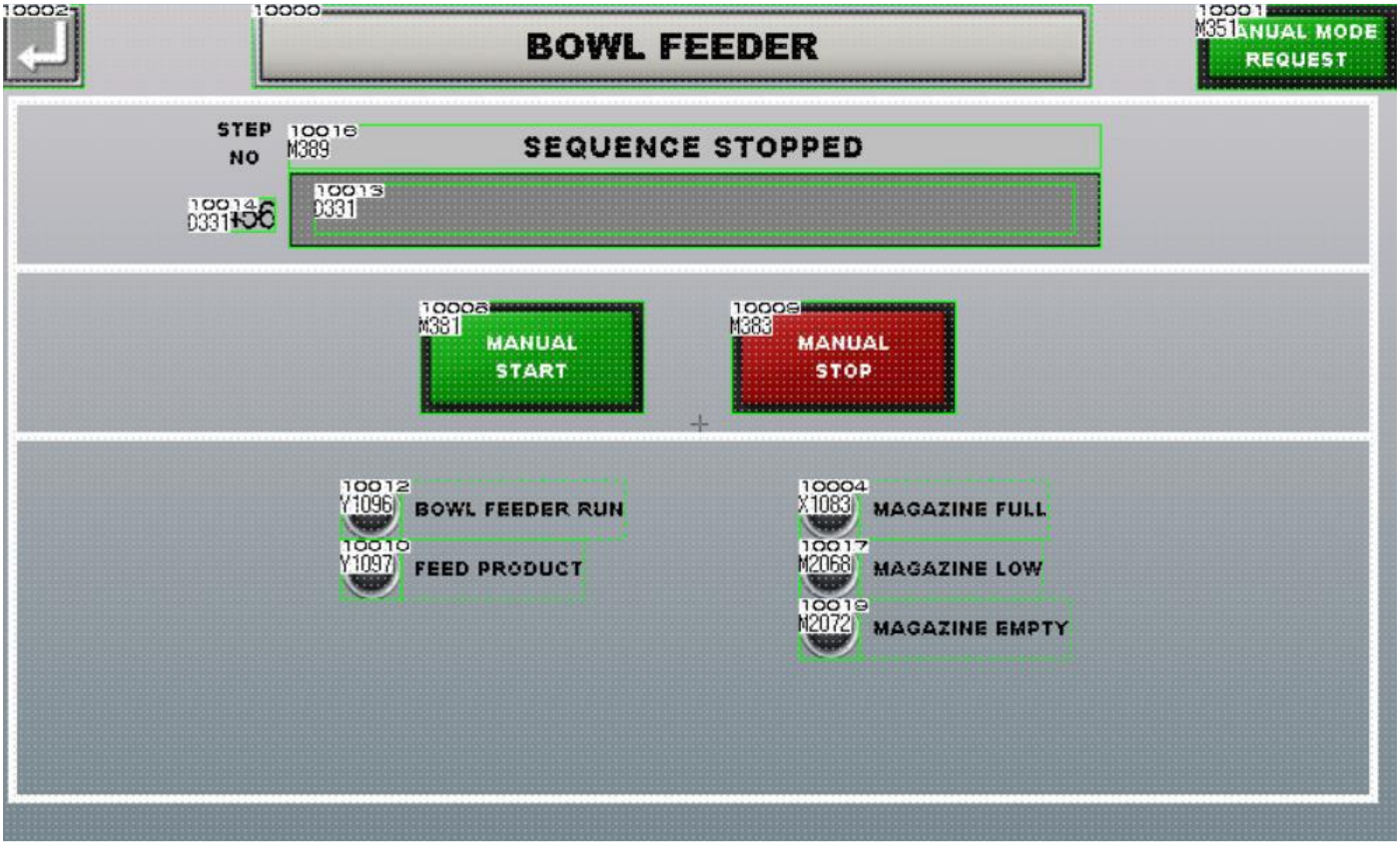


Allows Star wheel to be jogged in either direction.



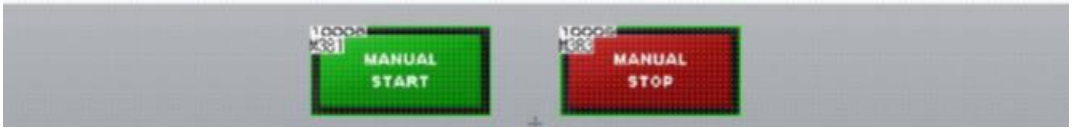
Monitors the star wheel drive status and allows local reset.

10.1.3 Bowl Feeder Main Screen



Monitors the Bowl feeder sequence

Allows an operator to start or stop the bowl feeder.



Monitors the bowl feeder and hopper status

10.1.4 ALARMS

10.1.5 Signal lamp stack

Red: Error

Green: Ready

Yellow: Hopper Product Level Warning

FRICTION FEEDER

Friction Feeder type MFc-220R

The feeder is positioned above the chain. The speed is synchronized by a rotary encoder, which is mounted on the chain.

Depending on the product thickness, the capacity of the magazine might vary.

Depending on the configuration the position of the servo motor and operator side can change.

10.1.2 Magazine loading

1000mm magazine with capacity for 13min runtime at 150PPM

10.1.3 Adjustment

Operation by touch panel and keys illuminated.

10.1.4 Level Control

Level control in the feeder magazine with signal lamp yellow on top of the operator panel.

10.1.5 Outfeed

Outfeed extension inclinable below 250 mm above 300 mm

10.1.16

Feed width 250mm or 300mm standard.

10.1.7 Product feeding

Magazine feeding tape with own drive and mounting support, clocked over level control photocell, side guides adjustable, tape mounted in line at feeder with mounting device Length [mm]: 1’500 . Vacuum support at the friction belts .Blast air with nozzles, clocked, Injector with pneumatic valve

10.1.8 Miss Feed

Missing sheet detection by product run-time monitoring

10.1.9 Stack Level

Vertical magazine on feeding tape – 600mm with level control in the feeder magazine with signal lamp yellow on top of the operator panel. Warning photocell for level in magazine feeding tape.

10.1.10 Fault

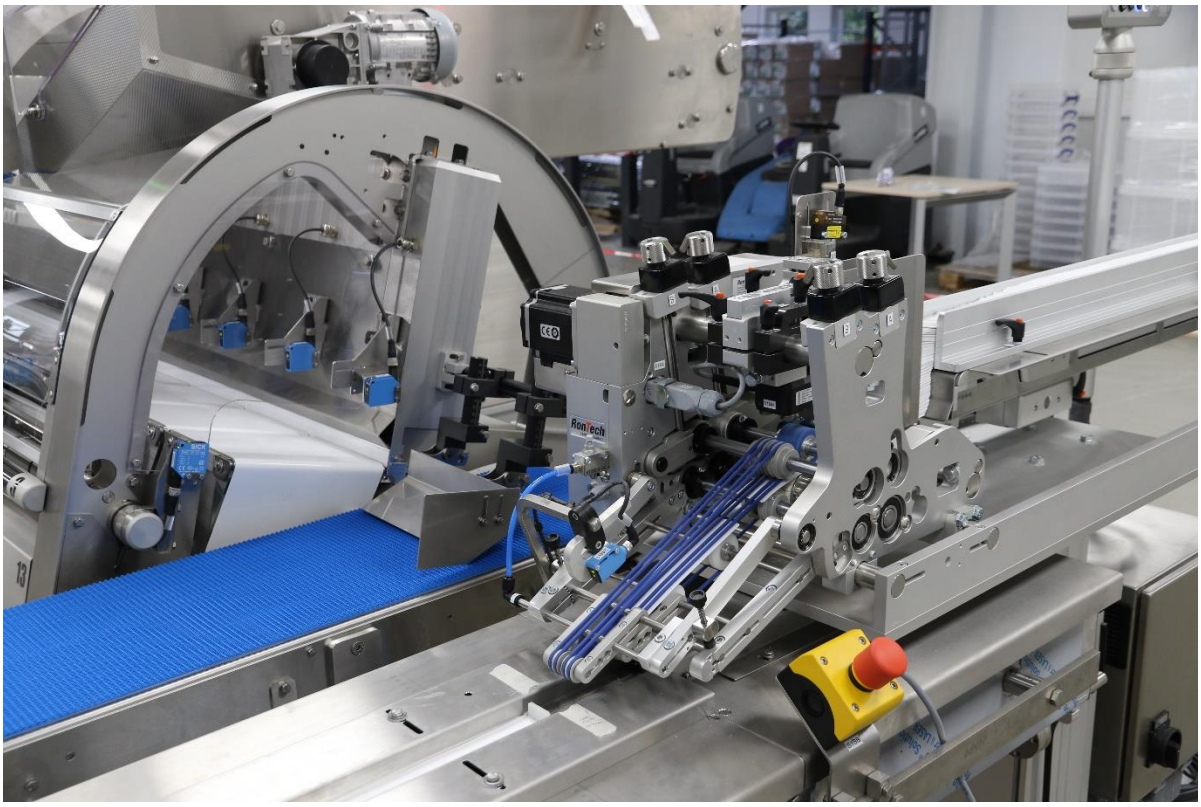
Control of malfunction contact: standard: to switch-off the machine over on/off .

10.1.11 Electrical

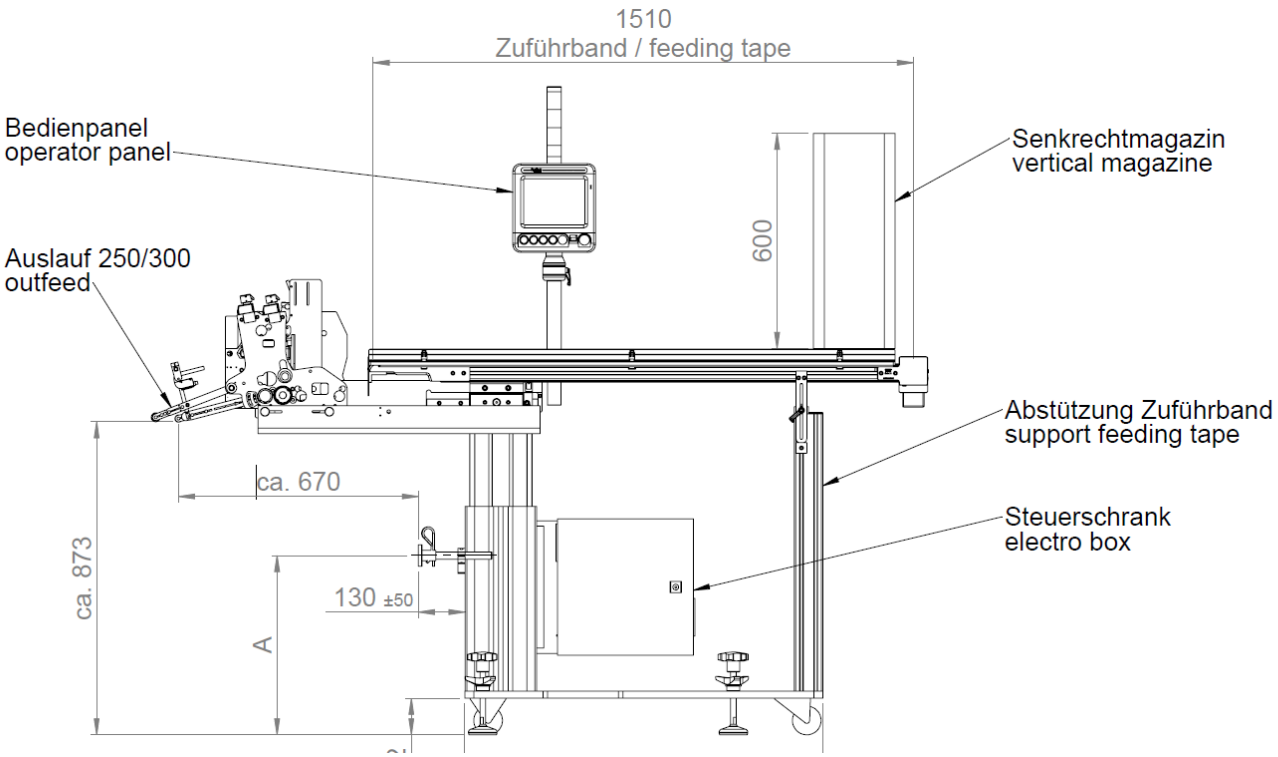
No 1 - Card Feeder	
Rated Voltage	**230V**
Rated Amps	**16**
Hz	**50/60**
Outputs	
Inputs	
E-Stop Signal	**Yes**

10.1.12 Technical Data

- Performance 10 - 150 m/min - max. 300 cycle/min
- Formats min. 25 x 60 mm max. 350 x 300 mm
- Quality min. 60 gr/m²
- Thickness: 0.1 – 25 mm



10.1.13 Dimension



10.1.14 Safety

Emergency stop standard / open door or emergency stop, security circle activation of

FM, double conduit.

11. Chain Conveyor

11.1.1 Length 15 Meter

11.1.2 Working Height 650mm

11.1.3 Flight Pitch 280nn

11.1.4 Material Stainless Steel

11.1.5 Colour N/A

11.1.6 Electrical

Chain Conveyor / Flow Wrapper	
Rated Voltage	400V 3PH + N
Rated Current	20A
Input	Flow Wrapper Running
Input	Stop Robot
Input	Home Position To Robot
Output	Start/Stop
Output	Synchronisation
Output	Cycle Stop
Output	Incomplete
Output	Gripper Safe Fast Stop
Output	Recipe Bit 0
Output	Recipe Bit 1
Output	Recipe Bit 2
Output	Recipe Bit 3
Output	Recipe Bit 4
Output	Recipe Bit 5
Analogue Output	0-10V Speed Signal
E-Stop Signal	4 x Outputs (2 x E-Stop - 2 x Guard Door)
E-Stop Signal	2 x Inputs (2 x E-Stop)

11.1.7 Operating Speed Range 20-150PPM 5-40meter/min

11.1.8 Belt Material Polyurethane

12. Pick Conveyor Robot Cell

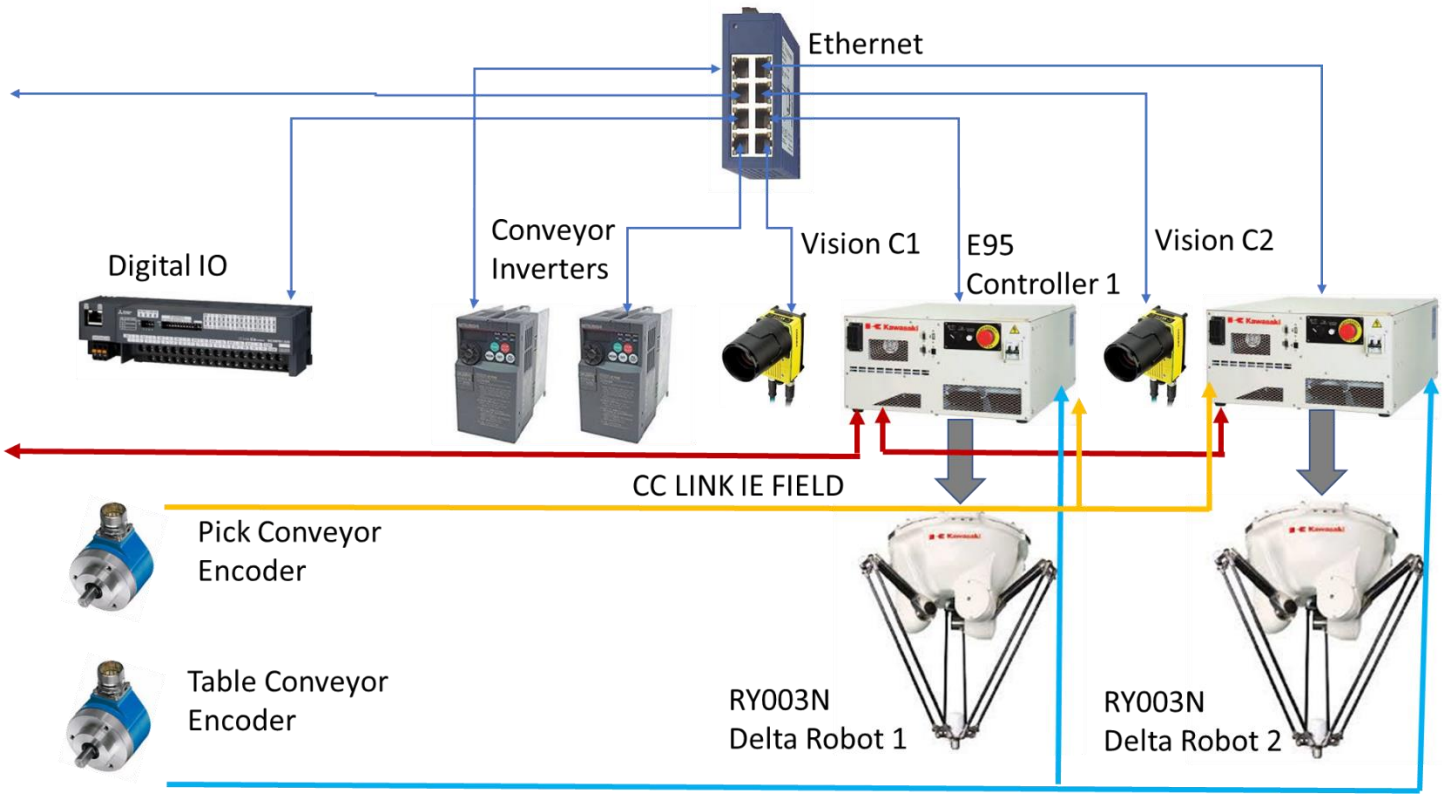
12.1.1 Electrical

Pick Conveyor Robot Cell	
Rated Voltage	**230VAC**
Rated Current	**6A**
Inputs	**NA**
Outputs	**NA**
Network	**CC LINK IE Field**
E-Stop Signal	**2 x Inputs**

12.1.2	Length	6 meter
12.1.3	Width	400mm
12.1.4	Working Height	650mm
12.1.5	Belt Material	Part Number
12.1.6	Frame Colour	RAL
12.1.7	Speed	2-40 Meters/min
12.1.8	Frame Material	Mild Steel

13. CELL A/B

13.1.1 Control Architecture



13.1.2 Pick Rate

Picking cell will be capable of 120-150 pick/min

13.1.3 Product

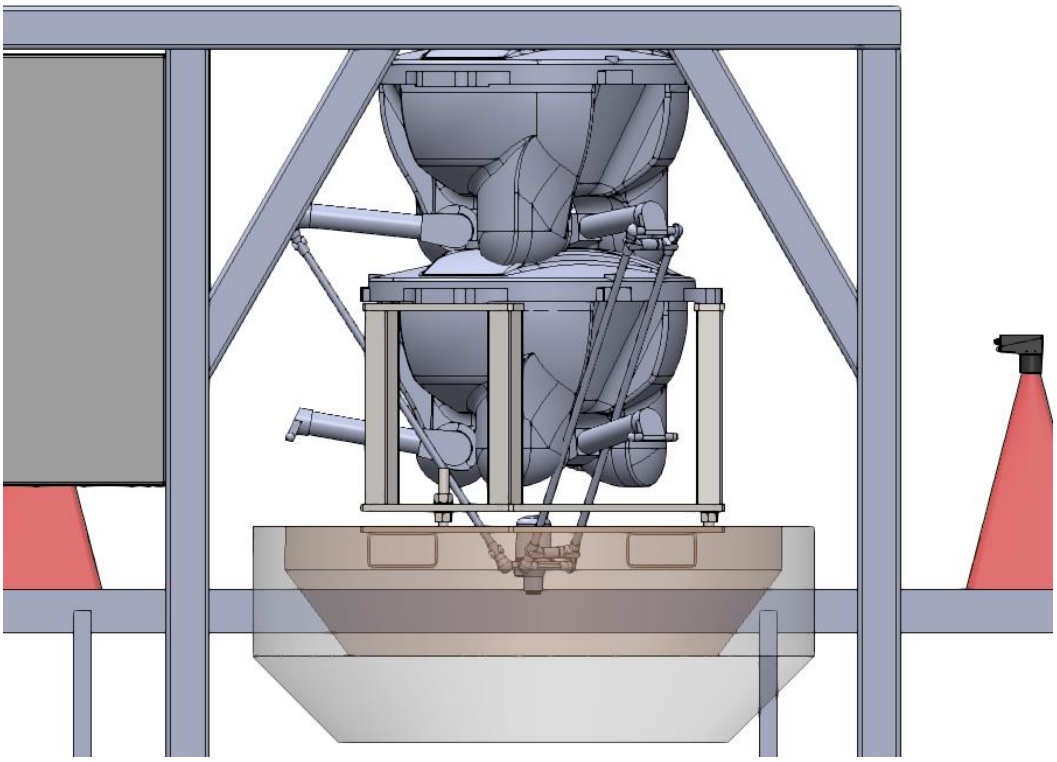
Picking cell will pick pipets or sachets.

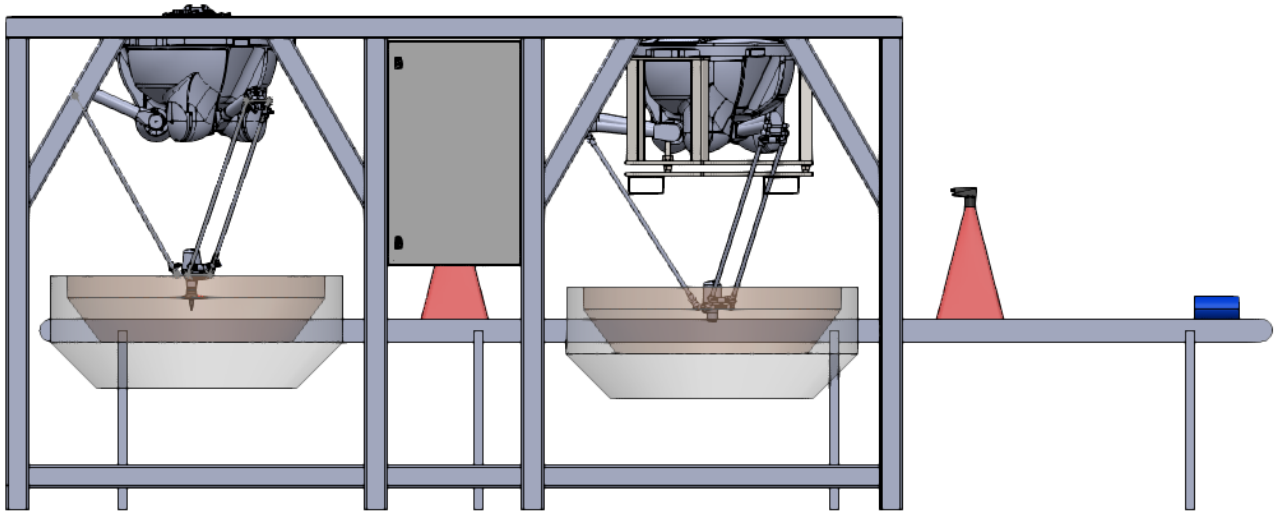
13.1.4 Synchronisation Method

Dual conveyor tracking. Using Encoder Tracking ad register points.

13.1.5 Robot Fitting Method

Robots are loaded into the cell from either side of the frame, using a purpose build frame will enable forklift truck to lift and position the robot.



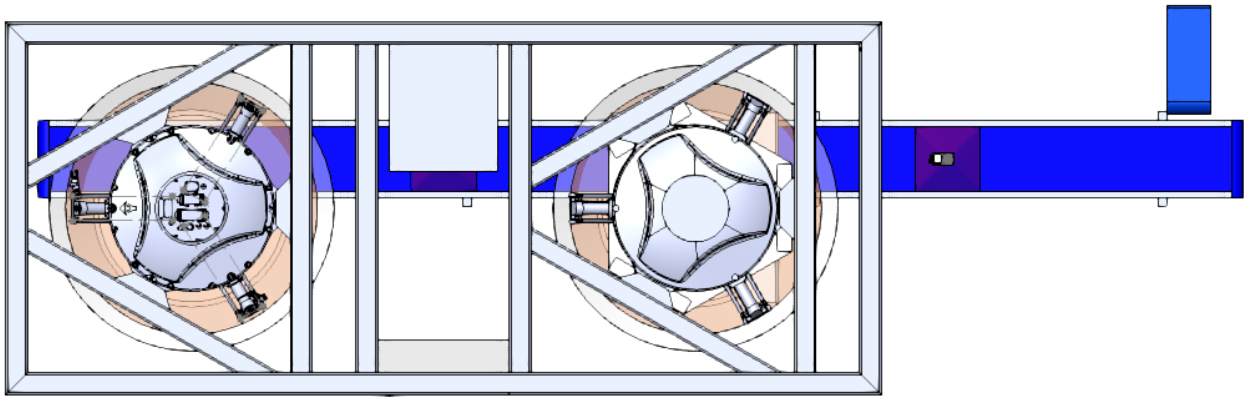


13.1.6 Electrical Panel Location

Electrical cabinet is in the centre of the frame.

13.1.7 Configuration

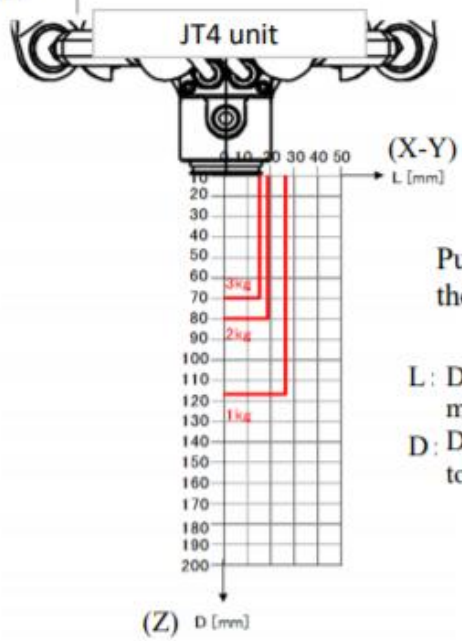
Two robots each with their own vision camera will reduce miss picks due to the product moving on the belt.



13.1.8 YF003N Robot Specification

1. Model	YF003N-A
2. Type	Delta Parallel Robot
3. Degree of freedom	4 axes
4. Max. payload	3 kg
5. Motion range	φ1,300 x H500 mm
6. Position repeatability	±0.10 mm conforms to ISO 9283
7. Angular repeatability	±0.10 °
8. Axis specification	

Operating axis	Motion range	Max. speed
Arm rotation 1 (JT1)	+95 ° - −52.5 °	1090.9 ° /s
Arm rotation 2 (JT2)	+95 ° - −52.5 °	1090.9 ° /s
Arm rotation 3 (JT3)	+95 ° - −52.5 °	1090.9 ° /s
Wrist twist (JT4)	±360 °	1714.3 ° /s

9. Cycle time (Payload)	0.27 s (1 kg), 0.45 s (3 kg) *Motion pattern (25mm up, 305mm horizontal, 25mm down in a to-and-fro motion)	
10. Load capacity of wrist		

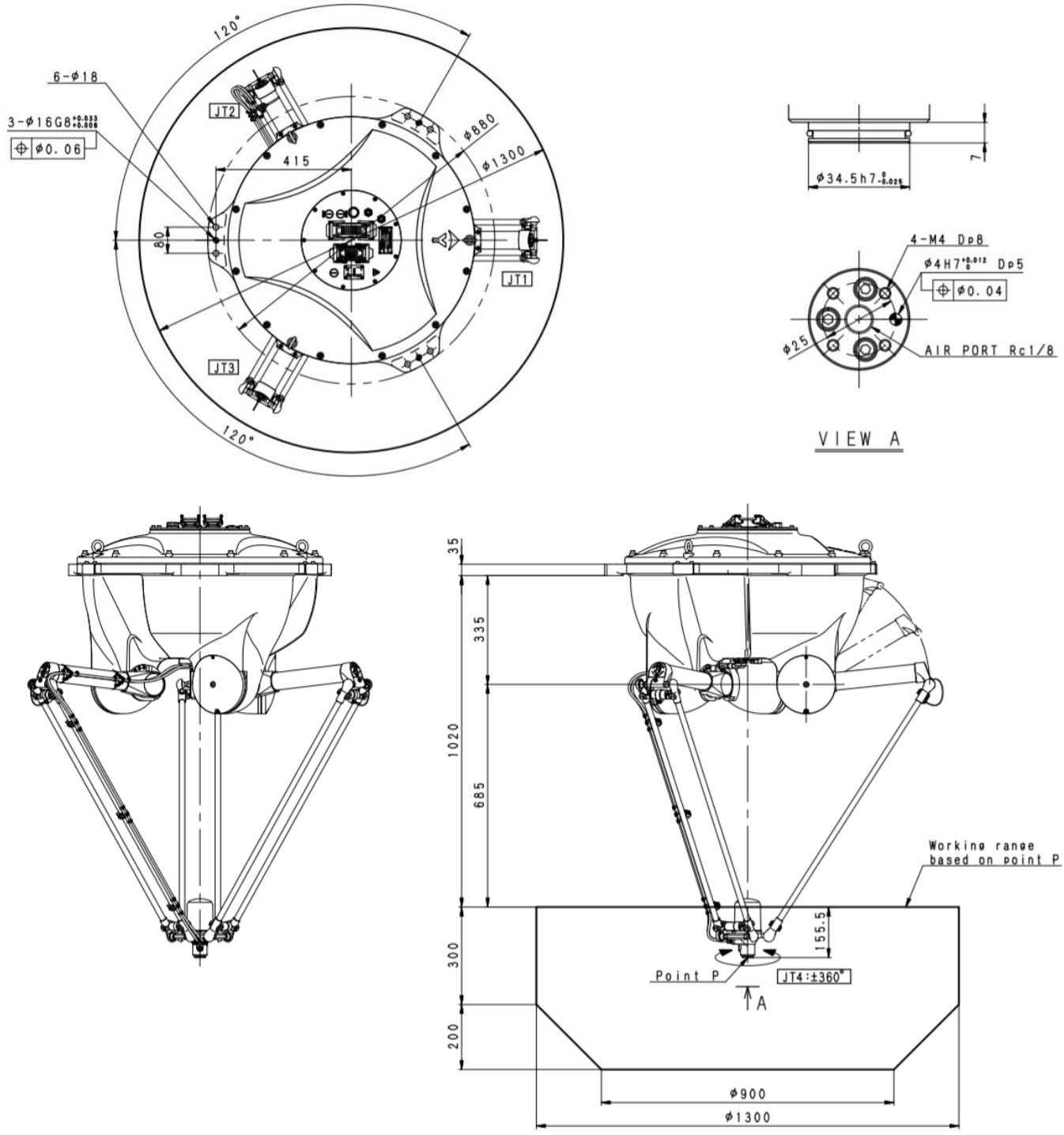
Load [-]	Max. Torque [Nm]	Max. Moment [Nm]
1kg	0.25	1.15
2kg	0.37	1.57
3kg	0.50	2.06

Put the center of mass inside of the line of the each load capacity.

L : Distance in X-Y dimension from Z-axis to the mass center of gravity of the load.
D : Distance in Z dimension from X-Y dimension to the mass center of gravity of the load.

11. Mass	145 kg (without options)	
12. Mounting	Ceiling mounting	
13. Installation Environment	Ambient Temperature :	0 - 45 °C
	Relative Humidity :	35 - 85 % (with no dew condensation)
14. Color	Munsell 10GY9/1 equivalent	
15. Degree of protection	IP65 equivalent	
16. Built-in utilities	Pneumatic piping (φ10 x 1 line)	
17. Options	Additional axis	5 Axis (Brakeless)
	Degree of protection	IP67 equivalent

13.1.9 YF003N Working Envelope



13.1.10 YF003N Safety

Sill ?? Guard system to satisfy EN…… with transparent Polycarbonate panels to prevent access to the cell.

13.1.11 Frame Material

Mild Steel 125x1257 TBC

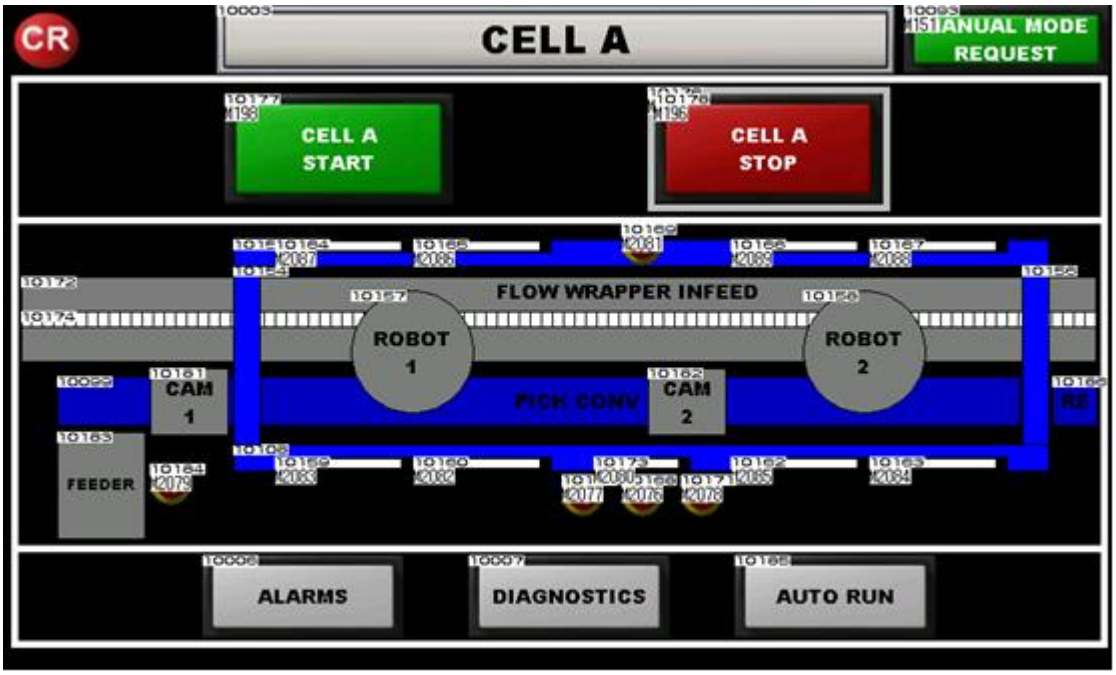
13.1.12 Frame Colour

RAL ??????

13.1.13 Guarding

10m Thick clear Polycarbonate Sheet with Stainless Steel Pelmet and siding

13.1.14 CELL A/B HMI



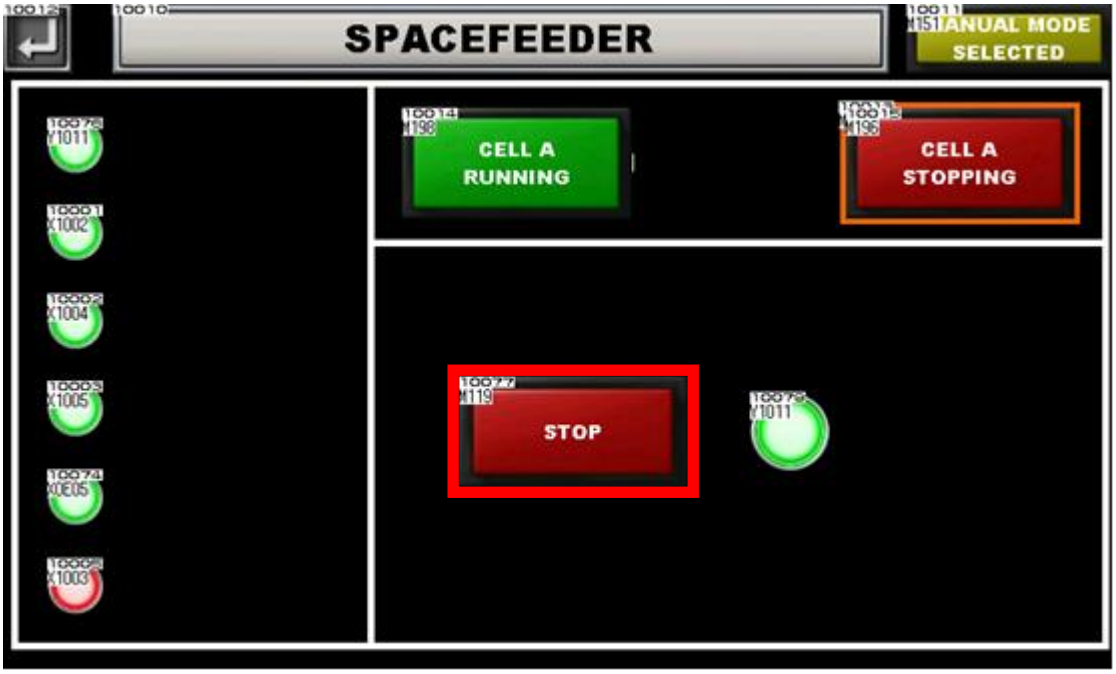
Starts The Cell

Stops the Cell

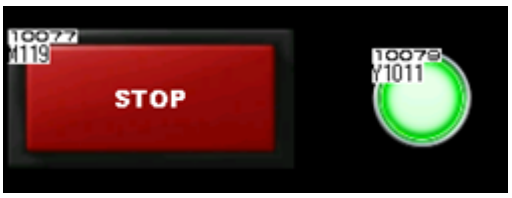
13.1.15 Manual Control

Allows access to manual control screen

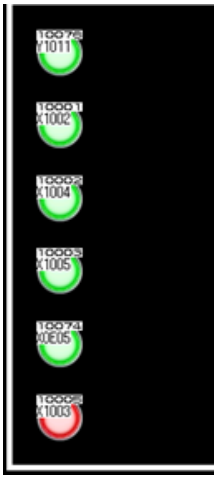
13.1.16 SPACE FEEDER MANUAL CONTROL



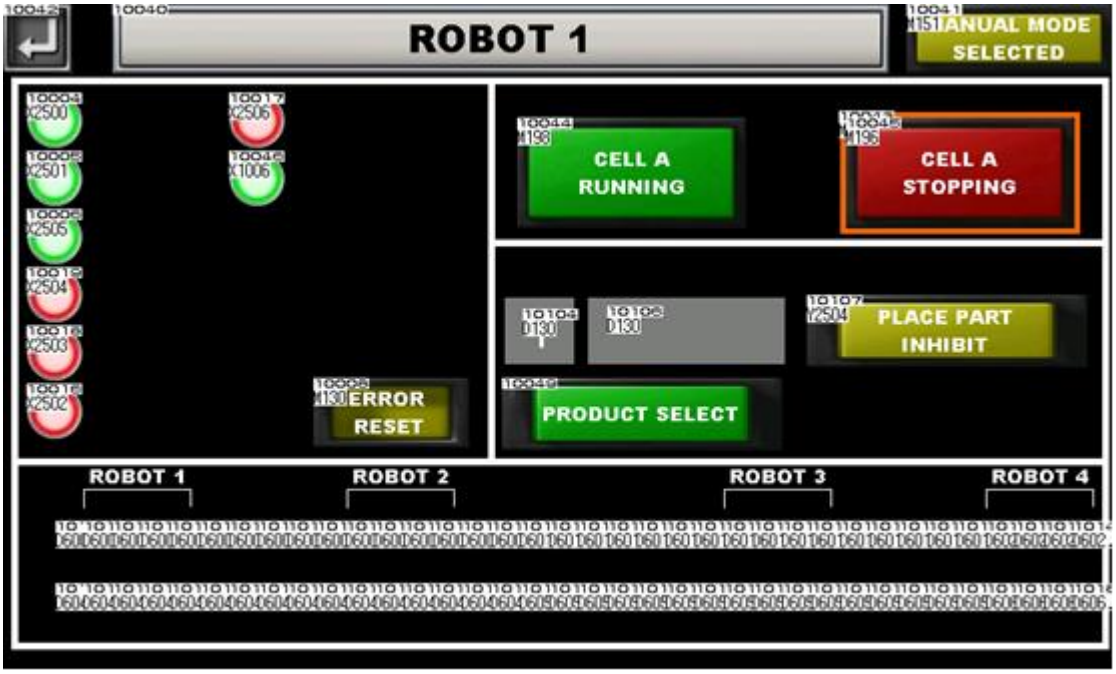
Starts and Stops the Space Feeder



Indicates the status of the Space Feeder

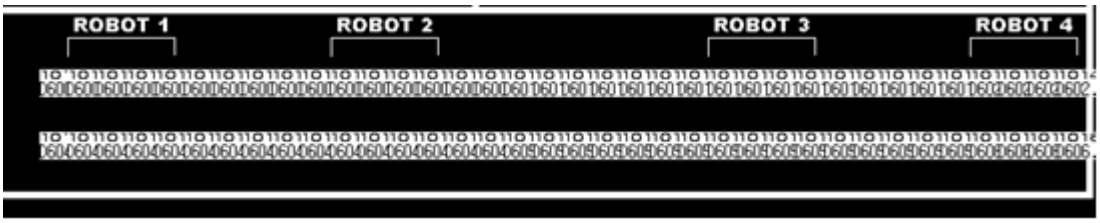


13.1.17 MANUAL ROBOT CONTROL



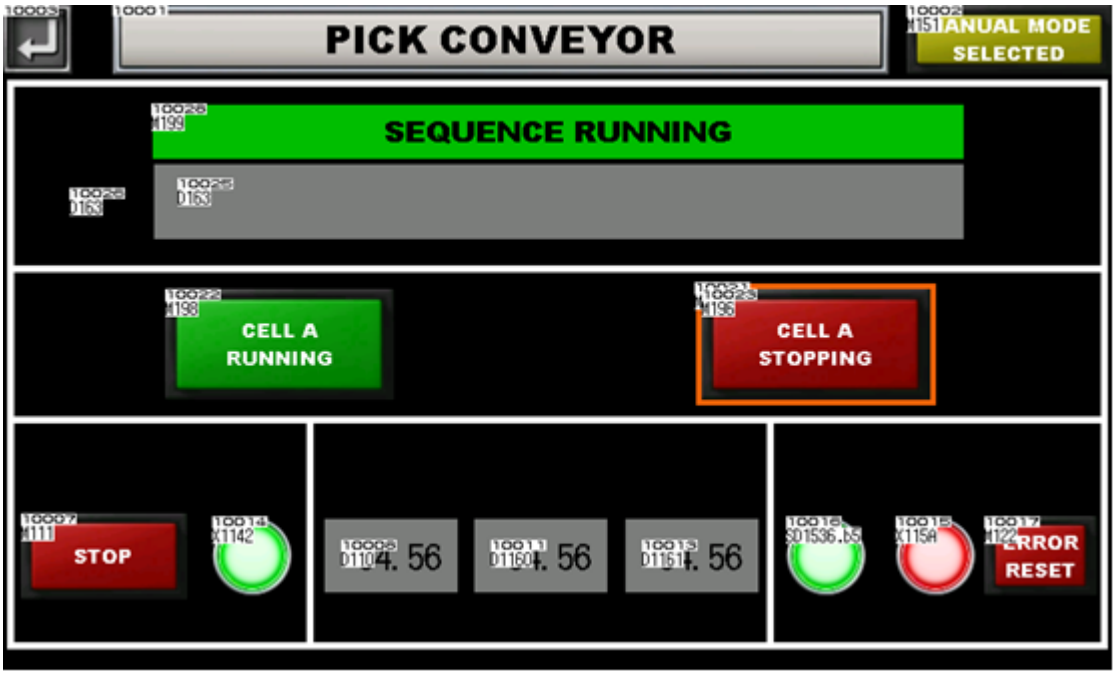
Allows different products to be selected for test proposes. This selection will be overridden once the CELL is returned to ait

Displays messages and status of the Picking Robots



Displays the status of the robot and allows alarms to be reset.

13.1.18 MANUAL PICK CONVEYOR CONTROL

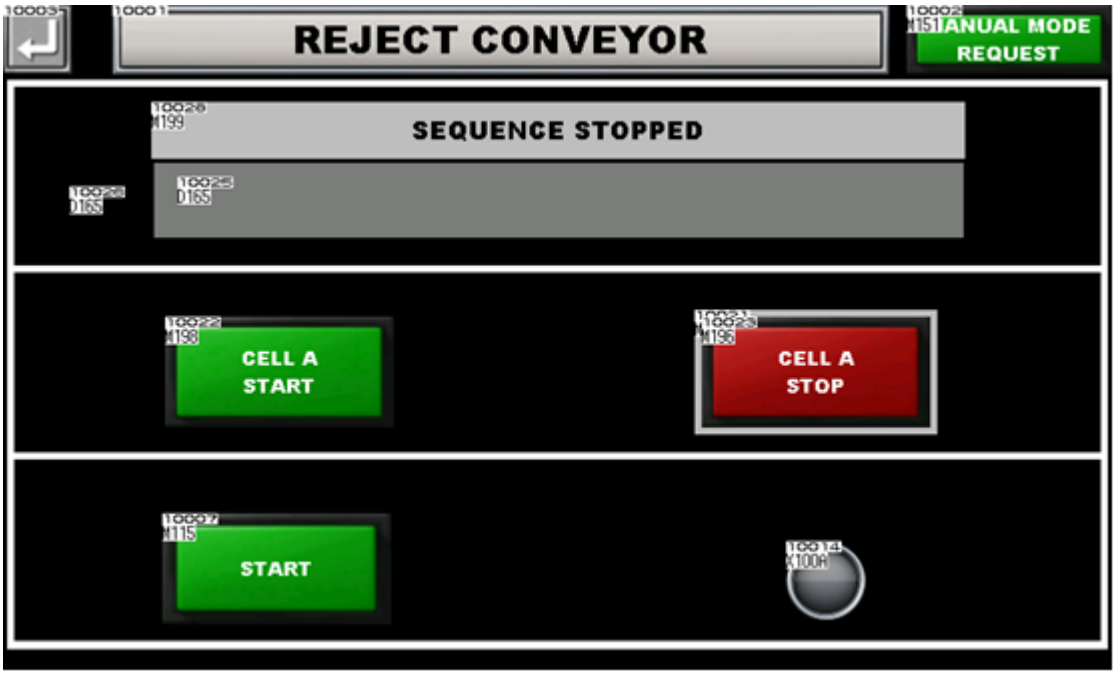


Allows the Pick Conveyor to be manually started and stopped.

Monitors the sped and allows a pre-set speed to entered.

Allows drive alarms to be reset.

13.1.19 MANUAL REJECT CONVEYOR CONTROL

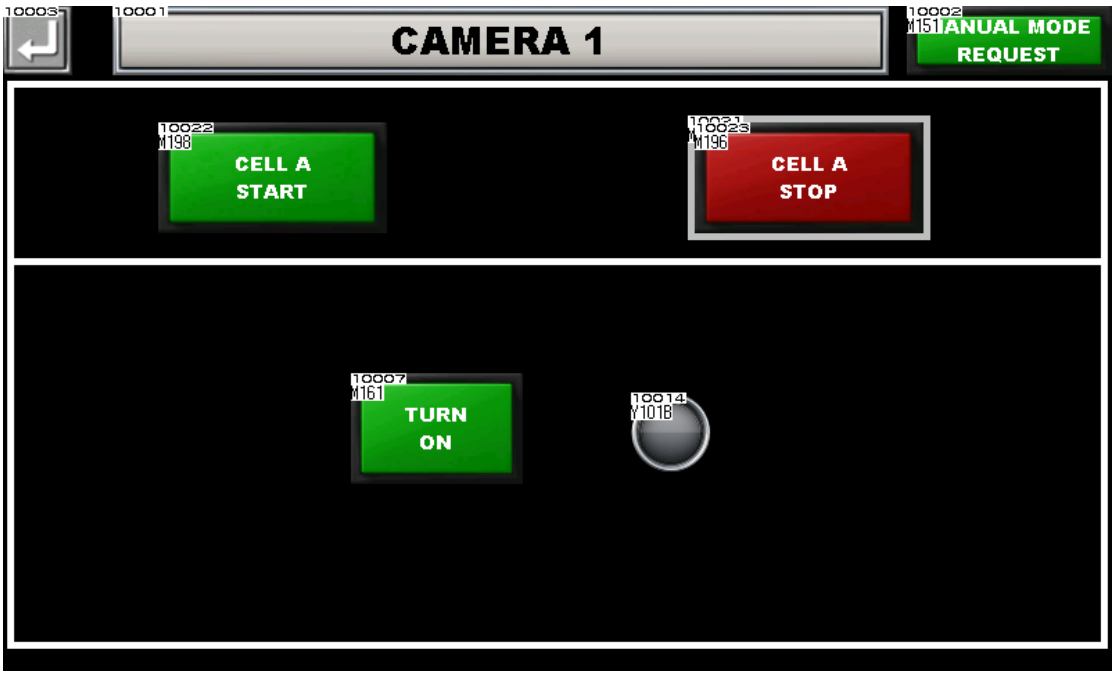


Displays error and status messages

Manually Starts and Stops the Conveyor

13.1.20 MANUAL CAMERA CONTROL

Allows the Camera to be switched on and off manually.

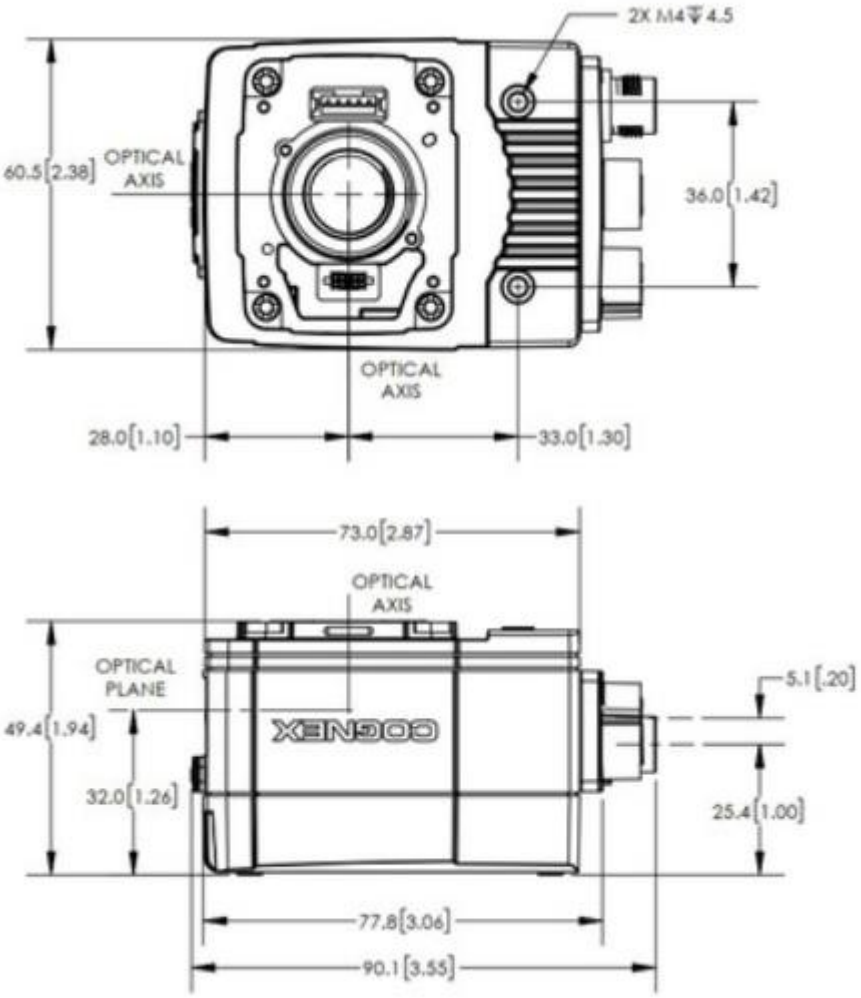


14. Vision System Specification

14.1.1 Electrical

Pick Cell Camera	
Camera	24VDC 1A Supply and IO
Camera	Ethernet
Camera Light	24VDC Supply
Network	TCP/IP
Protection	IP67
Refresh Rate	32 fps
Operating Temp	0-50 degrees C
OS	Patmax
Height	35.7
Width	60.1
Depth	90.1

14.1.2 Dimensions



14.1.3 Lighting

Red LED 24VDC

15. Tube Dispenser Specification

The tubes will be presented to the bowl feeder outlet, selected in a single line orientated all one way hanging from their cap ready for discharge down a proposed vibratory linear feeder.

15.1.1 Feed rate

minimum 150 PPM

15.1.2 Capacity

30 minutes between fill

15.1.3 Bowl Material

Mild Steel with Interior bowl coating of pharmaceutical polyurethane

15.1.4 Bowl diameter

800mm

15.1.6 Star wheel

A rotary star wheel will be mounted on top of the table and will collect tubes from the output of the bowl feeder depositing them into the table pockets. The star wheel will be synchronised to the table speed and pocket position. Sensors will ensure a successful deposit.

16. Flow Wrapper

16.1.1 Type

Syntogen **Pack 403** Horizontal Flow wrapper.

16.1.2 Maximum capacity

Real and maximum capacity depending on products and film.

16.1.3 Colour of all painted parts

RAL 9006, FDA approved.

16.1.4 Power requirements

3 x 400 Volts, 50 cycles with 0 and earth.

16.1.5 Air

Minimum pressure 6 Bar.

16.1.6 Ambient temperature

5 - 35 degrees Celsius.

16.1.7 Product Dimensions

205 x 40 x 17 mm. (L x W x H).

16.1.8 Product variations.

Aptima Cervical (302736)
Swab (R) - 500561
Brush - 501658
Transport Tube (G) – 401903
4.5mL liquid fill

Aptima Combo 2 (301041-01)
Swab (R) - 500561
Swab (G) – 105006-02
Transport Tube (P) – LR0233-01
2.9mL liquid fill

Aptima Vaginal (301162) &
Multi-Test (ASY-08848)
Swab (O) – 503747
Transport Tube (O) – LR0383
2.9mL liquid fill

Aptima Urine (301040-01)
Pipette - 104590
Transport Tube (Y/B) – LR0232-01
2.0mL liquid fill
& **Backer Card**

Progensa PCA3 (302430)
Pipette - 104590
Transport Tube (Y/W) – 401163
2.5mL liquid fill
& **Backer Card**

Pack consisting of:

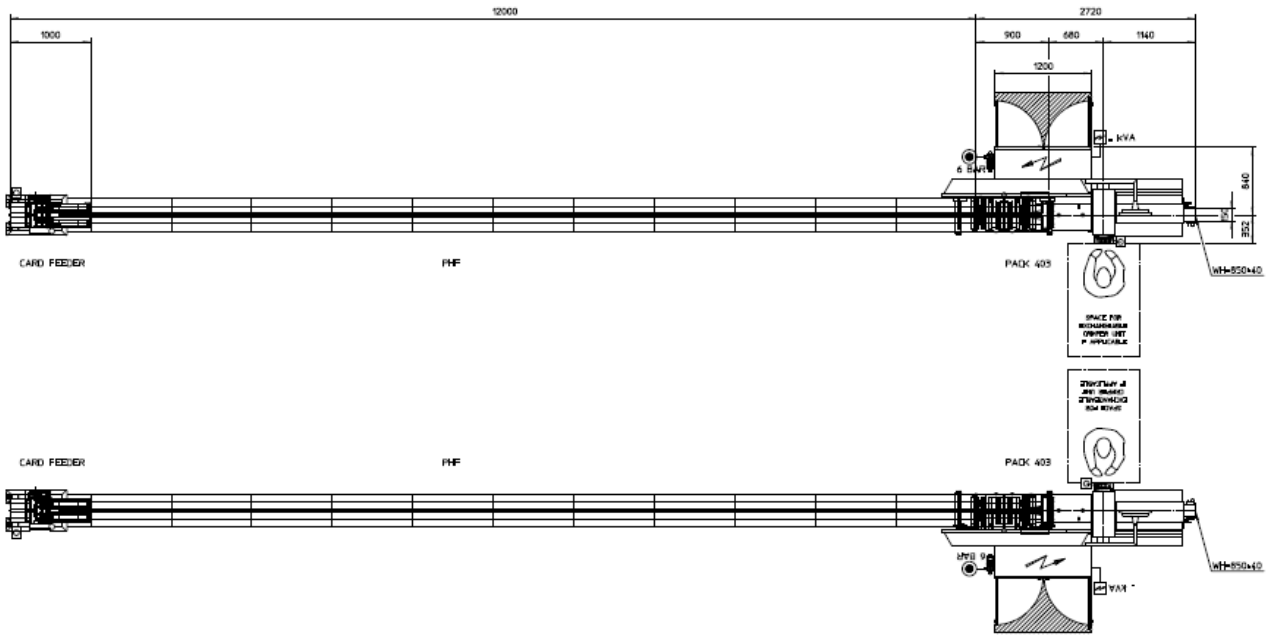
- Card
- Swabs (pre-packed)
- Brushes (pre-packed)
- Tubes
- Pipettes

To be confirmed by you and to be approved by us.

Product tolerances:

in length direction ± 1 mm;
in width direction ± 1 mm;
in height direction ± 1 mm;

16.1.9 Machine Dimensions



16.1.10 Reject

16.1.11 Printer

16.1.12 Print verification

16.1.13 Operation

16.1.14 Maintenance

16.1.15

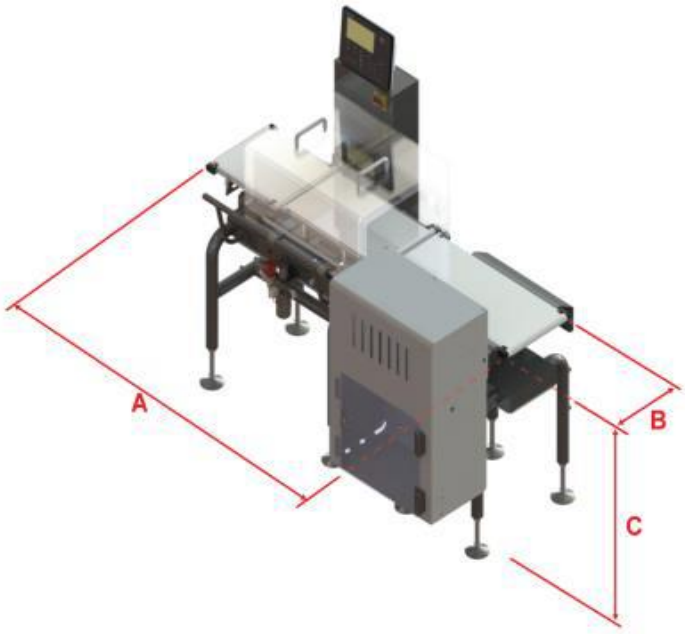
17. Check Weigher (Flow Wrap

17.1.1 Type

ISHIDA DACS-GN-SE012-24-SS-I-S

17.0.1.2 Dimensions

A x B x C (mm): 1704 x 300 x 650



17.1.3 Product

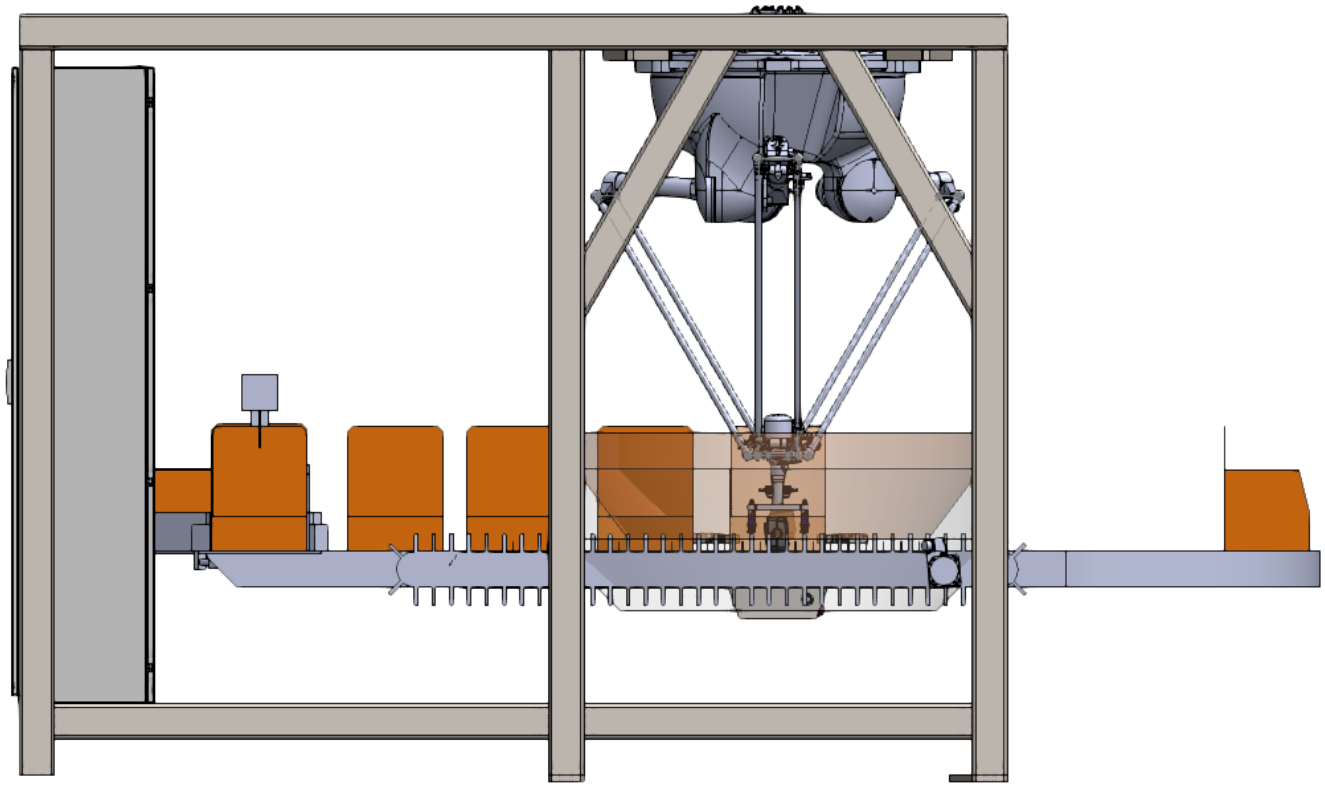
Product Description	Flow Wrapped Packet A	Flow Wrapped Packet B
Target Speed (per minute)	150	150
Target Weight (g)	8.6	6.1
Gross Weight (g)	8.6	6.1
Pack Length (mm)	248	248
Pack Width (mm)	51	51
Pack Height (mm)	30	30
Pack Type	Flow Wrapped Multipacks Confectionery	Flow Wrapped Multipacks Confectionery
Leading Edge	Narrow	Narrow

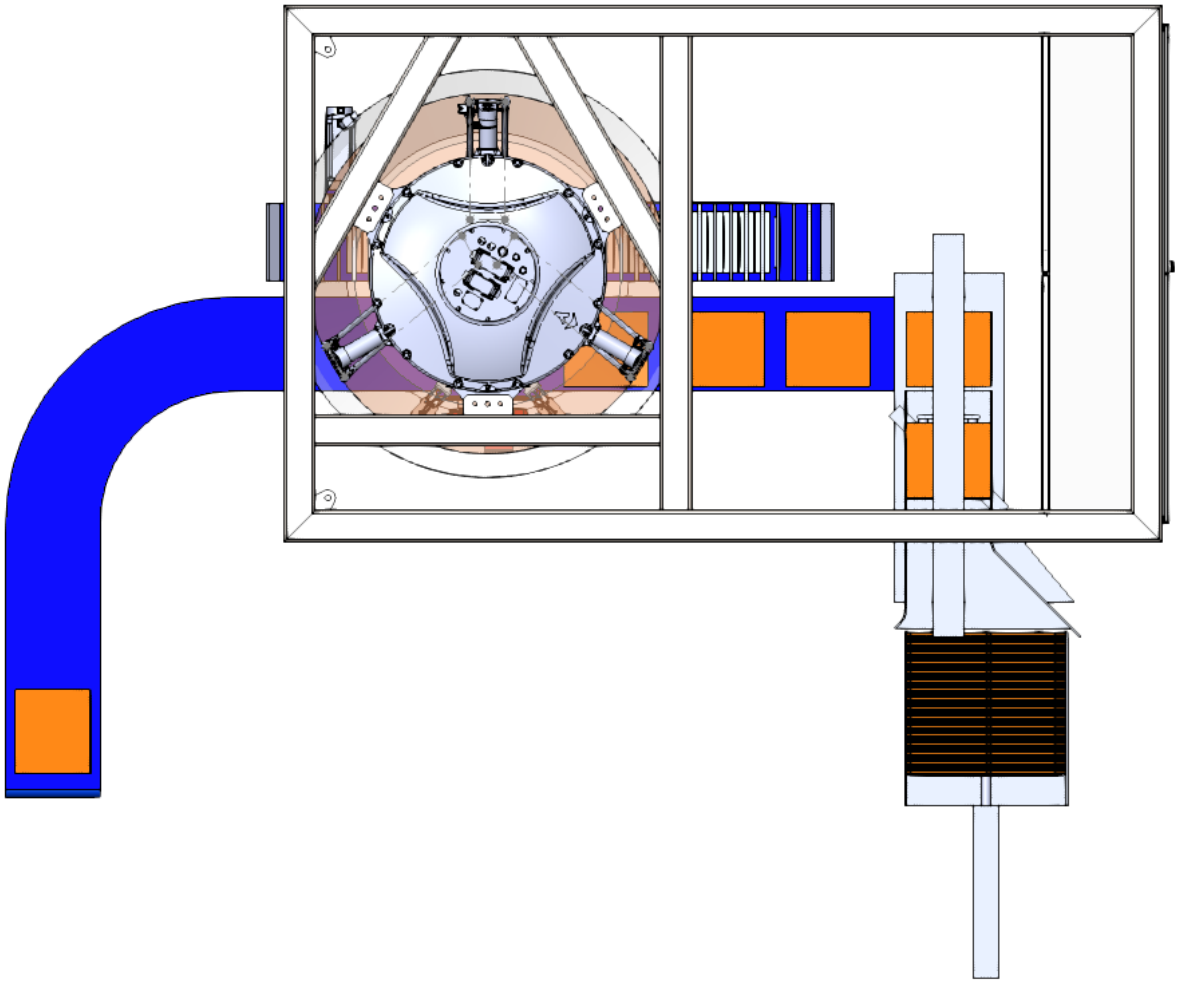
17.1.4 Reject

Reject	
1	Single Heavy Duty air blast reject (Incl Reservoir Kit) for 220mm x 550mm conveyor (Stainless Steel)
Reject Bins	
1	Stainless steel reject bin 220mm x 550mm long
Display	
1	Standard keypad display for DACS GN-SE
Communications	
1	Ishida Sentinel Remote Monitoring Software - FREE OF CHARGE LIFETIME ACCESS to the SENTINEL REPORTING PACK
Covers	
1	Wind Shield - Upper

17.1.5 Reject Direction

The direction of the feed required	Left to Right
Direction of reject for underweight product	Front
Direction of reject for overweight product	Front

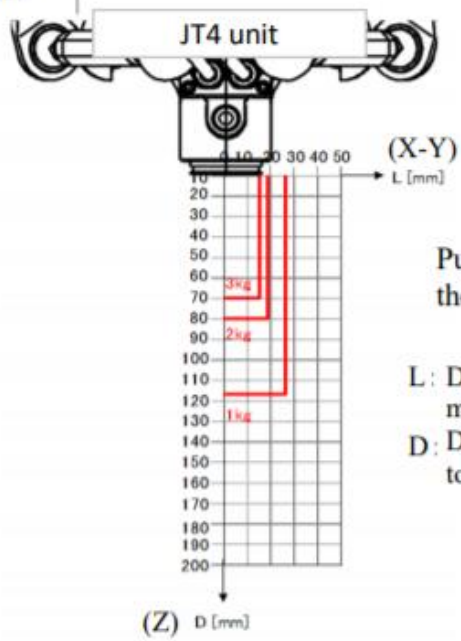




22.1.14 Kit Cell YN003N Robot

1. Model	YF003N-A
2. Type	Delta Parallel Robot
3. Degree of freedom	4 axes
4. Max. payload	3 kg
5. Motion range	φ1,300 x H500 mm
6. Position repeatability	±0.10 mm conforms to ISO 9283
7. Angular repeatability	±0.10 °
8. Axis specification	

Operating axis	Motion range	Max. speed
Arm rotation 1 (JT1)	+95 ° - −52.5 °	1090.9 ° /s
Arm rotation 2 (JT2)	+95 ° - −52.5 °	1090.9 ° /s
Arm rotation 3 (JT3)	+95 ° - −52.5 °	1090.9 ° /s
Wrist twist (JT4)	±360 °	1714.3 ° /s

9. Cycle time (Payload)	0.27 s (1 kg), 0.45 s (3 kg) *Motion pattern (25mm up, 305mm horizontal, 25mm down in a to-and-fro motion)
10. Load capacity of wrist	

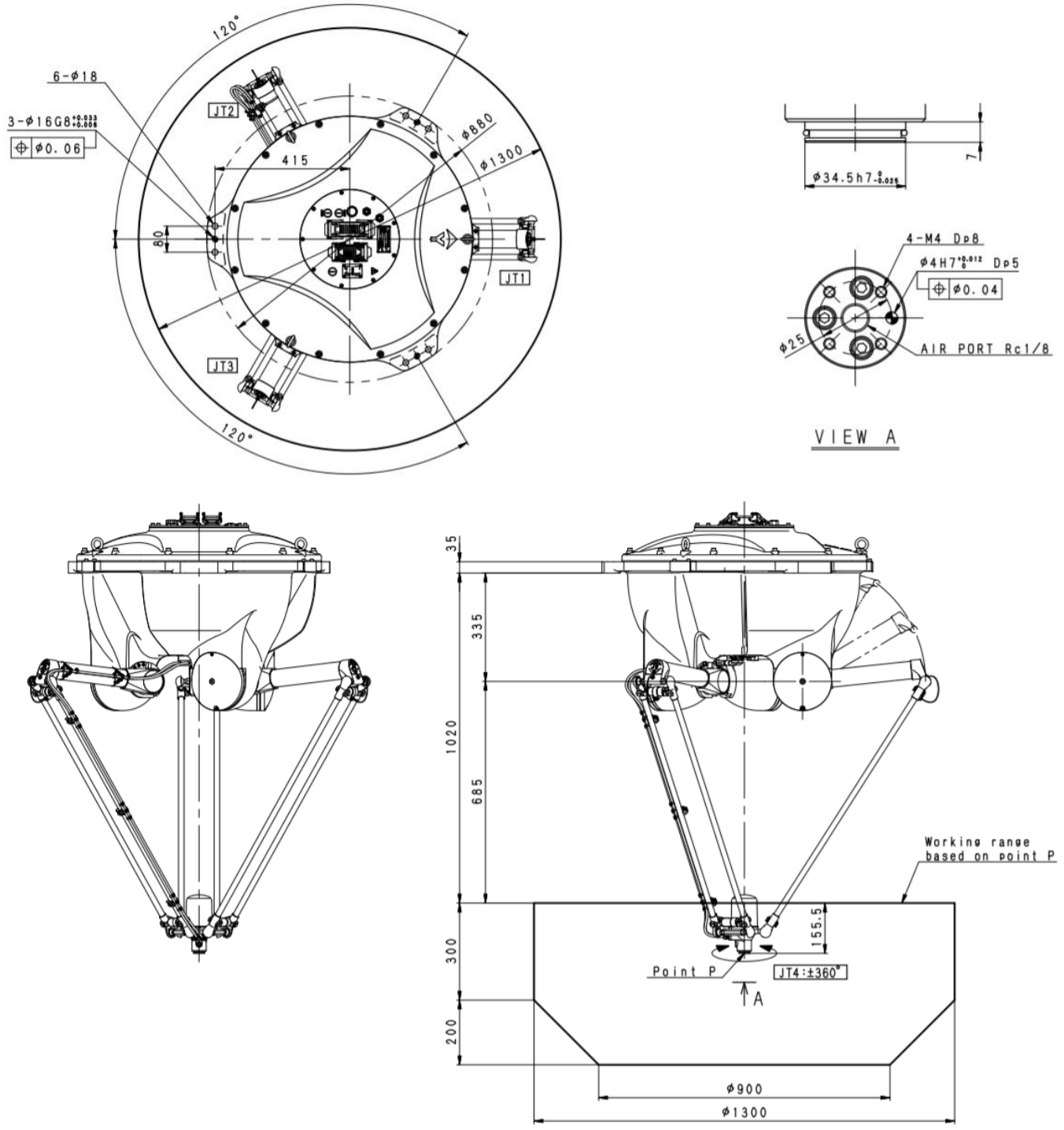
Load [-]	Max. Torque [Nm]	Max. Moment [Nm]
1kg	0.25	1.15
2kg	0.37	1.57
3kg	0.50	2.06

Put the center of mass inside of the line of the each load capacity.

L : Distance in X-Y dimension from Z-axis to the mass center of gravity of the load.
D : Distance in Z dimension from X-Y dimension to the mass center of gravity of the load.

11. Mass	145 kg (without options)	
12. Mounting	Ceiling mounting	
13. Installation Environment	Ambient Temperature :	0 - 45 °C
	Relative Humidity :	35 - 85 % (with no dew condensation)
14. Color	Munsell 10GY9/1 equivalent	
15. Degree of protection	IP65 equivalent	
16. Built-in utilities	Pneumatic piping (φ10 x 1 line)	
17. Options	Additional axis	5 Axis (Brakeless)
	Degree of protection	IP67 equivalent

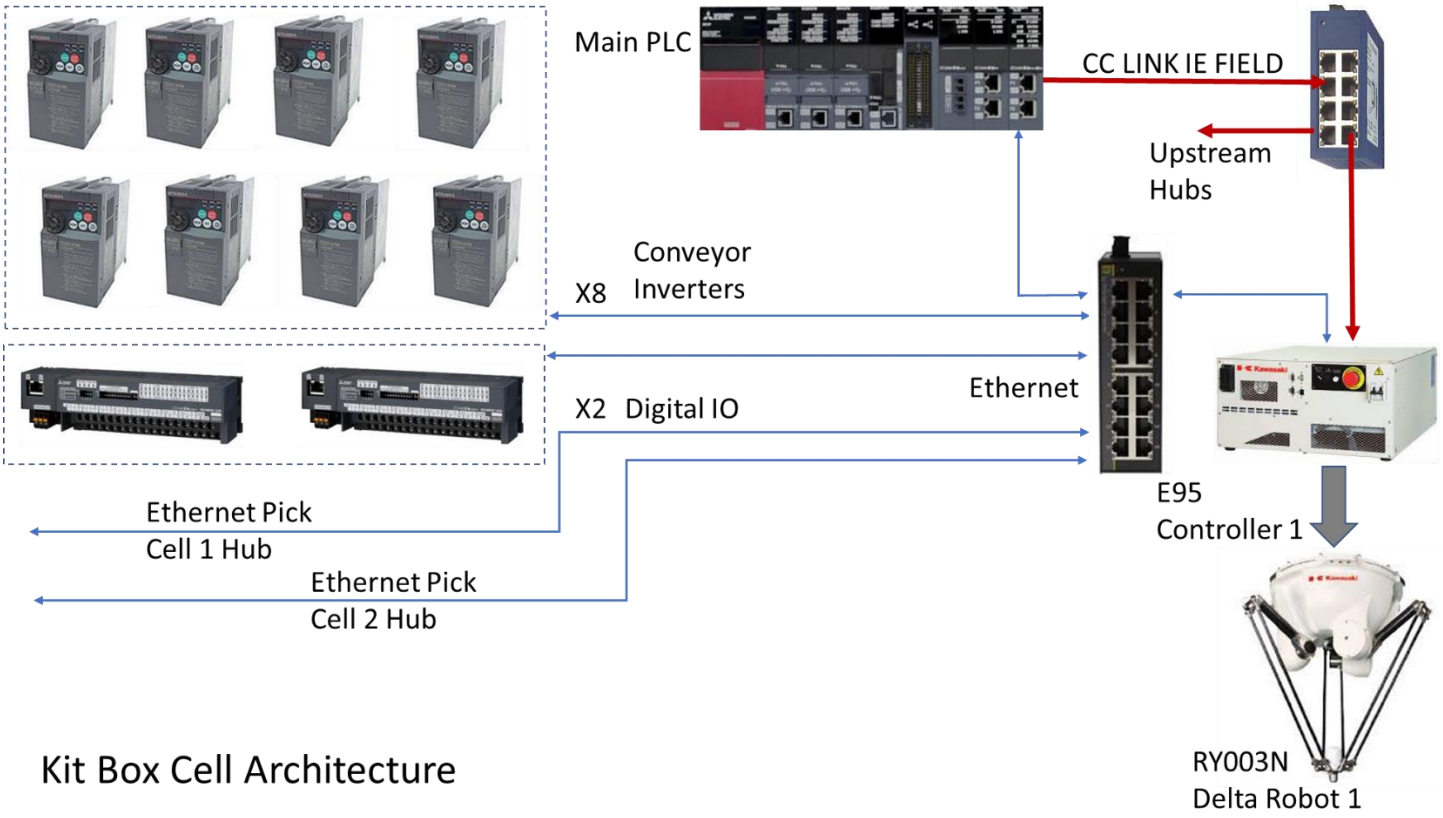
22.1.15YF003N Working Envelope



22.1.16 YF003N Safety

Sill ?? Guard system to satisfy EN…… with transparent Polycarbonate panels to prevent access to the cell.

22.1.17 Kit Box Cell Architecture



Kit Box Cell Architecture

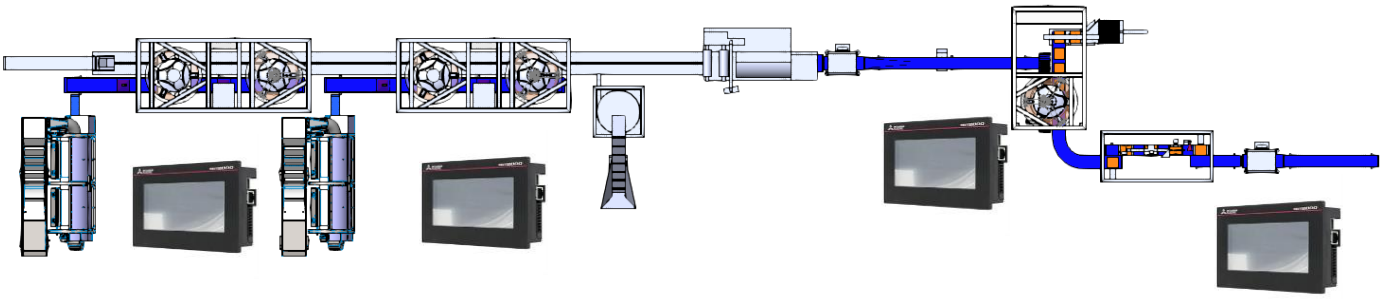
22.1.17 Control Overview

A PLC positioned in the Kit Box Cell control panel will act as a master control for the whole line, an Ethernet hub will connect to local conveyer inverters as well as local digital IO as well as remote hubs located at the picking cells and HMIs positioned along the line.

A separate CCLINK IE Field Network will connect all the robot controllers.

22.1.19 HMI

HMI stations will be positioned at points along the line.



Each HMI will allow access and control for each stage and will allow global control to start and atop the line