SOFTWARE DESIGN SPECIFICATION

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Equipment Name:	Stopper Insertion
Equipment Description:	Stopper Insertion & Screw Driver Station
Equipment Serial Number:	TM429-EMALC/4

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1   DOCUMENT APPROVAL

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5   REVISION HISTORY

Revision	Description	Date
1.0	First release	August 2025

6   NOMENCLATURE

Acronym	Description
FDS	**F**unctional **D**esign **S**pecification
SDS	**S**oftware **D**esign **S**pecification
PLC	**P**rogrammable **L**ogic **C**ontroller
HMI	**H**uman **M**achine **I**nterface
I/O	**I**nput **/ O**utput

7   EXTERNAL DOCUMENT REFERENCES

Ref. Number	File Name
TE1096_EMALC FDS	TE1096_Stopper Insertion_FDS_Rev1.0

8   INTRODUCTION

8.1   PURPOSE

This Software Design Specification (SDS) defines the design for the software controlling the Eagle Manual Assembly Line Consumable Stopper Insertion. This document defines the design that follows from the Functional Design Specification (FDS).

This Software Design Specification is generated to define the major software components required for the EMALC Stopper Insertion, to be designed and built by Tegan Innovations Ltd., and located at Jabil Healthcare in Bray, Ireland.

8.2 SYSTEM OVERVIEW

The EMALC Stopper Insertion system includes one stopper insert, one screw station, and one nest station. In the first station, the stopper is inserted based on distance and force. In the second station, the screw part is screwed into the threaded part. Finally, the last station moves the parts to the work position and ejects the nest at the end of the cycle.

This station has four positions: home position, work position 1 (to take the screw part and insert the stopper), work position 2 (to screw the screw part), and outfeed (when the cycle is done).

Once the EMALC Stopper Insertion has been initialized, the operator must press the Start button to enter Auto Cycle mode, provided that no errors are present. In this mode, the nest containing the parts must be inserted fully (until it reaches the end) and held by pressing two safety buttons with both hands to start the cycle.

Once the cycle starts, the nest moves to the first work position, where the screw part is picked up by the SMAC unit and the stopper is fully inserted by the Kistler unit. After the first process is complete, the nest moves to the second work position, where the screw part is screwed into the threaded part. After this process is finished, the nest moves to the outfeed position to be removed.

At the end of the cycle, the nest returns to the home position. Each station provides a result indicating whether the part has passed or failed according to its respective standard. If the parts meet all criteria, the system displays a PASS result; if they do not, the system displays a FAIL result.

9 SOFTWARE DESIGN

The Software Design encompasses the PLC and HMI design, it comprises of the following sections:

5.1 PLC Software

5.2 PLC Software Design

5.3 HMI Software

5.4 HMI Design

5.5 Alarms & Messages

9.1 PLC SOFTWARE

The PLC hardware and software used is Beckhoff C6015-0010 and Beckhoff TwinCAT v.3.1.4024.60 respectively.

The programme used is Structured Text which meets the IEC 61131-3 programming standard for PLC's.

9.2 PLC SOFTWARE DESIGN

The PLC Software Design is sub-divided into the following sections:

NAME	LEVEL	FUNCTION
Machine Status	1	This is the highest level of machine control. The Machine Status gathers information from the control buttons and presents the Master Control and machine stations.
Master Control	2	The Master Control synchronises the action of the machine stations. It used the information presented by the Machine Status.
Stations	3	Each Station function is defined here. A station only operates when instructed to do so by the Master Control.

Table 1: PLC Software Design Section

These levels are described in more detail in the following sections.

9.2.1   MACHINE STATUS

The Machine Status routine is the highest level of Machine / System control. The current status of the Machine / System is determined by the state of the main control buttons (Start, Reset, Cycle Stop) and from feedback from the Master Control. The diagram below at Figure 1 illustrates the basic flow of the Machine Status routine for during normal operation.
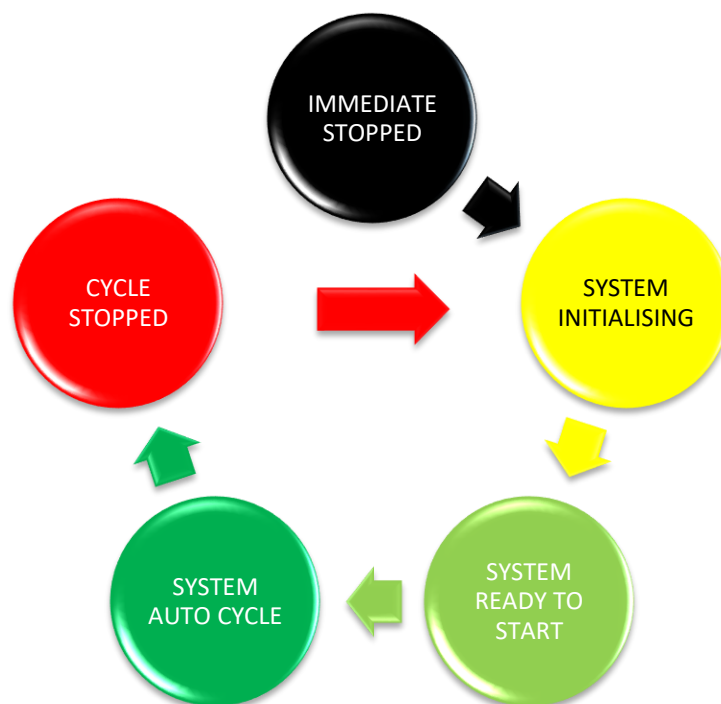
Figure 1: Machine Status Basic Diagram

A more detailed diagram of the full Machine Status routine is given in Figure 2. The Machine Status routine moves between states depending on the status of the main control buttons and feedback from the Master Control. Master Control feedback includes status on items such as Cycle Stop Faults, Immediate Faults or System Dwells.
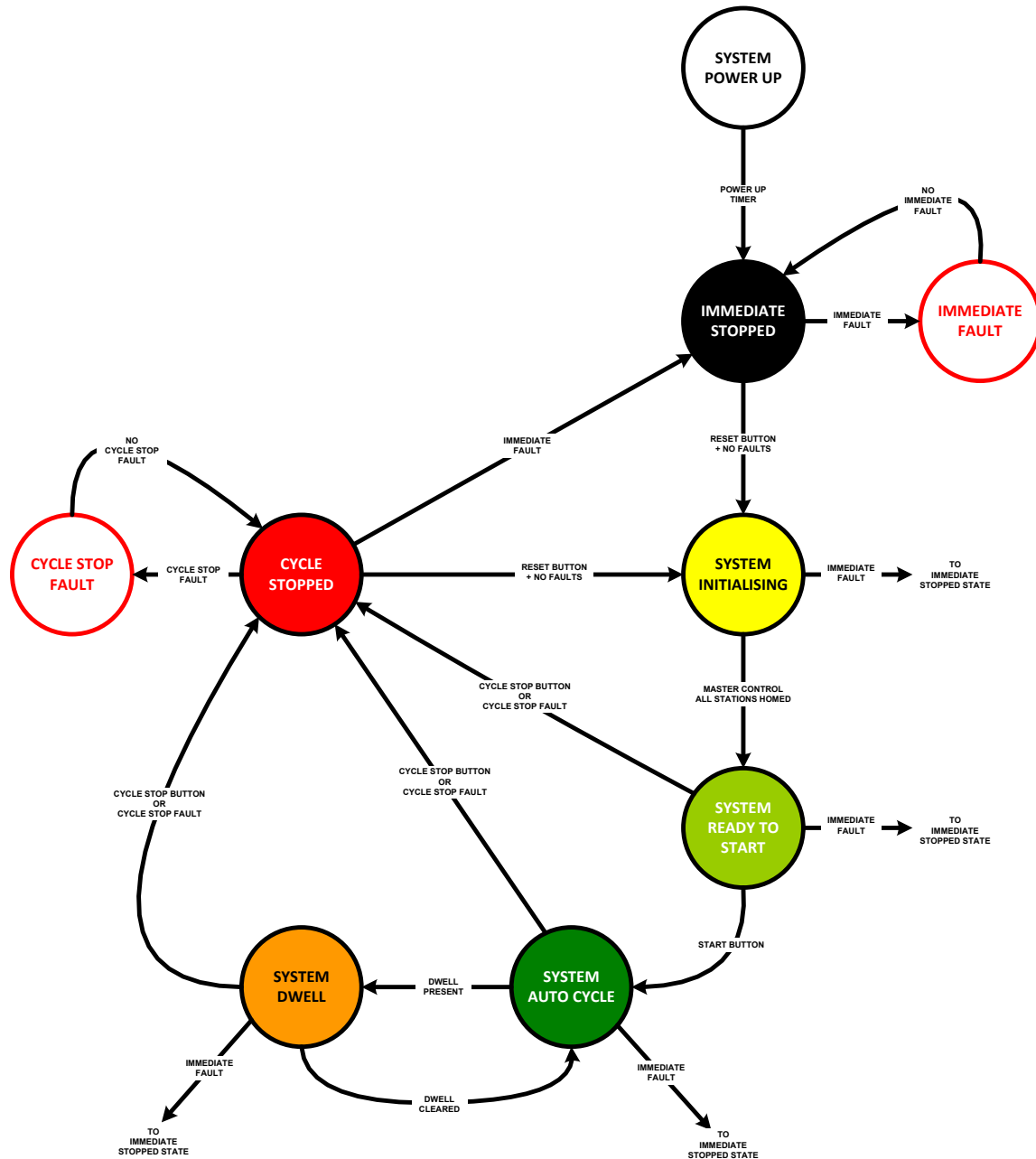
Figure 2: Machine Status Detailed Diagram

A detailed description of each System State is given in the next section, including state entry and state exit conditions.

9.2.2   SYSTEM STATES

9.2.2.1   SYSTEM POWER UP

STATE DESCRIPTION	The state the system enters automatically once power is applied to the system. Main Power and Air are not active during this state.
STATE ENTRY CONDITIONS	1. Machine or System Powered On.
STATE EXIT CONDITIONS	2. All Power-Up Timers must be complete. These may include PLC power-up timers, power-up sequence timers, peripheral device power-up timers, etc. The system will then enter IMMEDIATE STOPPED state.

Table 2: System Power Up

9.2.2.2   IMMEDIATE STOPPED STATE

| STATE DESCRIPTION	This state is active when system in IMMEDIATE FAULT and all the Immediate Faults are not active. All system/machines actions are immediately halted during this state.
STATE ENTRY CONDITIONS	1. SYSTEM POWER UP state is complete. 2. The Master Control triggers an Immediate Stop or Fault Condition.
STATE EXIT CONDITIONS	1. If an Immediate Fault is active, the system will enter the IMMEDIATE FAULT state. 2. If all Faults are cleared and the falling edge of the Reset button is detected, the system will enter the state SYSTEM INITIALISING.

Table 3: Immediate Stopped State

9.2.2.3 IMMEDIATE FAULT STATE

STATE DESCRIPTION	This state is only active when an Immediate Fault is active.
STATE ENTRY CONDITIONS	1. An Immediate fault is active at any stage.
STATE EXIT CONDITIONS	1. When all Immediate Faults have been cleared the system moves into the IMMEDIATE STOPPED state.

Table 4: Immediate Fault State

9.2.2.4 SYSTEM INITIALISING STATE

STATE DESCRIPTION	In this state all Stations are homing and all devices initialising.
STATE ENTRY CONDITIONS	1. The Reset Button is pressed, and all faults are clear when in state IMMEDIATE STOPPED. 2. The Reset Button is pressed, and all faults are clear when in state CYCLE STOPPED.
STATE EXIT CONDITIONS	1. The Master Control indicates that all stations are homed. The system then enters the READY TO START state. 2. The Master Control triggers an Immediate Stop. The system returns to the IMMEDIATE STOPPED state.

Table 5: System Initialising State

9.2.2.5   SYSTEM READY TO START STATE

STATE DESCRIPTION	All stations are homed during this state. The system or machine is now ready to start.
STATE ENTRY CONDITIONS	1. All stations are homed when in the SYSTEM INITIALISING state.
STATE EXIT CONDITIONS	1. The Start Button is pressed. The system enters the state SYSTEM AUTO CYCLE. 2. The Cycle Stop Button is pressed. The system enters the CYCLE STOPPED state. 3. The Master Control triggers a Cycle Stop. The system enters the CYCLE STOPPED state. 4. The Master Control triggers an Immediate Stop. The system returns to the IMMEDIATE STOPPED state.

Table 6: System Ready to Start State

9.2.2.6   SYSTEM AUTO CYCLE STATE

STATE DESCRIPTION	The system or machine is running in this state. The Master Control synchronises all stations to operate in the desired order.
STATE ENTRY CONDITIONS	1. The Start Button is pressed in the READY TO START state. 2. A Dwell has been cleared when in the SYSTEM DWELL state.
STATE EXIT CONDITIONS	1. A Dwell is activated. The system moves into the SYSTEM DWELL state. 2. The Cycle Stop Button is pressed. The system enters the CYCLE STOPPED state. 3. The Master Control triggers a Cycle Stop. The system enters the CYCLE STOPPED state. 4. The Master Control triggers an Immediate Stop. The system returns to the IMMEDIATE STOPPED state.

Table 7: System Auto Cycle State

9.2.2.7 SYSTEM DWELL STATE

STATE DESCRIPTION	The system enters this state if it is waiting for external action in order to continue in AUTO CYCLE. Examples of Dwells include empty nest(s). The SYSTEM DWELL state is used to alert the operator that the system is waiting for external action.
STATE ENTRY CONDITIONS	1. A Dwell is activated when in the SYSTEM AUTO CYCLE state.
STATE EXIT CONDITIONS	1. A Dwell has been cleared when in the SYSTEM DWELL state. The system returns to the AUTO CYCLE state. 2. The Cycle Stop Button is pressed. The system enters the CYCLE STOPPED state. 3. The Master Control triggers a Cycle Stop. The system enters the CYCLE STOPPED state. 4. The Master Control triggers an Immediate Stop. The system returns to the IMMEDIATE STOPPED state.

Table 8: System Dwell State

9.2.2.8 CYCLE STOPPED STATE

STATE DESCRIPTION	In this state the system or machine is stopped in a controlled manner
STATE ENTRY CONDITIONS	1. The Cycle Stop Button is pressed when in the SYSTEM READY TO START state. 2. The Cycle Stop Button is pressed when in the SYSTEM AUTO CYCLE state. 3. The Cycle Stop Button is pressed when in the SYSTEM DWELL state. 4. The Master Control triggers a Cycle Stop when in the SYSETM READY TO START state. 5. The Master Control triggers a Cycle Stop when in the SYSTEM AUTO CYCLE state. 6. The Master Control triggers a Cycle Stop when in the SYSTEM DWELL CYCLE state. 7. All Cycle Stop Faults are cleared when in the CYCLE STOP FAULT state.
STATE EXIT CONDITIONS	1. If a Cycle Stop Fault is active, the system will enter the Cycle STOP FAULT state. 2. If all Faults are cleared and the falling edge of the Reset button is detected, the system will enter the state SYSTEM INITIALISING.

Table 9: Cycle Stopped State

9.2.2.9   STOPPING STATE

STATE DESCRIPTION	In this state the system stops the current cycle in a controlled manner.
STATE ENTRY CONDITIONS	1- The Cycle Stop Button is pressed when in the SYSTEM AUTO CYCLE state.
STATE EXIT CONDITIONS	1- If is safely stopped the system will enter the state CYCLE STOPPED.

Table 10: Stopping State

9.2.2.10 MANUAL STATE

STATE DESCRIPTION	In this state the system allows the user to control perform a maintenance on the inputs and outputs of the machine.
STATE ENTRY CONDITIONS	1- Manual is request from master control when system in CYCLE STOPPED.
STATE EXIT CONDITIONS	2- Manual request is cleared the system will return to CYCLE STOPPED.

Table 11: Manual State

9.2.2.11 CYCLE STOP FAULT STATE

STATE DESCRIPTION	This state is only active when there is a Cycle Stop Fault.
STATE ENTRY CONDITIONS	1. A Cycle Stop fault is active when system in SYSTEM AUTO CYCLE.
STATE EXIT CONDITIONS	1. When all Cycle Stop Faults have been cleared the system moves into the CYCLE STOPPED state.

Table 12: Cycle Stop Fault State

9.2.3 MASTER CONTROL

The Master Control resides on level 2 of the System Hierarchy. The Master Control sends to the Machine Status, information in relation to the machine operation. In turn, the Master Control monitors the Machine Status and directs the machine accordingly. For example, if the Machine Status is in the 'IMMEDIATE STOPPED' state, the Master Control instructs the machine to halt immediately.

Alternatively, if the Machine Status is in the 'SYSTEM AUTO CYCLE' state, the Master Control synchronises the control and operation of the machine so that it performs the desired operations on or to the product.

The relationship of the Master Control to each Station is illustrated in Figure 3. The flow of information within the system can also be seen. The Master Control can determine the current status of the entire system at any one time. This is achieved via the feedback provided by the System Stations.

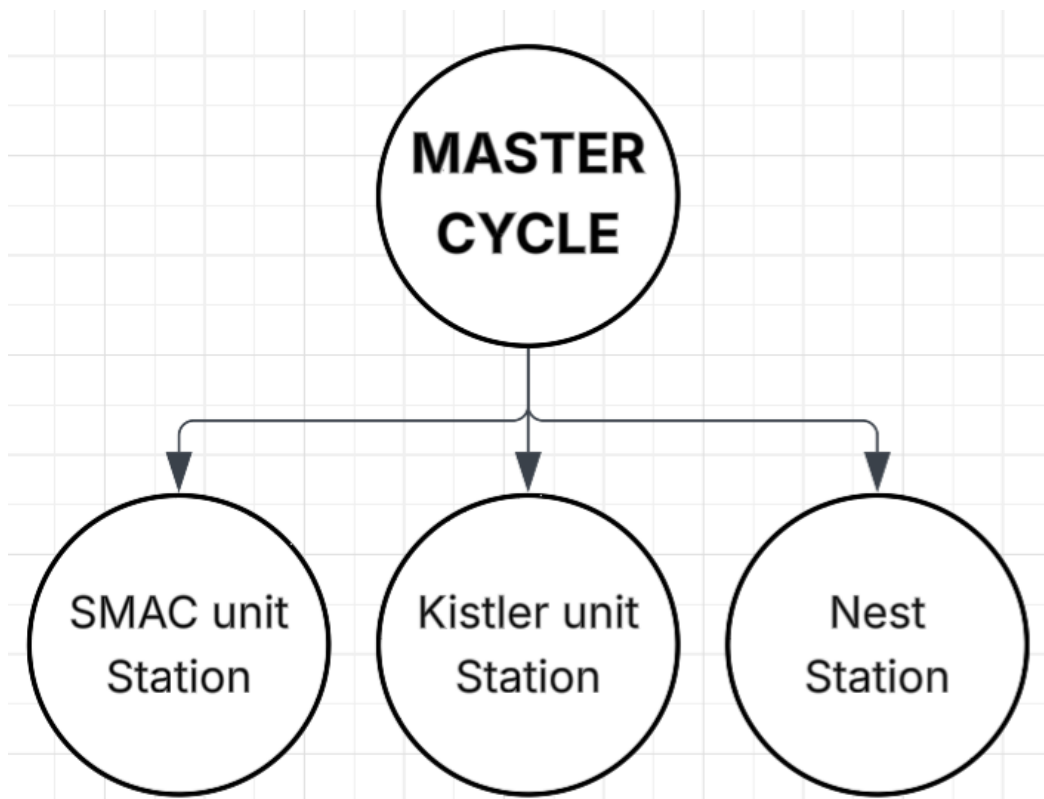**Figure 3: System Information Flow**

9.2.4   MACHINE CONTROL

Flowcharts outlining the sequence of operation of the individual stations on the machine are presented in the following sections.
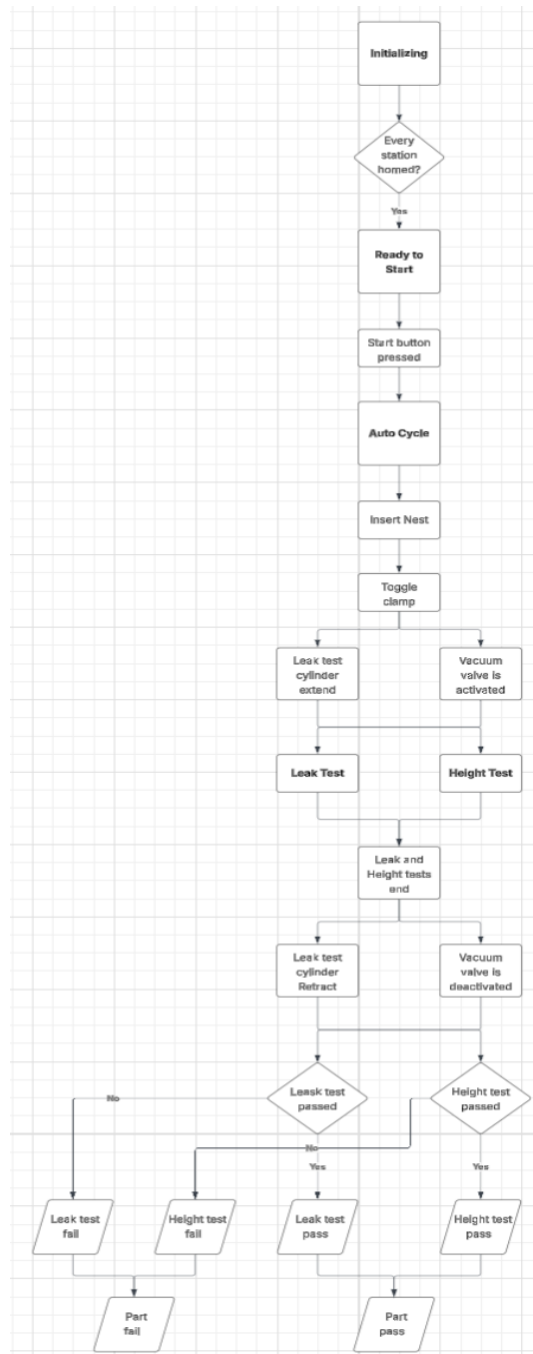
Figure 4: EMALC Stopper Insertion Overview Flowchart

9.2.4.1 Leak Test Station

The station receives a signal from PLC when the clamp is toggled, and then performs the vacuum leak test.

9.2.4.2 Height Station

The station receives a signal from PLC when the clamp is toggled, and then performs the height measurement. This process is carried out using four probes, with one probe serving as the reference point (Point 0). The probes must be calibrated at least once in order to establish the correct distance scaling between them.

9.3 HMI SOFTWARE

The HMI Software used is TCHMI. The runtime program resides on the Beckhoff C6015-0010 Processor and is displayed on the CP2912-0000 | Multi-touch Built-in Control Panel.

HMI Multi-Touch Control Panel via a DVI connection.

9.4 HMI DESIGN

The following screens shall be designed and included on the HMI Display.
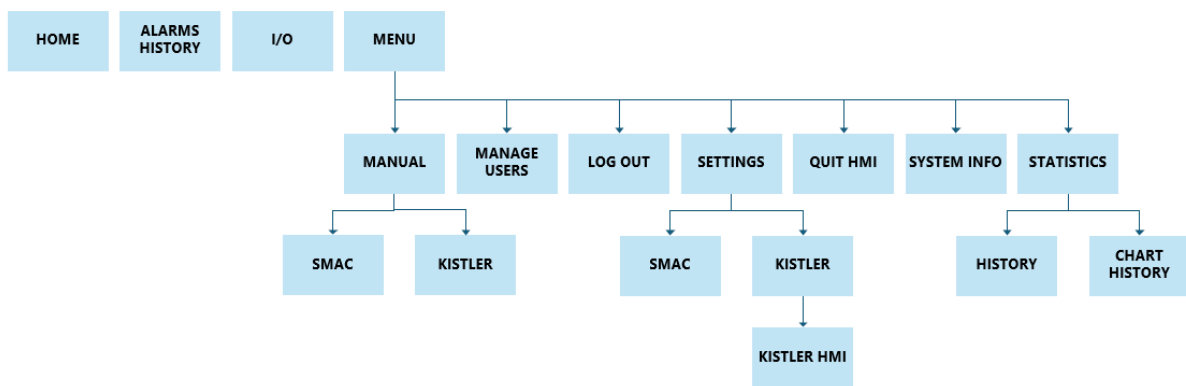
Figure 5: HMI Screens

Home: The Home screen is designed to give the operator a live graphical overview of the machine in its auto cycle state. This screen will show live values relating to control & state.

Alarms History: This screen shall display a list of all alarms that have occurred on the system since power up. Following a power cycle of the machine the list of alarms is not retained on the PLC.

I/O: The screen shall illustrate the status of the Digital Inputs and Outputs on the system.

System Info: The info of the machine are compiled in this screen.

Settings: The settings screen allows a user logged in with Admin level to make changes to system parameters of Mac station and Kistler Station.

Kistler HMI: The user have access to KISTLER HMI from machine HMI.

Manual: From this screen the Engineer can control the actions in each station.

Manage Users: This screen is to allow an operator (subject to login Admin level), to create, edit and delete users and access levels**.** Also shows user log.

Statistics: This screen shows statistics of the machine.

History: This screen shows the history of good and bad parts.

Chart History: This screen shows the chart history of the last 10 good and bad parts with their results.

All parameter changes require Admin or Engineer-level access. Operator level does not have access to the Settings screen neither Manual Mode. Only Engineer level can access to Manual Mode.

9.5 ALARMS AND MESSAGES

Alarms are generated by the PLC program as displayed on the HMI screen for operator attention. When alarms are active, the Machine status banner flashes to alert the operator. Alarms must be reset by pressing the reset button on the front of the machine. The following alarms and messages will be displayed on the HMI:

ALARM	TYPE	CAUSE	SOLUTION
TERMINAL 1 _ EK1100 - EtherCAT Coupler Not Operational	Immediate Fault	Beckhoff EK1100 Card Not Operational	Check status of Power and connections to card
TERMINAL 2 _ EL6070-0033- License Key Terminal for TC3 Not Operational	Immediate Fault	Beckhoff EL6070-0033 Card Not Operational	Check status of Power and connections to card
TERMINAL 3 _ EL6910 - Safety PLC - Virtual Channels Not Operational	Immediate Fault	Beckhoff EL6910 Card Not Operational	Check status of Power and connections to card
TERMINAL 4 _ EL1918 - 8 Channel Digital Safety Inputs Not Operational'	Immediate Fault	Beckhoff EL1918 Card Not Operational	Check status of Power and connections to card
TERMINAL 5 _ EL1918 - 8 Channel Digital Safety Inputs Not Operational	Immediate Fault	Beckhoff EL1918 Card Not Operational	Check status of Power and connections to card
TERMINAL 6 _ EL2904 - 4 Channel Digital Safety Outputs Not Operational	Immediate Fault	Beckhoff EL2904 Card Not Operational	Check status of Power and connections to card
TERMINAL 7 _ EL2904 - 4 Channel Digital Safety Outputs Not Operational	Immediate Fault	Beckhoff EL2904 Card Not Operational	Check status of Power and connections to card
TERMINAL 8 _ EL1809 - 16 Channel Digital Input Terminal Not Operational	Immediate Fault	Beckhoff EL1809 Card Not Operational	Check status of Power and connections to card

TERMINAL 9 _ EL1809 - 16 Channel Digital Input Terminal Not Operational	Immediate Fault	Beckhoff EL1809 Card Not Operational	Check status of Power and connections to card
TERMINAL 10 _ EL2809 - 16 Channel Digital Output Terminal Not Operational	Immediate Fault	Beckhoff EL1809 Card Not Operational	Check status of Power and connections to card
TERMINAL 11 _ EL9576 - Brake Chopper Terminal Not Operational	Immediate Fault	Beckhoff EL9576 Card Not Operational	Check status of Power and connections to card
TERMINAL 12 _ EL7211-0010 - Servo Motor Drive Not Operational	Immediate Fault	Beckhoff EL7211-0010 Card Not Operational	Check status of Power and connections to card
No user logged in	Immediate Fault	No user logged in	Log in
Safety	Immediate Fault	Safety Fault	Check Safety I/O Module
E-STOP Pressed	Immediate Fault	E-STOP Pressed	Remove E-STOP button and press "Reset"
Light beam Crossed	Immediate Fault	Light beam Crossed	Remove part between Lights and press "Reset"
Door opened	Immediate Fault	Door is open	Close the door and press "Reset"
PSU 1 FAULT	Immediate Fault	Power Supply PSU 1 FAULT	Check Power Supply PSU 1
PSU 2 FAULT	Immediate Fault	Power Supply PSU 2 FAULT	Check Power Supply PSU 2
PSU 3 FAULT	Immediate Fault	Power Supply PSU 3 FAULT	Check Power Supply PSU 3
E-Stop CH1 Signal	Immediate Fault	E-Stop CH1 Signal	press "Reset"

E-Stop CH2 Signal	Immediate Fault	E-Stop CH2 Signal	press "Reset"
System stopping timeout	Cycle stop fault	System stopping timeout	press "Reset"
10 Min Auto cycle stop	Cycle stop fault	10 Min Auto cycle stop	press "Reset"
Autocycle Timeout	Cycle stop fault	Autocycle Timeout	press "Reset"
10 Min Auto cycle stop	Cycle stop Request	10 Min Auto cycle stop	press "Reset"
Autocycle Timeout	Cycle stop Request	Autocycle Timeout	press "Reset"
No user logged IN	Cycle stop Request	No user logged IN	Log in
AXIS Y General Fault	Immediate Fault	AXIS Y General Fault	Check Axis Y and press "Reset"
Station 1 - Axis Y Homing Time Out	Cycle stop Request	Axis Y Homing Time Out	Check Axis Y and press "Reset"
Station 1 - Axis Y Out of limit	Cycle stop Request	Axis Y Out of limit	Check Axis Y and press "Reset"
Station 2 - Kistler Alarm	Immediate Fault	Kistler Alarm	Check Kistler Alarms, press E-Stop Button and Remove it and press "Reset"
Station 2 - Kistler Warning	Immediate Fault	Kistler Warning	Check Kistler and press "Reset"
Station 2 - Kistler Homing Time Out	Immediate Fault	Kistler Homing Time Out	Check Kistler and press "Reset"
Station 3 - SMAC Linear General Fault	Immediate Fault	SMAC Linear General Fault	Check SMAC Linear and press "Reset"

Station 3 - SMAC Linear Servo error	Immediate Fault	SMAC Linear Servo error	Check SMAC Servo Error and press "Reset"
Station 3 - SMAC Rotative General Fault	Immediate Fault	SMAC Rotative General Fault	Check SMAC and press "Reset"
Station 3 - SMAC Rotative Servo error	Immediate Fault	SMAC Rotative Servo error	Check SMAC and press "Reset"
Station 3 - SMAC STO Fault	Immediate Fault	SMAC STO Fault	Check SMAC and press "Reset"
Station 3 - SMAC I2T Fault	Immediate Fault	SMAC I2T Fault	Check SMAC and press "Reset"
Station 3 - SMAC Over temperature Fault	Immediate Fault	SMAC Over temperature Fault	Check SMAC and press "Reset"
Station 3 - SMAC Homing Time Out	Cycle stop fault	SMAC Homing Time Out	Check SMAC and press "Reset"
Station 3 - SMAC Linear Homing fail	Cycle stop fault	SMAC Linear Homing fail	Check SMAC and press "Reset"
Station 3 - SMAC Linear Phasing fail	Cycle stop fault	SMAC Linear Phasing fail	Check SMAC and press "Reset"
Station 3 - SMAC Rotative Homing fail	Cycle stop fault	SMAC Rotative Homing fail	Check SMAC and press "Reset"
Station 3 - SMAC Rotative Phasing fail	Cycle stop fault	SMAC Rotative Phasing fail	Check SMAC and press "Reset"

Table 13: Alarms and Messages