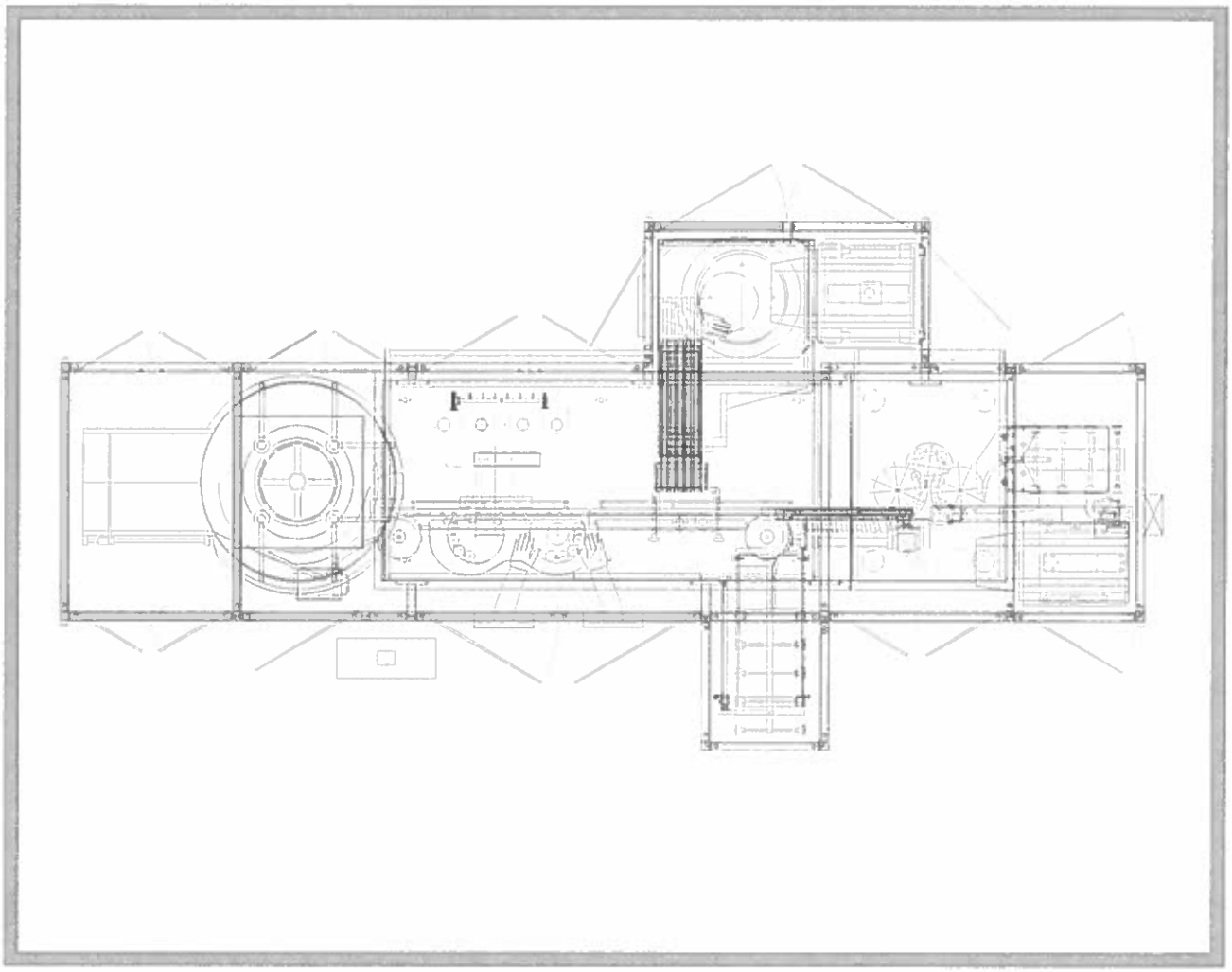
groninger	**FUNCTIONAL SPECIFICATION (FS)**		Version: 1.3
	Customer:	[redacted]	
	Machine type:	DFVK 6000 (DTE 1005, KVK 108 B)	
	Machine number:	5496 (5495, 5497)	

Vial filling and closing line



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1.1	15.08.2002	Second draft including comments from the sales department	As built	Hartmut Hanselmann
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1.3	19.08.2010	Fourth draft because comments from Health Protection Agency	As built	Karl-Heinz Bögner
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Table of Contents

1 Introduction

This document is produced by the qualification department of the **groninger & co. gmbh** company in cooperation with the specific departments (electrical department, mechanical department and sales department) on authorization of the [redacted]

The document is produced in accordance with following GAMP Guide:
Validation of Automated Systems in Pharmaceutical Manufacture, Version 5.0

The modified Software in year 2010 is in accordance with GAMP 5.0

This document forms the general functionality description of the following groninger machines:

Designation	Type	Number
Infeed rotary plate	DTE 1005	5495
Filling and stopper inserting machine	DFVK 6000	5496
Closing machine	KVK 108 B	5497

The document provides the design information needed to produce the system according to the customer's requirements.

This document is created by using Microsoft Word 2007.

2 Overview

2.1 Main process steps

The Functional Specification describes the tasks and functionality of the following main process steps of the vial filling and closing line:

- Infeed rotary plate (buffer for objects at infeed).
- Object transport system with infeed star wheel, 2 walking transport beams and a transfer scroll to the sealing station.
- In-line rotary piston pumps filling unit with 6 pumps.
- In process control system for the checking of the filling weight.
- Stopper inserting station consisting of a storage hopper, vibrator sorting bowl and feeding track (longitudinal vibrator) to transport the stoppers to the stopper inserting tool.
- Check stations stopper presence and stopper height.
- Discharge star wheel with magazining device 1 for filled and half stoppered objects (for further operation in the freeze dryer).
- Sealing station consisting of infeed star wheel, sealing rotor and discharge star wheel. Sealing caps are fed via storage hopper to the vibrator sorting bowl. The sealing caps are transported via a feeding track to the pick up chute for the caps.
- Check stations cap presence before sealing and cap presence after sealing.
- Machine discharge with magazining device 2.

Picture 1 at page 9 shows the location of the main process steps (overview) of the vial filling and closing line.

2.1.2 Capability of the machine

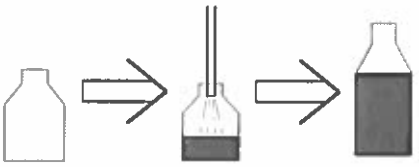
The vial filling and closing line shall be capable of running in the following ways:

- To fill and half-stopper a batch for freeze-drying.
- To overseal a stoppered batch from after freeze drying process.
- To fill, stopper and overseal a liquid batch.

2.1.2.1 Filling and half stoppering for freeze drying

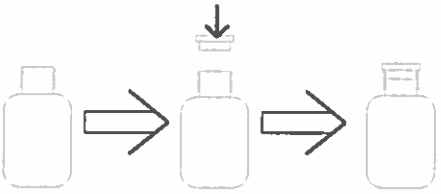
Discharge of objects into the discharge magazine after the stopper insertion station.
Select the button 'Stoppers' in the 'Operation' menu at the control panel.

- Filling



Process checking (IPC)

- Insertion of FD-stoppers



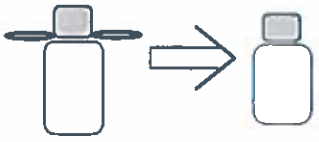
2.1.2.2 Oversealing a stoppered batch after freeze drying process

Switch off filling and stoppering stations.

Or

Select the corresponding format size at the operating manual.

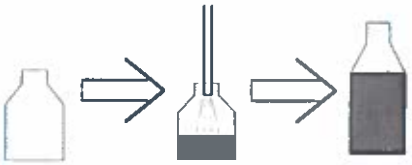
- Cap sealing (FD-stoppers)



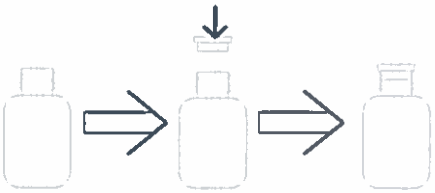
2.1.2.3 Filling, stoppering and oversealing a liquid batch

Select the buttons 'In line' and 'Caps' in the 'Operation' menu at the control panel.

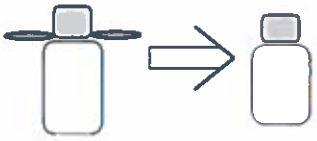
- Filling
- In process checking (IPC)

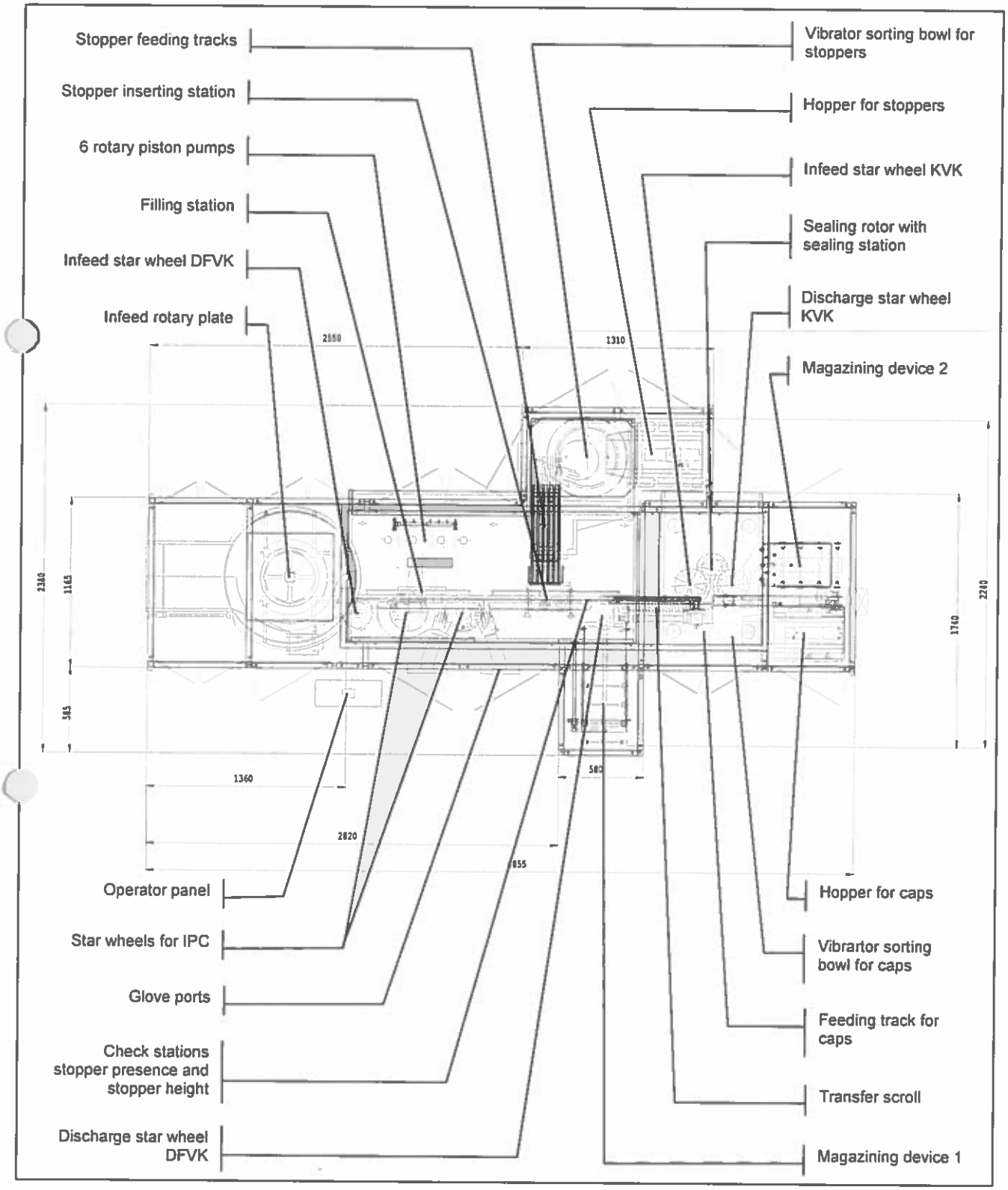


- Insertion of stoppers (liquid batch)



- Cap sealing





Picture 1: Overview of the vial filling and closing line

2.2 Interfaces to production process

The system interfaces for the production process of the vial filling and closing line are as follows:

- Accumulation at infeed circuit for vials at the machine infeed.
- Filling: Min. level product tank.
- Level checking circuit in the vibrator sorting bowl for stoppers: "Vibrator sorting bowl empty (stoppers)".
- Level checking circuit in the vibrator sorting bowl for caps: "Vibrator sorting bowl empty (caps)".
- Accumulation at discharge circuit for vials at the machine discharge.
- Reject of faulty operated vials into the reject station.

The detection of the different accumulations are realised by light barriers and controlled by the PLC.

No special equipment shall be manufactured to meet the requirements of the system. When standard independent components are used they are described in terms of functionality and interface to the main PLC.

The manufacturer's standard literature shall be provided as part of the Operation & Maintenance Manual. Their component content and design will not be detailed in this document.

3 Functional description

The following chapter describes all functionality of the vial filling and closing line beginning at the infeed rotary plate at the machine infeed, "walking through" the machine until the magazining unit at the vial discharge. All machine functions, the reaction of the machine at a malfunction and the produced messages of the PLC system are included.

3.1 Machine infeed via buffer infeed rotary plate

The vial infeed to the filling and closing machine have to be realised via buffer infeed rotary plate which is mechanically mounted to the infeed of the filling machine.

3.2 Level checking at the infeed rotary plate

A level checking sensor at the infeed rotary plate is checking the presence of objects.

The following message is generated:

Description	*Reaction of the machine*	*Message*
If there are too less objects for fabrication, a respective information message is displayed on the operator panel.	No effects.	Level infeed rotary plate is missing

3.3 Accumulation control at infeed

An accumulation control circuit at the vial infeed checks by means of a light barrier if enough objects are present at the machine infeed.

The following message is generated:

Description	*Reaction of the machine*	*Message*
The infeed accumulation circuit guarantees the stop of the machine in case of too less objects for fabrication.	In manual operation no effects. In automatic operation machine will run to home run position and stops.	Accumulation at infeed is missing

3.4 Working stations and controls at the filling and closing machine

The vials are passing the following working and control stations at different positions of the transport walking beam and the star wheels of the closing machine:

a) Object transport function
b) Object detection
c) Filling station
d) Process checking (IPC)
e) Vacuum stopper inserting station
f) Check stations for stopper presence and stopper height
g) Magazining device 1 at the filling machine → vial discharge or reject station
h) Capping and sealing station (sealing machine)
i) Check stations for cap presence before sealing and cap presence after sealing
j) Reject station at the closing machine
k) Machine discharge with magazining device 2

3.5 Object transport function

The object transport function realises the transport of the vials form the machine infeed to the machine discharge.
The object transport consists of the following units:

- Infeed star wheel
- Two transport walking beams
- Two star wheels for the process checking function
- Transfer scroll to sealing machine
- Transport star wheels at the sealing machine
- Transport conveyor at the reject station

The different units for the object transport function are checked for overload.

The following messages are generated:

Description	*Reaction of the machine*	*Message*
The machine stops, if the upper walking beam is moved out of its initial position.	Immediate stop of main drive.	Overload walking beam (above)
The machine stops; if the lower walking beam is moved out of its initial position.	Immediate stop of main drive.	Overload walking beam (below)
The discharge star wheel clutch of the filling machine locks out of place, if it is affected by a too big torque reaction, and the machine stops.	Immediate stop of main drive.	Overload star wheel (discharge DFVK)
The machine stops, if the infeed scroll of the sealing machine is moved out of its initial position.	Immediate stop of main drive.	Overload scroll (infeed KVK)
The infeed star wheel of the sealing machine is checked for overload. In case of an error, a message appears and the main drive stops immediately.	Immediate stop of main drive.	Overload star wheel (infeed KVK)
The discharge star wheel is checked for overload. In case of an error, a message appears and the main drive stops immediately.	Immediate stop of main drive.	Overload star wheel (discharge KVK)

3.6 Object detection

The presence of vials at the machine infeed is checked by a light barrier.
If a vial is present, a high signal is sent to the shift register of the PLC which effects that the following working stations are active for the operation of this vial.
If no vial is present, a low signal is sent to the shift register of the PLC and furthermore all operations are suppressed.

3.7 Filling station

The filling station consist of the following parts:
- Stainless steel manifold.
- Product tank (glass) with two level sensors. Product feeding and control.
- Rotary piston pumps. Pumps, connections and needle material are made of stainless steel.
- Two sets of pumps (dosing range 0,2 ml to 1,5 ml).

Functionality:
- If no vial is present at the respective filling position no filling process is activated.
- Product level control via two capacitive sensors located in the product tank.
- Automatic pre-setting of dosing volume by means of motored adjustment drive.
- Filling needle movement free configurable via teach in function.

3.8 Filling station: Pump stroke and filling level

Functionality:
- The pump rotation movement is checked for overload.
- If the filling level is fallen below the min. level, the machine stops and a respective error message appears.
- Function priming is used to remove the air from the filling tubes. During priming is active, a respective information message is displayed on the operator panel.

The following messages are generated:

Description	*Reaction of the machine*	*Message*
The machine stops, if a too big torque reaction affects the rotation movement of the pump.	Immediate stop of main drive.	Overload pump rotation
The filling level of the product tank is checked by means of 2 capacitive sensors.	Only in automatic operation: Machine runs to home run position and stops.	Min. level product tank
The function priming is required for the removal of air from the filling tubes. If the priming mode is active, a respective information message is displayed on the operator panel.	No effects.	Priming active

3.9 Filling station: Pump stroke adjustment drive

The pump stroke adjustment drive has the following functionality:

- To adjust a new pump stroke, the main drive has to be posit to the respective machine position. An information message informs the operator about.
- During the adjustment of the pump stroke an information message informs the operator about.
- During the adjustment of the pump stroke, the actual position of the pump stroke is checked against the max. final position.
- The rotation of the adjustment drive is checked.

The following messages are generated:

Description	*Reaction of the machine*	*Message*
An information message appears if the operator has to start the main drive in order to posit the drive in the right position for the adjustment of the pump stroke.	No effects.	Move to pump stroke adjustment position by "Drive Start"
During the adjustment of the pump stroke an information message informs the operator and the main drive could not be started.	Main drive cannot be switched on until pump stroke has been adjusted.	Pump stroke adjustment
During the adjustment of the pump stroke, the actual position of the pump stroke is checked against the max. final position.	No effects.	Pump stroke at max. final position
When the pump stroke drive is switched on, the rotation of the motor is checked. In case of blocking of the motor, it is switched off.	Immediate stop of main drive.	No rotation check signal (pump stroke adjustment)

3.10 Filling station: Filling needle drive

The filling needle drive has the following functionality:

The following messages are generated:

Description	*Reaction of the machine*	*Message*
Being in operation, the servo converter transmits a ready signal, which is checked constantly. In case of defect, the machine will be stopped.	Immediate stop of main drive.	Ready signal is missing (converter filling needle drive)
When filling needle drive is switched on, the rotation of the motor is checked. In case of blocking of the motor, it is switched off.	Immediate stop of main drive.	No rotation check signal (filling needle drive)
During filling needle teaching is active, a respective information message is displayed on the operator panel.	No effects.	Teaching active (filling needle drive)
During teaching of the filling needle it is not allowed to move the filling needle downward, in this case a respective information message is displayed on the operator panel to inform the operator about.	No effects.	Filling needle down not allowed (filling needle drive)
During the suction process of the pumps there is checked if the filling needles are in their upper final position, otherwise the machine stops and an error message appears.	Immediate stop of main drive.	Filling needles are not lifted
The upper final position of the positioning drive for the filling needle is checked by a limit switch. If the limit switch is reached an error message appears.	Immediate stop of main drive.	Final position reached (filling needle above)
The lower final position of the positioning drive for the filling needle is checked by a limit switch. If the limit switch is reached an error message appears.	Immediate stop of main drive.	Final position reached (filling needle below)

3.11 Process checking function

The process checking has the following characteristics:

- Stepper motor driven star wheels for tare and gross check weighing of vials.
- Automatically in-process weighing control with two scale systems, which have a measuring range up to 20 g and a resolution of 0.01 g.
- Alternative: The weighing process can be started by the operator via a button or automatically (frequently) via the PLC program.
- 6 vials are ejected to the tare star wheel for tare weighting. The tare weights are stored in the PLC. During the weighting process, the machine is still running.
- After the weighting process, the objects are again entered to the walking beam. The objects are filled at the filling station and again ejected for gross weighting at the gross star wheel. During the weighting process, the machine is still running.
- The weighting data is stored in the PLC for later print out.
- After weighting process, the 6 objects are again entered to the walking beam.
- If the measurement of the weight is out of the tolerance a respective error message is displayed on the operator panel and the object is ejected via the reject station.
- If the memory area for the storage of the weighing data is full, a respective information message informs the operator to print out the data.

The following messages are generated:

Description	*Reaction of the machine*	*Message*
When the distributing guiding does not open, the machine stops immediately and an respective error message is displayed on the operator panel	Immediate stop of main drive.	Distributing guide gross jammed
When the distributing guiding does not open, the machine stops immediately and an respective error message is displayed on the operator panel	Immediate stop of main drive.	Distributing guide tare jammed
The final position of the distributing guide at the gross star wheel is permanent checked. If the actual position is not equivalent to the set position, the machine stops immediately and an respective error message appears.	Immediate stop of main drive.	Final position is missing (distributing guide gross)
The final position of the distributing guide at the tare star wheel is permanent checked. If the actual position is not equivalent to the set position, the machine stops immediately and an respective error message appears.	Immediate stop of main drive.	Final position is missing (distributing guide tare)
The star wheel clutch of the load cells locks out of place, if it is affected by a too big torque reaction, and the machine stops.	Immediate stop of main drive.	Overload star wheel (load cells DFVK)
During the calibration process of the scales a respective information message is displayed on the operator panel.	No effects.	Calibration process active "please follow instructions"
If the measurement of the weight is out of the tolerance a respective information message is displayed on the operator panel and the object is ejected via the reject station.	No effects.	Check station: (weight filling place 1 out of tolerance)
If the measurement of the weight is out of the tolerance a respective information message is displayed on the operator panel and the object is ejected via the reject station.	No effects.	Check station: (weight filling place 2 out of tolerance)
If the measurement of the weight is out of the tolerance a respective information message is displayed on the operator panel and the object is ejected via the reject station.	No effects.	Check station: (weight filling place 3 out of tolerance)

Description	*Reaction of the machine*	*Message*
If the measurement of the weight is out of the tolerance a respective information message is displayed on the operator panel and the object is ejected via the reject station.	No effects.	Check station: (weight filling place 4 out of tolerance)
If the measurement of the weight is out of the tolerance a respective information message is displayed on the operator panel and the object is ejected via the reject station.	No effects.	Check station: (weight filling place 5 out of tolerance)
If the measurement of the weight is out of the tolerance a respective information message is displayed on the operator panel and the object is ejected via the reject station.	No effects.	Check station: (weight filling place 6 out of tolerance)
If the measurement of the weight is out of the tolerance in a sequence of measurements a respective information message is displayed on the operator panel and the object is ejected via the reject station.	In manual operation no effects; in automatic operation machine runs to home run position and stops.	Consecutive fault (weight filling place 1 out of tolerance)
If the measurement of the weight is out of the tolerance in a sequence of measurements a respective information message is displayed on the operator panel and the object is ejected via the reject station.	In manual operation no effects; in automatic operation machine runs to home run position and stops.	Consecutive fault (weight filling place 2 out of tolerance)
If the measurement of the weight is out of the tolerance in a sequence of measurements a respective information message is displayed on the operator panel and the object is ejected via the reject station.	In manual operation no effects; in automatic operation machine runs to home run position and stops.	Consecutive fault (weight filling place 3 out of tolerance)
If the measurement of the weight is out of the tolerance in a sequence of measurements a respective information message is displayed on the operator panel and the object is ejected via the reject station.	In manual operation no effects; in automatic operation machine runs to home run position and stops.	Consecutive fault (weight filling place 4 out of tolerance)
If the measurement of the weight is out of the tolerance in a sequence of measurements a respective information message is displayed on the operator panel and the object is ejected via the reject station.	In manual operation no effects; in automatic operation machine runs to home run position and stops.	Consecutive fault (weight filling place 5 out of tolerance)
If the measurement of the weight is out of the tolerance in a sequence of measurements a respective information message is displayed on the operator panel and the object is ejected via the reject station.	In manual operation no effects; in automatic operation machine runs to home run position and stops.	Consecutive fault (weight filling place 6 out of tolerance)
If an overload occurs on the scale or the pre load is to high, the machine stops and an error message appears on the operator panel.	Immediate stop of main drive.	Malfunction (load cell gross)
If an overload occurs on the scale or the pre load is to high, the machine stops and an error message appears on the operator panel.	Immediate stop of main drive.	Malfunction (load cell tare)
Being in operation, the step motor for the gross star wheel transmits a ready signal, which is checked constantly. In case of defect, the machine will be stopped.	Immediate stop of main drive.	Ready signal is missing (step motor star wheel gross)
Being in operation, the step motor for the tare star wheel transmits a ready signal, which is checked constantly. In case of defect, the machine will be stopped.	Immediate stop of main drive.	Ready signal is missing (step motor star wheel tare)
If the memory area for the storage of the weighing data is full a respective information message informs the operator to print out the data.	Machine runs to home run position and stops.	Storage for process checking data full, please print data

3.12 Vacuum stopper inserting station

The stopper inserting station will consist of a stainless steel storage vessel, vibrator sorting bowl, vibrator pre feeder and a vacuum inserting stopper shoe.

Functionality:

- The stopper storage vessel will be supplied with level control. An alarm is activated if the filling level is below min. level.
- A min. accumulation circuit at the feeding track for stoppers guarantees the stop of the machine in case of too less stoppers.
- The vacuum supply for the inserting vacuum rail is checked permanently.
- If the vacuum rail (stopper shoe) was mechanically pushed to spring suspension during transfer finger movement, an overload error message appears.

The following messages are generated:

Description	*Reaction of the machine*	*Message*
Filling level checking at sorting device for stopper detects no or too less stoppers.	No effects.	Hopper empty (Stoppers)
The min. accumulation circuit at the feeding track for stoppers guarantees that the machine will stop in case of lack of stoppers.	Only in automatic operation: Machine runs to home run position and stops.	Min. accumulation is missing (stopper track n) n= 1 to 6
If the vacuum supply for the stopper inserting station is missing, the machine stops and an error message appears.	Immediate stop main drive.	Vacuum is missing (stoppers)
The machine stops if the stopper shoe (vacuum rail) is mechanically moved in its springing during the stopper pick-up movement.	Immediate stop of main drive.	Overload stopper shoe

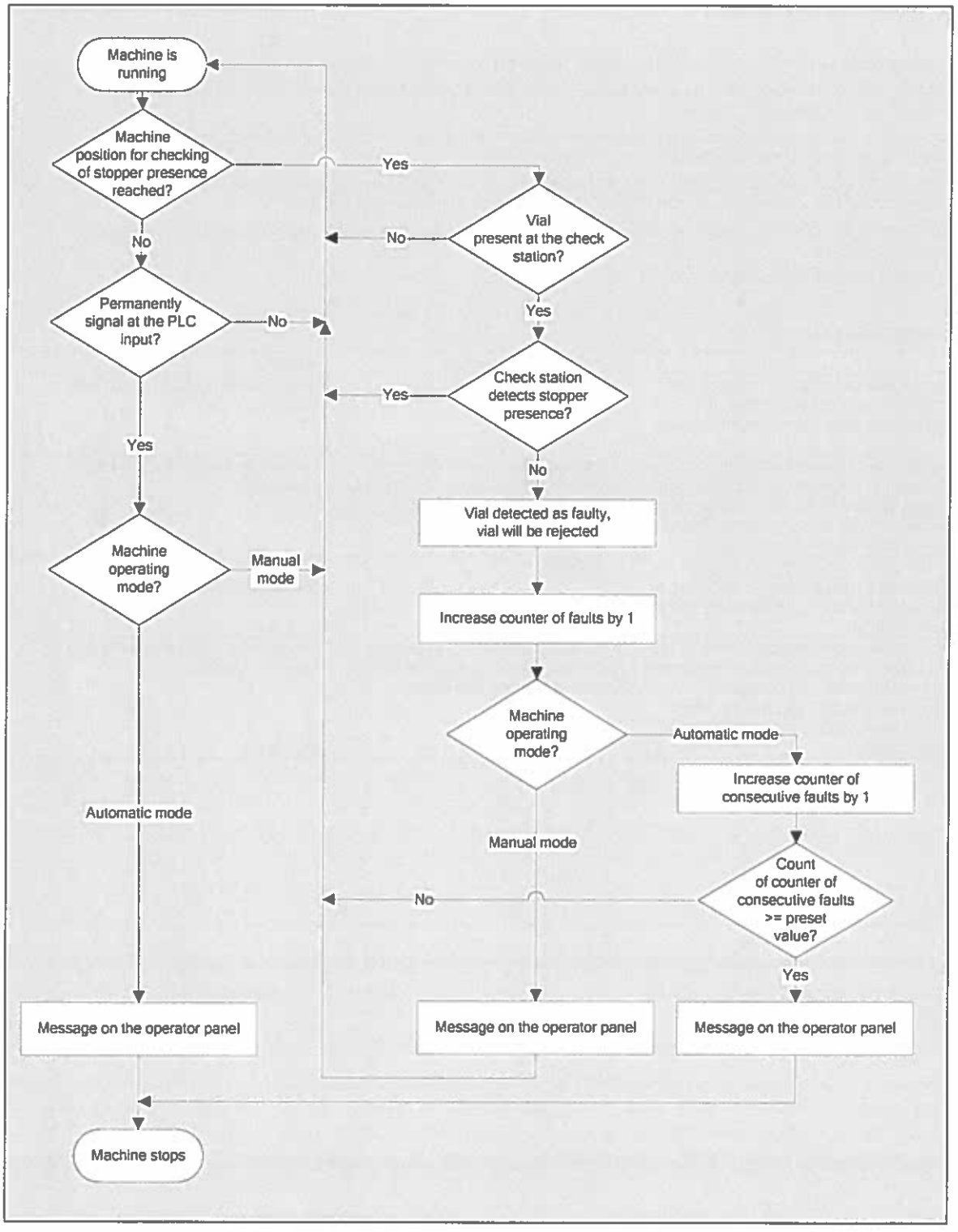
3.13 Check station stopper presence

- The presence of the stoppers on the vials at the filling machine will be detected by a light barrier.
- If the stopper is present, a high signal is sent to the shift register of the PLC which effects that the following operations are performed for this vial.
- If the stopper is missing, a low signal is sent to the shift register of the PLC which effects that all following operations are suppressed and the vial is ejected via the reject station.
- After a consecutive fault due to three (adjustable number) missing stoppers, the machine will be stopped and an error message (depending on the operation mode of the machine) is displayed at the operator panel.

The following messages are generated:

Description	*Reaction of the machine*	*Message*
The check station for stopper presence is permanently checked on function. In case of malfunction, a fault message is generated and the machine stops.	Immediate stop of main drive.	Check station defective (stoppers)
Manual mode: If the check sensor for the stopper presence checking detects no stopper, a fault message is generated, and the respective object is ejected via the reject station.	No effects.	Check station (stopper checking track n) n= 1 to 6
Automatic mode: In case of occurrence of several faults in succession at the check station for stopper presence, a fault message is generated and the machine stops in home run position.	In manual operation no effects; in automatic operation machine runs to home run position and stops.	Consecutive fault (stopper checking track n) n= 1 to 6

3.13.1 Flow chart check station stopper presence



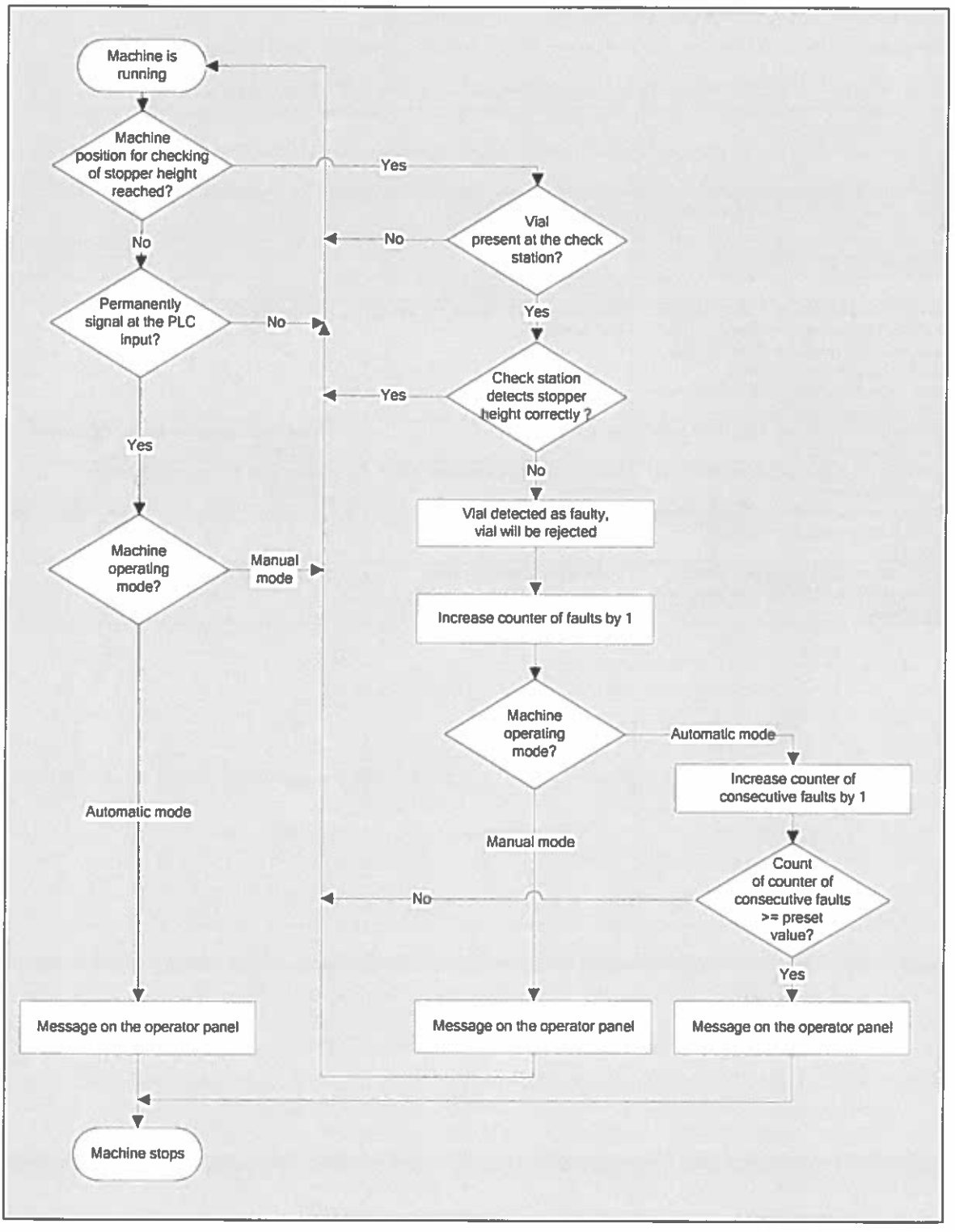
3.14 Check station stopper height

- The height of the stoppers on the vials at the filling machine will be detected by a light barrier.
- If the stopper height is not above the set limit, a high signal is sent to the shift register of the PLC which effects that the following operations are performed for this vial.
- If the stopper height is above the set limit, a low signal is sent to the shift register of the PLC which effects that all following operations are suppressed and the vial is ejected via the reject station.
- After a consecutive fault due to three (adjustable number) faulty stopper heights, the machine will be stopped and an error message (depending on the operation mode of the machine) is displayed at the operator panel.
- The vials with faulty detected stopper height will be rejected in the same reject station as the vials with faulty detected stopper presence (same procedure).
- Accuracy of stopper height detection is +/- 1 mm.

The following messages are generated:

Description	*Reaction of the machine*	*Message*
The check station for stopper height is permanently checked on function. In case of malfunction, a message is generated on the operator panel, and the machine stops.	Immediate stop of main drive.	Check station defective (stoppers height)
Automatic mode: In case of occurrence of several high stoppers in succession at the check station for stopper height, a message is generated on the operator panel, and the machine stops in home run position. Faulty detected vials are ejected via the reject station.	In manual operation no effects; in automatic operation machine runs to home run position and stops.	Consecutive fault (stopper height checking)
Manual mode: If the check sensor for the stopper height checking detects a high stopper, a message is generated on the operator panel, and the faulty vial is ejected via the reject station.	No effects.	Check station (stopper height checking track n) n= 1 to 6
Automatic mode: In case of occurrence of several high stoppers in succession at the check station for stopper height (depending on the track), a message is generated on the operator panel, and the machine stops in home run position. Faulty detected vials are ejected via the reject station.	In manual operation no effects; in automatic operation machine runs to home run position and stops.	Consecutive fault (stopper height checking track n) n= 1 to 6

3.14.1 Flow chart check station stopper height



3.15 Magazining device 1 (discharge for vials at the filling machine)

- The magazining device at the end of the filling machine is used for different tasks depending on the operating mode of the machine:
  - To fill and half-stopper a batch for freeze-drying, the magazining device is used as discharge for the stoppered objects.
  - For filling, stoppering and oversealing a liquid batch (parallel operation), the magazining device is used as reject station for objects with faulty stoppers.
- The objects for magazining are moved out of the transport walking beam by a discharge vacuum star wheel at the discharge of the filling machine.
- At the reject station the objects were ejected via a vacuum star wheel (discharge star wheel). The vacuum is supplied by a vacuum pump. If the vacuum is missing a respective error message appears.

The following messages are generated:

Description	*Reaction of the machine*	*Message*
If the machine is running in parallel operation (objects are operated for filling/ stoppering and closing), the magazining unit of the filling machine is additionally used as reject station for the filling machine. The machine stops if the reject station is full, so that the objects cannot block the star wheel.	Machine runs to home run position and stops.	Reject station is full (DFVK)
An information message is displayed if the discharge magazine is full or not pushed in.	No effects.	Warning: Magazine full or not pushed in (DFVK)
An information message is displayed if the discharge magazine is full or not pushed in. If no empty magazine was pushed in during a certain count of pieces, the machine stops and an error message is displayed.	Main drive stops in home run position.	Magazine full or not pushed in (DFVK)
If the vacuum supply for the discharge star wheel of the filling machine is missing, the machine stops and an error message appears.	Immediate stop main drive.	Vacuum is missing (DFVK)

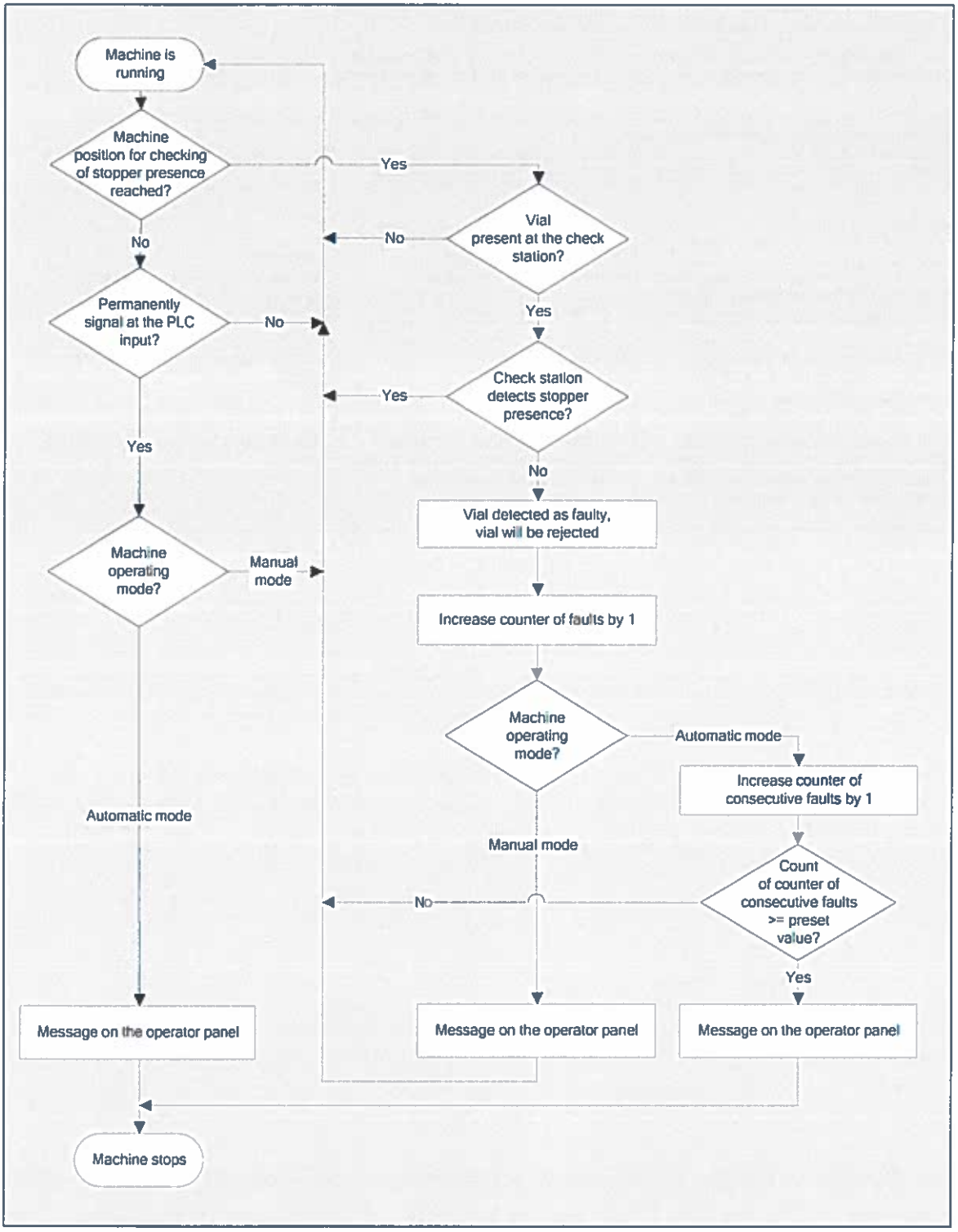
3.16 Check station stopper presence at the closing machine

- The presence of the stoppers on the vials is detected by an additional light barrier at the closing machine.
- If the stopper is present, a high signal is sent to the shift register of the PLC which effects that the following operations are performed for this vial.
- If the stopper is missing, a low signal is sent to the shift register of the PLC which effects that all following operations are suppressed and the vial is ejected via the reject station.
- After a consecutive fault due to three (adjustable number) missing stoppers, the machine will be stopped and an error message (depending on the operation mode of the machine) is displayed at the operator panel.

The following messages are generated:

Description	*Reaction of the machine*	*Message*
The check station for stopper presence at the closing machine is permanently checked on function. In case of malfunction, a fault message is generated and the machine stops.	Immediate stop of main drive.	Check station defective (stopper checking KVK)
Manual mode: If the check sensor for the stopper presence checking at the closing machine detects no stopper, a fault message is generated, and the respective object is ejected via the reject station.	No effects.	Check station (stopper checking KVK)
Automatic mode: In case of occurrence of several faults in succession at the check station for stopper presence at the closing machine, a fault message is generated and the machine stops in home run position.	In manual operation no effects; in automatic operation machine runs to home run position and stops.	Consecutive fault (stopper checking KVK)

3.16.1 Flow chart check station stopper presence at the closing machine



3.17 Sealing station

The sealing station consist of the following parts and functions:

- Vibrator pre feeder with SST hopper including level checking sensor.
- From vibrator sorting bowl caps will be transported via sliding track to the cap inserting shoe. A min. accumulation circuit checks the presence of caps in the sliding track.
- At the cap inserting shoe, the vial is sliding off the sealing cap from the sliding track and posits it onto the vial.
- The object is transported via a transport star wheel through the sealing rotor and the sealing cap is fixed onto the vial.

3.18 Cap feeding

- The storage vessel for the sealing caps will be supplied with level control. An alarm is activated if the filling level in the vibrator sorting bowl falls below the min. level.
- A min. accumulation circuit at the feeding track for caps guarantees the stop of the machine in case of too less stoppers.

The following messages are generated:

Description	*Reaction of the machine*	*Message*
An indication message appears if the hopper containing the caps is empty.	No effects.	Hopper empty (caps)
The min. accumulation circuit at the feeding track for caps guarantees that the machine will stop in case of lack of caps.	Only in automatic operation: Machine runs to home run position and stops.	Min. accumulation is missing (caps)

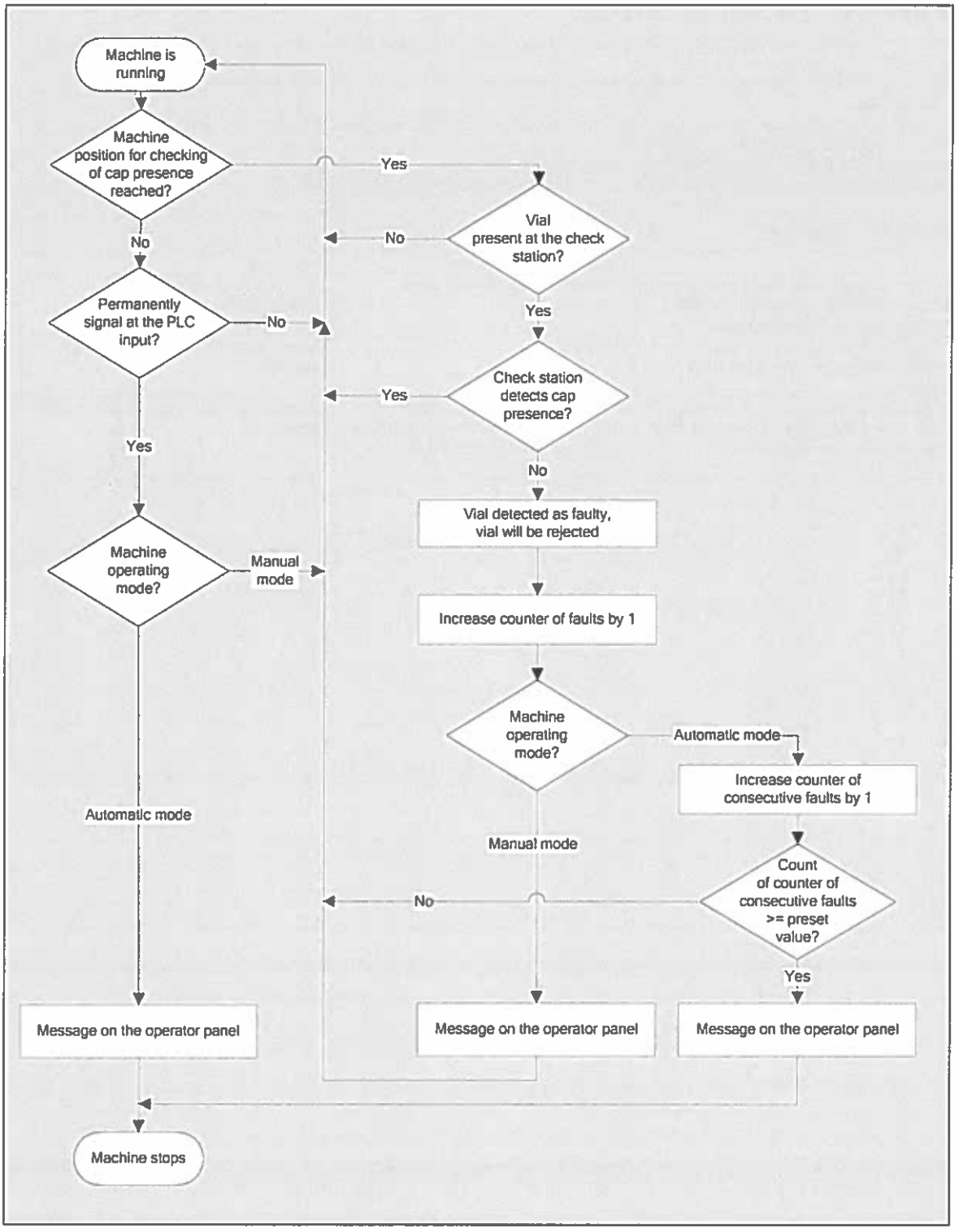
3.19 Check station cap presence before sealing

- The presence of the sealing caps before the sealing process is detected by a checking sensor (inductive initiator) at the infeed star wheel.
- If the sealing cap is present, a high signal is sent to the shift register of the PLC which effects that the following operations are performed for this vial.
- If the sealing cap is missing, a low signal is sent to the shift register of the PLC which effects that all following operations are suppressed and the vial is ejected via the reject station.
- After a consecutive fault due to three (adjustable number) missing sealing caps the machine will be stopped, and an error message (depending on the operation mode of the machine) is displayed at the operator panel.

The following messages are generated:

Description	*Reaction of the machine*	*Message*
The check station for caps before sealing is permanently checked on function. In case of malfunction, a fault message is generated and the machine stops.	Immediate stop of main drive.	Check station defective (cap checking before sealing)
Manual mode: If the check sensor for the cap checking before sealing detects no cap, a indication message is generated.	No effects.	Check station (cap checking before sealing)
Automatic mode: In case of occurrence of several faults in succession at the check station for caps before sealing, a fault message is generated and the machine stops.	In manual operation no effects; in automatic operation machine runs to home run position and stops.	Consecutive fault (cap checking before sealing)

3.19.1 Check station cap presence before sealing



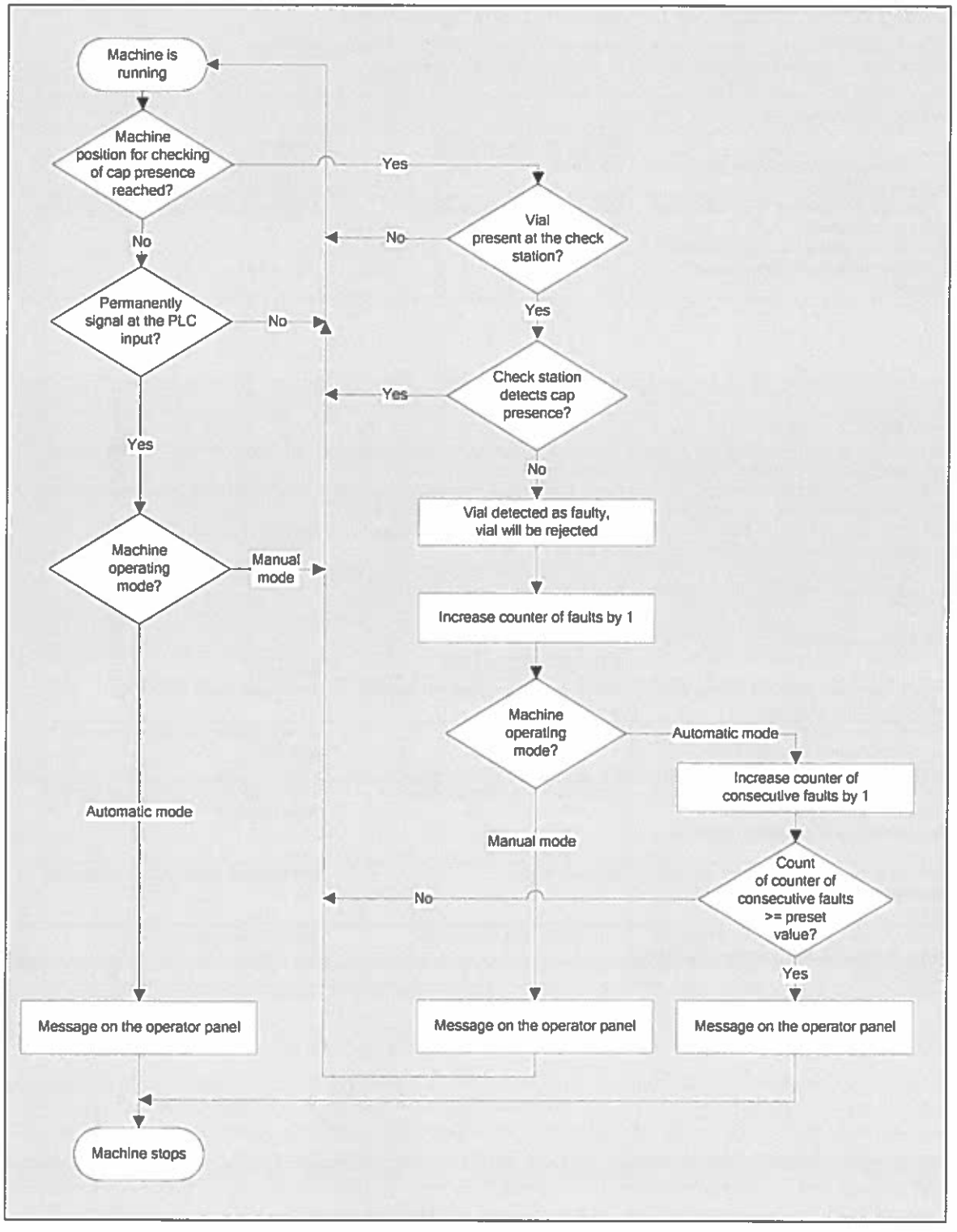
3.20 Check station cap presence after sealing

- The presence of the sealing caps after the sealing process is detected by a checking sensor (inductive initiator) at the discharge star wheel.
- If the sealing cap is present, a high signal is sent to the shift register of the PLC which effects that the following operations are performed for this vial.
- If the sealing cap is missing, a low signal is sent to the shift register of the PLC which effects that all following operations are suppressed and the vial is ejected via the reject station.
- After a consecutive fault due to three (adjustable number) missing sealing caps the machine will be stopped, and an error message (depending on the operation mode of the machine) is displayed at the operator panel.

The following messages are generated:

Description	*Reaction of the machine*	*Message*
The check station for caps after sealing is permanently checked on function. In case of malfunction, a fault message is generated and the machine stops.	Immediate stop of main drive.	Check station defective (cap checking after sealing)
Manual mode: If the check sensor for the cap checking after sealing detects no cap, a indication message is generated.	No effects.	Check station (cap checking after sealing)
Automatic mode: In case of occurrence of several faults in succession at the check station for caps after sealing, a fault message is generated and the machine stops.	In manual operation no effects; in automatic operation machine runs to home run position and stops.	Consecutive fault (cap checking after sealing)

3.20.1 Check station cap presence after sealing



3.21 Magazining device 2 (discharge for vials at the closing machine)

- The objects for magazining are moved out of the closing machine by a discharge vacuum star wheel.
- An electrical counter (integrated in the operator panel) counts all operated good vials.

The following messages are generated:

Description	*Reaction of the machine*	*Message*
An information message is displayed if the discharge magazine is full or not pushed in.	No effects.	Warning: Magazine full or not pushed in (KVK)
An information message is displayed if the discharge magazine is full or not pushed in. If no empty magazine was pushed in during a certain count of pieces, the machine stops and an error message is displayed.	Main drive stops in home run position.	Magazine full or not pushed in (KVK)

3.22 Reject station

- The vials which didn't pass all working and control stations successfully, i.e. didn't receive a high signal at each working station are faulty detected objects and therefore ejected into the reject station.
- The correct ejection of incomplete syringes into the reject station is permanently checked by a light barrier. If a fault occurs the machine stops immediately and a respective fault message appears on the operator panel.
- The function of the light barrier for the counter-control at the reject station is permanently monitored. If a fault occurs, a corresponding message is generated and the machine stops.
- At the reject station the objects were ejected via a vacuum star wheel (discharge star wheel). The vacuum is supplied by an external vacuum pump. If the vacuum is missing a respective error message appears.

The following messages are generated:

Description	*Reaction of the machine*	*Message*
The machine stops if the reject station is full, so that the objects cannot block the star wheel.	Machine runs to home run position and stops.	Reject station is full (KVK)
If the check sensor for the crosscheck of the reject station detects a missing object, an information message is generated.	No effects.	Check station (crosscheck reject station)
The check station for crosscheck of the reject station is permanently checked on function. In case of malfunction, a fault message is generated and the machine stops.	Immediate stop of main drive.	Check station defective (crosscheck reject station)
By means of a photoelectric cell, the correct ejection of an incomplete object via the reject station is constantly checked.	Machine stops.	Crosscheck reject station is missing
If the vacuum supply for the discharge star wheel of the closing machine is missing, the machine stops and an error message appears.	Immediate stop main drive.	Vacuum is missing (KVK)

3.23 Safety functions: Emergency stop

- If the hardware circuit for the emergency stop is opened although no switch is actuated, the machine stops and an error message is displayed on the operator panel.
- If an emergency stop push button is activated, the machine stops and an error message is displayed on the operator panel.

The following messages are generated:

Description	*Reaction of the machine*	*Message*
If the emergency stop circuit is open although no emergency stop switch is actuated, the machine stops and an error message appears.	Immediate stop of main drive and mains off.	Fault security circuit (emergency stop)
Actuation of the emergency stop push button leads to an immediate stop of the machine.	Immediate stop of main drive; control off.	Emergency stop actuated (machine front DFVK)
Actuation of the emergency stop push button leads to an immediate stop of the machine.	Immediate stop of main drive; control off.	Emergency stop actuated (machine rear DFVK)
Actuation of the emergency stop push button leads to an immediate stop of the machine.	Immediate stop of main drive; control off.	Emergency stop actuated (operator panel)

3.24 Safety functions: Guard doors

- If the hardware circuit for the emergency stop is opened although no switch is actuated, the machine stops and an error message is displayed on the operator panel.
- If an emergency stop push button is activated, the machine stops and an error message is displayed on the operator panel.

The following messages are generated:

Description	*Reaction of the machine*	*Message*
If the emergency stop circuit is open although no guard door is opened, the machine stops and an error message appears.	Immediate stop of main drive and mains off.	Fault security circuit (guard doors)
The opening of the guard doors causes the immediate stop of the machine.	Immediate stop of main drive.	Guard door opened

3.25 Safety devices

The following messages are generated:

Description	*Reaction of the machine*	*Message*
The actuation of a protective motor switch at the filling machine causes an immediate stop of the machine.	Immediate stop of main drive.	Protective motor switch released (DFVK)
The actuation of a protective motor switch at the closing machine causes an immediate stop of the machine.	Immediate stop of main drive.	Protective motor switch released (KVK)

3.26 Monitoring of main drive

The following messages are generated:

Description	*Reaction of the machine*	*Message*
When main drive is switched on, the rotation of the motor is checked. In case of blocking of the motor, it is switched off.	Immediate stop of main drive.	No rotation check signal (converter main drive)
The main drive is checked for overload.	Immediate stop of main drive.	Overload main drive (KVK)
Being in operation, the frequency converter of the infeed rotary plate transmits a ready signal, which is checked constantly. In case of defect, the machine will be stopped.	Immediate stop of main drive.	Ready signal is missing (converter infeed rotary plate)
Being in operation, the frequency converter of the main drive transmits a ready signal, which is checked constantly. In case of defect, the machine will be stopped.	Immediate stop of main drive.	Ready signal is missing (converter main drive)
Being in operation, the frequency converter of the sealing drive transmits a ready signal, which is checked constantly. In case of defect, the machine will be stopped.	Immediate stop of main drive.	Ready signal is missing (converter sealing drive)
Being in operation, the frequency converter of the conveyor transmits a ready signal, which is checked constantly. In case of defect, the machine will be stopped.	Immediate stop of main drive.	Ready signal is missing (converter conveyor)

3.27 Monitoring of the Profibus System

- The Profibus DP communication between the different Profibus DP participants permanently checked, if the communication fails, the machine stops and a respective error message appears.
- The communication between the PLC and the operator panel is permanently checked, if the communication fails, the machine stops and a respective error message appears.

The following messages are generated:

Description	*Reaction of the machine*	*Message*
The readiness of the Profibus DP bus modules in the electrical cabinet is permanently checked. In case of an error, the machine stops and an error message appears.	Immediate stop of main drive.	Failure Profibus (electrical cabinet)
The readiness of the Profibus DP of the load cell for the gross weight is permanently checked. In case of an error, the machine stops and an error message appears.	Immediate stop of main drive.	Failure Profibus (load cell gross)
The readiness of the Profibus DP of the load cell for the tare weight is permanently checked. In case of an error, the machine stops and an error message appears.	Immediate stop of main drive.	Failure Profibus (load cell tare)
The readiness of the Profibus DP bus modules in the terminal box of the filling machine is permanently checked. In case of an error, the machine stops and an error message appears.	Immediate stop of main drive.	Failure Profibus (terminal box DFVK)
The readiness of the Profibus DP bus modules in the terminal box of the closing machine is permanently checked. In case of an error, the machine stops and an error message appears.	Immediate stop of main drive.	Failure Profibus (terminal box KVK)
The communication between PLC and the operator panel is checked permanently. In case of fault, a malfunction message appears and the machine stops immediately.	Machine runs to home run position and stops.	Communication fault (operator panel)

3.28 Additional machine functions

The following section describes all additional machine functions of the machine.

The following messages are generated:

Description	*Reaction of the machine*	*Message*
If the buffer battery of the PLC control is discharged, a corresponding message appears.	No effects on machine operation!	Battery PLC low
After the switching-on of the main switch, the control (key F11) is always switched off.	Immediate stop main drive.	Control switched off
The main drive stops before a format change is initiated in the format of selection screen/ start up screen.	Immediate stop of main drive.	Format management active \>\> Machines locked
A message appears if the 'Drive on'- key is actuated in manual mode although the jog button is plugged in.	No effects.	Jog-button plugged in
After the actuation of the key 'Running empty', the infeed blocking opens, an indication message appears, and the machine runs empty completely.	The main drive of the machine will keep on running until all objects have been ejected, then the machine stops in home run position.	Machine is running empty, please wait...
A message appears if a function which can only be executed in automatic mode had been selected in manual mode.	No effects.	Only possible in automatic mode
A message appears if a function which can only be executed in manual mode had been selected in automatic mode.	No effects.	Only possible in manual mode

3.29 Monitoring and controlling panel

The monitoring an controlling panel guarantees the following basic functionality:

- The control cabinet for the operator panel is made of stainless steel.
- The machine control is realised by a Siemens PLC type S7 which is installed in the control cabinet.
- The setting of parameters can be done from operator panel. All machine parameter settings can be stored into the memory of the PLC. All fault and indication messages are displayed on the operator panel.

The following functions are integrated to the operator panel:

- Adjustment of the machine speed.
- Display of all alarms and information messages.
- Start/ Stop function via separate push buttons at the operator panel.
- The PLC is capable for minimum of 10 machine formats (sizes).
- The operator panel contains 5 different password levels:

Level	Password
[0] No password protection	-----
[3] Operator (e.g.: speed)	7531
[5] Mechanic (parameters e.g.: times, counters, cams, ...)	9513
[7] Administrator (start of external programs)	Supplier
[9] Programmer (free access to all data)	Supplier

3.30 Counter of pieces

A PLC integrated object counter counts the total count of operated objects.

The counter can be read in the basic menu and the info menu of the operator panel.

3.31 Counter of faults

The following PLC integrated counters of faults have to be implemented:

- Weights during the process checking concerning to the respective filling place
- Faults of weights on the load cell tare
- Faults of weights on the load cell gross
- Stopper presence at the filling machine
- Stopper height at the filling machine
- Stopper presence at the closing machine
- Sealing caps at the closing machine
- Pre printed data

The counters can be read in the info menu of the operator panel.

3.32 Running time meter

An operator panel integrated running time meter counts the total running time of the main drive. The running time meter can not be reset manually.

3.33 Speedometer

A integrated speedometer indicates the current machine speed in vials/minute.

3.34 Signal lamps

The following standard indications (signal lamps) have to be installed:

- Power supply on	white
- Machine is in normal operation	green
- Product/ objects are missing	yellow
- Stop condition without automatic restart	red

4 Data Section

The data, on which the system works is combined in different data blocks (DB's) internal the PLC.

Because of integration of check station stopper height following blocks are modified:

- DB 50 – Messages
- FC 16 – Networks 43-50

Software modifications (e.g. at following installation of new data block) are specified in OB 1 in network 1.

5 Interfaces Section

5.1 User interfaces

The user interface for the vial filling and closing line is a 12" TFT Touch panel from Siemens type MP 370.

5.2 Interface to other systems

There are no interfaces to other systems.

5.3 Interface with equipment

All interfaces to the independent devices connected to the PLC of the machine are provided by the means of digital inputs and outputs of the PLC system (Profibus DP bus modules from Beckhoff).

6 Non-functional Attributes Section

6.1 Objects to be proceeded and machine capacity

The following objects shall be processed:

Format	Object	Filling volume	Filling accuracy	Machine capacity
3 ml	Vial	0,3 ml	+/- 1%	12.000 vials / hour
3 ml	Vial	1 ml	+/- 0,5%	12.000 vials / hour

6.2 Technical Details

Output:	See table at chapter 6.1
Filling range:	0,2 ml - 135 ml, equipped with according pumps
Diam. range:	14 mm - 35 mm, height: 30 mm - 100 mm
Finish:	Stainless steel / aluminium
Operating height:	900 mm +/- 15 mm
Guarding:	Stainless steel frame with safety glass
PLC:	Siemens PLC type S7 300

6.3 Codes and Standards

- The machine must comply fully with cGMP regulations and guidelines as stated in "The Rules Governing Medicinal Products in the European Union: Volume 4: Good Manufacturing Practice for Medicinal Products" and the US Food and Drug Administration (FDA) Code of Federal Regulations Parts 11, 210 and 211.
- All process-wetted components must be of sanitary design and made of FDA compliant material and /or USP Class VI tested materials. All machine product or component contact parts are to be manufactured from 316L stainless steel.

6.4 Health and Safety

- The machine complies with the European Community regulation 100A and is "CE marked". groninger will provide a copy of the EC declaration of conformity.
- Groninger will ensure that the machine complies with all applicable current Health and Safety regulations including the UK Provision and Use of Work Equipment regulations 1998 and that it is safe to use.

6.5 Health and Safety information for commissioning, operation and maintenance

The supplier will design and manufacture the machine to ensure that:

- It is manufactured from materials and components suitable for its intended purpose.
- It complies with current EC electrical safety regulations.
- All hazardous moving parts of the machine are guarded and interlocked to stop the machine before an operator can access the operating zone. All interlocks must be resistant to being overridden.
- The machine is to be fitted with readily accessible emergency and stop controls that are readily identifiable and clearly visible.

6.6 Calibration

- All critical measuring instruments are to be loop calibrated. For this machine the balances for the check weight system have to be calibrated.

6.7 Design and Operating Conditions

The following design and operating requirements must be incorporated into the design of the equipment and into the finally supplied system.

- All machine finishes are to be hygienic, burr free and radiused. They are to be suitable for cleaning with aqueous solutions and for decontamination using formaldehyde vapour. Materials of construction are also to be resistant to paraformaldehyde residues.
- The machine and the necessary electrical and control equipment is to be suitable for sterilisation using the formaldehyde/water vapour method.
- The construction of the machine is to be such that it is easily cleanable with no "dead" spaces that are unreachable for cleaning.
- All controls and instrumentation to be protected to an ingress rating of IP 65.
- Product contact parts are to be sterilizable by autoclaving at 121°C on a standard equipment cycle.

6.8 Environmental Conditions

- The anticipated noise levels must be indicated in the tender.
- The machine is to operate in a Grade A/B clean room. Temperature range: 12°C to 30°C.

6.9 Materials of Construction and Finishes

- All external welds, surfaces, and nozzles shall be ground smooth and crevice free.
- Product contact surface finish should be less than 1.0 micron RA. Surface parts not specified above shall have surfaces free of such imperfections as weld splatter, undercuts, gouges, pits, burrs, and scratches. Welds are to be ground flush and polished. All product contact surfaces to be degreased.
- All process and relevant service connections to the vial filling machine are to be of the Tri-Clamp type, one inch and above to BS 0800. All other Tri-Clamp, where appropriate, should be half-inch and below.
- Clamp gaskets and machine gaskets shall be entirely constructed of or fully encapsulated in PTFE.
- All materials of construction must be resistant to formaldehyde fumigation.
- All lubricants must be confirmed as food grade.

6.10 Non conformances with the User Requirement Specification (URS)

There are no non conformances with the User Requirement Specification (URS.)

7 References

[1]	User Requirement Specification (URS) for Vial Stopper Height Detector, reference HPA-PD/URS/704

8 Glossary

The following table shows the definitions of terms which may be unfamiliar to the readership of this specification:

Term	Explanation
AC	Alternating current
CPU	Central processing unit
DC	Direct current
FAE	Fremd Aggregate Englisch (German abbreviation for vendor component list)
GAMP	Good Automated Manufacturing Practice
HMI	Human Machine Interface (keyboard and display for the operation of the machine)
PLC	Programmable logic controller
Profibus DP	Profibus Decentralized Peripherals
UPS	Uninterruptible power supply (to prevent critical devices/loads from power supply failures and voltage fluctuations)

9 Format of used date

The date used in this document has the following format:

dd.mm.yy or **dd.mm.yyyy** or **dd/mm/yy** or **dd/mm/yyyy**
dd = day, **mm** = month and **yy** or **yyyy** = year

10 List of appendices

There are no appendices.