

cfs 1200

***OPERATOR &
MAINTENANCE MANUAL***



CAPSUGEL®

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Chapter 1: Introduction

1.1 General

The CFS 1200 is a development-scale machine and is fully automated, GMP compliant and will fill and/or seal capsules using Capsugel's unique non-banding sealing technology at a rate of 1200 capsules/hour with liquid or semi-solid formulations. It is specifically designed to enable formulation scientists to better exploit the potential of lipid-based formulations for poorly soluble compounds. It helps accelerate the development time frame, particularly for Phase 1 studies, thereby achieving 'Faster Time to First in Man'

The CFS 1200 is a safe and reliable unit, which has been built according to the latest technology. If you follow the instructions in this manual, trouble free operation is guaranteed.

While every effort has been made to ensure that the information in this manual is correct, Capsugel does not assume responsibility for possible errors. Capsugel reserves the right to make changes without any prior notice.

1.2 Purpose of the Operator and Maintenance Manual

This operator and maintenance manual contains the information required for the flawless operation and maintenance of the CFS 1200. In addition it contains the troubleshooting procedures for the operator.

1.3 Structure of the Manual

The information in the manual is grouped in chapters; all chapters apply to the operator and must be read before operating the CFS 1200.

- Chapter 1: Introduction
Provides general information concerning the CFS 1200 and this manual.
- Chapter 2: Safety
Provides the safety information for operating the CFS 1200.
- Chapter 3: Description
Provides a full description of the CFS 1200 and its operation procedures.
- Chapter 5: Maintenance
Provides the CFS 1200 maintenance procedures for the operator.
- Chapter 6: Troubleshooting
Provides the CFS 1200 troubleshooting procedures for the operator.

1.4 Position Reference

When referring to a certain position, the following conventions are made:

- the front side of the CFS 1200 is the control panel side,
- the left side is where the liquid pump is located,
- the back side is where the FESTO suction pumps and the EFD valve are located,
- the right side is where the electric cabinet is located.



Figure 1 – CFS 1200 Position Reference

1. Front
2. Left

3. Back
4. Right

1.5 List of Abbreviations

Abbreviation	Description
A	Ampere
AC	Alternating Current
AWG	American Wire Gauge
°C	degrees Celsius
CTRL	Control
h	hour
HMI	Human Machine Interface
Hz	Hertz
kg	kilogram
l	litres
LEMS	Liquid Encapsulation Microspray Sealing
m	meter
mbar	millibar
mg	milligram
LCD	Liquid Crystal Display
mm	millimeter
N	Newton
PID	Proportional Integrating Differentiating
PLC	Programmable Logic Control
psi	pound square inch
T:	Time
V	Volt

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Chapter 2: Safety

2.1 Safety Precautions

2.1.1 Notes, cautions and Warnings

Whenever people handling, operating or servicing the CFS 1200 are exposed to a hazard, the hazard and the appropriate safety measures will be described by a Note, a Caution or a Warning. Although a Note does not typically indicate a safety risk, it is also listed with the safety indications because it can contain important information.

A NOTE is indicated with the symbol below.



Indicates a general remark, used to clarify the text.

A CAUTION is indicated with the symbol below.



Advises the operator or the technician to be careful, more specifically, to prevent damage to the equipment.

A WARNING is indicated with the symbol below.



INDICATES THE IRREVERSIBLE EFFECT OF AN OPERATION OR INDICATES THAT AN OPERATION MAY IMPLY DANGER WITH REGARD TO THE PHYSICAL SAFETY OF THE OPERATOR OR THE TECHNICIAN

2.1.2 General Remarks



IF ANY STATEMENT DOES NOT COMPLY WITH LOCAL LEGISLATION, THE STRICTER OF THE TWO SHALL BE APPLIED. STATEMENTS IN THIS MANUAL SHOULD NOT BE INTERPRETED AS SUGGESTIONS, RECOMMENDATIONS OR INDUCEMENTS THAT SHOULD BE USED IN VIOLATION OF ANY APPLICABLE LAWS OR REGULATIONS.

Three definitions for the purpose of this directive:

- "danger zone": any zone within and/or around machinery in which an exposed person is subject to a risk to health or safety.
- "exposed person": any person wholly or partially in a danger zone.
- "operator": the person or persons given the task of installing, operating, adjusting, maintaining, cleaning, repairing or transporting machinery.

The working places are situated around the machine with most of the time the operator working on the front side (operator side).

2.1.3 Essential Health and Safety Requirements for Pharma-Foodstuff Machinery

Where machinery is intended to prepare and process foodstuffs, the following hygiene rules must be observed:

- materials in contact, or intended to come into contact, either with the capsules or with the sealing liquid must be cleaned before each use,
- no ancillary substances (e.g. lubricants, etc.) should come into contact with the capsules.

2.1.4 Personal Protection Equipment

It is recommended to wear personal protection equipment in compliance with the operating area, such as:

- Eye protection
- Heat resistant gloves when handling hot parts.

2.1.5 Energy Supply

When electricity is shut off, the machine immediately stops.

The compressed air supply does not shut off automatically.

When the electricity comes back on, the machine will not restart. The machine must be reset and the start up procedure must be carried out from the beginning.

2.1.6 Compressed Air

The air pressure can be removed manually from all the components of the CFS 1200 on the main air regulator.

When the compressed air is available, the machine will not restart. The start up procedure must be carried out from the beginning.



To access the main air regulator, the transparent cover has to be opened and then, the machine can not be operated.

2.1.7 Safety and Control Features

The CFS 1200 is equipped with a number of safeties and controls:

2.1.7.1 Safeties

- Safety switch on the transparent cover providing access to the operational section.
- Safety switch on the door providing access to the mechanical section of the dosing pump.
- Emergency button on the control panel.

2.1.7.2 Machine Control and Protections

- Main switch on the front side.
- Switch to START/STOP/RESET the operations on the control panel.
- Thermal protection on the main drive motor.
- Circuit breaker on the heating system of the dosing unit.
- A fuse for the stirrer motor.
- Pressure control on main compressed air regulator.
- Pressure control at the inlet of the tank which contains the sealing mixture.

2.1.8 Potential Hazards during the CFS 1200 Operation

This paragraph lists all Cautions and Warnings in this Operator Manual. This allows all parties involved in the operation of the CFS 1200, to survey all potential hazards in advance.



ELECTRIC SHOCK HAZARD. THE ELECTRIC CABINET HAS DANGEROUS VOLTAGES INSIDE. DO NOT OPEN THE ELECTRIC CABINET DOOR.



PRESSING THE EMERGENCY STOP BUTTON REMOVES THE ELECTRIC POWER FROM THE CFS 1200. AS A RESULT THE CFS 1200 WILL STOP IMMEDIATELY. ELECTRIC POWER REMAINS PRESENT IN THE ELECTRIC CONTROL UNIT. DO NOT OPEN THE ELECTRIC CABINET DOOR UNLESS ABSOLUTELY REQUIRED.



PRESSING THE STOP BUTTON DOES NOT REMOVE THE ELECTRIC POWER FROM THE CFS 1200 CIRCUITS, THE CFS 1200 IS ONLY STOPPED.



TURNING OFF THE POWER SWITCH REMOVES THE ELECTRIC POWER FROM THE CFS 1200. DO NOT USE THE POWER SWITCH TO STOP THE CFS 1200; DOING SO RENDERS THE CFS 1200 CONTENT USELESS. ONLY TURN OF THE POWER SWITCH AFTER THE CFS 1200 WAS STOPPED.



TAKE INTO ACCOUNT ALL APPLICABLE SAFETY PRECAUTIONS FOR CHEMICAL OR PHARMACEUTICAL PRODUCTS.



Unless absolutely required, never open the cover of the CFS 1200 when it is operating. Doing so will stop the CFS 1200 immediately and render all the capsules useless.



Pressing the EMERGENCY STOP button renders the CFS 1200 content useless. Do not press the EMERGENCY STOP button unless absolutely required. Immediately remove all capsules from the CFS 1200 when pressing the EMERGENCY STOP Button.



After an EMERGENCY STOP the CFS 1200 needs additional care.

Chapter 3: Description

3.1 Technical Specifications

3.1.1 Mechanical

CFS 1200 packed

Width	1000 mm (39.4")
Height	930 mm (36.6")
Depth	600 mm (23.6")
Mass	150 kg (330 lbs)

CFS 1200 unpacked

Width	720 mm (28.4")
Height	520 mm (20.5")
Depth	380 mm (15")
Mass	100 kg (220 lbs)

3.1.2 Electrical

Mains

Voltage *	230 V AC - 1 phase	110 V AC - 1 phase
Frequency	50 Hz	60 Hz
Current	7 A max.	14 A max.

(*) Voltage is fixed, no voltage selector available.

Mains cable

Number of wires x section + ground wire	2 x 2.5 mm ² (+ 2.5 mm ² grounding wire) 3 x 13 AWG (+ 13 AWG grounding wire)
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3.1.3 Compressed Air Supply

Compressed air

Air	dry, oil-free
Connection type	8 x 12 mm minimum
Pressure	6 bar (87 - 90 psi) minimum operating pressure = 4.5 bar (65 psi)

3.1.4 Environmental

Operating

Room temperature	15 °C / 25 °C
Relative humidity	35% / 65%
Air consumption	8.4 m ³ /hour average @ 6 bar

Storage

Room temperature	10 °C - 40 °C
Relative humidity	max. 80% non-condensing

3.1.5 Production Related Specifications

CFS 1200 compatible LICAPS size	4 / 3 / 2 / 1 / 0 / 00 / 00EL / 00EL (*) / 000
Liquid fill tank capacity	700 ml (approx. 1 h autonomy for size 0)
Sealing solution tank	90 ml (approx. 3.5 h autonomy for size)
Capsule hopper	approx. 1000 capsules size 0 (approx. 1 h autonomy)
Production Capacity	max. 1200 CAPSUGEL LICAPS [®] capsules/h

(*) only 1 sized parts set included in the standard delivery, other sized parts sets available as an option

3.1.6 Transportability

The CFS 1200 can be moved by two persons however four persons are recommended.

3.1.7 Consumables

Gear grease

Lubricant type	OKS 1110
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Sealing liquid

Composition (typical)	50/50 w/w Ethanol - water
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3.1.8 Example of Settings

Example of settings for the dosing of peanut oil at Room Temperature.



Below settings are guidelines that were established with the CFS 1000 (earlier version). Modifications might be possible as more experience will be gained with the CFS 1200. Those settings are given as guidelines. They may need to be modified according to the capsules and fill characteristics.

LICAPS tr/tr	Size 00el	Size 00	Size 0el	Size 0	Size 1	Size 2	Size 3	Size 4
Produit	Peanuts oil	Peanuts oil	Peanuts oil	Peanuts oil	Peanuts oil	Peanuts oil	Peanuts oil	Peanuts oil
Settings								
- Motor speed (%)	100	100	100	100	100	100	100	100
- Strirring speed (%)	To set	To set	To set	To set	To set	To set	To set	To set
- Capsules suction	10-200	10-200	10-200	10-200	10-200	10-200	10-200	10-200
- Capsules detection	140-170	140-170	140-170	140-170	140-170	140-170	140-170	140-170
- Pression spray : 0.3 bar	ON	ON	ON	ON	ON	ON	ON	ON
- spray	70-105	70-95	70-95/105	70-105	70-105	70-105	70-100	70-100
- Spray suction 1	115-145	105-145	100/120-145	115-145	115-145	115-145	110-145	110-145
- Spray suction 2	180-330	180-330	180-330	180-330	180-330	180-330	180-330	180-330
- Capsules ejection	60-110	60-110	60-110	60-110	60-110	60-110	60-110	60-110
- Stop position	180	180	180	180	180	180	180	180
Filling								
- Filling T° (°C)	RT	RT	RT	RT	RT	RT	RT	RT
- Filling knob position	29.4	27.3	22.0	22.0	17.8	12.3	9.6	7.7
- Nozzle type (mm)	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Sealing								
- Temp. in drying tunnel (°C)	45	45	45	45	45	45	45	45
- Tank pressure (bar)	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
- Valve position	0.38	0.36	0.36	0.36	0.30	0.30	0.28	0.28
- Valve setting (mm)	0.84	0.80	0.80	0.80	0.76	0.76	0.73	0.73
- Spray quantity (µl)	45	40	40	40	30	30	25	25

3.2 Functional Description

3.2.1 General Descriptions

The CFS1200 is designed to fill and to seal two-piece capsules, with the filling material being either liquid or semi-solid. It features CAPSUGEL's Liquid Encapsulation Microspray Sealing (LEMS) technology, and is designed for use with Licaps brand capsules. Licaps capsules are designed for optimal sealing with the LEMS system.

3.2.1.1 Main Components

The main components of the machine are indicated below.



Figure 2 – Main Components of the CFS 1200 - Front Side

- | | |
|--|--|
| 1. Dosing pump and liquid feeding tank | 6. Capsules discharge port |
| 2. Feeding unit and capsule feeding hopper | 7. Bodywork and access to mechanical section |
| 3. Control panel | 8. Transparent cover |
| 4. Electric cabinet | 9. Removable catch tray |
| 5. Main ON/OFF switch | |

- The operational sections are located behind a transparent cover.
The function of the transparent cover is to protect the components and to prevent manual intervention during operation. The transparent cover is equipped with a safety precaution: the machine cannot be operated when transparent cover is open.
- Mechanical and electric sections are separated from sections which are in contact with capsules, filling liquid and sealing mixture. Electric components and compressed air connections and valves are located at the back of the electric cabinet.
- The main ON/OFF switch is located on the right side of the front panel and allows the operator to shut down the unit completely.

- The capsule discharge station is located on the front side of the front panel of the mechanical section.
- The removable catch tray collects the excess sealing fluid.

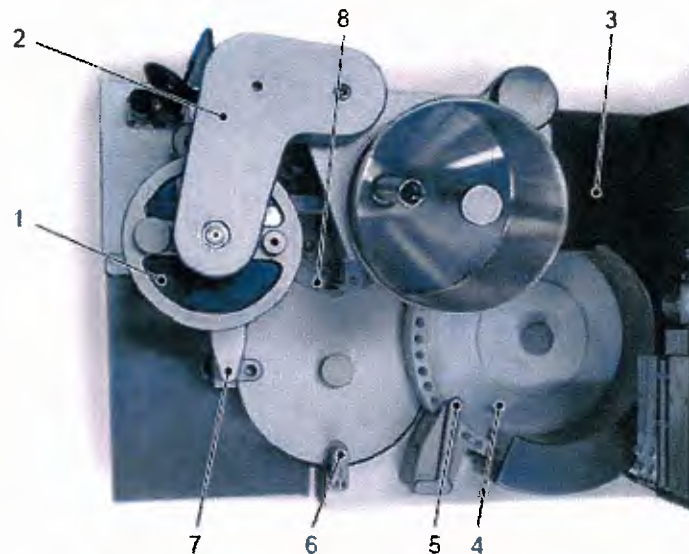


Figure 3 – Main Components of the CFS 1200 - Top Side

- | | |
|----------------------------|------------------------------|
| 1. Liquid feed tank | 5. Capsule discharge station |
| 2. Stirrer paddle assembly | 6. Capsule closing station |
| 3. Sealing station | 7. Dosing station |
| 4. Sealing/Drying disk | 8. Rectification station |

- The dosing unit is located on the left side and the liquid feed tank is equipped with a stirrer paddle. The transparent cover needs to be opened to fill the tank with liquid after the stirrer assembly has been raised.
- Capsule feeding and rectification units are located in the centre of the machine. The capsules are introduced in the capsule feed hopper through the transparent cover: capsules can be added into the capsule feed hopper when the CFS 1200 is operating.
- Sealing and drying sections are located at the right side of the operational section. The transparent cover needs to be opened to fill the sealing tank with sealing mixture.
- Capsules are ejected on the front side of the machine with a burst of compressed air.

3.2.1.2 Main Cycles

The main cycles are described below:

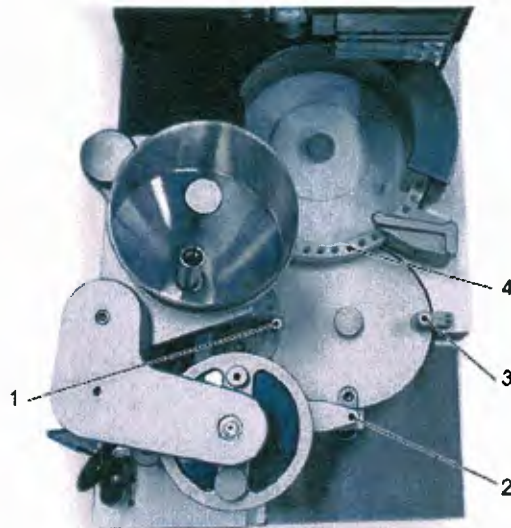
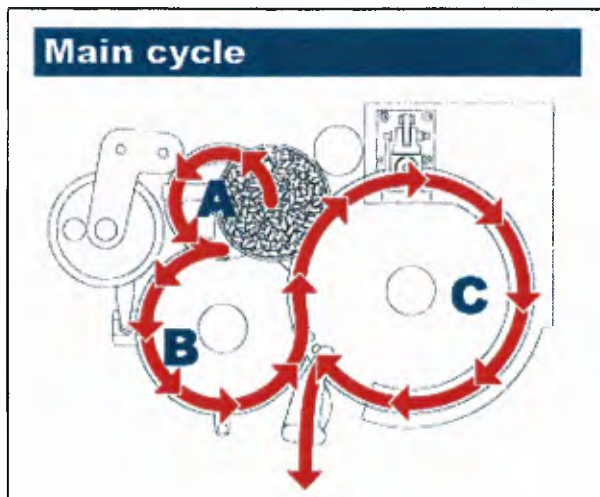


Figure 4 – Main Cycles of the Operation

- | | |
|--------------------|-------------------------------|
| 1. Opening station | 3. Closing station |
| 2. Dosing station | 4. Transfer to drying section |

There are four operating stations per cycle and consequently four bushings that hold capsules during machine operation.

We can also describe the main cycle in 3 sections:



- Section A:
Feeding + rectification
- Section B:
Opening + filling + closing
- Section C:
Sealing + drying

Figure 5 – main cycle section

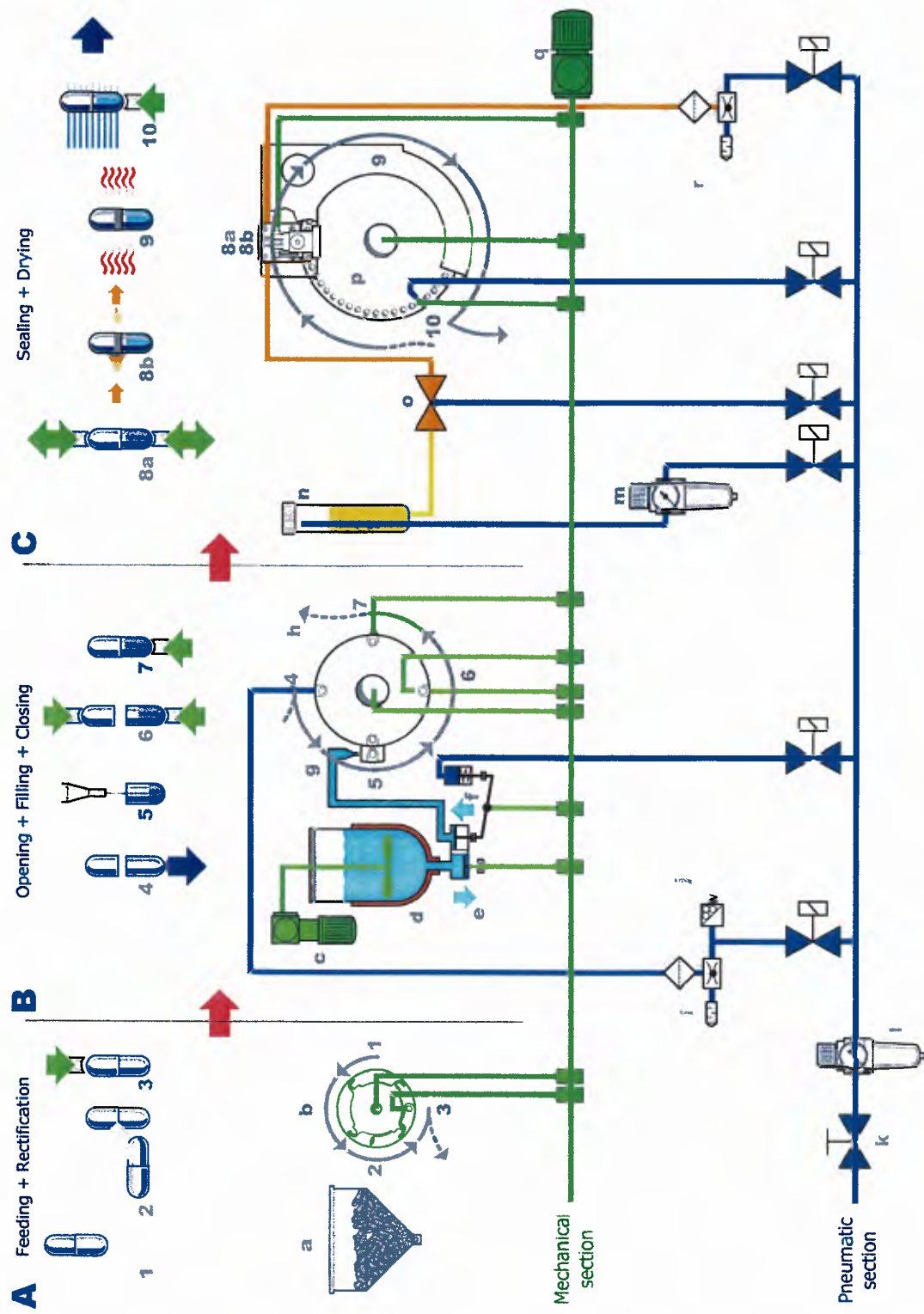









Figure 6 – PID diagram

Legend

	: Motor
	: Time / pressure valve
	: Pneumatic switch
	: Electrovalve
	: Pneumatic manometer
	: Suction pump
	: Pneumatic detection sensor

-
- 1 : Capsule feeding
 - 2 : Capsule rectification
 - 3 : Capsule transfer to opening station
 - 4 : Capsule opening
 - 5 : Capsule filling
 - 6 : Capsule closing
 - 7 : Capsule transfer to drying disk
 - 8a : Capsule positioning
 - 8b : Capsule spraying
 - 9 : Capsule drying
 - 10 : Capsule ejection

-
- a : Capsule feeding hopper
 - b : Feeding + rectification unit
 - c : Stirrer motor with variable speed
 - d : Liquid feeding tank with its heating element
 - e : Suction piston
 - f : Dosing piston with its non drip suction system
 - g : Dosing nozzle
 - h : Main cycle of the operation
 - i : Capsules suction pump for opening station
 - j : Vacuum based detection sensor
 - k : Main compressed air switch
 - l : Main compressed air manometer
 - m : Compressed air regulator of the sealing tank
 - n : Sealing fluid tank
 - o : Sealing fluid delivery valve
 - p : Drying and sealing section
 - q : Main motor
 - r : Sealing fluid suction pump