

# High-precision numerical filling management system.

*Malyps*®



# Principle :

*« Use advanced motion management systems to obtain an unmatched filling accuracy as well as a flexibility of use ... »*

# Advantages :

- Designed in accordance with cGMPs
- HMI meets the latest safety rules and traceability
- Ergonomic use
- Repeatability and accuracy
- Easy implementation
- Standalone or integrated
- Built with finest components
- Low maintenance or maintenance-free versions available
- Many versions and options adaptable to customer specifications

# Designed in accordance with cGMPs :

1. All parts in direct or casual contact with products are made in compliant materials :

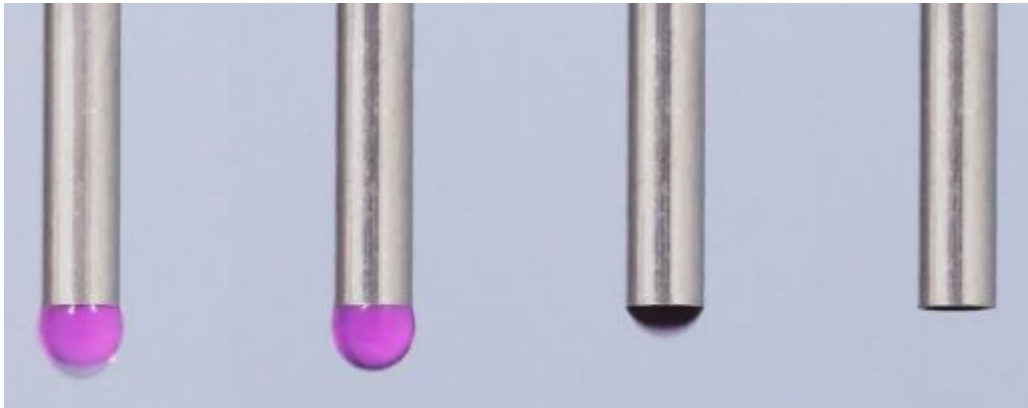
- 316L • Silicone • PTFE / PEEK FEP • Radel • Others ...

2. Pharmaceutical grade finishes:

- 316L stainless steel passivation and electropolishing
- Adapted roughness  $Ra \leq 0.8$
- No retention zone
- Easy cleaning
- Tight construction

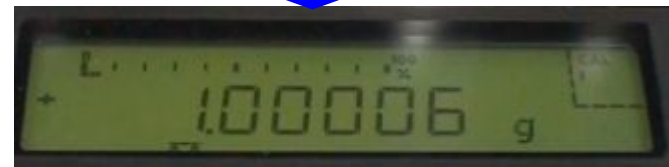
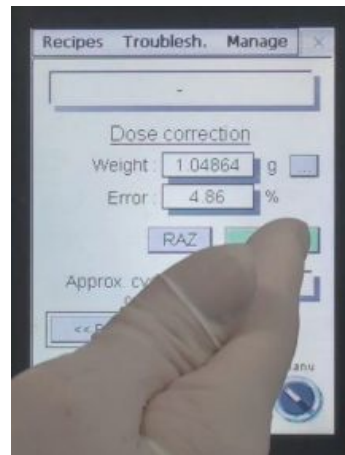
# Fine adjustment of the ejection of the dose

- In most of cases the precise management of the cam motion allows the elimination of dropping problems without performing any reaspiration.
- These adjustments will also allow you to avoid splashing coal generators bulbs, seal failure of tubes and blisters, non-conforming vials and syringes ...



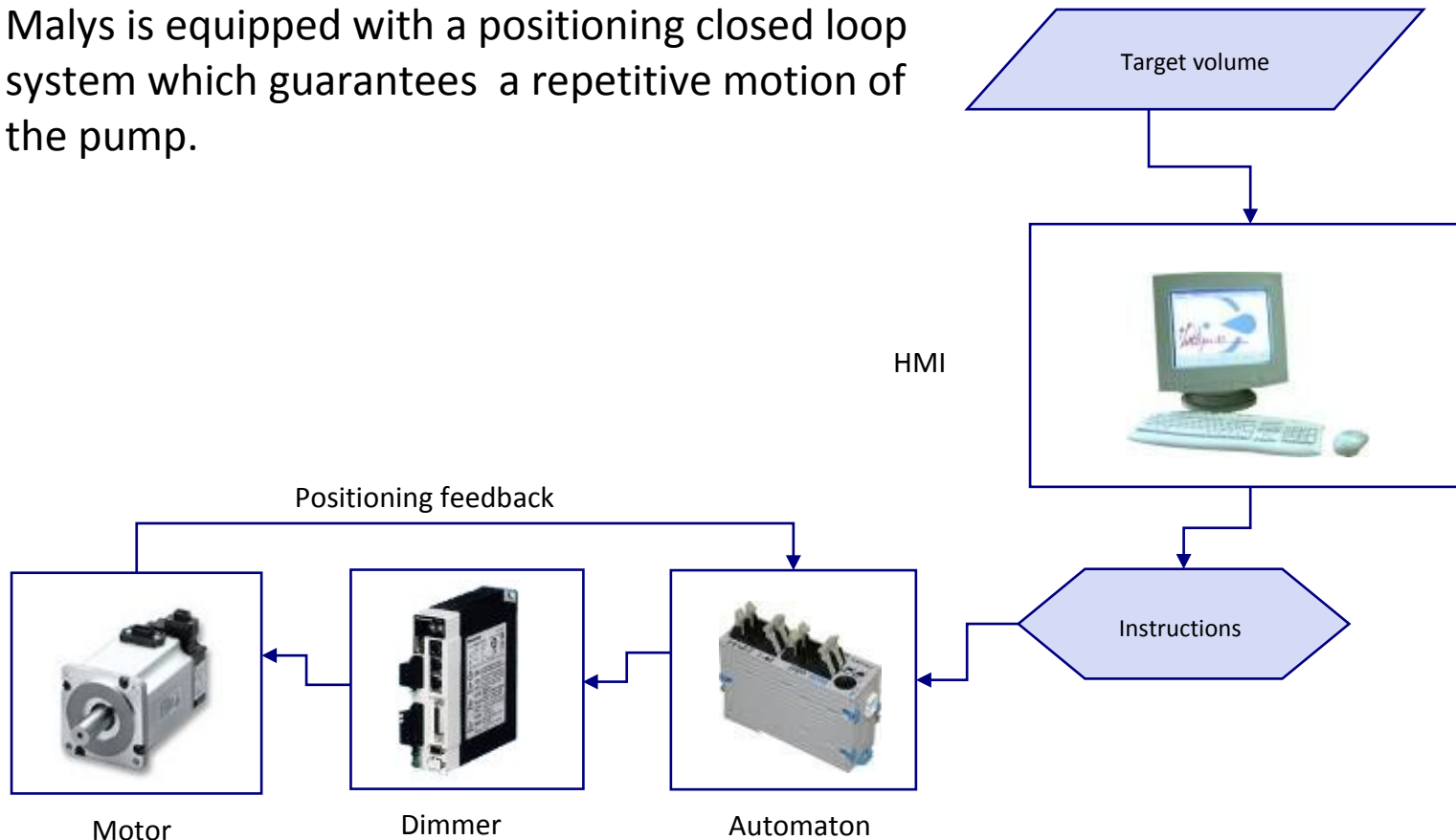
# Adjusting the dose

- The adjustment of the filled volume is done by weighing and value entry in the Malypass interface
- These adjustments can be automated by a connection to a scale (lines equipped with systems **CPI**)

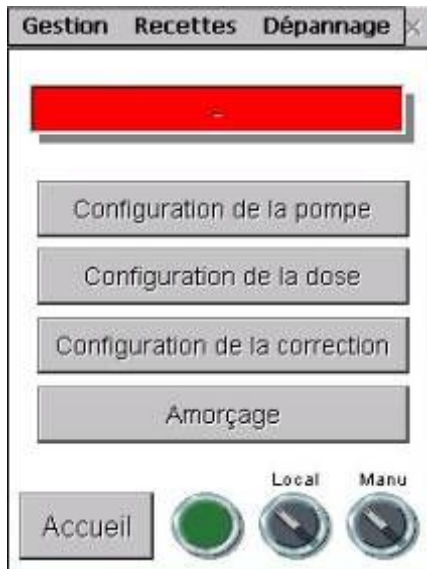


# Motion control in a closed loop

Malys is equipped with a positioning closed loop system which guarantees a repetitive motion of the pump.



# Light version "LT"



- Bright color screen for better ergonomics



- All parameters of the digital cam can be accessed and modified



- Multi language GUI with three levels of connection and independent management of users passwords



# Light version "LT"



The screenshot shows the 'Correction de la dose' screen. At the top, there's a tab bar with 'Gestion', 'Recettes', and 'Dépannage'. Below it is a 'DEFAULT' button. The main section is titled 'Correction de la dose'. It contains two input fields: 'Poids' with the value '0.60000' and unit 'g', and 'Erreur de' with the value '20.00' and unit '%'. Below these are two buttons: 'RAZ' and 'Corriger'. Further down is 'Cadence approx.' with the value '83259914' and the unit 'Cycles par heure'. At the bottom left is a '<< Précédent' button. At the bottom right are three buttons: 'Accueil', 'Local', and 'Manu'.

- Dose adjustment by typing the controlled weight

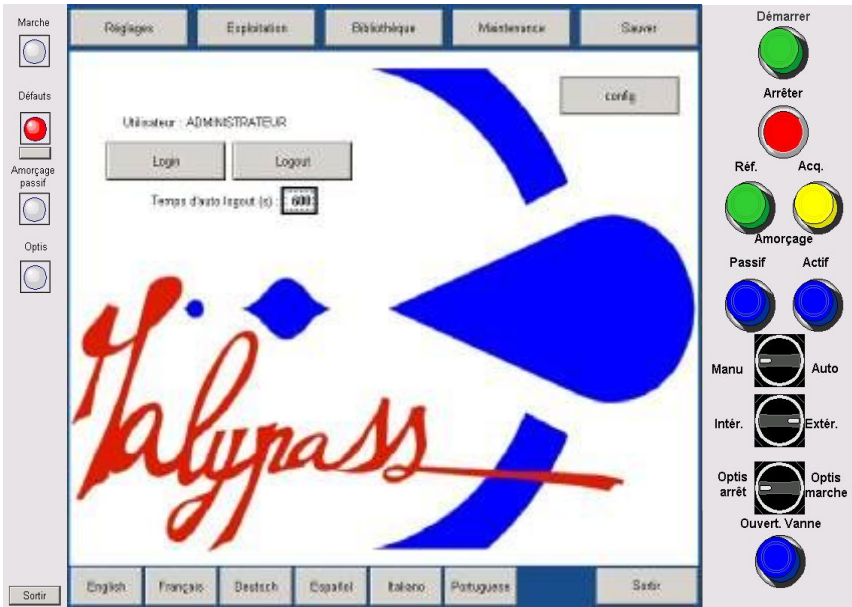
The screenshot shows the 'Seuils de correction' screen. It has the same top tab bar. The main section is titled 'Seuils de correction'. It contains two sections: 'Zone verte' and 'Zone orange'. Each section has two input fields: 'de' and 'à', both followed by a '%' sign. For 'Zone verte', the values are '-5.00' and '5.00'. For 'Zone orange', the values are '-10.00' and '10.00'. At the bottom are the same three buttons: 'Accueil', 'Local', and 'Manu'.

- Customizable alert threshold

The screenshot shows the 'Recettes' screen. It has the same top tab bar. The main section is titled 'Recettes'. It contains a dropdown menu labeled 'Recettes enregistrées' with 'DEFAULT' selected. Below it are two buttons: 'Charger' and 'Effacer'. Further down is another dropdown menu labeled 'Recette à enregistrer' with 'DEFAULT' selected. Below that is a 'Sauver' button. At the bottom are the same three buttons: 'Accueil', 'Local', and 'Manu'.

- Recipe management with unlimited number of saving

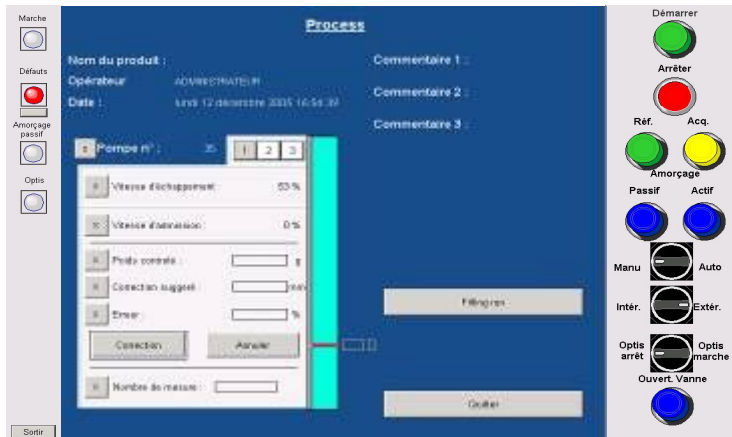
# Full version « CFR 21 Part 11 »



- Complete HMI based on Industrial PC
- 15inch screen display

- All digital cam parameters can be accessed and modified
- Pumps can be managed independently
- Batch numbering management

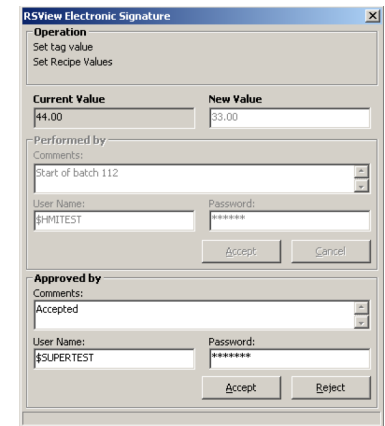
# Full version « CFR 21 Part 11 »



- Secure SQL database collecting events and storing recipes.
- Client / server features



- 5 customizable access levels
- Advanced management of users-based on Windows users and groups



- Actions plotted with signatures and comments
- Audit trail with search filters

# MALYS range: as many versions as applications



"S" Version : common translations



"C" Classic version : independant management of each pump



"T" Version mechanical parts in the upper side



"UWL" Version : mechanics Under Working Level

# Pumps used

## 1. Full range of SPC France's seal-less pumps

- Standard MC pumps : one piece designed
- Differential High-precision pumps
- Differential CIP / SIP pumps , SPC France patented, 2 parts in direct contact without valve

## 2. Fits all other seal-less pumps



# Patented pump fast-locking/unlocking system



- Quick installation of the pump
- Easy cleaning
- No screws, nuts, tools ...
- Suitable for all machines
- System without gap, perfect isostatism



Step 1



Step 2










Step 3





# Standard equipment used

Item	Brand
<u>Gear, bal screw and mechanical standards</u>	 Harmonic Drive AG    The Mark of Linear Motion 
<u>Stepper motors</u>	<b>Orientalmotor</b>
<u>Servomotors</u>	 <b>Rockwell Automation</b> <b>SIEMENS</b>
<u>Stepper motors automata</u>	<b>Panasonic</b>
<u>Stepper motors drives</u>	<b>Orientalmotor</b>
<u>Servomotors automata</u>	<b>Panasonic</b> <b>Rockwell Automation</b> <b>SIEMENS</b>
<u>Servomotors drives</u>	<b>Panasonic</b> <b>Rockwell Automation</b> <b>SIEMENS</b>
<u>Malypass</u> « LT » HMI	<small>INDUSTRIAL AUTOMATION SOFTWARE</small> <b>progea</b>  <small>MONITORING VISION AND CONTROL</small>
<u>Malypass</u> HMI «CFR 21 part11 ready»	<b>Rockwell Automation</b> <b>FactoryTalk</b> View

# Machine Revamping / Retrofit, Examples

The logo for Malys, featuring the word "Malys" in a stylized, cursive blue font. A small registered trademark symbol (®) is located at the bottom left of the letter 'M'.



Malys 1 UWL integrated  
in a belgian site on an existing line

Year 2008

# Before

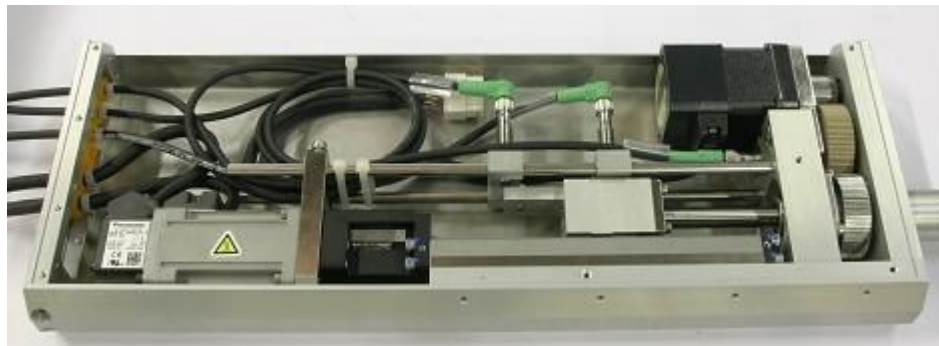
- 2 machines with 1 pump
- Total rate : 12' 000 vials / hour
- No motion fine tuning
- Accuracy not high enough



# After



- 2 machines with 2 pumps
- Fine tuning on each pump
- High accuracy
- High speed with no splashing
- No mechanics on the top of the line
- Total rate : 18' 000 vials / hour



Malys 2 UWL integrated  
on 2 new lines with RABS in 2008 and 2010

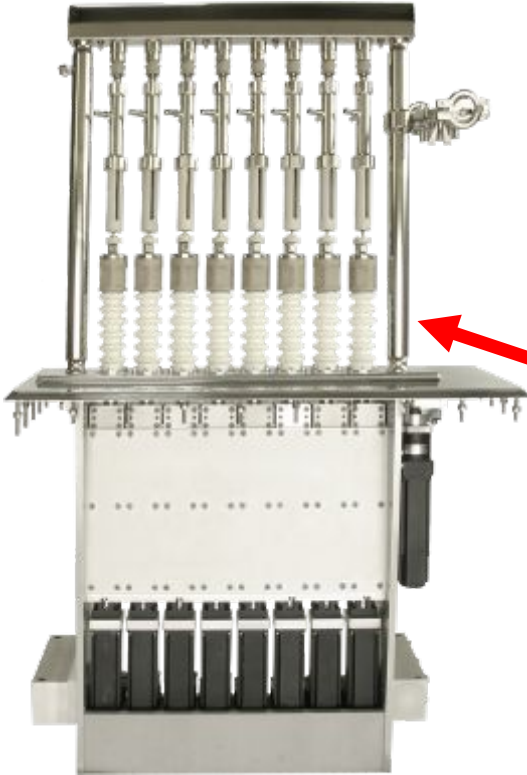


# Before



- Peristaltic pumps
- No accuracy
- Drops
- Problems with the product viscosity (70 % sugar, 5°C)

# After, on a french new line



- Safe Handling Seal-less pumps
- Klyx system for fast pump exchange
- High accuracy
- No dropping





# After, on a german new line



- 10 Safe Handling Sealess pumps system
- High accuracy
- No dropping
- Fast pump locking/unlocking system



Stand-alone Malys T in a french site  
on a Baush+Ströbel line

Year 2008



# Before



- Hard to clean
- Works with solenoid valves
- Unsatisfactory accuracy
- Non-ergonomic HMI

# After



- Easily cleanable system
- No retention
- Sealless pumps
- High accuracy
- Operator friendly HMI



Malys T with 4 indepedant pumps on  
a site in USA with a new italian  
thermoforming machine  
Year 2009

# Before

## **Time-pressure system :**

- Between one and two hour to adjust a batch starting
- Poor accuracy
- Changes in dosage results during the day

# After



- No adjusting at starting only a recipe to load
- High accuracy
- No adjusting during the batch no time deviation with volumetric system



# They already trust SPC Engineering...



# Contact information

## **SPC Engineering**

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Malys, demo video

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