Pouch Inspector & Cut&Roll Manual

blister partner

Version	:	2.2
Date	:	31-08-2018
Author	:	Leon van Zanten
Department	:	Research & Development

Address : Dr. Lelykade 14b
2583 CM
Den Haag
The Netherlands

1 Index

2 General description

The Pouch Inspector is a stand-alone inspection machine that scans the packaged pouches, verifies the content of the pouches with the ordered medication and customer details and documents the results for further reference.

A roll of pouch strips is placed on the Pouch Inspector. It will instant scan at a speed of 3-5 pouches per second (180-300 pouches per minute). No need to push a button, just swipe it through the machine.

The content of each pouch is automatically compared with the prescribed medication and customer details and the results are stored in the database for processing and documentation.

Unknown tablets are marked and automatically integrated into the analysis without process interruption. The inspection status of each pouch is immediately displayed on the screen. The results of an order can either be displayed on the touchscreen or at a separate PC in your network and the pouches are accordingly manually checked and corrected before the order is approved for dispatch.

3 Installation

3.1 Ergonomics

To move the Pouch Inspector (PI) around be aware of the weight: 27kg.
Lift the PI preferably with 2 people and hold it by the housing, not the stainless steel arms. This to prevent damage to the arms because of the weight of the PI.

3.2 Connection to the packaging machine

We'll connect the Pouch Inspector to your network and packaging machine. The medication descriptions will be automatically loaded into the PI. This saves you manually typing the descriptions.

3.3 Barcode layout

We've provided you with a strip of pouches with the correct layout of the barcodes. This layout has been proven to work without any problems and therefore are recommended:

	Header | Footer Barcode	**Pouch Barcode**
Type	Datamatrix	Code128
Width		
Height		
Position x		
Position y		

3.4 Improper use of the Pi

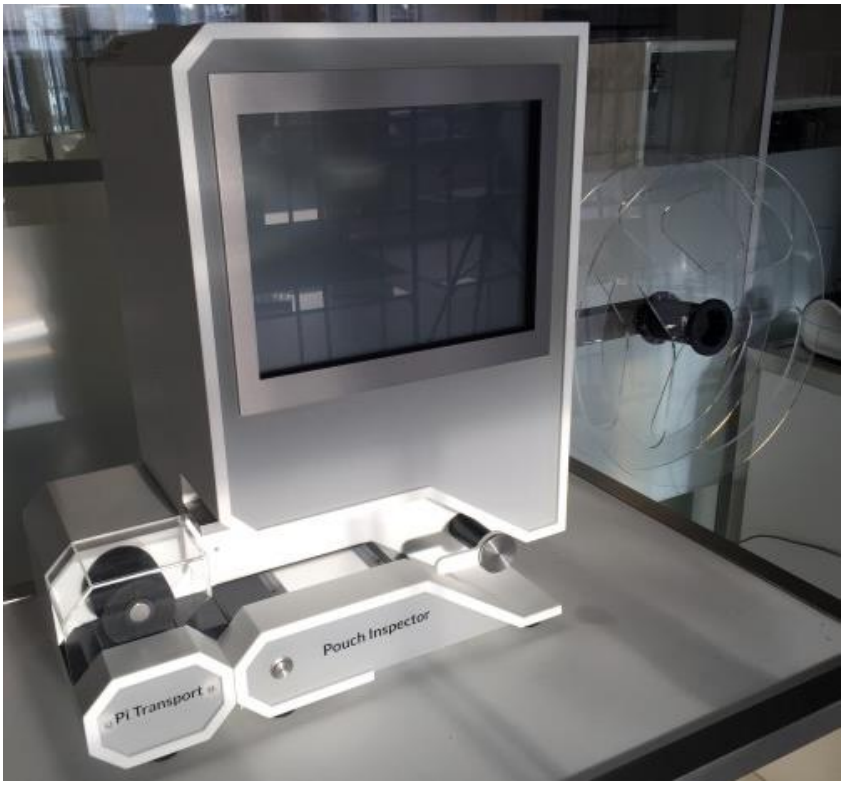
DON'T lift the Pi on its arms. It's better to lift the Pi holding the white housing.

DON'T look into the LED's while they're on.

4 Getting Started

4.1 Pouch Inspector Reel to Reel

4.2 Pouch Inspector + Pi Transport



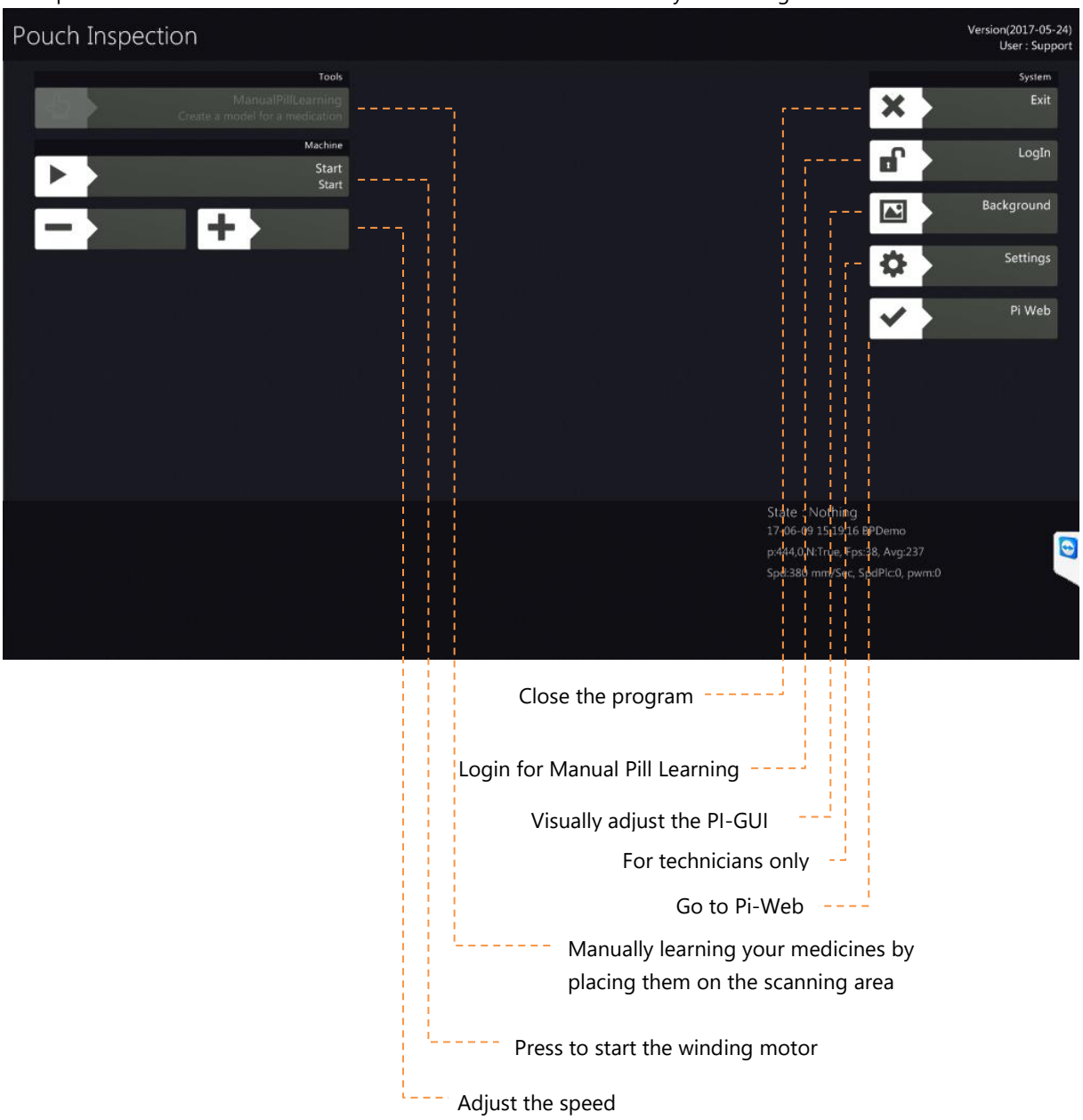
4.3 Pouch Inspector + Cut&Roll

5 Pouch Inspector (Reel to Reel or Pi Transport)

- If you have a pouch inspector i.c.w. a Cut&Roll, go to chapter 6.

5.1 PI-GUI (Graphical User Interface)

The options on the touchscreen are minimized to ensure the easiest way of working.



5.1.1 Start button

If a batch is guided through the machine you can press the start button to start the Pi Transport or to start the motorized arm. From this moment the Pouch Inspector will start scanning.

5.1.2 ManualPillLearning button

This is the place to manually learn you medicines. In chapter Learning your medication the method of learning your medication is explained.

5.1.3 Exit

This button closes the program.

5.1.4 LogIn

Here you can log in with your credentials. These credentials can be made via Pi Web.

5.1.5 Background

You can visually change the Pi Gui by selecting different colors.

5.1.6 Settings

This is for support only.

5.1.7 Pi Web

After scanning the batch you can go to Pi Web to do the final check. You can also visit Pi Web from any other station in your network. In chapter PI Web 3.0.242

5.2 Place a batch

Place the spool on the right arm of the Pouch Inspector. The pouches should be guided clockwise. On the scanning area the pouches should lay with the text to the bottom and the seal to the back.

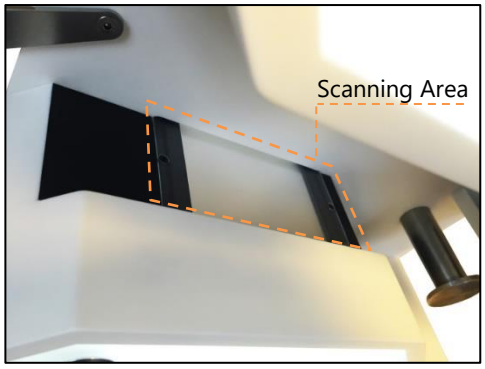
Seal to the back

Text to the bottom

NOTE:

- During installation we have run a sequence test to load (most of) the medicines into the system
- We have provided a strip of pouches with the layout of the barcodes which work without any problems on the Pouch Inspector. Other layout are possible but not recommended.
- You will receive 3 Spools on which you can roll the pouches. This Spool can be placed onto the right arm of the PI.
- An empty Spool must be placed on the left arm of the Pi.
- We can also provide a Pouch Winder which will wind the pouches directly from your packaging machine onto a perfect roll for the Pouch Inspector.

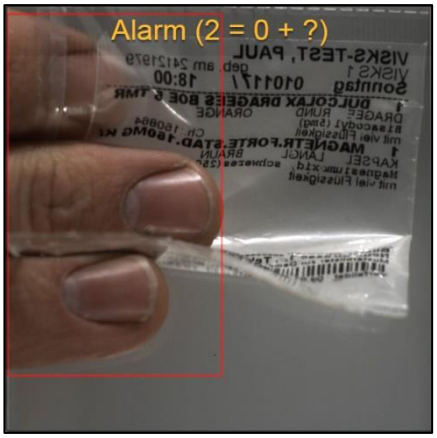
5.3 Start scanning / Batch loaded

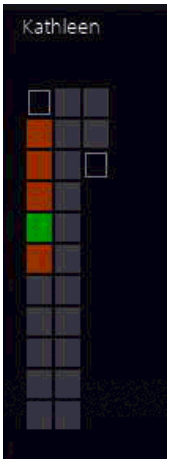


There is no ON or OFF button, while you swipe the pouches through the machine it will start scanning automatically.

First pouch is empty
Hold the first empty pouch and pull the strip over the scanning area.

First pouch is not empty
Push the strip over the scanning area and grab it on the other end.
Don't go over the scanning area with your hand.
This is important, otherwise the first photo of the first pouch will be with fingers and will raise an alarm.





If a batch is loaded in the left bottom corner the patient will be shown.

Patient name
Pouches:

- Red = Alarm
- Green = Approved
- Dark Grey = Expected pouches – to be scanned
- Black = Empty pouch
- *Light Grey = Barcode estimated (for support)*
- *White = Barcode read (for support)*

5.4 Reel to reel (Spool on the left)

Swipe the pouch strips through the machine. Click it onto the Spool on the left arm and press START on the touchscreen. It will automatically roll up and scan the batch.

It's also possible to swipe the pouch strips through the machine manually without using the left arm.
Swipe it through with a maximum speed of 5 pouches per second and all the pouches will be scanned.

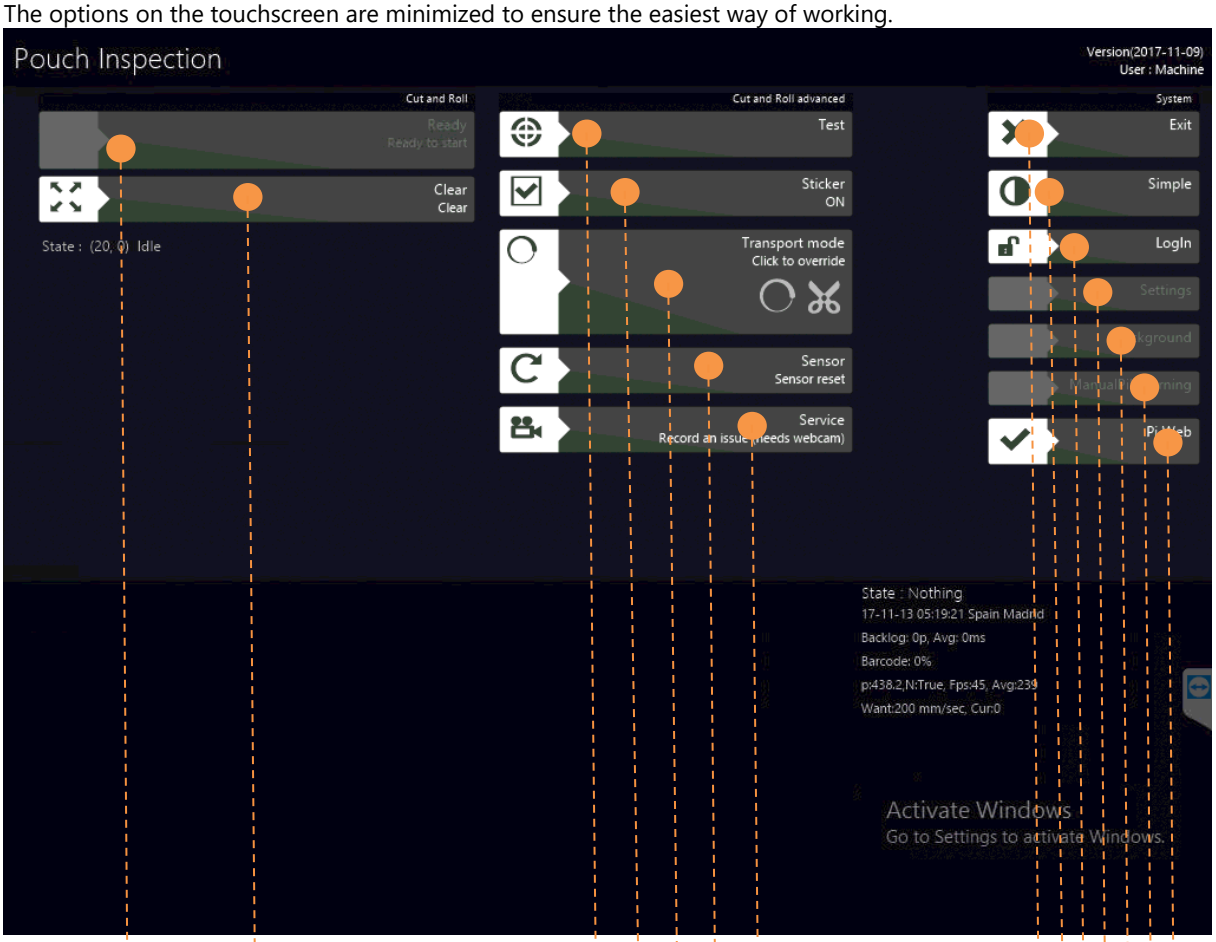
5.5 Pi Transport

Swipe the pouch strips through the machine till the foam roll and press on start. The foam roll starts spinning and the Pi will scan the batch.

6 Pouch Inspector i.c.w. Cut&Roll

6.1 Touchscreen | PI-GUI (Graphical User Interface)

The options on the touchscreen are minimized to ensure the easiest way of working.



Calibrate:
If this button is active you have to press it before you can start. The Cut&Roll sets itself to it's default setting.

Clear:
Pulls back the pins and the valve to release the pouches.

Test:
Brings you to the test screen for testing the various moving parts. This is used for support.

Sticker ON | Sticker OFF:
Turns the sticker ON or OFF

Transport Mode:
 transports, winds and cuts the pouches
 transport the pouches, doesn't cut, sticker and wind

Sensor:
Calibrates the sensors. Used in case of malfunctioning (i.e. early start of rotating pins)

Service:

Exit:
Closing the program.

Simple:
Makes the layout simpler.

LogIn:
For extra features. Same login used for Pi Web.

Settings:
For support engineer only.

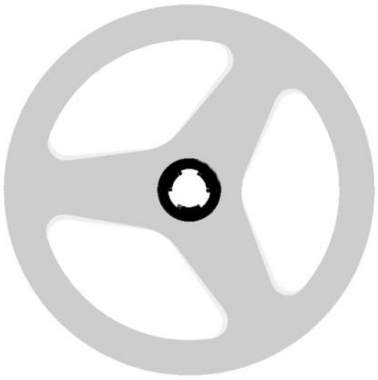
Background:
Changing the background colors.

ManualPillLearning:
Manually learning your medicines by placing them on the scanning area

6.2 Place a batch

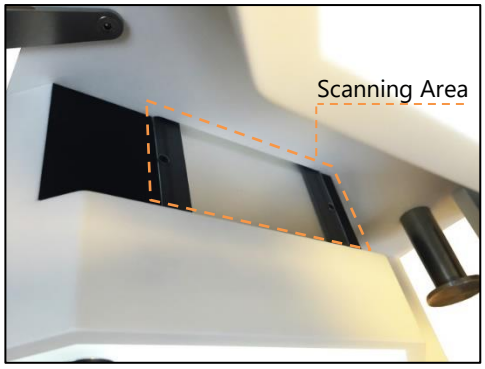
- You will receive standard 3 Spools on which you can roll the pouches. These spools can be placed onto the right arm of the PI

- If you have your own spools of pouches it can also be used. We will provide an adapter for your spindles. Only in a combination with a Cut&Roll or a Pi Transport. With the Pi Reel to Reel you will need the Blisterpartner Spools.



NOTE:
We can also provide a Stand Alone Winder which will wind the pouches directly from your packaging machine onto a perfect roll for the Pouch Inspector. This system prevents tearing the pouches apart by pulling from the packaging machine because it's using smart sensors to detect the tightness of the pouches.

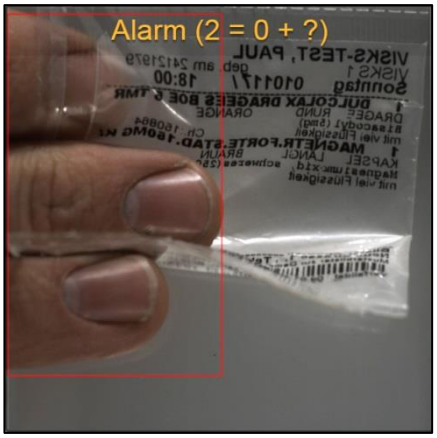
6.3 Start scanning

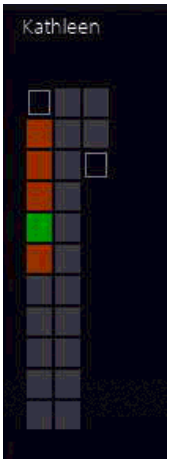


There is no ON or OFF button, while you swipe the pouches through the machine it will start scanning automatically.

First pouch is empty
Hold the first empty pouch and pull the strip over the scanning area.

First pouch is not empty
Push the strip over the scanning area and grab it on the other end.
Don't go over the scanning area with your hand.
This is important, otherwise the first photo of the first pouch will be with fingers and will raise an alarm.





If a batch is loaded in the left bottom corner the patient will be shown.

Patient name
Pouches:

- Red = Alarm
- Green = Approved
- Dark Grey = Expected pouches – to be scanned
- Black = Empty pouch
- *Light Grey = Barcode estimated (for support)*
- *White = Barcode read (for support)*

6.4 Automatic transport

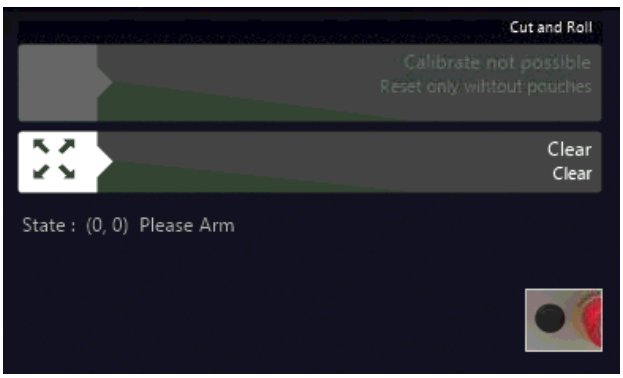
Push the pouches through the opening of the Cut&Roll. The Cut&Roll will grab the pouches and will do the work for you. The foam roll starts spinning automatically.

6.4.1 In case the foam roll doesn't start spinning a few things can be the case:

You haven't calibrated:
Before you can start you have to hit the Calibrate button if it's available. Therefore nothing can be on top of the scanning area. On the picture is shown that you have to remove the pouches first before you can hit the calibrate button.

NOTE:
If nothing is under the camera but this picture is shown you have to hit the **Sensor** button 5 times after eachother and wait till it's calibrated. If this doesn't work we can change a setting for you.

Hit the calibrate button to reset all the motors (this is only needed after an intervention like opening the door or pressing the Clear button).



Emergency button is pressed:
The Emergency button is armed. You can't continue till the button is disarmed and the reset button is pressed.
To disarm the Emergency button (red) either rotate to the button to the left or to the right (depending on the verson you have). After disarming press the Reset button (black).
Now you can calibrate and continue with your batch.

No communication:
This means that either the power at the back of the Cut&Roll is switches off or the Network cable is disconnected from the computer.

Door is open:
You have opened the door. If you have done this the machines stops, safety issue.

Door closed (after opening it):
The machine is in pause mode because you opened the door. Probably to fix something. Now there are two options:

- Continue, the machine continues where it stopped.
- Clear, the machine drops the pouches, pulls back the pins and the foam roll goes up. Now you can pull back the pouches to start over.

7 Learning your medication

We can do this automatically or manually

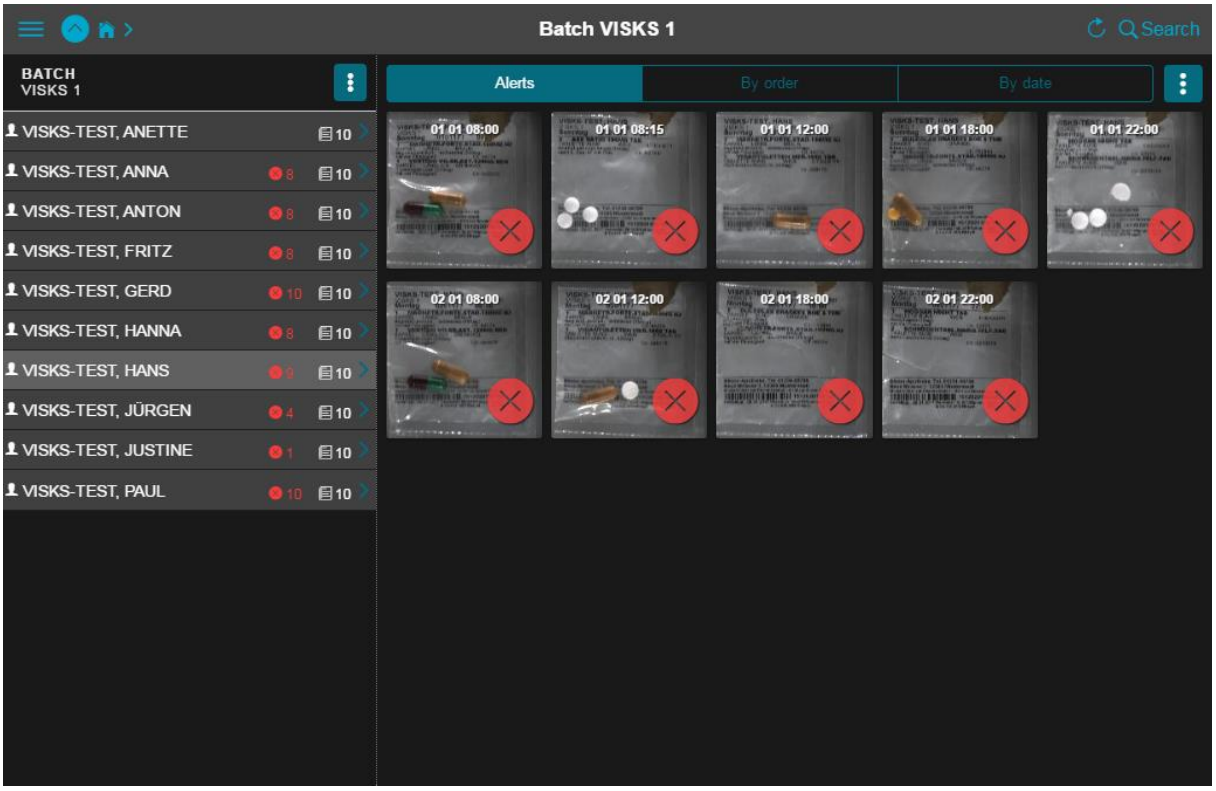
7.1 Automatically (sequence test)

During installation we will need a sequence test from the packaging machine. These strips we can run through the machine and this way the first medications are scanned and placed in the database for further update. It's necessary to update and fill your database with the pills you have in stock to improve the validation rate, decrease the false alarms and optimize the inspection.
We recommend 4-5 various models per pill.

7.1.1 Just begin with your pouch control

The PI will scan and document all the blisters with all the medications, known and unknown. There will be alarms on the pouches as he won't recognize the pills. But that's okay, that'll be the next step. The benefit is that there is no process interruption with unknown medications.

Result on Pi-web:



7.1.2 Pill verification on screen

During this step you will verify the pills, but our software makes it possible that if you learn medication A in one blister, it will recognize medication A in all the blisters. So you only need to learn a pill once.

Example: you verified 1 pill, the software checked and approved 5 blisters containing that pill.

7.1.3 Benefits

1. This saves time
2. Easy and fast implementation of your medications
3. No process interruption during pouch inspection due to unknown medication

7.1.4 Notes

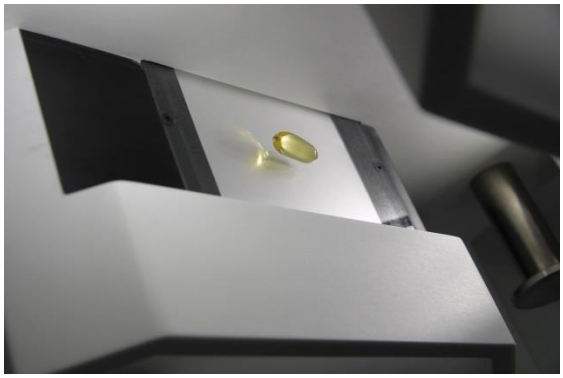
During the first scan of a particular medication the program saves a photo (or multiple, depending on the users input) of that medication. It might not be the best picture but that doesn't matter, it recognized the medication. During further inspection you have to add models to the database of that particular medication which makes the verification process better and more accurate. More explanation in chapter PI Web 3.0.242.

7.2 Manually (pill by pill)

This process will give the best results possible because the pills are scanned while they don´t move and different sides can be photographed if desired.

7.2.1 Learning per pill

- Place the pill on the scanning area
- Press the *ManuallyPillLearning* button
    - If you can't press it because it's gray that means that you haven't logged in or you are not authorized to learn medication
- Type the medication name
    - it automatically searches in your database
- Press the *Get Models* button
    - It will take a photo of the pill
    - if it's a transparent model press the Transparant button
    - add a description if you want
- Press the *Save* button
    - add various models by pressing Save



To increase the reliability of the future scans it's wise to make a few photos:

- Top and bottom (especially if they have different imprints)
- Different sides / angles

7.2.2 Transparent pills

There's an option to learn transparent pills. Rotate the pill after each scan to implement multiple photos and enhance the verification results.

7.2.3 Difficult | variable pills (granular)

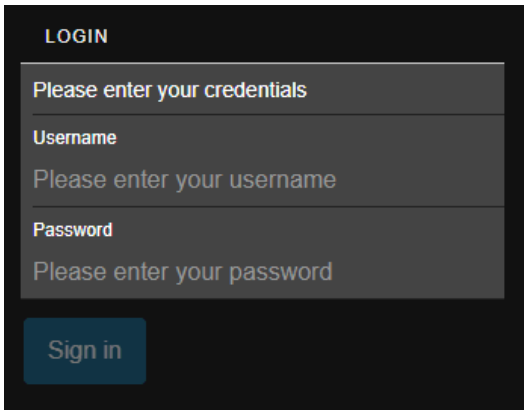
There's an option to learn two capsule pills. Especially with granular pills this is required. They can look different each scan as the granular inside the pills shifts. To verify that the right pill will be found you can:

- Make multiple photos (shake the pill after each photo to create different shots)
- You can adjust the tolerance to this particular pill (see next chapter)

8 PI Web 3.0.242

This Web Application is a tool to increase efficiency in the validation, documentation and archiving process of your controlled batches.
The PI-Web application can be used from every PC in the network.

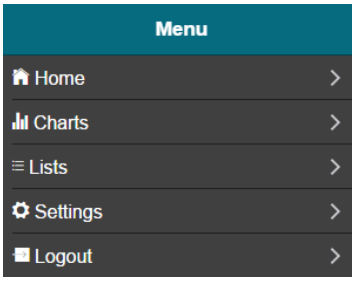
- Install Google Chrome as your standard browser for the best functionality.
- Type the following URL in your browser:
  - Pi
- Login with your credentials
  - Username:
  - Password:



8.1 Menu Options

Click on the menu button to open the menu options:

The options are:

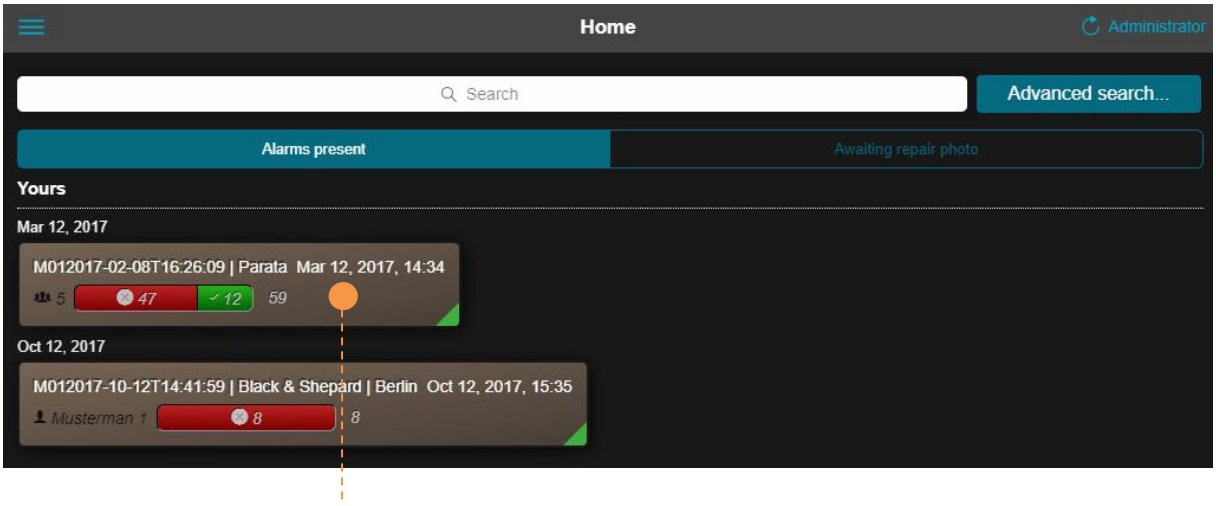


8.2 Home | To Do Screen

The Home screen is the ToDo screen. All the batches scanned with the PI and not yet validated are placed in this screen.

Alarms Present:

These batches are scanned and have alarms. They need to be checked:



Explanation of the batch and icons:

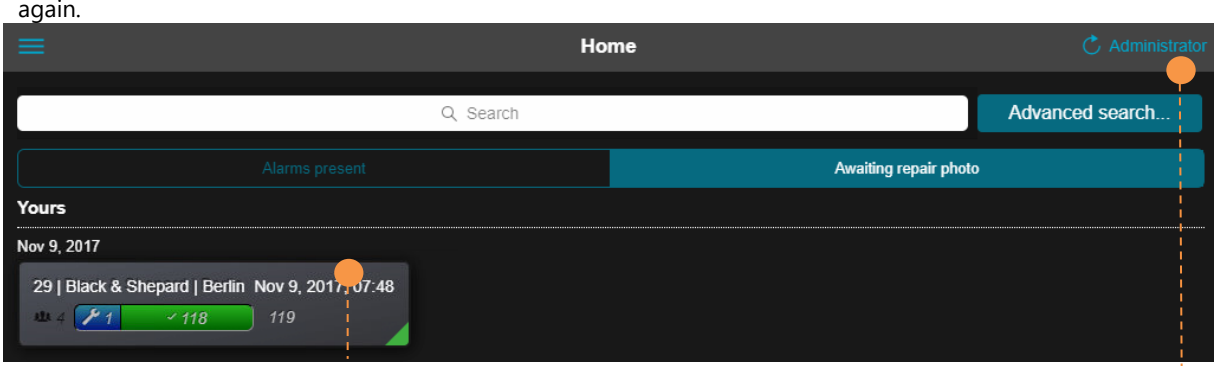
- Batch name | Location | Date | Time of inspection
- 5 patients in this batch | 47 alarms | 12 approved | 59 pouches in total

Awaiting repair photo (optional)

The alarms in these batches are checked but need verification by adding an extra photo using our webcam or swipping it through the Pouch Inspector again.

Complete (if awaiting repair photo is checked out):

After checking the alarms and approving them all, the batch is placed in Complete. Awaiting to be Finalized.



Explanation of the batch and icons:

- Batch name | Location | Date | Time of inspection
- 4 patients in this batch | 1 repair done | 118 approved | 119 pouches in total

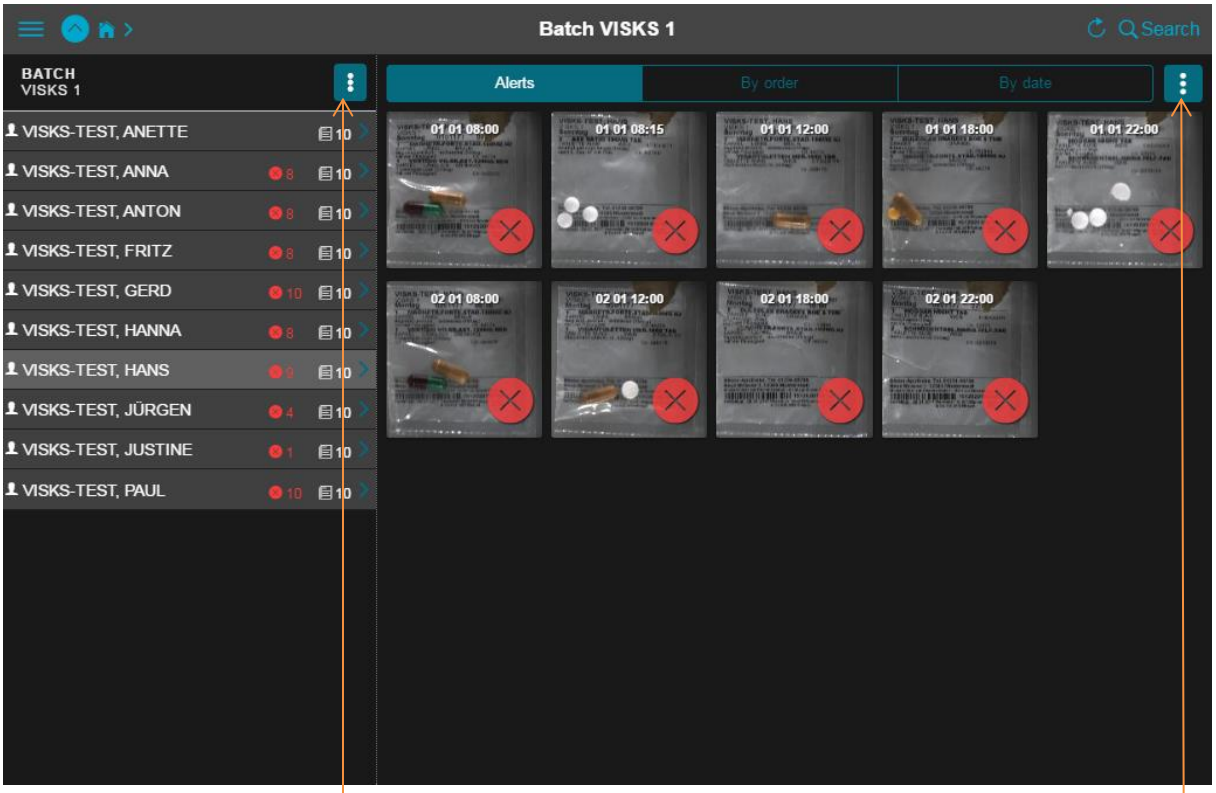
Advanced search:

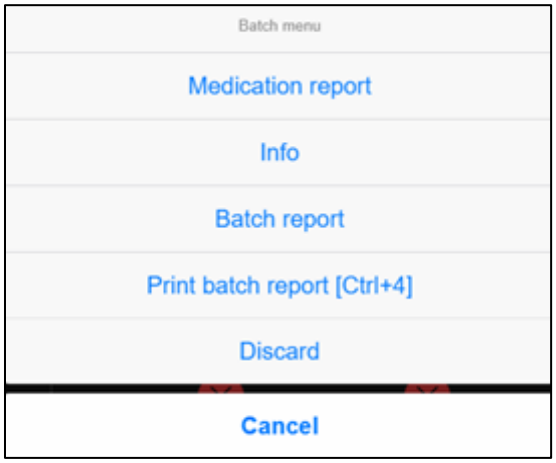
No need for explanation. These are the advanced search options.

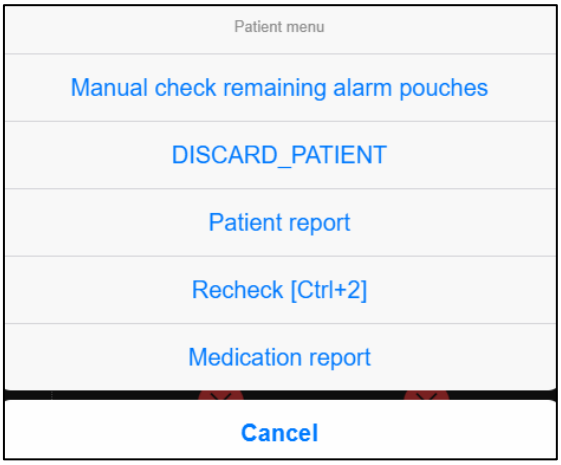
8.3 Batch screen

In here you'll find your scanned batch divided per patient. You can directly see the alarms, repairs and finished scans.

There's the option to filter by *Alerts, By order, By date, By time, Calendar*







Medication Report let's you print a report of the medications used in this batch

Info let's you see info regarding this batch:

- Batch
- Location
- Packaging machine
- Production date
- Check date

Batch report opens the batch report.

Print batch report let's you directly print the batch report with the alarms and repairs.

Discard let's you discard the hole batch. This can be done if the batch is not needed or wrong.

Manual check remaining alarm pouches approves all the alarms left for this patient. This can't be undone so make sure before you want this before approving.

Discard_Patient let's you exclude / remove the selected patient. It's not needed anymore to check that patient to finalize the batch. This can be undone.

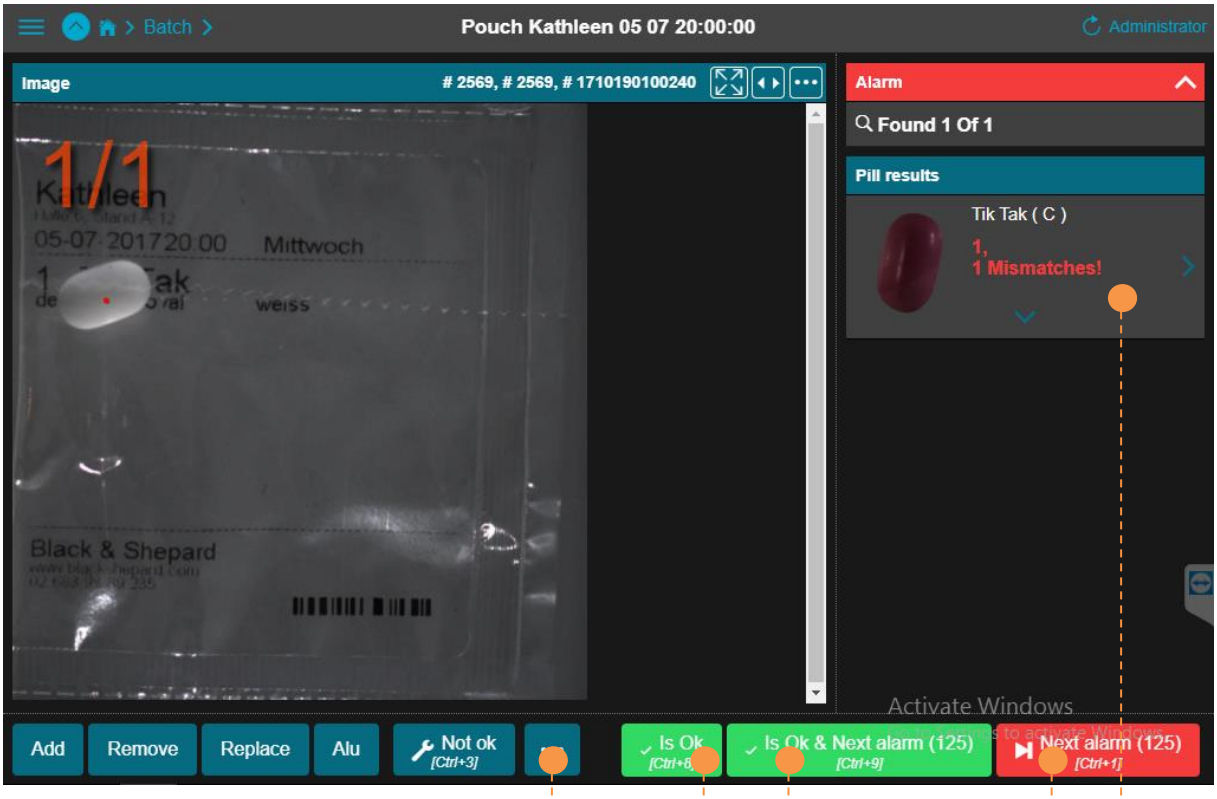
Patient report let's you print a document specifically for this patient.

Recheck let's you recheck the whole patient at once. This can be handy when there is an alarm with a pill and you just added a model of that pill. You can recheck the whole patient with this new model.

Medication report let's you print a report of the medications used for this patient.

8.4 The Pouch screen

By clicking on a pouch in the *Batch screen* you can look into the selected pouch.
Here you can check the content, fix the alarm and/or repair the pouch.



If a pouch needs repair there're multiple options to repair:

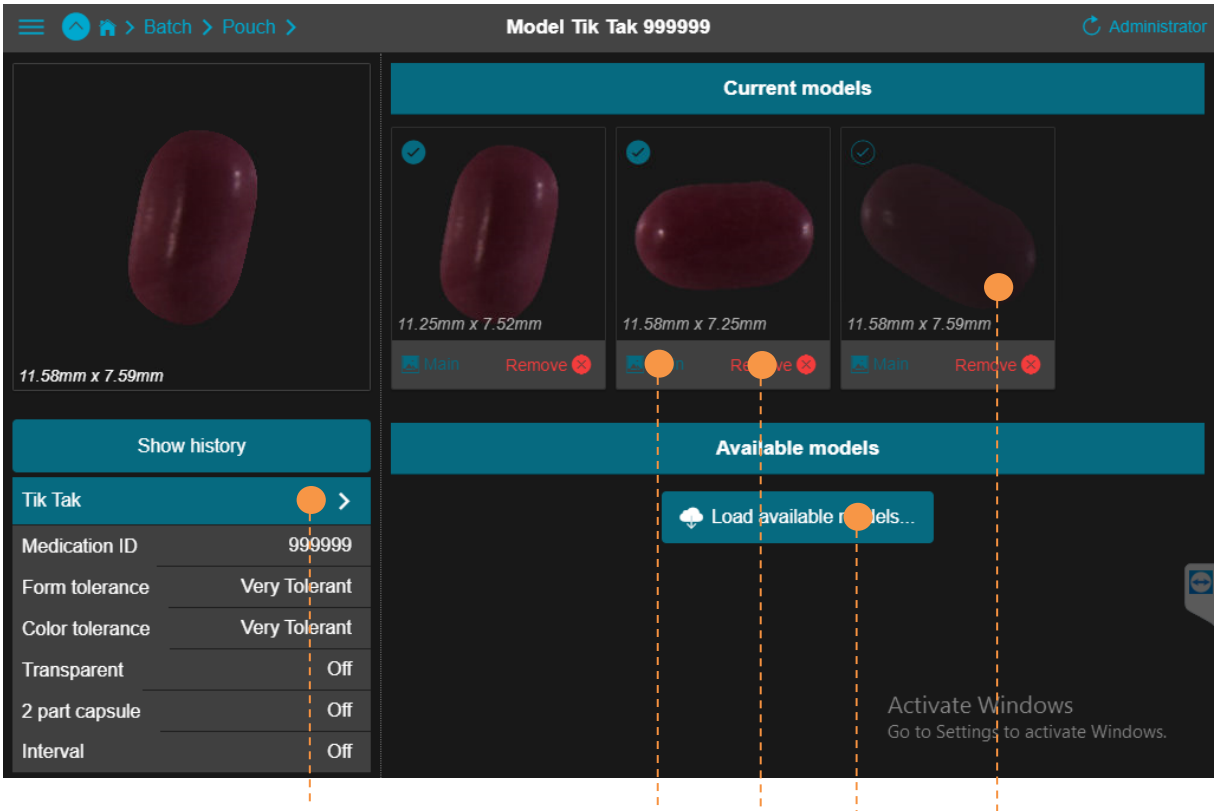
- Add | Remove | Replace | (these are the quick repair types)
- Not ok (gives all the repair types
  - Repair types can manually be added in *Settings*
- Repair image (optional)
  - If this setting is turned on you can add a verification by repair image. You can make a photo with a webcam and it will be added to this pouch. Multiple photos can be taken.
- Options:

Is Ok sets the pouch to okay.
Is Ok & Next alarm sets the pouch to okay and immediately goes to the next alarm.
Next alarm goes to the next alarm without setting the current pouch to okay.
Pill, by clicking you go to the medication model screen.

8.5 The medication screen

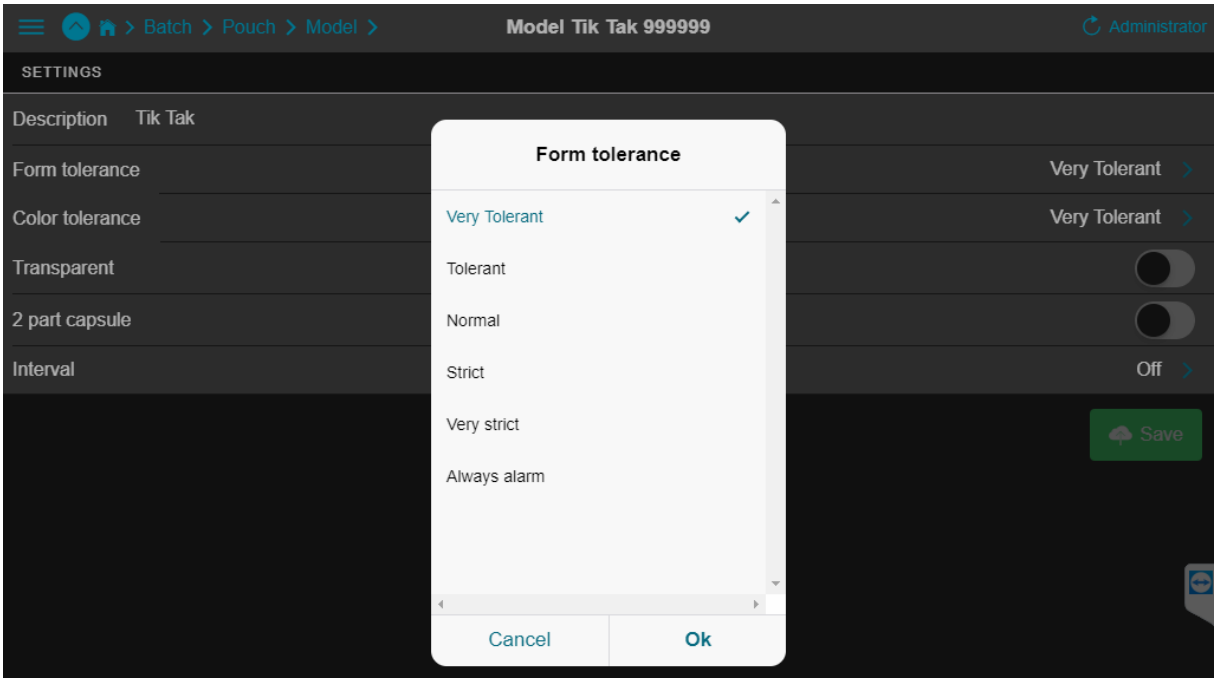
By clicking on a medicine you can enter the *Medication screen.*

Here you can add or remove photos of that particular medicine. As well as setting the tolerance for this particular medication.



Tolerance can be added in the tolerance screen.
Main, by clicking here you set this model as the preview model in the pouch screen
Remove this model from the list. The Pouch Inspector won't use this model anymore to inspect
Load available models will search in the database for more expected models
Enable / Disable the model by clicking on it (this on is disabled)

8.6 Tolerance screen

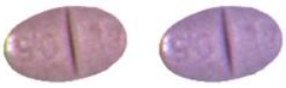


Description can be added for this particular medication
Form tolerance can be set from *Very Tolerant* (shape can vary) to *Very Strict* (must be almost 100% good) to *Always alarm* (which will always raise an alarm on this particular medication)

- Very tolerant…form can differ each scan (for example: chipped pills will be accepted)
- Always alarm…always check manually as the form confirmation is highly important

Color tolerance can be set from *Very Tolerant* (color can vary) to *Very Strict* (must be exact the same color)

- Very tolerant…the color is not the most important part of the scan
- Very strict…it's a distinctive part of the validation



Transparent, it will focus it's scanning technique on transparent pills, if activated.

2 part capsule, it will focus it's scanning technique on capsules made of 2 parts, if activated.

Interval

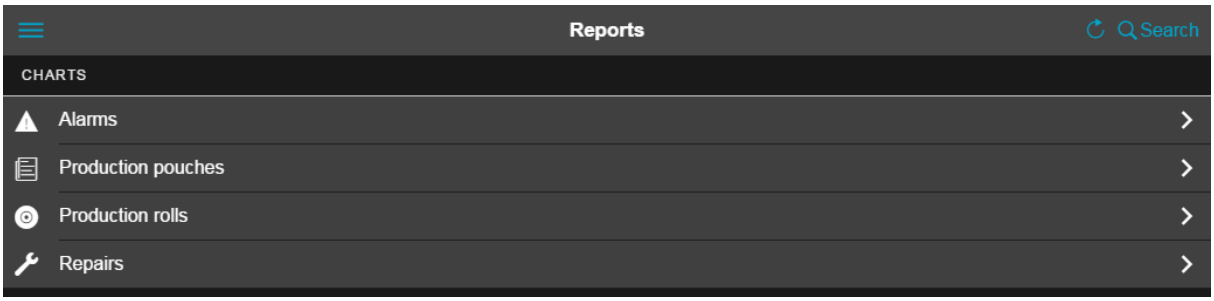
- OFF…no interval alarm during pouch verification
- 1000…scan #1000 of that particular pill will give an alarm. It needs to be manually approved to validate the pouch.
- 1…every scan of that particular pill will give an alarm. It needs to be manually approved to validate the pouch.

Note:
Don’t forget to press SAVE after adjusting the settings.

8.7 Charts

In the charts page you can see various statistics like:

- Percentage alarms
- Production pouches
- Production rolls
- Percentage repairs



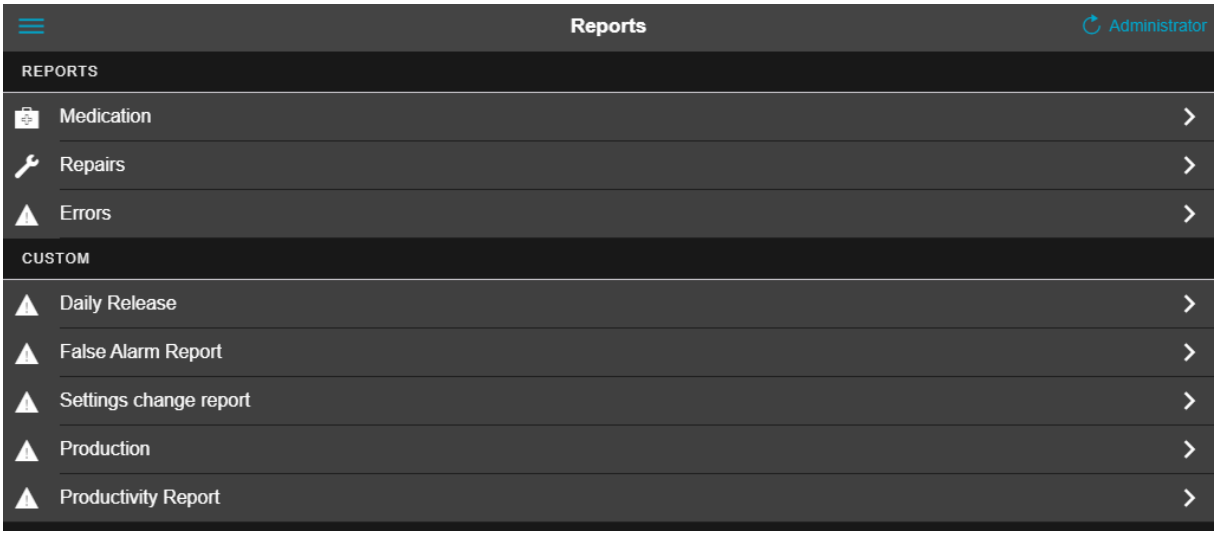
8.8 Lists

In the lists page you can see, print and download (Excel document) various reports like:

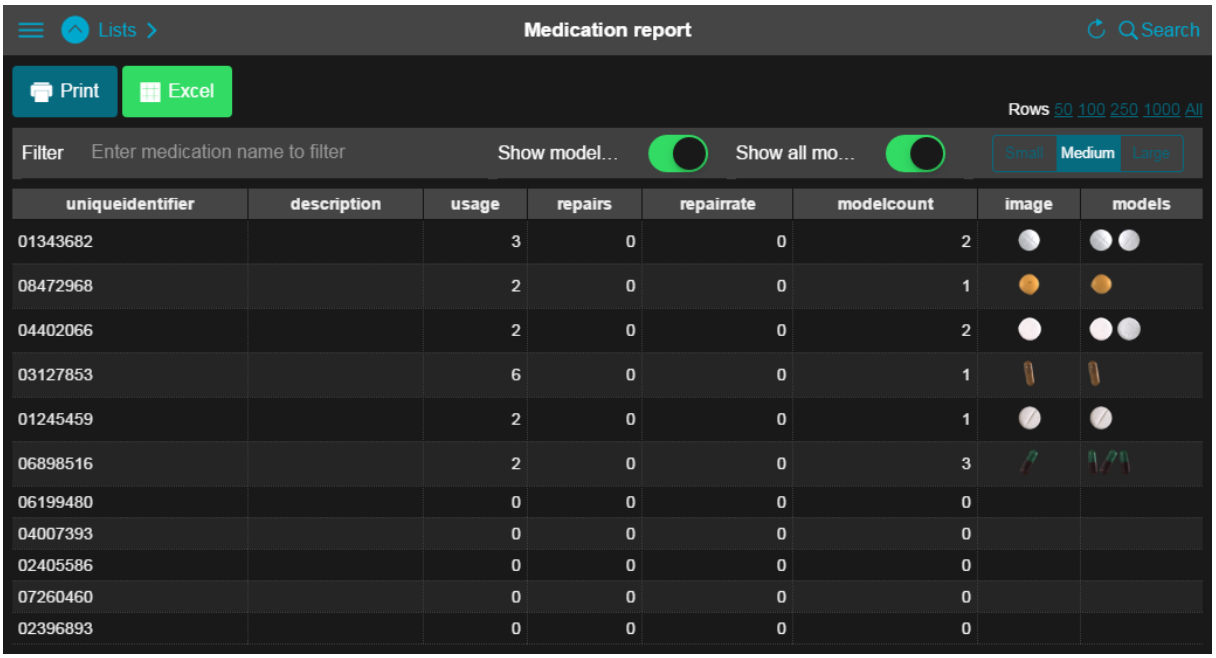
- Medications
- Repairs
- Errors

We can also make custom reports for you, i.e.:

- Daily release
- False alarm report
- Settings change report
- Production
- Productivity report



Example Medication report page:



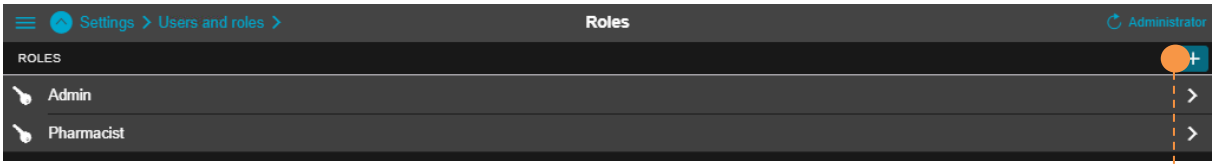
uniqueidentifier	description	usage	repairs	repairrate	modelcount	image	models
01343682		3	0	0	2		
08472968		2	0	0	1		
04402066		2	0	0	2		
03127853		6	0	0	1		
01245459		2	0	0	1		
06898516		2	0	0	3		
06199480		0	0	0	0		
04007393		0	0	0	0		
02405586		0	0	0	0		
07260460		0	0	0	0		
02396893		0	0	0	0		

This list is easy to use when you want to update and check your model database. By clicking on the pill you automatically go to the Medication screen. Here you can add or remove the models you want. This way you keep your database up to date.

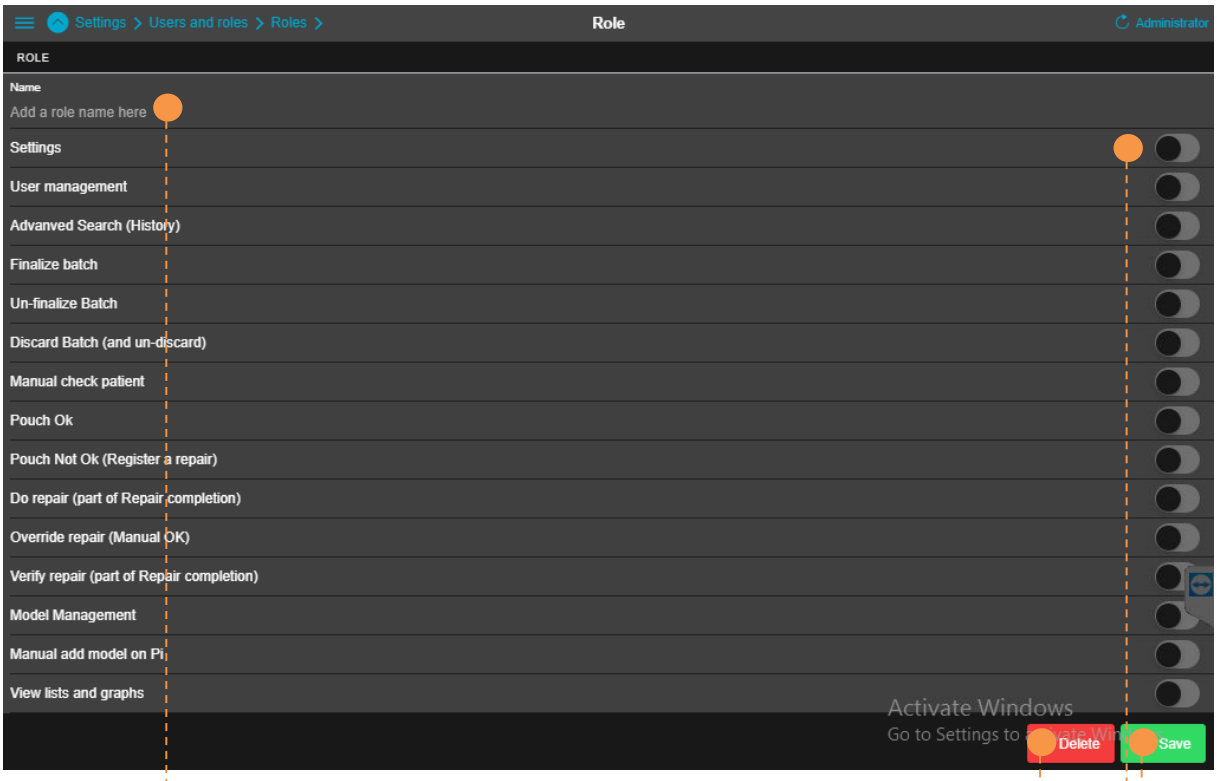
8.9 Settings – Users and Roles

You can add or remove users and adjust their roles and rights

8.9.1 Roles



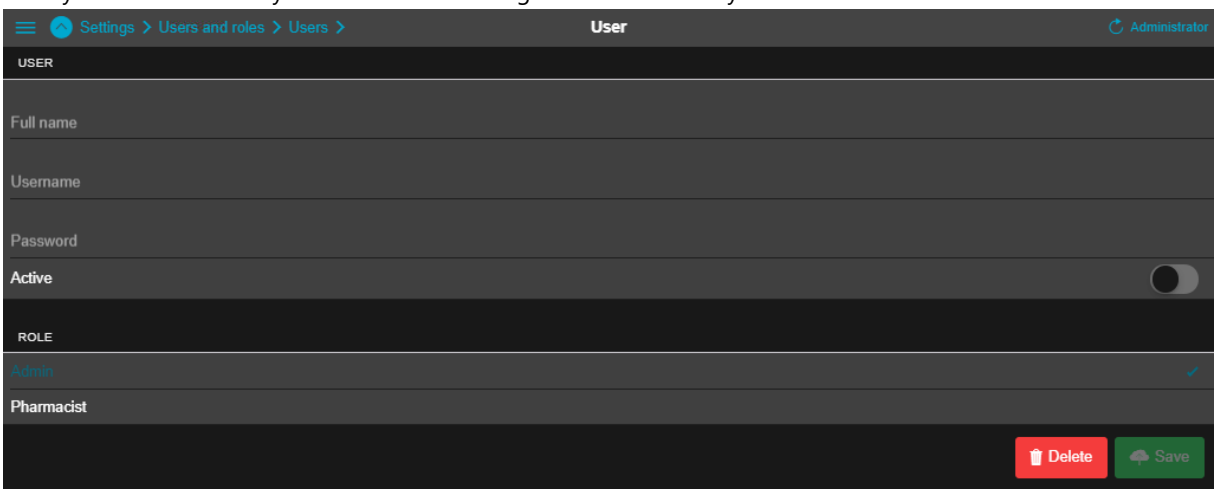
You can add a Role here
In this example two roles are already made, Admin and Pharmacist



Add a role name here, it can be anything you like
Delete this role
Choose the settings which these role can have by clicking them on or off
Save this role

8.9.2 Users

After you made the roles you can add users and give them the roles you've made.



8.10 Settings – Parameters

Various settings regarding the functionality of the Pi Web can be adjusted here.

General settings:

- Batch report
- Other
- Repair
- HD-Medi Validation
- Validation Other

Advanced settings:

- Language
- Pouch Images
- Webcam usage
- Date and time
- HD-Medi connection
- Tolerances

8.11 Settings – Repair Types

- Add or remove your own repair types
- By default, i.e.:
    - Removed Pill
    - Added Pill
    - Replaced Pill

8.12 Shortcuts

In the Pi-Web you can use shortcuts for easier and faster usage.

	Batch Screen	**Pouch Screen**	**Medication Screen**
Ctrl + 1	Go to *Next Alarm*	Go to *Next Alarm*	
Ctrl + 2	Recheck Patient	Recheck Pouch	Search Models
Ctrl + 3	Finalize Batch		Open Models
Ctrl + 4	Print Batch Report		
Ctrl + 5		Open First Medication	
Ctrl + 9		Set Pouch Okay	

8.12.1 Mini Keyboard

We can provide a mini-keyboard which uses the shortcuts so you won't have to search on your keyboard.

The functions of the keyboard are:

- OK (pouch)
- Finalize (the batch)
- Report (print)
- Redo (recheck the pouch)
- Back (to previous pouch)
- Next (to next pouch)
- Zoom (the pouch)
- Refresh (the screen)

9 Maintenance Pouch Inspector

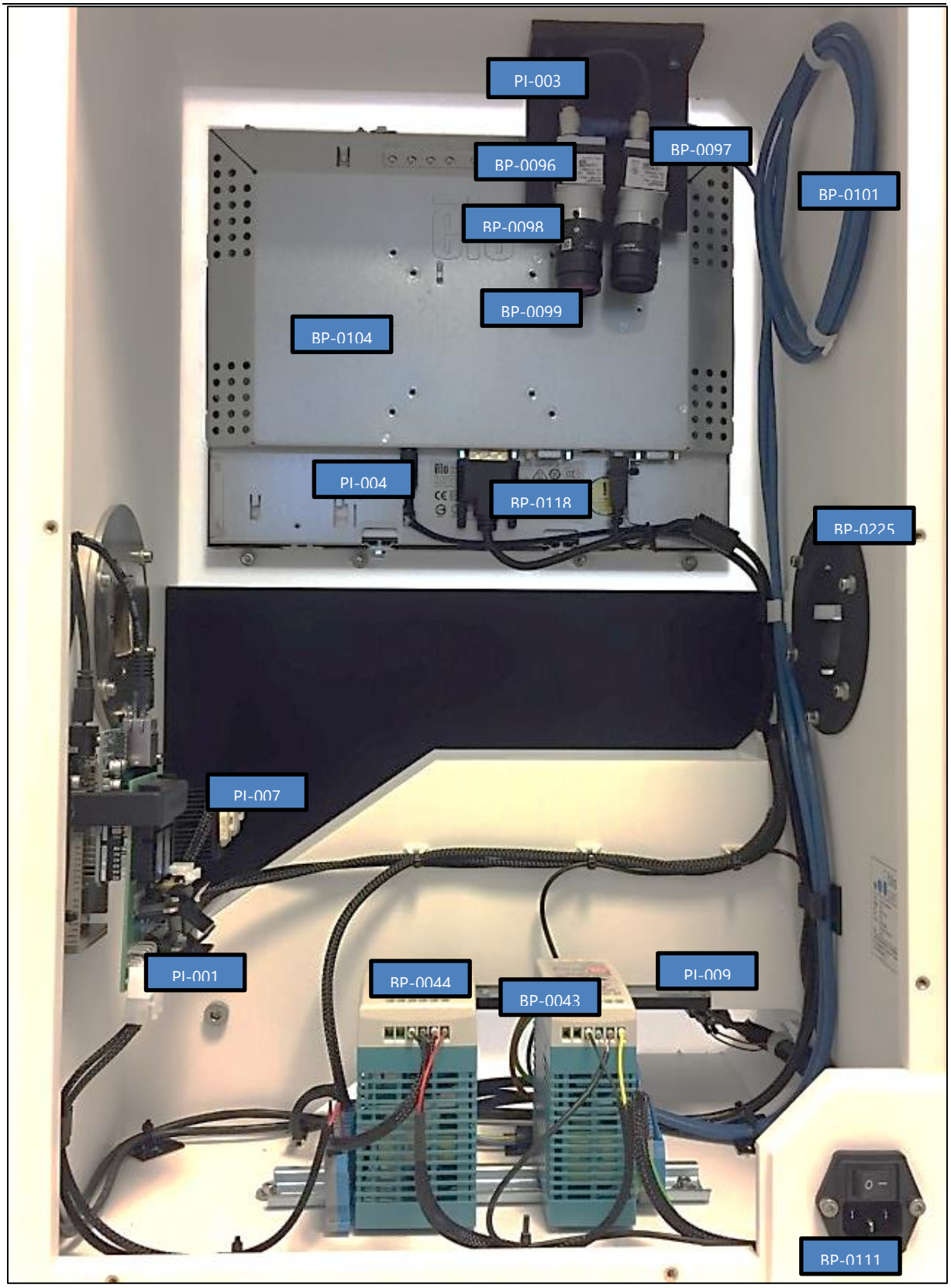
In case of maintenance follow the steps below to insure maximum safety.

1. Shut down the computer
2. Shut down the Pi using the button at the front, click it ones and wait for it to shut down.
3. At the back, click the button off
4. Discard the power cable
5. Now it's safe to open the lid

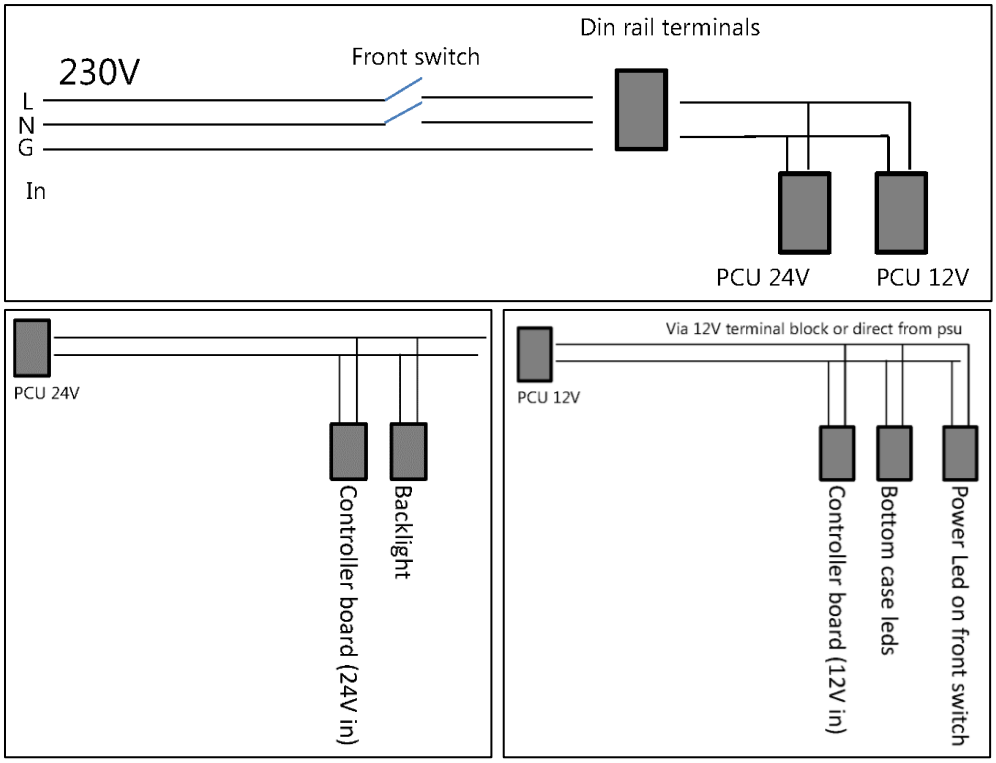
9.1 Part numbers

BP-0043	Power Supply 24V
BP-0044	Power Supply 12V (big)
BP-0096	USB 3 camera Mono
BP-0097	USB 3 camera Color
BP-0098	Lens
BP-0099	Filter
BP-0101	USB camera (2x)
BP-0104	Touchscreen
BP-0111	Power Inlet 230V
BP-0118	HDMI-DVI cable
BP-0152	Crouzet Motor
PI-001	PCB Board
PI-004	Touchscreen to 12V cable
PI-007	Front Lights (2x LED)
PI-009	Backlight

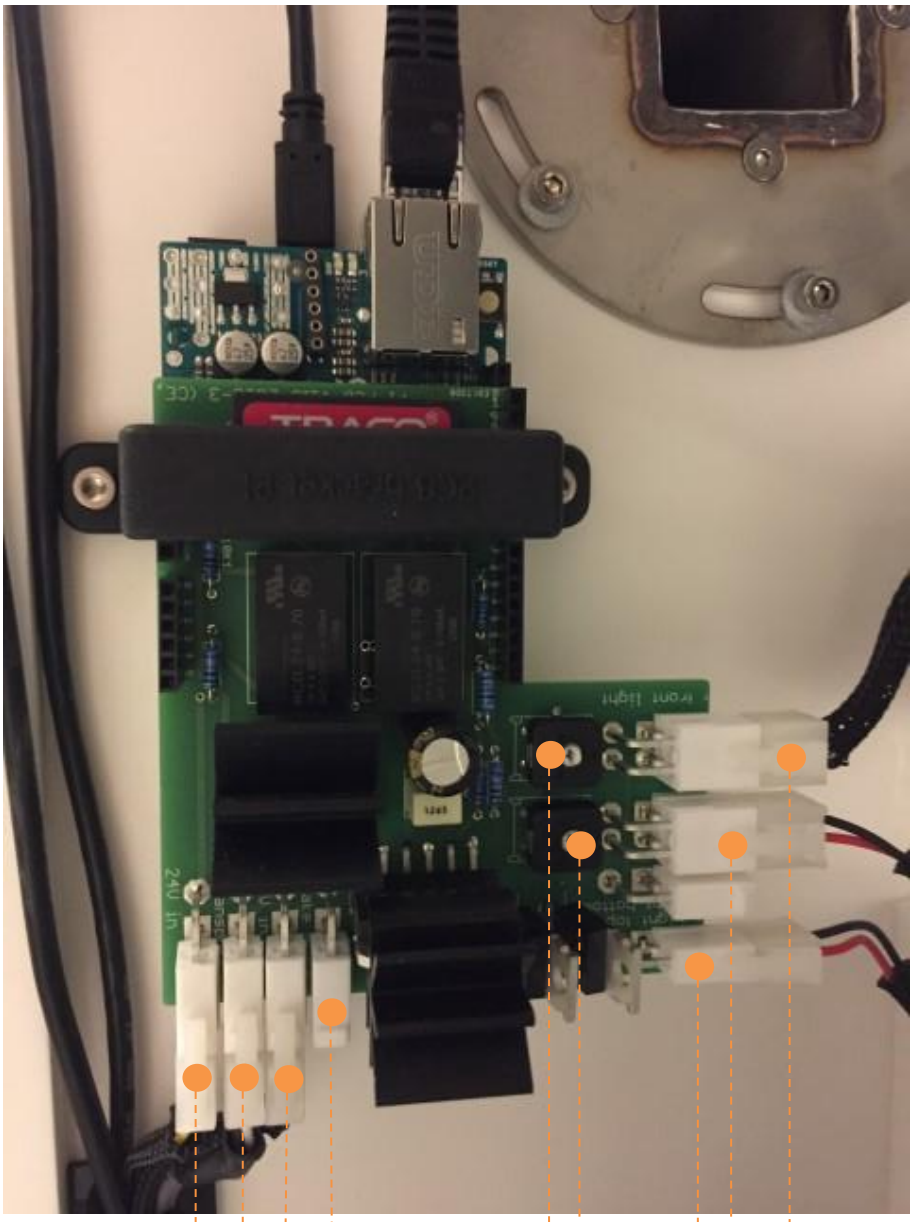
9.2 What's inside - Back



9.3 Circuits (230V | 24V | 12V)



9.4 PCB



24V
Transport – Motorarm of the Pouch Inspector or Pi Transport
12V
Shaker
Pot Meter strength LED's right side (2x)
Pot Meter strength LED left side (1x)
Esthetic light front bottom
Front Light LED left
Front Light LED right

10Maintenance Cut&Roll

In case of maintenance follow the steps below to insure maximum safety.

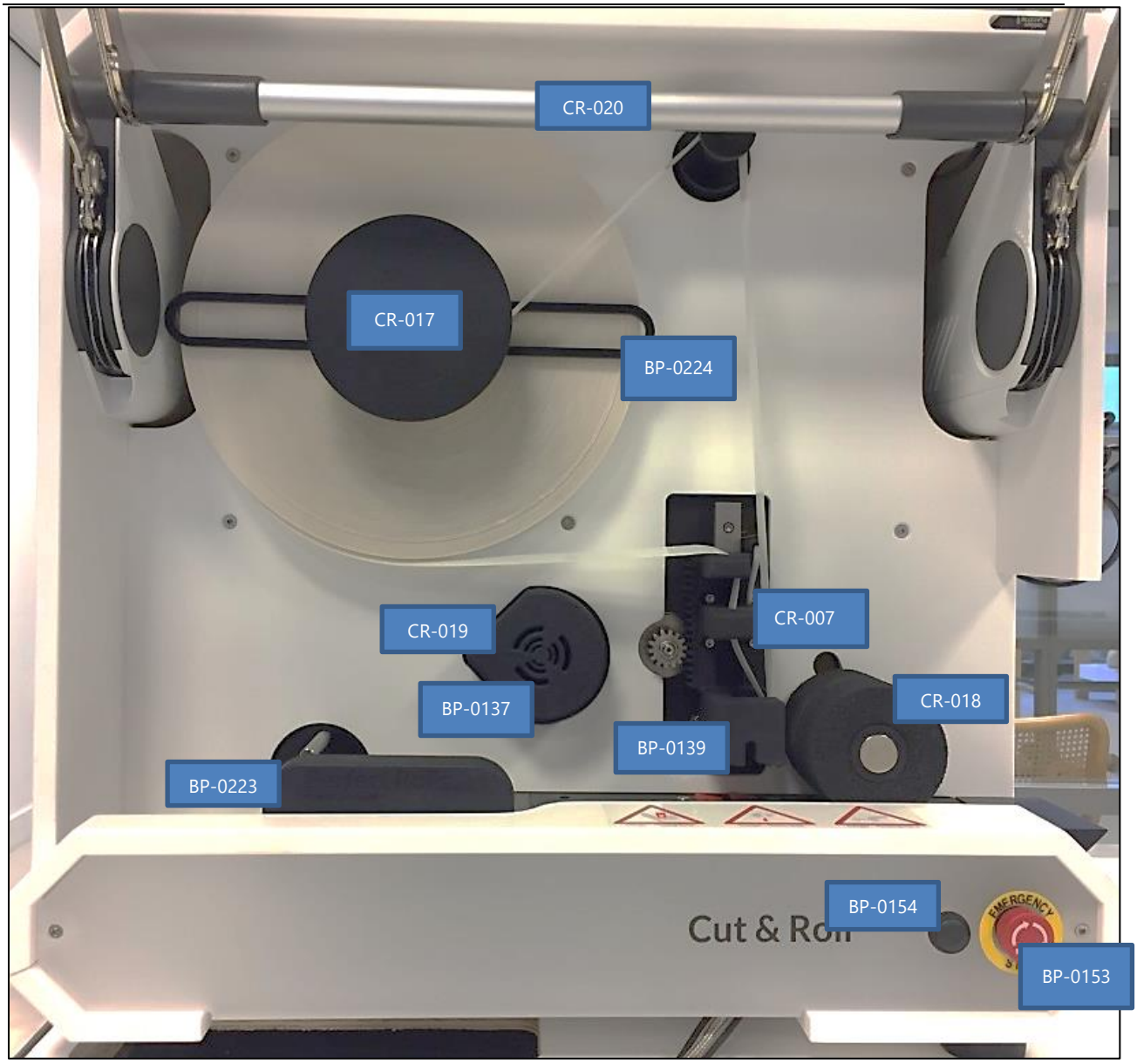
1. Shut down the computer
2. Shut down the CR using the Emergency button at the front
3. At the back, click the button off
4. Discard the power cable
5. Now it's safe to open the lid

10.1 Part numbers

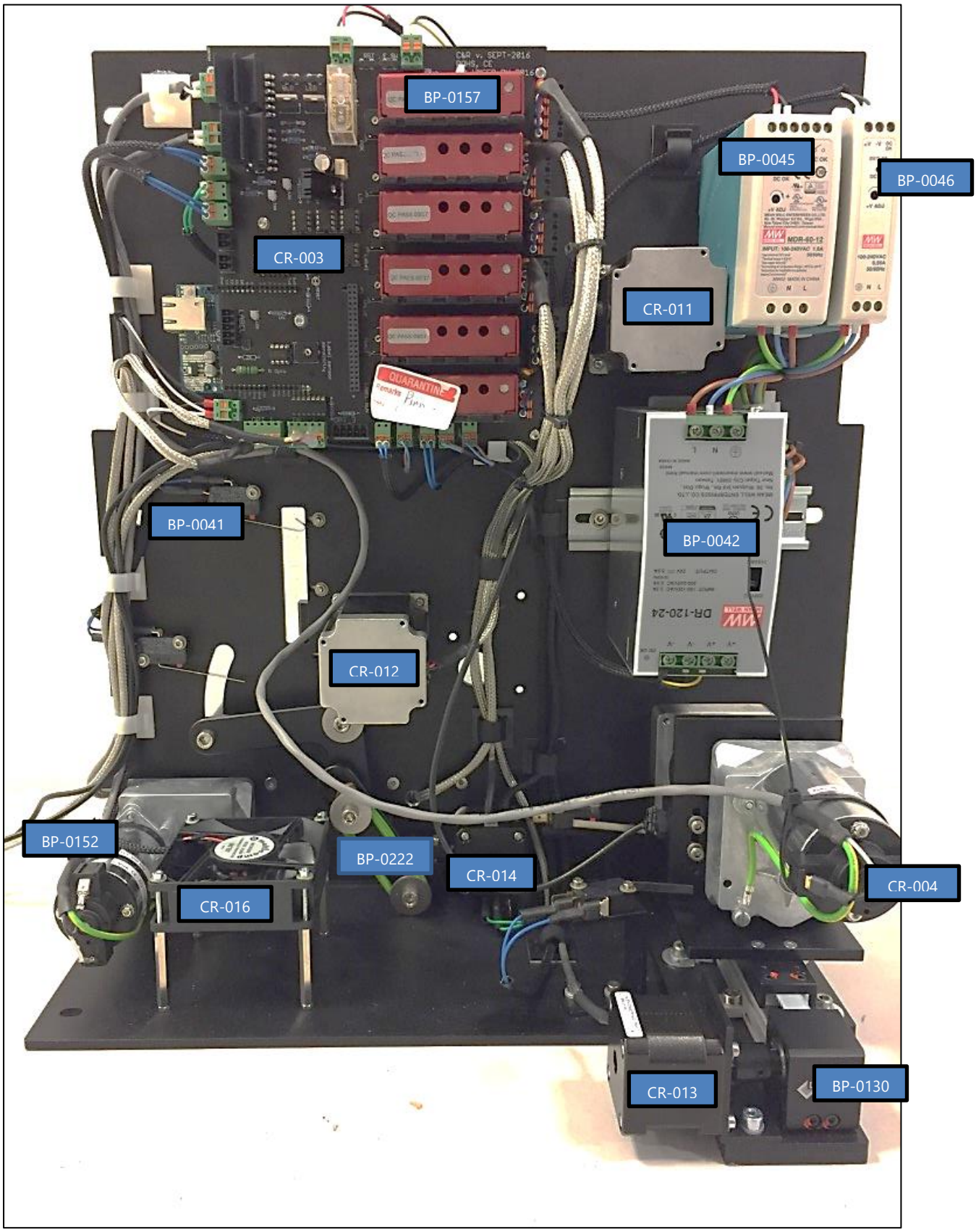
CR-001	Magnet Sensor
CR-002	Lower Foam Roll
CR-003	PCB – Board
CR-004	Crouzet Cable Pin Rotation
CR-005	Emergency Button Cable
CR-006	Microswitch cable
CR-007	Sticker Sensor
CR-008	Sensor 2
CR-009	Door Magnet cable
CR-010	Door Magnet
CR-011	Stepper Motor Sticker Roll (big)
CR-012	Stepper Motor Pushing Rod (big)
CR-013	Stepper Motor Linear Guide (small)
CR-014	Stepper Motor Release Valve (small)
CR-015	Stepper Motor Transport Roll (small)
CR-016	Fan / Cooling
CR-017	It's a Wrap
CR-018	Upper Foam Roll (complete)
CR-019	Blower
CR-020	Stabilizer Bar
BP-0041	Microswitch (5x)
BP-0042	Power Supply 24V (big)
BP-0045	Power Supply 12V
BP-0046	Power Supply 5V
BP-0111	Power Inlet 230V
BP-0130	Linear Guide
BP-0137	Blower holder
BP-0139	Pushing Rod
BP-0152	Crouzet Motor (2x)
BP-0153	Emergency Button
BP-0154	Reset Button
BP-0157	Stepper Driver (6x)
BP-0222	Silicon Straps (3x)

BP-0223	Perfect Rolls
BP-0224	Sticker Roll Protection
BP-0225	Cut&Roll Connection

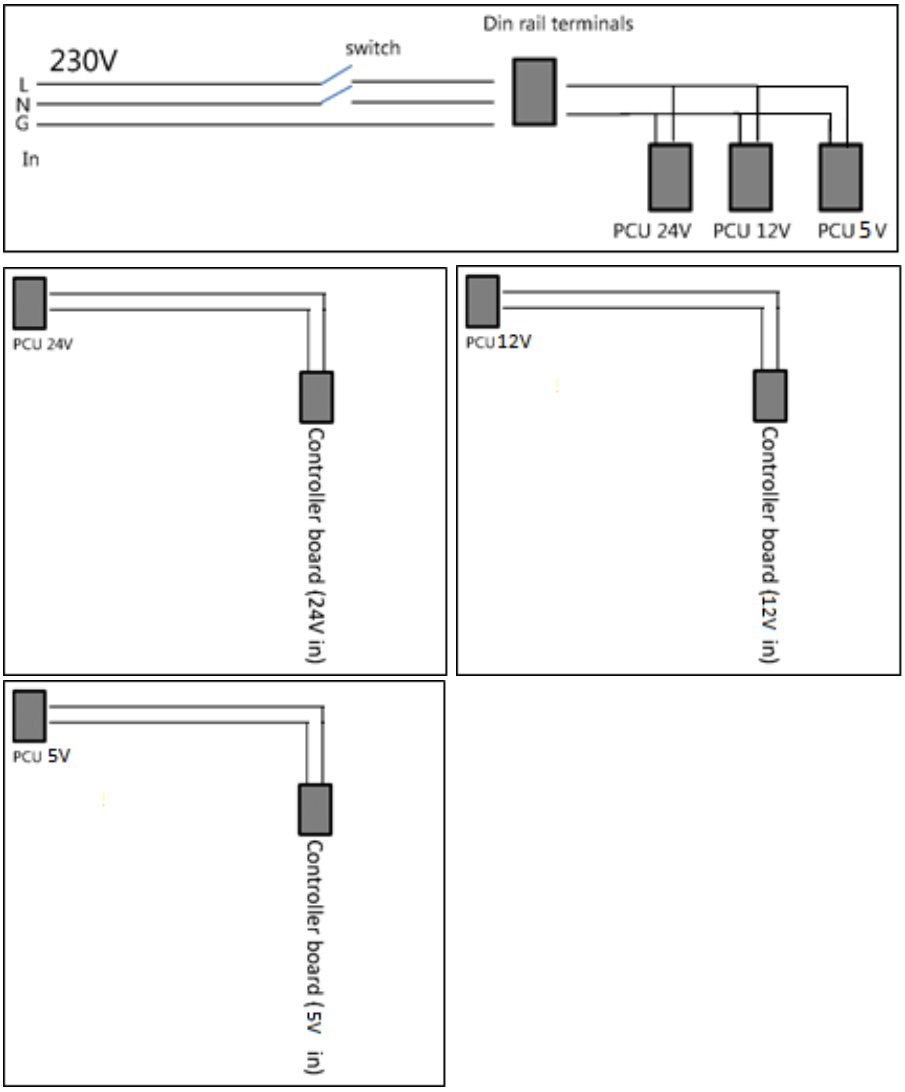
10.2 What's Inside - Front



10.3 What's inside - Back



10.4 Circuits (230V | 24V | 12V | 5V)



11Spare Part Kit

- BP-0001 | 230V Power Cable 1,5m | 1x
- BP-0041 | Microswitch | 2x
- BP-0119 | Arduino Due | 1x
- BP-0120 | Arduino Ethernet Shield 2
- BP-0147 | Springs Cut&Roll
- BP-0152 | Crouzet Motor
- BP-0157 | Stepper Driver G201x
- BP-0213 | USB 2.0 micro cable
- BP-0222 | Silicone straps
- BP-0248 | Cable USB 3.0 for camera
- CR-001 | Magnet Sensor
- CR-002 | Lower Foam Roll
- CR-004 | Crouzet Cable Pin Rotation
- CR-006 | Microswitch Cable
- CR-007 | Sticker Sensor
- CR-008 | Sensor 2
- CR-009 | Door Magnet Cable
- PI-003 | Camera Interconnect Cable
- PI-008 | Crouzet Cable
- PI-014 | Cable 12V to PCB
- PI-015 | Cable 24V to PCB
- PT-001 | Crouzet Cable

12 Spare Part Kit Advanced Upgrade

- PI-001 - PLC Pouch Inspector
- PI-002 - LED Module Right (2x LED)
- PI-007 - LED Module Left (1x LED)
- PI-009 - Backlight
- PI-011 - Computer with image (no MIL license)
- CR-003 - PLC Cut&Roll
- CR-012 - Stepper Motor Pushing Rod (big)
- CR-013 - Stepper Motor Linear Guide (small)
- BP-0042 - Power Supply 24V (big)
- BP-0043 - Power Supply 24V
- BP-0044 - Power Supply 12V (big)
- BP-0045 - Power Supply 12V
- BP-0046 - Power Supply 5V
- BP-0096 - Camera mono
- BP-0097 - Camera color

13EC-Declaration of Conformity

In accordance with EN ISO 17050-1:2004

Blister Partner

Dr. Lelykade 20
2583 CM Den Haag
Nederland

Year of affixing CE Marking: 2016

In accordance with the following Directive(s):

2006/95/EC	The Low Voltage Directive
2004/108/EEC	The Electromagnetic Compatibility Directive
2006/42/EC	Machine Directive

Hereby declare that:

Type:	Pi 2 (BP-Pi-101) & Cut&Roll 2 (BP-CR-201)
Equipment:	Inspection device for medication packages
Model number:	Model Basic
Rating:	Class I appliance

Is in conformity with the applicable requirements of the following documents:

Standard	Title
EN ISO 12100: 2010	Safety of machinery
EN 60335-1:2012	Household and similar electrical appliances - Safety - Part 1: General requirements
EN 55022: 2011 Class A	Radiation Emissions Class A
EN 55024: 2010	Radiation immunity
EN 61000-4-2: 2009	Electrostatic discharge
EN61000-4-3: 2006 + A1: 2008 + A2:2010	Radio-Frequency, Electromagnetic field
EN 61000-4-4: 2004	Electrical Fast Transient
EN 61000-4-5: 2006	Immunity to surges
EN 61000-4-6: 2009	Conducted Radio-frequency
EN 61000-4-11: 2004	Voltage dips and interruptions

I hereby declare that the equipment named above has been designed to comply with the relevant sections of the above referenced specifications. The unit complies with all applicable Essential Requirements of the Directives.

Signed by: 

Name: Gijs van Schelven
Position: Managing Director
Done at: 24 May 2016
At: Den Haag, the Netherlands

CE