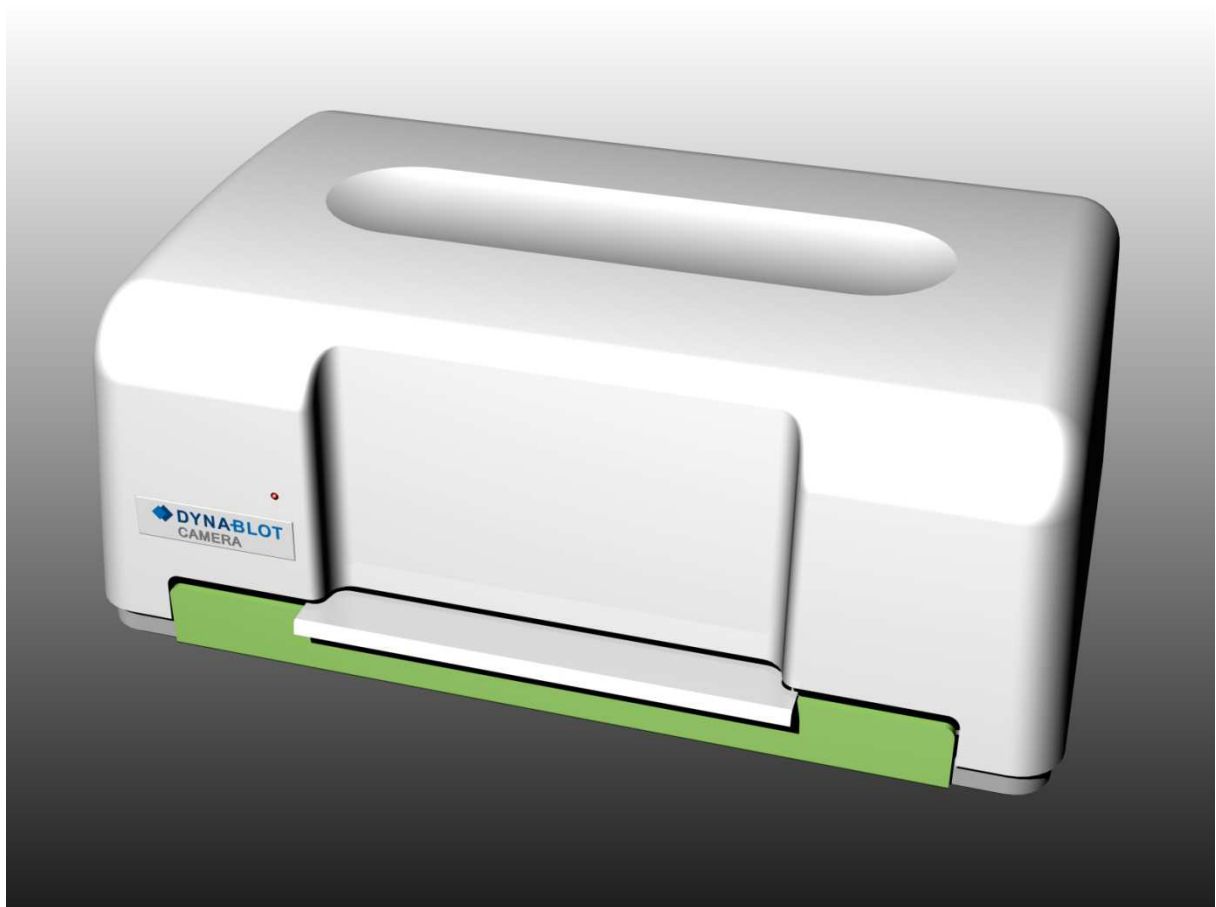


DYNACAM

A device for scanning immunoblot images



Device operation and maintenance manual

CE

The information contained in this manual are required for operation of this device. Therefore, please, read this manual carefully. Take notice of the notes related to safe operation of the device.

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Manufacturer:

DYNEX TECHNOLOGIES, spol. s r.o.

Vodičkova 971/41

110 00 Praha 1

Czech Republic

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1 Revision table

| Revision | Date | Changes |
|-----------------|-------------|-------------------------------|
| 0 | 7-14 | First publication |
| 1 | 4-15 | Changes in the controlling SW |
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2 General instructions and safety

2.1 About the manual

The device operation and maintenance manual is meant for users of this DYNACAM device (e.g. laboratory technicians) and provides information about this device. The manual contains instructions needed for the installation, operation and general maintenance of this device.

Please read the whole manual before you start using the device. Place the manual near the device for easy access by anyone using it.

2.2 Symbols and labels

These symbols will provide you with basic information as well as alert you to possible danger.

I On

0 Off



In vitro diagnostics medical device



Warning: danger of damaging your health or your immediate surroundings



Manufacturer



Date of manufacture



Separate collection of electrical and electronic equipment

2.3 Range of use

Dynacam is a device for scanning images of immunoblot and Westernblot strips according to specifications described in this manual.

The device is intended only for „IVD – In Vitro Diagnostic“!

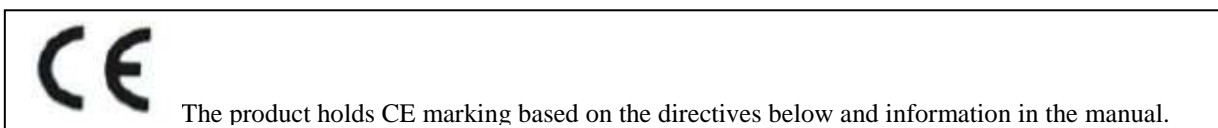
All image scanning methods must be validated by the user in combination with the system in accordance with the appropriate laboratory practice and local laws before using the DYNACAM device for IVD.

The device can only be used by laboratory technicians instructed in its use.

The device can only be used in accordance with the designated range of use.

Caution: If the user uses the device in a different way than intended by the manufacturer the safety of work equipment might be violated.

2.4 CE marking



**For more information see Declaration of Conformity.*

2.4.1 Directive 2004/108/EC: Electromagnetic compatibility (EMC)

The device was tested by an independent accredited test laboratory, which found the device to meet requirements of technical norm ČSN EN 61326-1 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

Measurement of radiated disturbances

Testing and verification was carried out in accordance with technical norm EN 55011 Class B Industrial, scientific and medical equipment– Radio-frequency disturbance characteristics Limits and methods of measurement

Resistance

The device was tested by an independent accredited test laboratory, which found the device to meet requirements of technical norm ČSN EN 61326-1 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

Testing and verification was carried out in accordance with the following technical norms:

ČSN EN 61000-3-2 Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)

ČSN EN 61000-3-3 Electromagnetic compatibility (EMC) – Part 3-3: Limits. Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection.

ČSN EN 61000-4-2 criterion A Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test

ČSN EN 61000-4-3 criterion A Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test

ČSN EN 61000-4-4 criterion A Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test

ČSN EN 61000-4-5 criterion A Electromagnetic compatibility (EMC) - Part 4-5: Surge immunity test

ČSN EN 61000-4-6 criterion A Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields

ČSN EN 61000-4-11 criterion A, C Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests

2.4.2 Directive 2006/95/EC Electrical safety (LVD)

The device was tested by an independent accredited test laboratory in accordance with ČSN EN ISO/IEC 17025, No. 1004.3 and is in accord with provision NV č. 17/2003 Sb., which is in conformity with directive 2006/95/EC as for electrical safety.

Testing and verification was carried out in accordance with the following technical norms:

EN 61010-1 ed.2:2011 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements

2.4.3 Directive 2002/96/EC on waste electrical and electronic equipment

Recommendation for waste disposal

This device contains printed circuit boards and lead soldered electrical wiring. Dispose of it in accordance with directive 2002/96/EC.



When recycling/disposing, contact your supplier. Please note that in the event of contamination of the device it is the duty of the user to secure decontamination of the device before the disposal as well as a certificate of decontamination for his supplier securing the waste disposal.

2.4.4 98/79/EC on in vitro diagnostic medical devices

A risk management analysis was conducted for this device. This analysis is a part of company ISO documentation and device CE documentation.

3 Device description

DYNACAM is a tabletop device for scanning images of immunoblots and Westernblots placed in plate wells in which the processing of tests took place.

Scanning is carried out by a monochromatic CCD camera. Green LED lights are used as a source of light for image scanning. Strips are scanned one by one.

The device is equipped with an appliance for forced airflow around the plate for acceleration of the needed drying of strips before scanning.

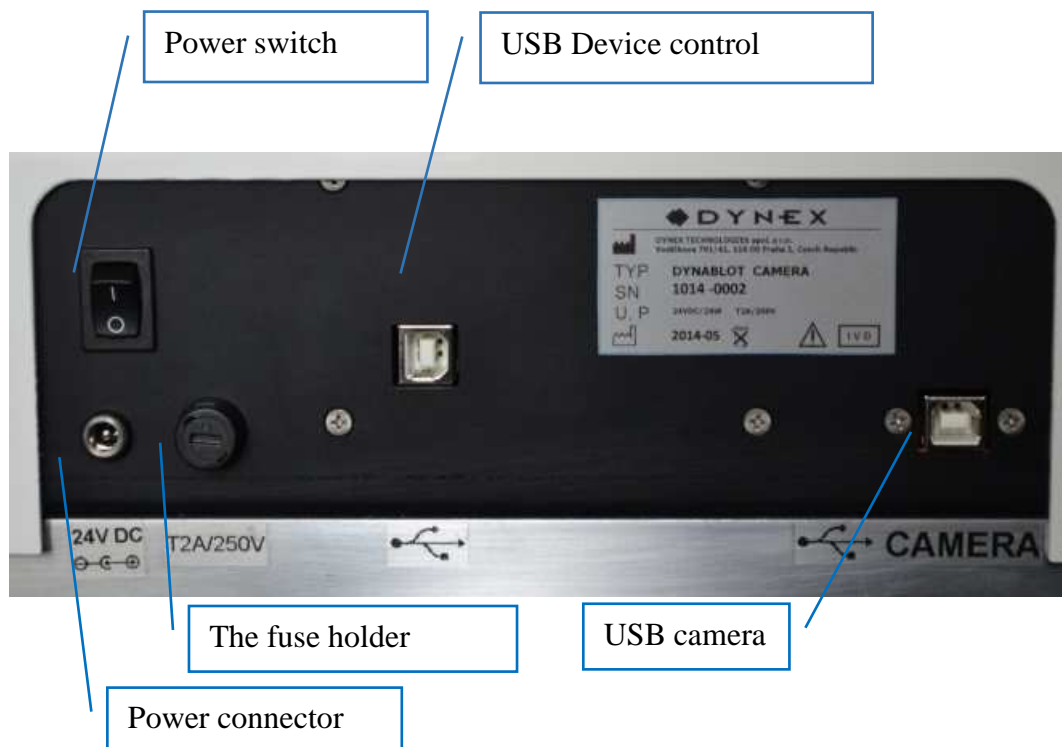
The plate with strips is inserted into a drawer in the front part of the device. The construction of the drawer lets it to be used with plates of different dimensions and different number of wells.

The device is controlled by a PC using a USB connection with it.

Selecting of functions is carried out by DLL libraries. These are used by the creators of SW for evaluation of image data.

For system operation validation it is possible to run the control SW on display (for description of functions see below).

Description of connection ports on the rear side of the device



4 Technical specification

| | |
|----------------------------------|--------------------------------------|
| Control of device | By PC using SW Dynacam dll interface |
| Operating system | Windows 7, 32 or 64 bit and higher |
| Communication with PC | 2 x USB 2 |
| Image scanning principle | CCD camera, 5 Mpixel, monochromatic |
| Resolution | 500 DPI |
| Camera viewing area | 460 x 130 mm |
| LED lighting dominant wavelenght | 525 nm |
| Drying of strips | Airflow with an ambient temperature |

| | |
|---|---|
| Power | 22 - 24 V DC (e.g. Switch adapter 100-240V, 50-60 Hz) |
| Fuses | T2,5 A 250 V |
| Maximum power input | 85 VA |
| Average power consumption during operation assays | 35 VA |

| | |
|------------|-----------------------------------|
| Dimensions | 620 mm(W) x 390 mm(D) x 270 mm(H) |
| Weight | 15,5 kg |

5 Package contents

1. DYNACAM
2. Switching adapter 100 – 240 V 50Hz / 24 V DC
3. USB cable 2 pcs
4. Operation manual

6 Device transportation, installation and assembly

6.1 Device transportation and unpacking

The device and its components are transported in special shipping packaging protecting them from damage.



Before unpacking the device please check its packaging and then the device and all accessories. In the event of the device or its packaging being damaged please immediately contact both the shipping company and the contact person of the authorized supplier. Keep the packaging for inspection by the carrier. A representative of the manufacturer shall provide immediate repair or replacement of the device.

Unpack the device and its accessories and check the completeness and condition of each item according to chapter Package contents.

In the event of damage of some part of the shipment or its incompleteness, contact DYNEX TECHNOLOGIES, spol. s r.o. or its representative.

6.2 Environment requirements

The device is intended for indoor use. Place the device in the room so it is protected from too much dust, vibrations, strong magnetic field, direct sunlight, draught, high levels of humidity or significant temperature fluctuations.

| | |
|----------------------------|---|
| Operating temperature: | +5°C - +40°C IMPORTANT: If the device was exposed to temperatures outside this range, it has to be let to temper itself before turning on to be able to properly function in given temperature range. Neglecting of this procedure may lead to damaging of this device. |
| Storage temperature: | 1°C – 50°C |
| Operating altitude: | up to 2000 msl |
| Maximum relative humidity: | 80%, non-condensing |

6.3 Device assembly

Place the device on workspace so that the power switch is accessible. In front of the device there has to be enough space for the plate well drawer to eject. It is convenient to place the control PC within reach of the device, preferably on its right side.

Plug the external power supply power cord into an electrical outlet. Plug the output power cable into the power connector on the right rear side of the device.

Connect the control PC with the corresponding SW installed using two USB cables with plugs on the rear side of the device (its order is not important).



Caution! The power supply must be plugged into an electrical outlet providing voltage and current in ranges shown on the source label. Using incompatible electrical outlet may cause electric shock and cause fire hazard.

7 Device control description

Turn the device on using the switch on its rear right part. Flashing of green/red LED light on the front of the device indicates that the device is switched on.

Turn on the PC and run corresponding SW.

Eject the plate well drawer and place the spacer according to the type of plate being used.



Put the plate with strips into the defined space. Make sure it is freely movable in anteroposterior direction. That will allow the plate to take correct position when the drawer is closed.



Insert the drawer into the device and make sure the springs closed the drawer all the way.



Carry out drying and image scanning using the control SW.

Afterwards take the plate with strips out of the device.

8 Software

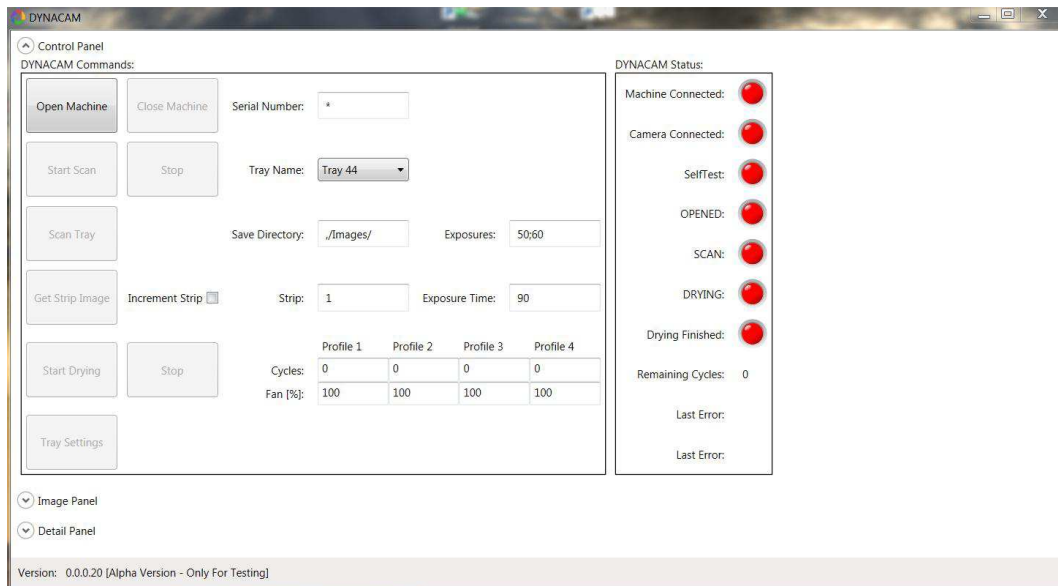
SW package is used to control the DYNACAM device. Using the function offered the device is controlled by the software for evaluating the results of samples. Necessary information for DYNACAM control implementation are shown in a document “DYNACAM interface”.

Direct run of the program Dynacam.exe from the SW package can be used for a trial of its functions. A test interface is opened and the device can then be controlled using elements shown in the window on display. In the event of running of this program using DLL library the window is not shown on the screen and user controls must be a part of the superordinate software.

8.1 Test interface description

8.1.1 Basic window

In the directory in which DYNACAM SW package is located find the Dynacam.exe file. Double-click it to run. A window opens:



Buttons and fields description:

Open Machine

Carries out connection and initialisation of the device. If there is a symbol * in the field **Serial Number**, any device connected to the PC is initialised. A specific device is connected by typing its serial number into this field. A part of initialisation is a performance of self-test. The arm with camera assumes a default position and for a short period of time the drying fans and inner lighting start up.

After the self-test is carried out successfully, green LED indicators light up.

Close Machine

Stops the communication between the device and PC.

Start Scan

Preparation for scanning of strip images. Before using this button it is necessary to choose the plate well type being put into the device in the field **Tray Name**. Clicking on the arrow on the side of the field unrolls a menu with names types of plate wells. Items on the list correspond to xml files, which contain parameters of each type of plate wells and are saved in the directory *C:\ProgramData\Dynex\Dynacam\Data\Trays*.

After the device receives the Start Scan command, the indicatory LED light begins to flash.

Stop

Cancel the readiness of the device to scan. The arm returns to its default position and inner lighting is turned off. After the device receives the Stop command its LED light is green.

Scan Tray

Executes the scanning of strip images according to the type of plate well set at Start Scan. Exposure time is set in milliseconds in the **Exposures** field. If multiple scanning of every strip with different exposure times is required, all times are entered into the field divided by a semicolon. Files with the scans are saved in a directory shown in the field **Save Directory** either absolutely by showing the whole address or relatively (e.g. ./Images/), where the certain directory is in the directory where Dynacam.exe is. Image files are automatically named in the format "image_01_30.png" where the first number means the position of the well and the second means exposure time in milliseconds.

Get Strip Image

Scans a strip image in a well with a serial number shown in the field **Strip** or with exposure time according to the value set in the field **Exposure time**. The image file is saved identically with the previous function. If **Increment strip** is marked, the value in the field **Strip** is automatically incremented after every scan.

Start Drying

Starts the drying of strips. Fans are switched on and the arm inside of the device performs movement over the whole workspace of the plate well drawer. The progress of drying can be put together based on four profiles (Profile 1 – Profile 4). Every profile contains a number of cycles (**Cycles**) and a fan output (**Fan [%]**). The number of cycles defines the time of drying. One cycle means a movement of the arm from its default position to the second lateral one and back. One cycle lasts 1 minute. The output of the fan is set in values 0 – 100 %. After beginning of drying the cycles are successively executed in the order 1 – 4. If the cycle is not used the value in the field **Cycles** will be set to 0. During drying a green LED indicator flashes. After completion of the drying cycles the fan in the rear wall of the device stays turned on for another 40 seconds to ventilate the residual humidity.

Stop

Stops the drying process before reaching the set number of cycles. After pressing the button the device finishes the arm movement in progress and then ends drying. It can take up to 30s.

Tray Settings

Opens dialog window for creation of collection of parameters of the new plate of strips (see the next chapter).

In the **Camera Machine Status** frame are the instrument status indicators and some performance information. Red colour indicates non active state, while green indicates active state.

Machine Connected

Activates after the command **Open Machine** if the PC and the device are successfully connected.

Camera Connected

Activates after the command **Open Machine** if the PC and the camera in the device are successfully connected.

SelfTest

Activates after the command **Open Machine** if the device self-test is performed successfully.

OPENED

Activates after the command **Open Machine** when the initialisation sequence is performed successfully.

SCAN

Activates after the command **Start Scan** if the scan conditions are fulfilled.

DRYING

It is active during drying cycles.

Remaining Cycles

During the drying shows the number of remaining drying cycles.

Drying Finished

Activated during the drying of strips after finishing all the set drying cycles. It stops to be active after the command **Open machine** or **Start Drying**.

Last Error

Numerical designation of the last generated error. If the numbers are 0-0, there was no mistake.

Last Error

Text description of the last generated error.

There are also these areas in the window:

Image panel in which the last scanned image is displayed. By right-clicking on it the dialog Save As is opened. This allows the creation of a file of this image.

Detail panel with internal performance information between the PC and the device.

8.1.2 Setting of plate type window

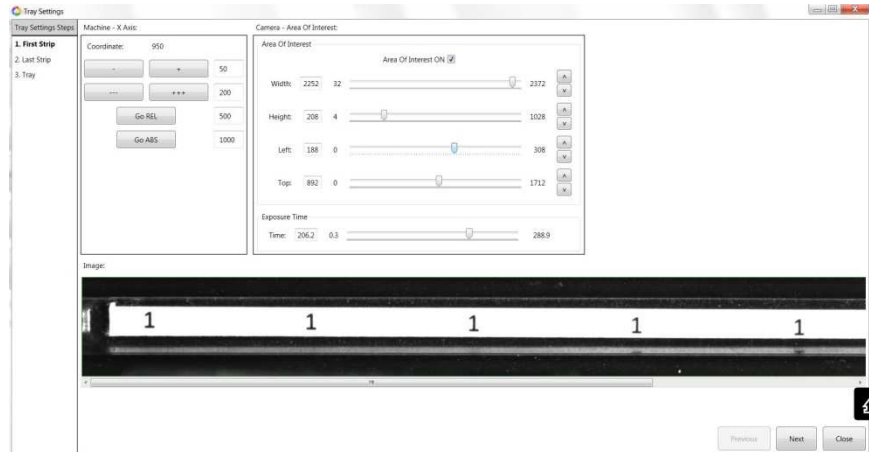
There has to be created an xml file with parameters for every plate well being used. The name of the file corresponds with the name of the type of the plate. Files saved in directory *C:\ProgramData\Dynex\Dynacam\Data\Trays* are displayed in the field **Tray names**.

Parameters of a type of plate define a position of the arm when scanning the first well, the arm's shift offset between two neighbouring wells, Area of interest (AOI) of the camera view during scanning. A combination of these parameters enables an exact setting of the characteristic of the scanned image with respect to the lighting of strips and elimination of light reflection in the well walls of different shapes.

An example of strip plate parameters:

```
<?xml version="1.0" encoding="utf-16"?>
<TrayData>
  <WellOffset>574</WellOffset>
  <FirstWellPosition>200</FirstWellPosition>
  <WellNumber>44</WellNumber>
  <AoiWidth>2224</AoiWidth>
  <AoiHeight>110</AoiHeight>
  <AoiLeft>164</AoiLeft>
  <AoiTop>874</AoiTop>
</TrayData>
```

Pushing the **Tray Settings** button in the basic window opens a window in which it is possible to choose an existing plate or set up a new one.



A setting of a type of a plate consists of 3 steps. These are shown in the left column **Plate settings steps**. The step being done is in bold. Buttons **Previous** and **Next** are used for movement between steps, **Close** ends the setting process. Live camera feed is in the **Image** area.

1. First strip

Set a position of the arm over the first well of the plate using buttons in the **Machine – X axis** area and a live feed. An actual position of the arm is displayed in the upper part of the area (**Coordinate**). Buttons with symbols + and – move the arm a number of steps set in the neighbouring fields. The **Go REL** button similarly moves the arm a value in the neighbouring field (it can attain positive or negative values). The **Go ABS** button moves the arm into the position absolute coordinate (max. value is approx. 30800).

Specification of the boundaries of the focus is done by sliders **Width, Height, Left** and **Top**. Brightness of the live feed can be set by the **Exposure time** slider (this value is not saved into the parameters). When the mark **Area Of Interest** is checked, only a selected area is displayed in the live feed area **Image**. A complete camera view is displayed by unchecking the AOI mark. The complete camera view eases the AOI placing decision in the terms of mirror geometry and inner lighting (suppression of reflections and shadows).

2. Last strip

Set the focus on the last well of the plate using the buttons in the **Machine – X axis** area as well as live feed.

3. Tray

Fill the **Tray name** and **Well number** fields (The name of the strip plate and the number of wells). Create the parameter file by pressing the **Save** button.

Tray Settings

Tray Settings Steps

1. First Strip
2. Last Strip
- 3. Tray**

| Tray Settings Data | Tray File |
|--|---|
| Tray Name: <input type="text" value="Tray 44"/> | Tray Name: <input type="text" value="Tray 44"/> |
| Well Number: <input type="text" value="44"/> | Well Number: <input type="text" value="44"/> |
| First Well Position: <input type="text" value="950"/> | First Well Position: <input type="text" value="950"/> |
| Last Well Position: <input type="text" value="25668"/> | Well Offset: <input type="text" value="575"/> |
| Well Offset: <input type="text" value="575"/> | AOI Width: <input type="text" value="2252"/> |
| Well Offset Reminder: <input type="text" value="-7"/> | AOI Height: <input type="text" value="208"/> |
| | AOI Left: <input type="text" value="188"/> |
| | AOI Top: <input type="text" value="892"/> |

9 Maintenance

The device is relatively maintenance free. It is important to keep the surface where the plate is inserted clean. The plate must be able to move as it adjusts itself into the correct position after the drawer is closed.

9.1 Device cleaning

Clean both the surface of the device and the surface inside the drawer. If particularly dirty, use detergent.

Use isopropanol to clean the surface of the drawer.

Cleaning of the optical system components under the cover of the device must be carried out by a service technician during regular inspections of the device.