



Instruction Manual

Document No.: 010
Version: 9
Modification Date: 2020-11-04

© 2020 IBA GmbH

Product Specifications

Item:	FABian®
Product Version:	<i>Laboratory Version</i>
Software Version:	<i>FABian firmware 1.0</i>
Item-No.:	<i>6-6100-260</i>
Delivery Content:	<i>FABian®, PSU & Power Cable, 50 ml Tube Holder, Syringe Adapter 10 ml, Instruction Manual, SD-Card, Return Form, Decontamination Declaration</i>
Revision Index / -Date	<i>Rev. 9, 2020/11/04</i>

IBA GmbH

Bosestr. 4
04109 Leipzig
Germany

Phone: +49 (0)341 – 99 38 98-29
Fax: +49 (0)341 – 99 38 98-19
E-Mail: info@iba-lifesciences.com
Homepage: www.iba-lifesciences.com

On behalf of the IBA GmbH, the instruction manual has been designed and engineered by Cell.Copedia GmbH.



This instruction manual may not be copied in whole or in part without the authorization of IBA GmbH. The figures in this instruction manual may differ from the actual design and are not displayed on full scale (1:1).

Index

0	Preface	5
1	Explanation of Symbols	5
2	Product Description and Technical Data	6
2.1	General Product Information and Unit Design	6
2.2	Delivery Content	7
2.3	Technical Data	7
3	For your Safety	8
3.1	Warning Signs and Security Level	8
3.2	Intended Use and Foreseeable Improper Operation	8
3.3	Target Group, Staff Qualifications	9
3.4	Personal Protective Equipment	9
3.5	Safety Instructions for Commissioning	9
3.6	Operating Conditions of the Product	9
3.7	Safety Instructions For Operation	10
3.8	Safety Instructions for Cleaning, Maintenance	10
3.8.1	Cleaning	10
3.8.2	Maintenance	11
3.9	Decommissioning, Dismantling, Disposal	11
4	Transport and Storage	12
4.1	Transport	12
4.2	Storage	12
4.3	Storing and Protecting between Usage Periods	12
5	Prepare FABian® for Use	13
5.1	Select Installation Place	13
5.2	Prepare Installation	13
5.3	Install Unit	14
6	Operation of FABian®	16
6.1	Commissioning	16
6.2	Normal Operation	16
6.2.1	Inserting the Syringe	16
6.2.2	Inserting the Tube Holder	18
6.2.3	Inserting the Tubes	18
6.2.4	Operating Keys and Program Selection	20
6.2.5	Program Run	20
6.2.6	Stopping the Program, Removal of the Sample and of the Syringe	22
6.3	Fault Repair	24
6.4	Technical Support	24
7	Maintenance and Cleaning	25
7.1	Cleaning	25
7.2	Maintenance and Repair by the Customer Service	26
8	Provided Accessories, Consumables, Spare Parts	27
8.1	Consumables	27
8.2	Spare- and Replacement Parts	28
9	Information on Special Tools, Devices, Materials	31
10	Decommissioning, Dismantling, Disposal	34
11	Annexes	35

Tables of Figures

Figure 1 – Overview Unit Design.....	6
Figure 2 – Insert SD-Card	14
Figure 3 – Power Connection to the Device.....	15
Figure 4: FABian® Syringe.....	17
Figure 5: Insertion of the Syringe (1).....	17
Figure 6: Insertion of the Syringe (2).....	18
Figure 7 - Notch for Locking Mechanism.....	18
Figure 8 - Tube-Contents	19
Figure 9 – Operating Keys.....	20
Figure 10 – Program Selection – Green Illuminated Keys	20
Figure 11 – Program Selection.....	21
Figure 12 - Program A Is Running.....	21
Figure 13 – Removal of the Target Product: Tube 9, 10 und 11	23
Figure 14: Image of a Tube	27
Figure 15: Image of a Syringe	27
Figure 16 – Image of the Tube Holder, SD-Card, PSU & Power Cable.....	29
Figure 17: Image of Syringe Adapter incl. Tool	30
Figure 18: Removal of the Screws From the Bottom Part of the Adapter	31
Figure 19: Unscrewing the Screws From the Upper Part of the Adapter	31
Figure 20: Removal of the Syringe Adapter	32
Figure 21: Insertion of the Bottom Part of the Adapter.....	32
Figure 22: Installation of the Bottom Part of the Adapter	32
Figure 23: Insertion of the Upper Part of the Adapter	33
Figure 24: Tightening the Upper Part of the Adapter	33

List of Tables

Table 1 – Explanation of the Appliance Switches and Symbols	5
Table 2 – List of Supplied Parts.....	7
Table 3 – Overview Technical Data.....	7
Table 4 - Checklist.....	13
Table 5 – Key Functions.....	20
Table 6 – List of Consumables	27
Table 7 – List of Spare parts and Accessories.....	28

Abbreviations

AC	Alternating Current	PSU	Power Supply Unit
°C	Degree Celsius	SELV	Safety Extra Low
Voltage			
DC	Direct Current	UPS	Uninterruptible Power
Supply			
EU	European Union	V	Volt
F	Fahrenheit	W	Watt
g	Gram		
Hz	Hertz		
lb	Pound		
kg	Kilogram		
m	Meter		
ml	Milliliter		
mm	Millimeter		
PBS	Phosphate-Buffered Saline		

0 Preface

In order to ensure a safe and appropriate usage, read the instruction manual and further product-related documents carefully and keep them in safe custody for future use!

- ▶ This instruction manual contains important information, which must be read and understood in full before the device is used. A precondition for safe operation is the observance of all safety and handling instructions specified in this instruction manual.
- ▶ This instruction manual is part of the product, must always be kept near the device and should be available for the personnel at any time.
- ▶ In case of loss or damage of the instruction manual, please request a replacement.
- ▶ In addition to the instructions in this manual, the regulations of the employers' liability insurance association for health protection and industrial safety apply.

Exclusion of Liability:




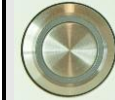


The manufacturer will not assume any liability, if:

- the regulations in this manual are not being followed,
- the device has been used improperly or has not been used for the specified purpose,
- spare parts, accessories or consumables are being used, that are not approved by the manufacturer
- the device has not been operated by trained and instructed personnel,
- the housing has been opened or removed,
- the device has been repaired or maintained by a non-authorized person.

Furthermore, users are forbidden to modify FABian®. If there is still any modification, the product warranty will cease. IBA GmbH is not responsible for possible consequences caused by a modification and will be exempted from all kinds of customer care commitments. In this case, the safety of FABian® cannot be guaranteed anymore. The manufacturer will not accept any liability for damages resulting from modifications.

1 Explanation of Symbols

Table 1 – Explanation of the Appliance Switches and Symbols

Symbols und Appliance Switches	
	Type Plate (placed on the bottom side of the device)
	Do not dispose of the device with normal household garbage!
	Symbol Protection Class III (SELV)
	On / Off-Switch → Device is turned on and off; Initialization of the device
	Start-Stop-Button → Program is started / stopped; device is in transport position
	Program Selection Keys

2 Product Description and Technical Data

2.1 General Product Information and Unit Design

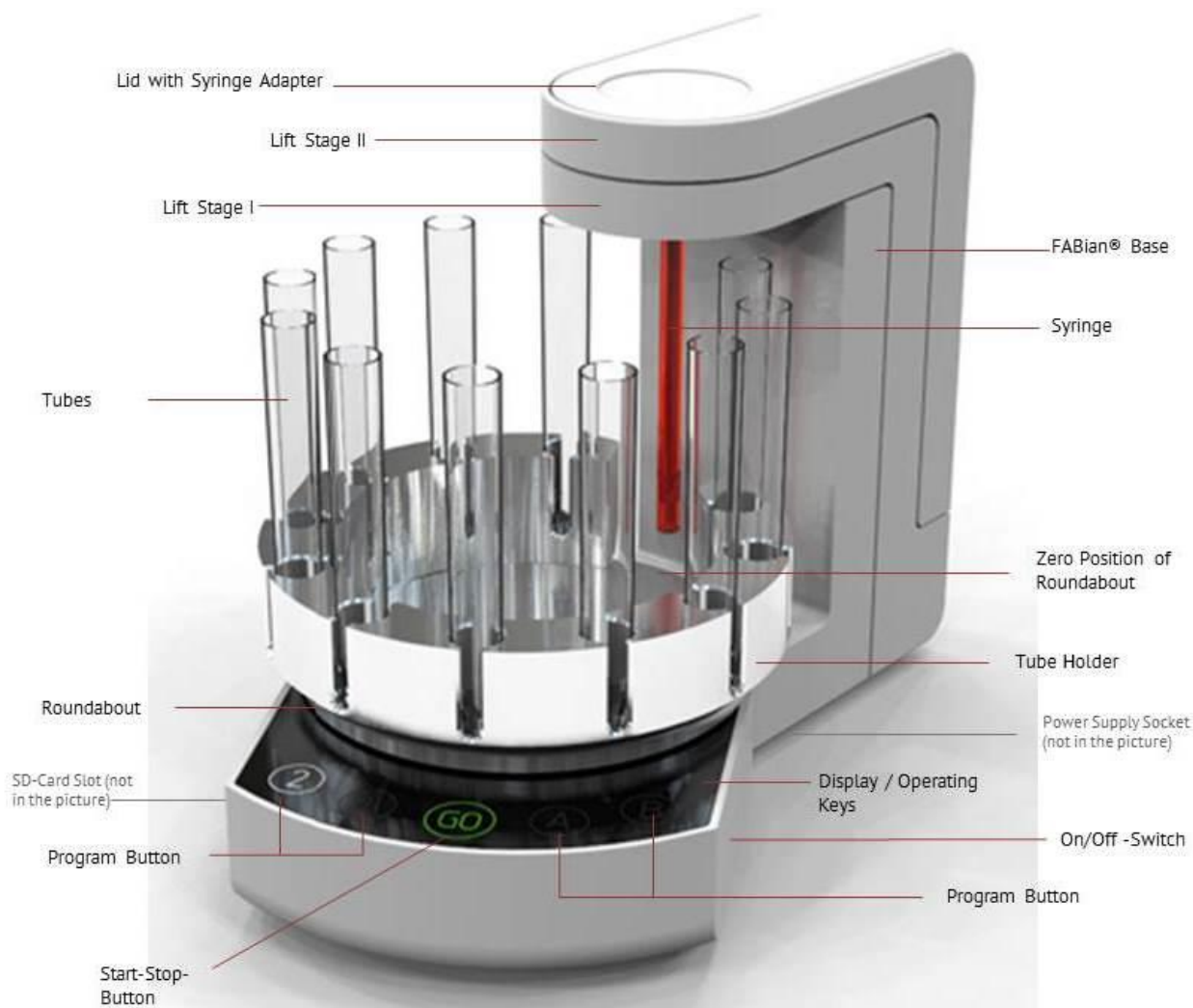


Figure 1 – Overview Unit Design

FABian® is an automatic benchtop device for the selection of cells from a suspension (e.g. blood or other single cell suspensions) and is designed for research use only. The system may be operated exclusively in a laboratory environment by qualified and specially trained personnel. The selection process is performed with the help of disposable products: max. 11 tubes on a round tube holder and the special FABian®-syringe are necessary to gain the pure, minimal manipulated and non-activated target product. The operation of FABian® is simple and intuitive. By pushing the on/off-Switch on the right side of the device FABian® starts the initiation program. For the operation, FABian® is equipped with 5 operating keys – 4 program selection keys and one start-stop-button. After the insertion of the syringe and the tubes and after the program is chosen, the device is passing the specific selection steps. Depending on the chosen program the whole selection process takes about 30-90 minutes (duration depending on chosen program) to provide purified target cells which can be removed from the tubes afterwards.

2.2 Delivery Content

Table 2 – List of Supplied Parts

Amount	Item-No.	Description	Additional Information
1	6-6100-260	FABian® Device	Spare Part
1	6-6104-050	50 ml Tube Holder	Spare Part
1	6-6105-010 / 6-6106-010	Syringe Adapter 10 ml (already mounted in the cover)	Spare Part
1	6-6103-000	SD-Card with preinstalled program selection	Spare Part
1	6-6101-000	PSU	Spare Part
1	6-6102-000	Power Cable	Spare Part
1		FABian® Instruction Manual, english	Keep in safe custody!
1		Return Form	to complete by the customer
1		Decontamination Declaration	to complete by the customer

2.3 Technical Data

Table 3 – Overview Technical Data

Dimensions / Weight (Mass, Capacity, Power)	
Measurements	
Width	198 mm
Depth	315 mm
Height	230 mm
Operation Height	455 mm
Weight (net)	3840 g (Basic Unit 3088 g, Tube Holder 752 g)
Power Supply Data	
Power Supply Unit	
Input Voltage	90... 264 V AC
Frequency	47 - 63 Hz
Power	max. 20 W
Input Voltage Device	24V DC
Safety Devices	integral, self-resetting
Protection Class (according to DIN 61140)	III (SELV)
Protection Type (IP-Code)	IP30
Environmental Conditions	
Environment	Use indoors only!
Ambient Temperature	
Operation	+10 °C (50 F) - +35 °C (95 F)
Storage	+10 °C (50 F) - +35 °C (95 F)
Humidity	
No condensating humidity	
Operation	0% - 75%
Storage	0% - 75%
Air Pressure	Usage up to 2.000 m above sea level
Application Parameters	
Device Temperature	25 °C
Maximum Load	
Tubes	11 Tubes à 30 - 50 ml
Syringe	1 Syringe à 10 ml







3 For your Safety



WARNING!

- The non-compliance with the described safety regulation may result in health damages or may lead to damages to the device. The manufacturer cannot be made liable for any damage caused by the non-compliance with the safety regulation.

3.1 Warning Signs and Security Level

Warning Signs	
	General Danger
	Electric Shock Danger
	Risk of Crushing
	Explosion Danger
	Biological Hazard
	Note

Security Level	
DANGER	Will lead to serious injuries or death
WARNING	Can lead to serious injuries or death
CAUTION	Can lead to moderate or minor injuries
ATTENTION	Can lead to property damage
Note	Indicates useful information

3.2 Intended Use and Foreseeable Improper Operation

FABian® is an automatic device for the selection of cells from a suspension (e.g. blood or other single cell suspensions) with the help of a syringe and tubes and is designed for research use only. The selection device is intended only for the purposes determined and any other application (e.g. therapeutic application) or any further purposes shall be considered as improper.

IBA GmbH shall not accept liability for any damage arising as a result of the above mentioned modifications. The intended use also includes the attention of all references of the instruction manual, the compliance with maintenance and inspection work as well as the observation of the installation instructions and of the cleaning and maintenance notes.

Residual Risks

Although the device is constructed and qualified in accordance with the current state of the art and with recognized safety regulations and standards, the operation of the device involves a certain amount of risks. Residual risks result from crushing fingers by the piston- and syringe lift stages in the event of non-compliance with the safety regulations as well as from electric shock, if you operate the device with a power supply unit which is not indicated here.

Faults which may adversely affect the safety shall be promptly notified to the IBA GmbH.

According to the fault type it will be decided individually, if the error can be resolved by the user or by the service personnel of the IBA GmbH.

3.3 Target Group, Staff Qualifications

FABian® may be operated exclusively for commercial use by trained and qualified personnel, who have fully read and understood the instruction manual. The user must be familiar with the unit's functions. This knowledge can be achieved by reading the instruction manual and by additional information- and training offers by the IBA GmbH.



By purchasing the first devices we recommend training courses for a safe and appropriate usage.



WARNING!

Danger of Injuries and Device Damages as a Result of Incorrect Operation by Non-qualified Personnel

- Misapplications of FABian® and the non-compliance with security regulations may result in injuries caused by e.g. electric shock or crushing.
- An improper operation of the device can lead to total loss of the target product, accessories and consumables and can cause serious damages to the device.

3.4 Personal Protective Equipment

The device shall only be used with laboratory protective equipment. The users must observe the occupational safety regulations of the operating company as well as the national regulations for occupational safety.



WARNING!

Risk of Biological and Chemical Contamination by Used Reagents

- If biological or chemical hazardous materials are involved, please observe the relevant warnings and protection provisions for those materials and wear appropriate personal protective equipment.

In case of usage of biological or chemical hazardous materials protective gloves, protective clothing and safety glasses shall be worn.

3.5 Safety Instructions for Commissioning



WARNING!

Danger Causes by Improper Power Supply

- FABian® may only be operated with the voltage specified on the power supply unit. Connect the device to a properly earthed and fused power socket only.

The power cable must be routed in such a way that it does not represent a tripping hazard and that no damages can be caused by other devices. Use only the original power cable.



DANGER!

Electric shock Caused by Device Damages or Power Cable

- Activate the unit only if it is secured that the device and the power cable are intact.
- Only start up devices, which are professionally installed or properly maintained.

3.6 Operating Conditions of the Product

FABian® is designed to be used exclusively indoors. For a safe usage a dry condition is required (see ambient temperature and humidity chapter 2.3), e.g. a ventilated laboratory.



DANGER

Explosion Danger

- Do not use FABian® in rooms susceptible to explosions.
- Do not use FABian® with radioactive, explosive or corrosive materials.

**ATTENTION****Damaged Component Parts Can Lead to Injuries and to a Loss of the Target Product**

- Periodically check all component parts of the device and make sure that they work perfectly.
- Damaged tubes and syringes can lead to damaged samples / target product and can cause damages to the device.
- Be sure that there are no component parts in use, whose expiry date has passed.

3.7 Safety Instructions For Operation

Protection Devices, Emergency Stop

An emergency stop, which is installed inside or outside of the laboratory, is desirable for disconnecting the power supply in case of failures. We recommend the connection to an in-house emergency power unit that will take over the power supply in case of an electricity failure. This can often be identified by green labeled power sockets.

**DANGER!****Life-Threatening Voltage by Opening the Device**

- Make sure, that the housing is intact and closed, so that no risks can arise from the inside of the device.
- It is not allowed to remove the cover of the device. All work on the device should be performed exclusively by service personnel of the IBA GmbH.

Precautions during operation

For the operation of the device movable components are required. The tube holder and the inserted tubes can fall from accidental collisions. To avoid risks and accidents, do not touch the device during operation. We recommend placing the device as far away as possible from table edges, to prevent a falling of the device and personal injury. Do not under any circumstances connect an injection needle to the syringe for device operation. There is a risk of puncturing the fingers, if you accidentally place your fingers under the injection needle during operation.

**CAUTION!****Crushing of Fingers by Device Levels**

- Do not touch the device during commissioning and operation. Do not place your fingers between the device levels. Your fingers may get between the device levels and the process might be interrupted.

Should your fingers nevertheless become trapped between the device levels, you can release your fingers with your other hand or with the help of another person by lifting the device level manually.

Never leave the device unattended while in operation. Please stop the process in case of device damages, abnormal sounds, odors or any other irregularities; switch the device off, pull out the power plug and call the service technician. When unplugging the power plug hold it by the plug only and remove it carefully.

3.8 Safety Instructions for Cleaning, Maintenance

3.8.1 Cleaning

The device must always be cleaned after use.

**DANGER!****Electric Shock Caused by Damp Device and Leaking Liquids**

- Switch off the device and disconnect the power supply previous to the cleaning process.
- Ensure that no liquids leak into the inside of the device.
- Only if the device and the power cord are completely dry, connect the device to the power supply and switch it on again.

**Risk of Biological and Chemical Contamination by Used Reagents**

- ➔ If hazardous materials were used, a careful decontamination of the device must be carried out. It is strictly forbidden to use contaminated devices or accessories.
- ➔ The decontamination and disposal of consumables are performed according to the applicable provisions.

3.8.2 Maintenance

Before each use, the device must be subjected to a visual inspection. If device damages are visible or the function of FABian® is restricted, it must be maintained.

**The user is not permitted to perform the maintenance**

- ➔ If the device has been maintained by a non-authorized person, any claim under warranty and any service will cease.

3.9 Decommissioning, Dismantling, Disposal

FABian® should be stopped immediately when a safe and proper function is no longer guaranteed. The same applies to all accessories and spare parts.

It is prohibited to dismantle the device. Return the device to IBA GmbH or properly dispose of the device.

Do not dispose of the device with normal household garbage!

For more detailed information, see chapter 10.

4 Transport and Storage

4.1 Transport

The manufacturer is responsible for the first transport. The operator is however obliged to immediately check the device upon receipt. If externally detectable transport damage is found refuse the delivery or accept it under reserve. Specify the suspected damage and inform the IBA GmbH immediately.

The following instructions should be followed when transporting FABian®:

- transport the unit in its original packaging only
- do not place the carton upside down or on the side.

4.2 Storage

If the device needs to be stored until the commissioning, please note the following instructions:

- Store product in dry conditions. The relative humidity should not exceed 75 %.
- Device must not be stored outdoors. The floor of the storage room must be flat and dry.
- Do not expose the device to direct sunlight and moisture.
- Storage temperature should be between +10 °C (50 F) and +35 °C (95 F).
- Avoid mechanical shocks and damages. Store the device safe and stable; if necessary install additional safety elements.
- If you store the device without original packaging, ensure a dust-free environment.

The used consumables must be stored in a cool place. Please note the storage conditions as indicated in the instruction manual of the respective reagents.

4.3 Storing and Protecting between Usage Periods

If you do not use FABian® for a longer period, please ensure a safe and dust-free storage. The device should be cleaned immediately after use (see chapter 7.1) and should be subsequently kept in the original packaging. Even between usage periods the environmental conditions, as described in chapter 4.2, apply, especially the provisions concerning temperature and space.

5 Prepare FABian® for Use

5.1 Select Installation Place

The installation place for FABian® must meet the following criteria:

- power supply according to type plate available
- stable, flat and resonance free (laboratory) table, on which the device with a weight of 3,85 kg (basic unit & tube holder) can be positioned safely
- put the device on a slip-resistant, non-flammable and water-resistant surface
- keep at least 30 cm of space on every side of the device; be aware that the device gets 23 cm higher during operation; to avoid an additional external heating it is necessary to choose a well ventilated environment which is protected against direct sunlight
- be sure, that the device does not come into contact with open flame; do not expose the device to moisture and condensation water and ensure that the position of the device is not subjected to vibrations and extreme temperature fluctuations
- ambient temperature is between +10 °C (50 F) - 35 °C (95 F)
- relative humidity of the device environment should not exceed 75 %.



Danger in Case of Failure

- Provide an emergency switch close to the unit to disconnect the power supply in case of failure.

WARNING!

5.2 Prepare Installation

To prepare the installation process it is important to select an appropriate place (see 5.1) and to remove the package. While unpacking proceed as follows:

1. Put the box with the lid on top – open it.
2. Remove the first small box which contains single parts and accessories.
3. Remove the first styrofoam cover and lift the device out of the box.



Please keep the original packaging material for transport purposes, for a complaint and / or for the storage between usage periods.

After unpacking, check the components for external integrity. The device should be delivered together with the following components:

Table 4 - Checklist

Component	Included in scope of delivery
FABian® Device	<input type="checkbox"/> (please tick off)
PSU / Power Cable	<input type="checkbox"/>
SD-Card	<input type="checkbox"/>
50ml Tube Holder	<input type="checkbox"/>
Syringe Adapter 10 ml (already mounted in the cover)	<input type="checkbox"/>
Instruction Manual	<input type="checkbox"/>
Return Form	<input type="checkbox"/>
Decontamination Declaration	<input type="checkbox"/>

**ATTENTION!****Device Damages Caused by Improper Transport and Condensation**

- ➔ After the transport from a cooler to a warmer environment condensation is possible. Please wait at least 3 hours, before connecting the device to the power supply. Any transport-induced temperature differences could be compensated.

FABian® is free-standing device and does not need an additional holder. Due to the low weight the configuration and connection of the device can be performed by one person.

**ATTENTION!****Damages of FABian® or of Devices in the Immediate Environment**

- ➔ To ensure a secure process and to avoid damages of devices in the immediate environment, keep a safety distance of at least 30 cm during operation according to EN 61010-2-020.

5.3 Install Unit

For the installation of the unit proceed as follows:

1. Put the device safely and stable on a flat (laboratory) table (see chapter 5.1 Select Installation Place).
2. Locate the device in such a way that the program selection keys are pointing towards you.
3. Take the provided SD-card and insert it with the backside facing upwards into the corresponding slot at the lower left of the basic unit (see figure 2) until you hear a clicking sound. The SD-card has to remain in the unit during operation.



Figure 2 – Insert SD-Card

**ATTENTION!****Defective Selection Process by Premature Removal of the SD-Card**

- ➔ Do not remove the SD-card from the device during operation. Otherwise the selection process can be interrupted.

4. Make sure that the AC line voltage is the same as the operating voltage of the PSU before you connect it up. If the ratings for voltage (V) and maximum current (A) do not match, the device must not be connected.

**WARNING!****Danger Caused by Incorrect Power Supply**

- ➔ An incorrect power supply may result in malfunctions or in permanent damages.

5. Plug the low-voltage plug of the power cable in the low-voltage socket of the device. The low-voltage socket is located on the bottom side of the device (see figure 3).



Figure 3 – Power Connection to the Device

6. Plug the power cable in a properly installed and fused power socket.



Electric shock Caused by Device Damages or Power Cable

- ➔ Please check plug and power cable for damage before connection.
- ➔ Damaged parts must never be used for the connection and must be replaced by original parts.

7. Make sure that the power cable is not subjected to tensile or pressure forces.

6 Operation of FABian®

6.1 Commissioning

Before commissioning the device, the entire body as well as any accessories, which could compromise the operational safety, should be checked thoroughly for any defects. Please check the power supply and the power cable for damage regularly. If there is any damage, you should not use the device under any circumstances. Disconnect the power plug and replace the damaged parts by original spare parts.

Connecting

- ▶ Check, that no used syringe has remained from the last selection process



ATTENTION!

Danger of Leaking Liquids by Premature Insertion of the Syringe

- ➔ If you insert the syringe too early – before the device is initialized – the liquids in the syringe can be dispensed prematurely.
The device can become dirty, which can lead to the invalidity of the selection.

- ▶ Please make sure that the cables are properly extended on the floor along the device and ensure that the cables are routed away from moving parts (e.g. under lift stage I & II).



ATTENTION!

Danger of a Faulty Selection Process and of Leaking Liquids

- ➔ If the cable is not routed properly, it can slip between the device levels and interrupt the process.
- ➔ The leaking of liquids is possible.

1. Activate the device with the on/off-switch. To do this, please press the silver button on the lower right side of the device.
2. The device is initializing, which is recognizable by significant noises, by up- & down-movements of the two lift stages as well as by the movement of the roundabout towards the zero position. All switches flash in orange color.
3. The initialization is finished when the operation noises are gone and the roundabout is on zero position. The program selection keys flash green.



WARNING!

Crushing of Fingers by Device Levels

- ➔ Do not touch the device during commissioning. Do not place your hand between the device levels, your fingers can be crushed and the process can be aborted.

Before first commissioning a check is required to ensure the completeness and functionality and to recognize possible damages. This check includes a functional and visual inspection according to a checklist, which you will find in Appendix A of the instruction manual. Enter your results into the checklist and keep it in your product documentation for the length of the warranty.

The system is now ready for operation.

6.2 Normal Operation

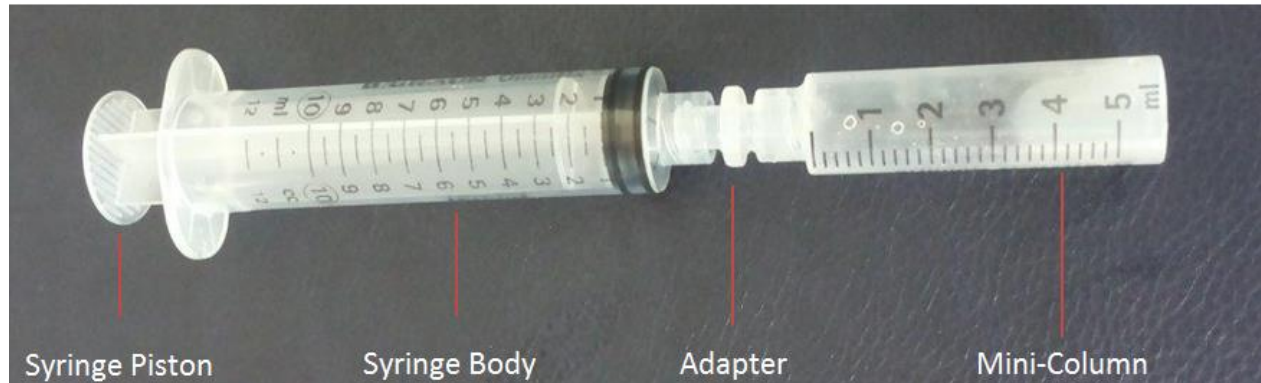
6.2.1 Inserting the Syringe

The device has been positioned in such a way that the program selection keys are pointing towards you. Only insert the syringe when the device is switched on (recognizable by the flashing of the program selection keys), the device has initialized completely and is standing still. Before use, ensure that the roundabout is on zero position.

1. To insert the syringe remove it from the packaging and remove existing safety elements. The design of the syringe and the designation are shown in figure 4.

**WARNING!**
Use Only Original Fabian® Syringes (Without Needle), Risk of Injury

- ➔ FABian® may be operated exclusively with the original syringe.
- ➔ It is forbidden to use other syringes equipped with needles. These kinds of syringes are not applicable for the selection process and can puncture your fingers and other body parts.


Figure 4: FABian® Syringe

2. Insert the syringe into the round opening of the syringe adapter below the syringe lift stage with the piston facing upwards (see figure 5). Push the syringe as far as possible towards the lid.


Figure 5: Insertion of the Syringe (1)

3. Ensure that the syringe piston is correctly placed in the designated notch. Then push the syringe with the syringe body in the direction of the housing until it locks into place and until the syringe body is firmly attached in the adapter (see figure 6).

**ATTENTION!**
Danger of Damages by Turning the Mini-Column

- ➔ Do not turn the mini-column to avoid a loosening.
- ➔ An opening of the syringe can lead to a loss of materials and liquids can leak into the device.



Figure 6: Insertion of the Syringe (2)

6.2.2 Inserting the Tube Holder

Carefully place the tube holder on the device and fill it with the tubes afterwards. If you are already practiced in the handling you can place an already filled tube holder on the device. Please place the tube holder in such a way, that the opening is pointing toward the rear (zero position).



Risk of Injury from Sharp Edges of the Tube Holder

- ➔ Maintain a distance as far as possible from the device and from moveable parts.
- ➔ Use the device with caution, to avoid injuries.

ATTENTION!

With the help of a notch (see figure 7) the tube holder has to be accurately locked to the roundabout.

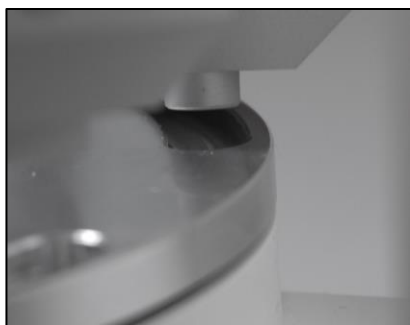


Figure 7 - Notch for Locking Mechanism



Interruption of the Process by Incorrect Insertion of the Tube Holder

- ➔ Be sure, that the tube holder is properly inserted. If the tube holder is not properly pointing toward the rear, interruptions of the process and device damages can appear.

ATTENTION!

6.2.3 Inserting the Tubes

Now you can load the tube holder with the tubes. The order of the tubes is already fixed in the manual of the consumable kit and of great importance. Please comply with the requirements of your selected program. An interchanging of the tubes can invalidate the selection.

FABian® is equipped with preset programs. An exemplary program setting is shown in the following figure, however it may vary. For that reason, please refer to the instruction manual of the consumable kit for the exact order.

In the example setting shown here, the following ingredients and tubes are necessary and to arrange as follows:

4 x wash solution (PBS)

2 x biotin

1 x Fab-fragment

1 x blood / cells

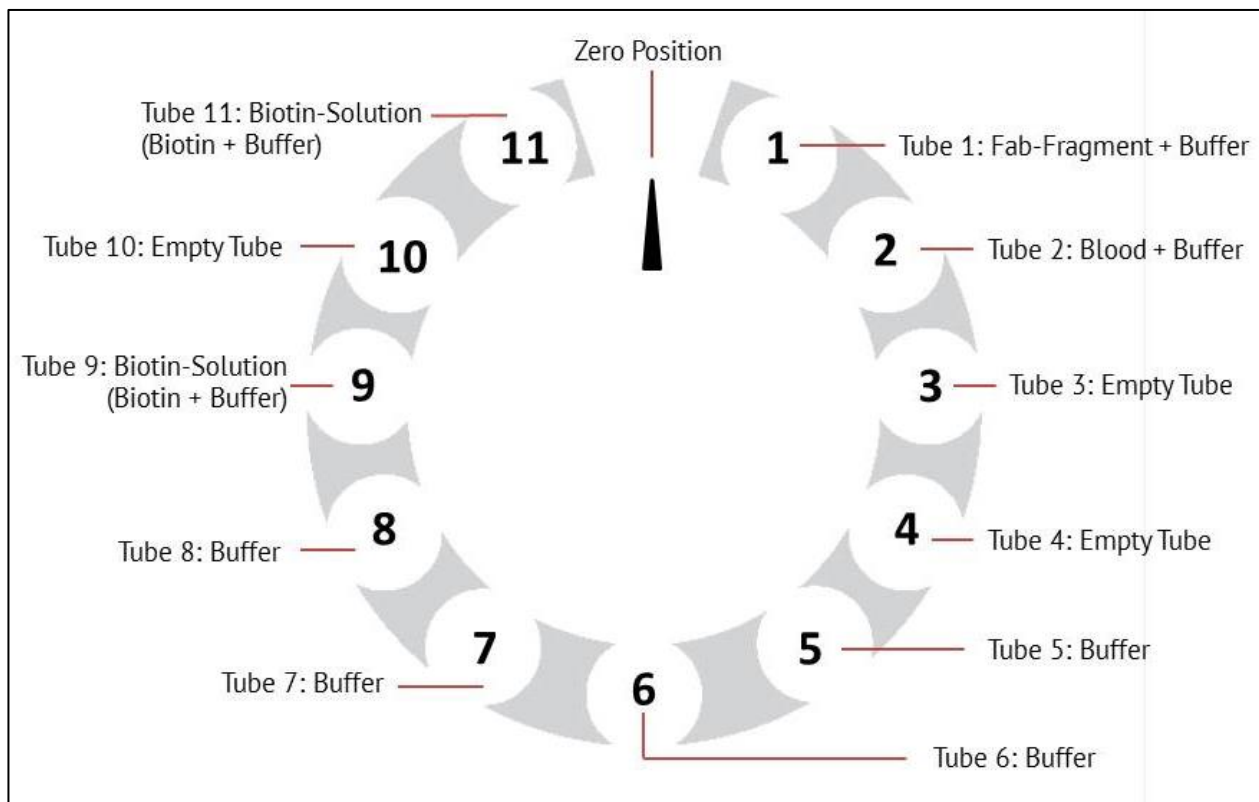


Figure 8 - Tube-Contents



WARNING!

Danger of Interchanging Tubes

- ➔ Every interchanging of the tubes can lead to an incorrect selection process and can make the used reagents unusable.
- ➔ Your research results are being distorted, if the reagents / the tubes are interchanged.

If you accidentally spill liquids during the insertion of the tube holder or the tubes, an ordinary cleaning of the device is sufficient:

1. Switch off the device.
2. Disconnect the device from the power supply.
3. Perform a comprehensive cleaning of the device and of all accessories according to the specifications in chapter 7.1.



ATTENTION!

Device Damages Caused by Spilling Liquids from Tubes or Syringe

- ➔ Make sure, that the device is completely clean and dry before continuing.
- ➔ Spilled liquids can cause device damages.

FABian® is now ready for program start.

6.2.4 Operating Keys and Program Selection

The operating keys (see fig. 9) are used for program selection and to start and stop the unit.



Figure 9 – Operating Keys

Please refer to the following chart for the description of the different key functions.

Table 5 – Key Functions

Switches & Buttons	Function
On / Off-Switch	Turns FABian® on and off and initializes the device; by pressing the on / off-switch the emergency stop can be activated.
GO	1. Start-Stop-Button: Pushing the GO-button confirms the program selection; the process starts 2. Pause-Button: Pushing the pause-button during operation interrupts the program; it continues by pushing the GO-button again 3. By a long pressure of the GO-button during operation the program will be stopped and the device turns back into its zero position
A, B	Program Selection Keys
1, 2	Program Selection Keys
1 + A	By a long pressure of this button-combination the device runs back into the compact transport position

6.2.5 Program Run

1. If the syringe is inserted and the tube holder is loaded and locked the selection process can be started. All program selection keys flash green (see figure 10).



Figure 10 – Program Selection – Green Illuminated Keys

2. At first, select the preferred program with the program selection keys. To do so, briefly press the key with the number or letter of the preferred program. This key now lights green, GO flashes green and all non-selected program keys light yellow. Please confirm the program selection by briefly pushing the GO-button (Start-Stop-Button). As an example, program A is shown in the following figure.

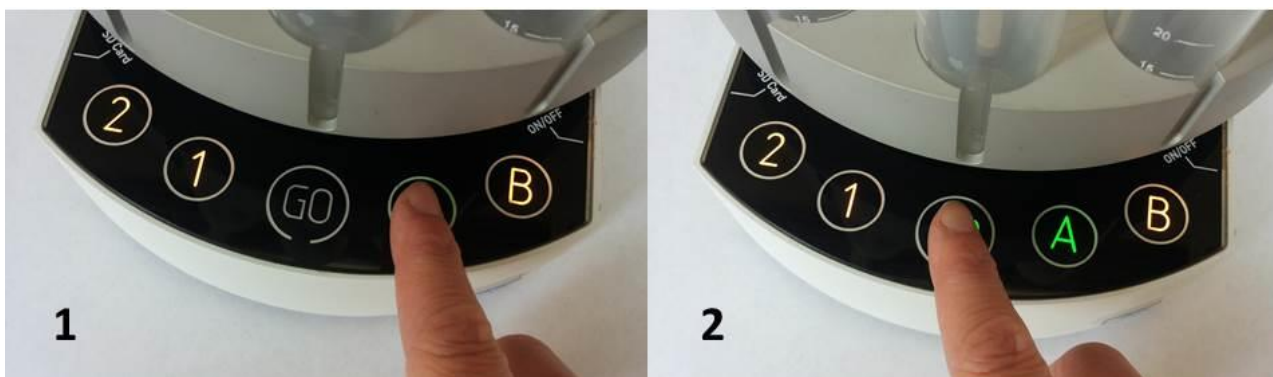


Figure 11 – Program Selection

3. As long as the program is running error-free and there is no need for further input from the user the start-stop-button and the selected program key are lighting green (see Figure 12).



Figure 12 - Program A Is Running



WARNING!

Crushing of Fingers by Device Levels

- ➔ Do not touch the device during operation. Do not reach into gaps between the device levels. Your fingers could be crushed during ongoing operation which can cause a termination of the process.

- ▶ If you do not start the selected program by pushing the Go-button you can choose another program at any time, as described above.



ATTENTION!

Danger of Faulty Process Caused by Touching the Device/the Roundabout

- ➔ Do not touch and push the device / the roundabout during operation, because it may lead to a faulty process and to liquid leaking.

4. Please bear in mind that once a program has been started it normally runs to completion automatically. However, it is possible at any time to stop the program by pushing the start-stop-button. The start-stop-button will then flash green, the program selection key lights green.

**ATTENTION!****Deficient Selection and Loss of Target Product by Program Interruption**

- ➔ By stopping a running program via the start-stop-button the high quality of the target product cannot be guaranteed anymore.
- ➔ Please use this function exclusively in exceptional cases and on your own responsibility! IBA GmbH is not liable for restrictions on the quality and quantity of the target product.

5. By pushing the start-stop-button again the program will continue at the interrupted point. The start-stop-button and the program selection key light up green continuously.

- ▶ In case of emergency the program can be stopped during operation by a long pressure (min. 3 sec.) of the GO key. The device turns the tube holder back to its starting position. Also, the device can be switched off by pushing the start-stop-button. Please use this function exclusively in exceptional cases!

**ATTENTION!****Destruction of Reagents by Premature Interruption of the Program**

- ➔ In case of an emergency stop by pushing the on / off-switch or the emergency stop a safe selection process and the high quality of the target product cannot be guaranteed anymore. When the emergency stop is activated please dispose of the consumables and start a new selection with new consumables.

- ▶ In case of emergency stop all consumables have to be exchanged before the start of a new program. Before switching the device on again, please remove the inserted syringe. Otherwise the device will not continue.

**ATTENTION!****Danger of uncontrolled Pressing out of Syringe Liquids**

- ➔ To avoid an uncontrolled pressing out of syringe liquids remove the inserted syringe before switching the device on again.

6.2.6 Stopping the Program, Removal of the Sample and of the Syringe

If the program has been completed, the program selection keys flash white and the start-stop-button will light up green. The movements and noises of the device stop and the tube holder is turning back to zero position.

Begin with the removing of syringe and tube holder:

**ATTENTION!****Do not Interrupt the Running Process!**

It is very important to note, that the syringe can only be removed when:

- ➔ the program is definitely complete and the device movements stop,
- ➔ the device is turned off and the switches are not flashing anymore.

1. Push the syringe with the syringe body toward you, until it disengages from the locking mechanism.
2. Pull the syringe downwards. Make sure, that the syringe adapter does not get dirty from the used syringe. If this is the case clean the adapter comprehensively (see chapter 7.1).
3. Remove the loaded tube holder. You will find the selected target product in tube 9, 10 or 11 or in all of these three tubes (see fig. 13).

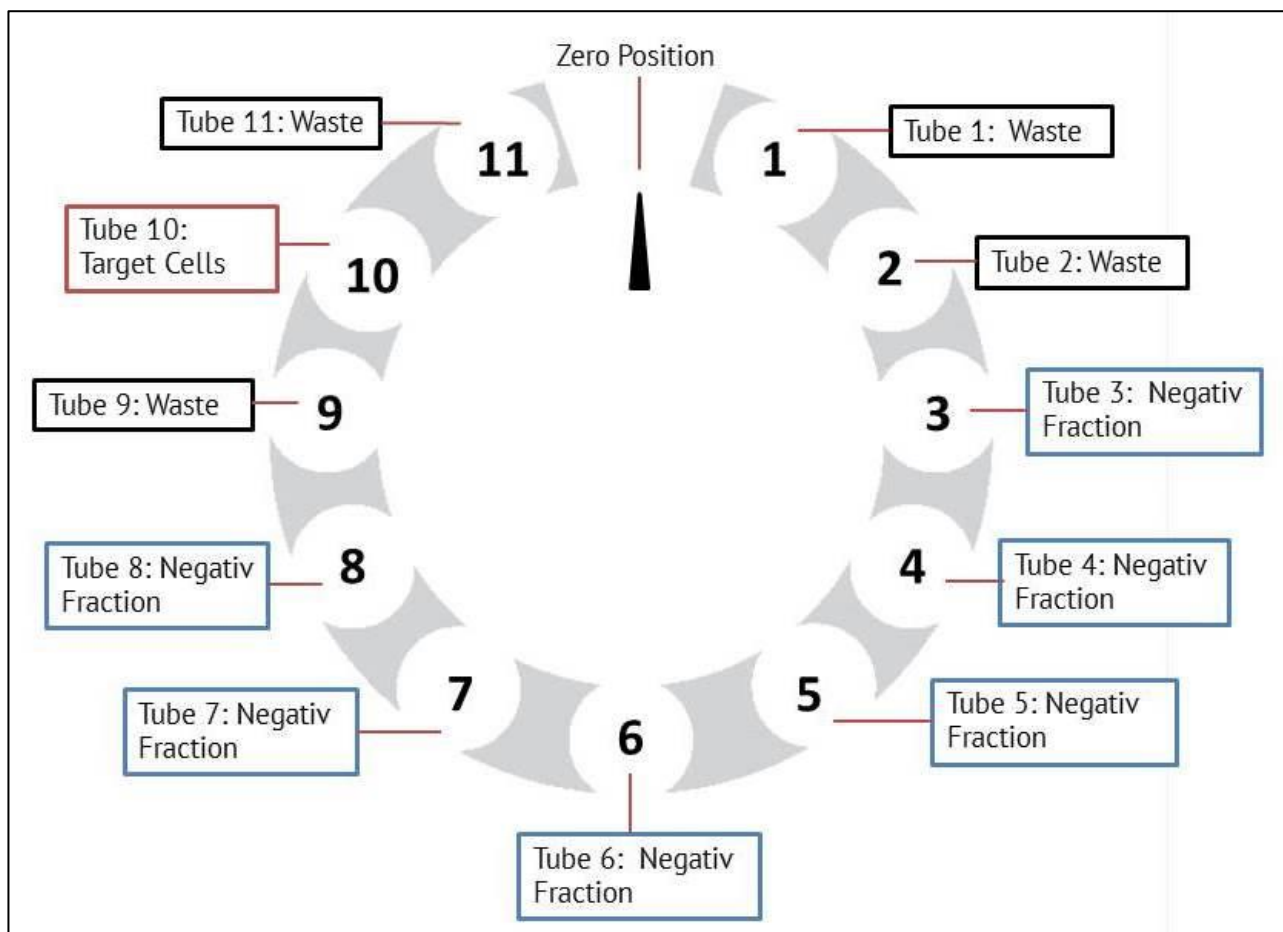


Figure 13 – Removal of the Target Product: Tube 9, 10 und 11

4. The removal of the target product is for illustrative purposes only. The realistic image is shown in the instruction manual of the consumables. In this example you can find the target cells in tube 10.
5. In this state the target cells are blended with fab. You can e.g. separate the cells from fab by centrifugation.
6. If the negative fraction is required, a mixing up of the reagents from tube 3 – 8 is necessary for an optimum use.

After the syringe and the tubes are removed, you can switch off the device or insert new consumables for another FABian® run.

7. Press GO for 3 seconds; the lift stag II will go down and all program keys flash green again. The selection of a new program is now possible or alternatively you can now switch-off the device.
8. Set FABian® to the transport position by pushing the key-combination 1+A for 3 seconds. The lift stages move up and down, the roundabout is turning back to zero position and the buttons 1, GO and A light blue.
9. Switch off the device with the on / off-switch on the right side of the unit.

6.3 Fault Repair

In case of operational disturbances please check the following points:

- ▶ Check the connection of the device and the power supply.
- ▶ Check the connection of the power cable.
- ▶ Make sure that the syringe is inserted properly.
- ▶ Make sure that all operations were performed correctly.



ATTENTION!

Danger Caused by Use of Deficient Device

- ➔ If the operational disturbance cannot be eliminated, please contact the IBA GmbH.
- ➔ Do not work with the device anymore under no circumstances.

6.4 Technical Support

Should any unusual situations or errors occur, please contact the IBA GmbH. Do not open the device or carry out any repair and maintenance without the permission of the IBA GmbH. When opening the device housing any warranty will cease.

For any comment, error messages and questions please contact:

IBA GmbH

Bosestr. 4

04109 Leipzig

Germany

Phone: +49 (0)341 – 99 38 98-29

Fax: +49 (0)341 – 99 38 98-19

E-Mail: info@iba-lifesciences.com

Homepage: www.iba-lifesciences.com

7 Maintenance and Cleaning

7.1 Cleaning

FABian® should be cleaned immediately after use.



Electric Shock Caused by Damp Device and Leaking Liquids

- Switch off the device and disconnect the power supply previous to the cleaning process.
- Ensure that no liquids leak into the inside of the device.
- Only if the device and the power cord are completely dry, connect the device to the power supply and switch it on again.



Damage to FABian® by Aggressive Chemicals

- Do not use aggressive chemicals for cleaning FABian®. These include e.g. strong and weak alkalis, strong acids, mercury- and copper solutions and other heavy metal ions, halogenated hydrocarbons, concentrated salt solutions and phenol.
- The use of organic solvents like phenol or chloroform can reduce and damage the strength of plastic material.



Damages Caused by UV- and Other High-Energy Radiations and Sources

- Do not use UV-, beta- and gamma radiation, infrared or other high-energy radiations and sources for the disinfection of the device.
- Only use mild detergents.

Cleaning Process

1. Switch off FABian® (start-stop-button).
2. Disconnect the power supply.
3. Wipe off all accessible areas of the device with a damp cloth including the accessories and the power cable. Please use mild detergents for cleaning. Do not use solvents which contain higher portions of phenol derivatives, alcohol, chlorine compound or peracetic acid.
4. Disinfect the dirty areas properly. It is recommended to use disinfectants based on aldehydes (ethanol, isopropanol). Please do not use abrasive cleaners, acetone or other solvents.
5. Of particular importance is the thorough cleaning of the syringe adapter. Disinfect the syringe adapter and clean it with a thin cloth or rather a thin brush which will be pass through the adapter.
6. It must be ensured, that no liquids leak into the inside of the housing cover. Under no circumstances power sockets and plugs should get wet.



Risk of Biological and Chemical Contamination by Used Reagents

- If hazardous materials were used, a careful decontamination of the device must be carried out. It is strictly forbidden to use contaminated devices or accessories.
- The decontamination and disposal of consumables are performed according to the applicable provisions.



If you have questions or remarks concerning the cleaning and disinfection, please contact the service team of the IBA GmbH. You will find the contact details on page 2 and 24 of this instruction manual.

7.2 Maintenance and Repair by the Customer Service

Repair and maintenance activities must be carried out only by the personnel of IBA GmbH (manufacturer). Basically, defect devices or components will be exchanged or replaced within the warranty period.

The IBA GmbH complies with the legally required warranty services.

For the return of the device to IBA GmbH we recommend to use the original packaging. Make sure, that FABian® has been cleaned and disinfected extensively. The device has to be dry and clean.

We recommend a conclusion of a maintenance agreement in which the maintenance intervals are defined.

Basically (regardless of the maintenance agreement), we recommend an annual technical inspection by our trained personnel.

Defective components (power cable, power plug, SD-card, tube holder, syringe adapter, instruction manual) must be replaced immediately.

Use Only Original Parts!



CAUTION!

- ➔ Please use exclusively original accessories, consumables and spare parts from IBA GmbH.
- ➔ For damages caused by not original parts or by improper use of parts, any claim under warranty and any liability will cease.

8 Provided Accessories, Consumables, Spare Parts



CAUTION!

Possible Damages Caused by Wrong not Original Parts

- ➔ Please use exclusively original accessories, consumables and spare parts from IBA GmbH.
- ➔ For damages caused by not original parts or by improper use of parts, any claim under warranty and any liability will cease.

8.1 Consumables

As standard FABian® >Selection Kits are equipped with 30 ml tubes and with a 10 ml syringe (both can be ordered from IBA GmbH). Depending on customer requirements 15 ml tubes as well as 1 ml, 3 ml and 5 ml syringes can be delivered. This shall require an additional order of a corresponding syringe adapter and tube holder (see chapter 8.2).

Table 6 – List of Consumables

No.	Name	Manufacturer	Amount	Frequency of Use
1	Tubes 15 ml	IBA GmbH	11	Disposable
2	Tubes 30 ml (standard)	IBA GmbH	11	Disposable
3	Syringe 1 ml	IBA GmbH	1	Disposable
4	Syringe 3 ml	IBA GmbH	1	Disposable
5	Syringe 5 ml	IBA GmbH	1	Disposable
6	Syringe 10 ml (standard)	IBA GmbH	1	Disposable

The consumables have to be disposed of according to the guidelines for autoclavable laboratory waste.

1. Tubes

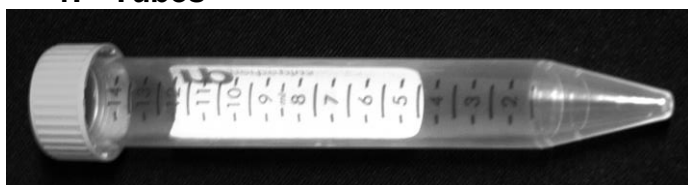


Figure 14: Image of a Tube

The tubes are disposables which are necessary for the selection process. They contain the different reagents which will be absorbed and released by the syringe in a defined order. At the end of the selection process the target product and the high purified cells are located in three of the 11 tubes. Please refer to the specific product information in terms of storage, transport and stability of the tubes. The tubes are consumables for single use. It is not allowed to re- or misuse them or to fill them up.

2. Syringe



Figure 15: Image of a Syringe

The syringe is a disposable which is essential for the selection process. The syringe contains the novel matrix which forms the basic structure of the affinity chromatography and of the selection process. Please refer to the specific product information in terms of storage, transport and stability of the syringe. Only use just one syringe per selection. Each syringe may only be used once and has to be removed after the program is finished. It is not allowed to re- or misuse the syringe or to fill it up.

**WARNING!**

Use Only Original Fabian® Syringes (Without Needle), Risk of Injury

- ➔ FABian® may be operated exclusively with the original syringe.
- ➔ It is forbidden to use other syringes equipped with needles. These kinds of syringes are not applicable for the selection process and can puncture your fingers and other body parts.

8.2 Spare- and Replacement Parts

Table 7 – List of Spare parts and Accessories

No.	Name	Product-No.	Supplier	Availability
1	FABian® Device	6-6100-000	IBA GmbH Service	continuous
2	PSU	6-6101-000	IBA GmbH Service	continuous
3	Power Cable	6-6102-000	IBA GmbH Service	continuous
4	Preset SD-Card	6-6103-000	IBA GmbH Service	continuous
5	Instruction Manual		IBA GmbH Service	
6	50 ml Tube Holder	6-6104-050	IBA GmbH Service	continuous
7	15 ml Tube Holder	6-6104-015	IBA GmbH Service	continuous
8	Syringe Adapter 1 ml	6-6105-001 / 6-6106-001	IBA GmbH Service	continuous
9	Syringe Adapter 3 ml	6-6105-003 / 6-6106-003	IBA GmbH Service	continuous
10	Syringe Adapter 5 ml	6-6105-005 / 6-6106-005	IBA GmbH Service	continuous
11	Syringe Adapter 10 ml	6-6105-010 / 6-6106-010	IBA GmbH Service	continuous

FABian® Device

In case of error messages or malfunctions please contact the service team of IBA GmbH. The device has to be replaced or to be maintained by the qualified personnel of IBA GmbH. Please refer to chapter 10 for instructions regarding the disposal.

Power Supply Unit incl. Power Cable, SD-Card, Tube-Holder

Figure 16 – Image of the Tube Holder, SD-Card, PSU & Power Cable

Power Supply Unit and Power Cable

If any damage of the power cable / PSU is suspected you should turn off the device immediately and replace it. Ignoring damages and malfunctions may lead to life-threatening electric shocks. Please contact IBA GmbH for the replacement of the power supply unit and the power cable. Only use original spare parts of IBA GmbH. The unauthorized use of other power supply units and cables will invalidate the warranty. Comply with the relevant regulations when disposing of electronic devices. Do not dispose of with normal household garbage.

Tube Holder

The tube holder for 30 - 50 ml tubes is part of the initial delivery of FABian®. It serves as a holder for a maximum of 11 tubes and is to be locked to the roundabout. The notch on the roundabout guarantees the accurate locking of the tube holder. If the tube holder is damaged or mounted, please replace it. For the replacement please contact the personnel of IBA GmbH. Do not use any self-constructions or parts of other companies. Otherwise an error-free and a safe selection process can no longer be guaranteed. Comply with the relevant regulations when disposing of metallic materials or return the materials to IBA GmbH.

SD-Card

The SD-card includes preprogrammed functions and programs, which can be selected with the program selection keys of FABian®. Without the SD-card the device cannot be operated. If the SD-card is damaged please contact IBA GmbH for replacement. By request the SD-card can be equipped with new or additional programs. To dispose of, please make the SD-card unusable (e.g. cutting or slashing) and throw it in the household garbage.

Instruction Manual

The instruction manual must be kept safely near the device for the entire life cycle of FABian®. It should be available for any user at any time. In case of loss or damage of the instruction manual you can request a copy from the service team of IBA GmbH or it can be downloaded by visiting www.iba-lifesciences.com.

Syringe Adapter



Figure 17: Image of Syringe Adapter incl. Tool

The syringe adapter is consisting of a top and bottom part and of altogether five screws. A 10 ml version of the syringe adapter is already mounted in the cover. If you should change the syringe volume a corresponding syringe adapter is necessary. Please refer to table 7 for possible adapter variations. The replacement of the adapter is demonstrated in chapter 9. Please use exclusively original syringe adapters. When using self-constructions or parts of other companies any warranty will cease and a harmless selection process cannot be guaranteed anymore. To dispose of, return the adapter to IBA GmbH or throw into the normal household garbage.

9 Information on Special Tools, Devices, Materials

No special devices and tools are required for normal operation of FABian® and its supplied accessories.

In case you want to use syringes with different volumes (1 ml, 3 ml, 5 ml) it is necessary to replace the inserted syringe adapter. The tools and materials required for the exchange – 5 screws and an allen wrench - will be supplied together with the adapter. Please refer to the following steps for the exchange of the syringe adapter:

Exchange of the Syringe Adapter

For the exchange of the syringe adapter it is necessary to dismantle the old adapter.

1. Remove the 4 visible screws from the bottom part of the adapter by using the allen wrench (see fig. 18).



Figure 18: Removal of the Screws From the Bottom Part of the Adapter

2. Unscrew the screw from the upper part of the adapter. To realize, guide the allen wrench centrally through the opening of the adapter just below the cover (see fig. 19).



Figure 19: Unscrewing the Screws From the Upper Part of the Adapter

3. Now open the cover of FABian® by sliding it toward the rear (1) and remove both parts of the syringe adapter (2 & 3) – (see figure 20).

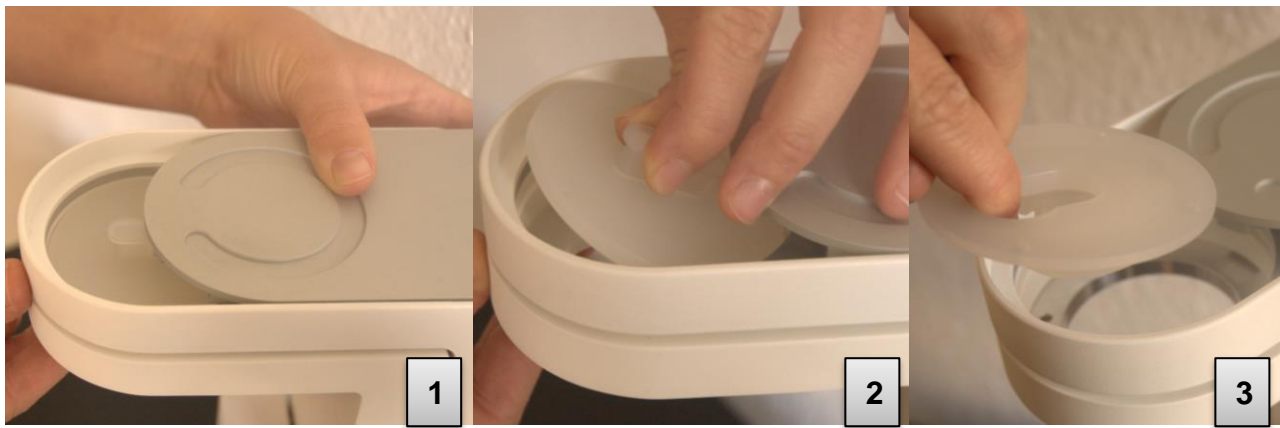


Figure 20: Removal of the Syringe Adapter

4. Now take the new syringe adapter. First insert the bottom part of the adapter into the notch of the device head with the curved side facing downwards (see figure 21).

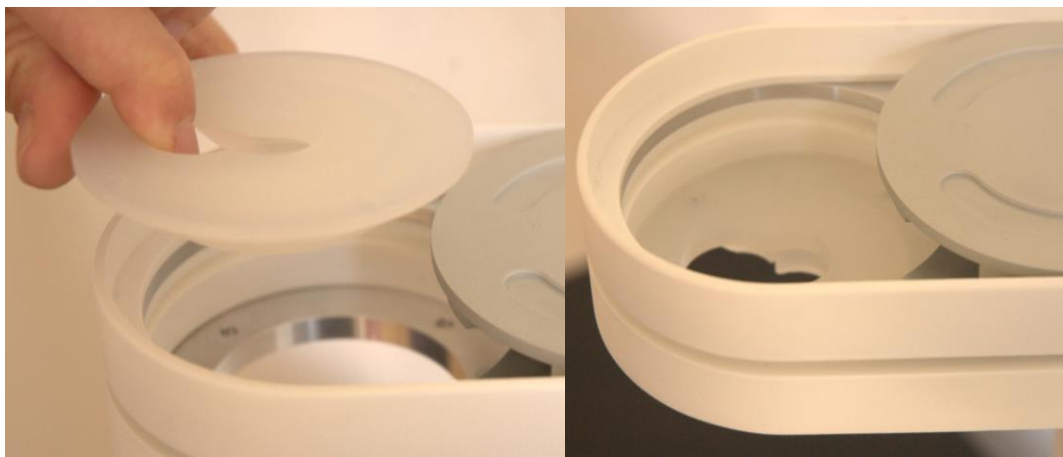


Figure 21: Insertion of the Bottom Part of the Adapter

5. Use 4 M3 x 6 mm screws to install the bottom part (see figure 22).

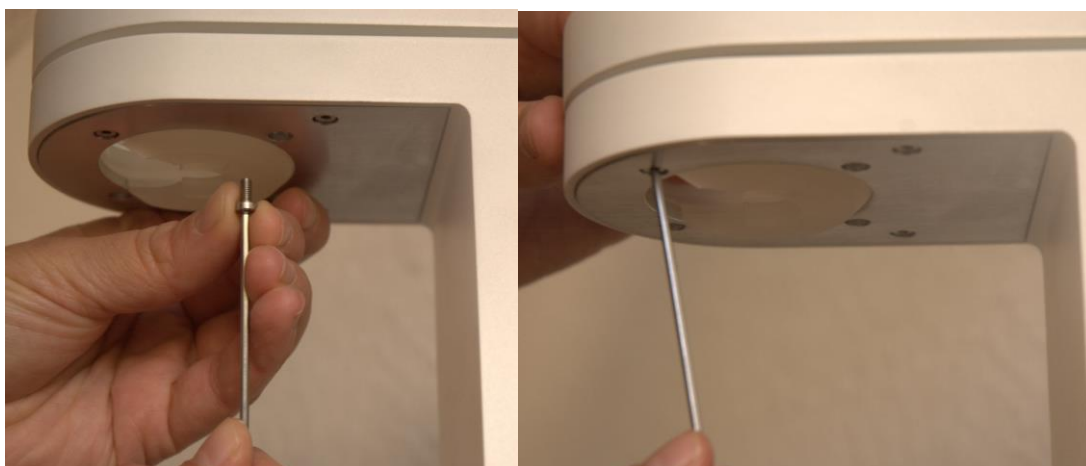


Figure 22: Installation of the Bottom Part of the Adapter

6. Insert the upper part of the adapter into the notch of the device head with the bar facing upwards. Close the cover. Take care that the bar of the upper part of the syringe locks into the notch. Therefore, push the upper part of the adapter from below against the cover and close it slowly (see figure 23).



Figure 23: Insertion of the Upper Part of the Adapter

7. Now tighten the screw below the upper part of the adapter by using the allen wrench (see fig. 24).



Figure 24: Tightening the Upper Part of the Adapter

10 Decommissioning, Dismantling, Disposal

Decommissioning

1. Turn off FABian® with the Go-button.
2. Disconnect the power supply.
3. Remove all consumables.
4. Clean FABian® according to the instruction (chapter 7.2).

Dismantling

It is prohibited to dismantle the device. Return the device to IBA GmbH or properly dispose of the device in accordance to the below chapter.

Recycling

If you decide to return the device to IBA GmbH we recommend use of the original packaging.

Disposal

Information about the disposal of electric and electronic devices within the European community:
Within the European Union the disposal of electrically driven devices is regulated by the EU-guideline 2012/19/EU *Waste of Electrical and Electronic Equipment* (WEEE). Pursuant to this regulation it is not allowed to dispose of the device with normal household garbage. This is indicated by the following sign.



The regulations of disposal may differ within the European Community from country to country. Please follow the appropriate legal regulations. If necessary you can ask the personnel of IBA GmbH or its suppliers.

For Germany applies, that the manufacturer has to offer an appropriate opportunity of a return. In this case please contact IBA GmbH for further procedure.

If you should decide to dispose of the device yourself, it is your responsibility to properly discard the waste at an authorized collection and recycling point. In case of biological, chemical or radiological contamination you are equally responsible to decontaminate the device in such a way that persons who are involved with the disposal and recycling of the device are not exposed to health risks.

11 Annexes

Author:	IBA GmbH	Checklist Initial Commissioning FABian®
Status	Revision 6	
Date:		
Form filled in by: (name of user)		

	A – Positioning of the device	yes	no*
1	FABian® - Check external damages?		
2	Complete Removal of the packaging?		
3	All device parts and accessories are included in the delivery?		
4	Instruction manual have been read and understood?		
5	Instruction manual is kept near the device available for every user		
6	To avoid device damages caused by condensation or transport shocks, you had waited three hours at least for the connection of the device?		
7	The device is positioned slip-resistant and stable on a non-flammable surface?		
8	The installation location complies with the requirements of the instruction manual: <ul style="list-style-type: none"> o sufficiently protected against dust, direct sunlight and humidity o room temperature from +10°C (50 F) - +35°C (95 F). o dry environment, sufficient room ventilation o room humidity should not exceed 75%? 		
9	The distance of at least 30 cm to every side of the device is kept?		
10	Device is positioned freestanding, so that no risk arises from the lifting of the device levels and a proper functionality can be guaranteed?		

	B – Connecting the Device	yes	no*
1	The intended voltage are compatible with the PSU?		
2	The power cable is undamaged and fully functional?		
3	The PSU is undamaged and fully functional?		
4	All protection devices (housing, plugs etc.) are proper and free of defects?		
6	The emergency stop is available within a reachable distance of the device?		
7	The emergency stop is fully functional?		
8	The cables are installed in a way that avoids damages and tripping?		
9	Only original parts were used?		
10	The perfect readability of the safety & warning instructions and of type plate is guaranteed?		
11	The power socket is properly installed and fully functional?		

	C – Initialization / Functional Testing of the Device	yes	no*
1	You are wearing personal protective equipment?		
2	The device is clean, dust free and all consumables were removed?		
3	FABian® is positioned in a way that the program selection keys are pointing towards you?		
4	The on/off-switch was activated to start initialization?		
5	Initialization completed?		
6	All programmed buttons light up green?		
7	The buttons are fully functional?		

	D – Prepare Consumables	yes	no*
1	The tubes are sterile and originally filled?		
2	The tube holder is loaded with tubes?		
3	The tube holder is properly and safely locked to the device?		
4	The syringe is sterile and originally filled?		
5	The syringe was NOT inserted BEFORE initialization?		
6	The syringe was properly inserted after the commissioning and the initialization?		

* If you answer one of these points with „no“, you have to rectify these points or mistakes immediately, before FABian® is put into action.



Konformitätserklärung
Declaration of conformity

Name und Adresse der Firma / Name and address of the company

Cell.Copedia GmbH (Hersteller)
Bosestraße 4
D-04109 Leipzig

Tel.: +49 (0)341 – 99 38 98 20
Fax: +49 (0)341 – 99 38 98 19
E-Mail: info@cellcopedia.com
Homepage: www.cellcopedia.com

Wir erklären in alleiniger Verantwortung, dass das Produkt / We declare under our sole responsibility that the device

Bezeichnung / name

FABian®
einschließlich Zubehör / including accessories

Artikel-Nr. / article number

200-100-100

allen Anforderungen der Richtlinie 2006/42/EG entspricht, die anwendbar sind /
meets all the provisions of the directive 2006/42/EEC which apply

Bei einer nicht-autorisierten Änderung des Produktes oder einer nicht bestimmungsgemäßen Verwendung des Produktes
erlischt die Gültigkeit dieser Erklärung / The declaration becomes invalid in case of unauthorized modifications to the
product or an unintended use of it.

Angewandte harmonisierte Normen / Applied harmonized standards

EN ISO 9001:2015/AC:2009; IEC 61010-1:2010; IEC 61010-2-081:2015; IEC 61326-1:2012

Angewandte nationale Normen oder andere normative Dokumente / Applied national standards or other normative documents

DIN EN ISO 9001:2015; DIN EN 61010-1:2011-07; DIN EN 61010-2-081:2015-11; DIN EN 61326-1:2013-07

Die Aufbewahrung der Technischen Dokumentation erfolgt bei / The keeping of the technical documentation is carried out by

Hersteller / Manufacturer

Ort, Datum / Place, date



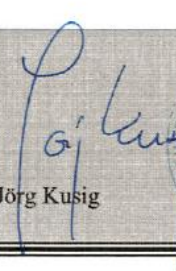


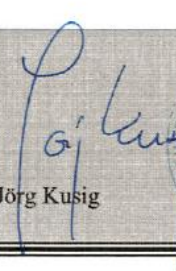


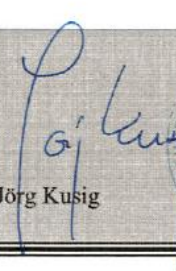

Leipzig,
04.11.2020



Ausgabe/issue/édition: 2020-11-04


Name & Funktion / Name & Function



Cell.Copedia GmbH
The Cell Isolation Company
Dr. Wilhelm Gerdes, CEO
Bosestraße 4 D-04109 Leipzig

	Ref. Certif. No. DE-6-G5160009		
IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC			
<table style="width: 100%;"> <tr> <td style="width: 40%; vertical-align: top;"> CB TEST CERTIFICATE Product Produit Name and address of the applicant Nom et adresse du demandeur Name and address of the manufacturer Nom et adresse du fabricant Name and address of the factory Nom et adresse de l'usine <small>Note: When more than one factory, please report on page 2 Note: Lorsque il y a plus d'une usine, veuillez indiquer la 2^{ème} page</small> Ratings and principal characteristics Valeurs nominales et caractéristiques principales Trademark (if any) Marque de fabrique (si elle existe) Type of Manufacturer's Testing Laboratories used Type de programme du laboratoire d'essais constructeur Model / Type Ref. Ref. De type Additional information (if necessary may also be reported on page 2) Les informations complémentaires (si nécessaire, peuvent être indiqués sur la 2^{ème} page A sample of the product was tested and found to be in conformity with Un échantillon de ce produit a été essayé et a été considéré conforme à la As shown in the Test Report Ref. No. which forms part of this Certificate Comme indiqué dans le Rapport d'essais numéro de référence qui constitue partie de ce Certificat </td> <td style="width: 60%; vertical-align: top; background-color: #f0f0f0; padding: 10px;"> CERTIFICAT D'ESSAI OC Automatisches Laborgerät für wissenschaftliche Forschungszwecke Cell.Copedia GmbH Bosestraße 4, 04109 Leipzig GERMANY Cell.Copedia GmbH Bosestraße 4, 04109 Leipzig GERMANY Cell.Copedia GmbH Bosestraße 4, 04109 Leipzig GERMANY Ratings: 100-240 VAC / 47-63Hz FABian /. FABian® IEC 61326-1:2012 (ed. 2.0) <small>National differences</small> None G0M-1509-5104-EC01LAB-V01 <div style="text-align: center; opacity: 0.5; font-size: 2em; font-weight: bold;">eurofins</div> </td> </tr> </table>		CB TEST CERTIFICATE Product Produit Name and address of the applicant Nom et adresse du demandeur Name and address of the manufacturer Nom et adresse du fabricant Name and address of the factory Nom et adresse de l'usine <small>Note: When more than one factory, please report on page 2 Note: Lorsque il y a plus d'une usine, veuillez indiquer la 2^{ème} page</small> Ratings and principal characteristics Valeurs nominales et caractéristiques principales Trademark (if any) Marque de fabrique (si elle existe) Type of Manufacturer's Testing Laboratories used Type de programme du laboratoire d'essais constructeur Model / Type Ref. Ref. De type Additional information (if necessary may also be reported on page 2) Les informations complémentaires (si nécessaire, peuvent être indiqués sur la 2 ^{ème} page A sample of the product was tested and found to be in conformity with Un échantillon de ce produit a été essayé et a été considéré conforme à la As shown in the Test Report Ref. No. which forms part of this Certificate Comme indiqué dans le Rapport d'essais numéro de référence qui constitue partie de ce Certificat	CERTIFICAT D'ESSAI OC Automatisches Laborgerät für wissenschaftliche Forschungszwecke Cell.Copedia GmbH Bosestraße 4, 04109 Leipzig GERMANY Cell.Copedia GmbH Bosestraße 4, 04109 Leipzig GERMANY Cell.Copedia GmbH Bosestraße 4, 04109 Leipzig GERMANY Ratings: 100-240 VAC / 47-63Hz FABian /. FABian® IEC 61326-1:2012 (ed. 2.0) <small>National differences</small> None G0M-1509-5104-EC01LAB-V01 <div style="text-align: center; opacity: 0.5; font-size: 2em; font-weight: bold;">eurofins</div>
CB TEST CERTIFICATE Product Produit Name and address of the applicant Nom et adresse du demandeur Name and address of the manufacturer Nom et adresse du fabricant Name and address of the factory Nom et adresse de l'usine <small>Note: When more than one factory, please report on page 2 Note: Lorsque il y a plus d'une usine, veuillez indiquer la 2^{ème} page</small> Ratings and principal characteristics Valeurs nominales et caractéristiques principales Trademark (if any) Marque de fabrique (si elle existe) Type of Manufacturer's Testing Laboratories used Type de programme du laboratoire d'essais constructeur Model / Type Ref. Ref. De type Additional information (if necessary may also be reported on page 2) Les informations complémentaires (si nécessaire, peuvent être indiqués sur la 2 ^{ème} page A sample of the product was tested and found to be in conformity with Un échantillon de ce produit a été essayé et a été considéré conforme à la As shown in the Test Report Ref. No. which forms part of this Certificate Comme indiqué dans le Rapport d'essais numéro de référence qui constitue partie de ce Certificat	CERTIFICAT D'ESSAI OC Automatisches Laborgerät für wissenschaftliche Forschungszwecke Cell.Copedia GmbH Bosestraße 4, 04109 Leipzig GERMANY Cell.Copedia GmbH Bosestraße 4, 04109 Leipzig GERMANY Cell.Copedia GmbH Bosestraße 4, 04109 Leipzig GERMANY Ratings: 100-240 VAC / 47-63Hz FABian /. FABian® IEC 61326-1:2012 (ed. 2.0) <small>National differences</small> None G0M-1509-5104-EC01LAB-V01 <div style="text-align: center; opacity: 0.5; font-size: 2em; font-weight: bold;">eurofins</div>		
This CB Test Certificate is issued by the National Certification Body Ce Certificat d'essai OC est établi par l'Organisme National de Certification			
<table style="width: 100%;"> <tr> <td style="width: 40%;">  Eurofins Product Service GmbH Storkower Strasse 38c D-15526 Reichenwalde b. Berlin Germany </td> <td style="width: 60%; text-align: center;"> <div style="display: flex; align-items: center; justify-content: center;">   </div> Signature: Jörg Kusig </td> </tr> </table>		 Eurofins Product Service GmbH Storkower Strasse 38c D-15526 Reichenwalde b. Berlin Germany	<div style="display: flex; align-items: center; justify-content: center;">   </div> Signature: Jörg Kusig
 Eurofins Product Service GmbH Storkower Strasse 38c D-15526 Reichenwalde b. Berlin Germany	<div style="display: flex; align-items: center; justify-content: center;">   </div> Signature: Jörg Kusig		
Date: 2016-01-25			

	Ref. Certif. No. DE-6-G5160010
<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME </div> <div style="width: 48%;"> SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC </div> </div>	
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <h3 style="text-align: center;">CB TEST CERTIFICATE</h3> <p>Product Produit</p> <p>Name and address of the applicant Nom et adresse du demandeur</p> <p>Name and address of the manufacturer Nom et adresse du fabricant</p> <p>Name and address of the factory Nom et adresse de l'usine</p> <p><small>Note: When more than one factory, please report on page 2 Note: Lorsque il y a plus d'une usine, veuillez utiliser la 2^{ème} page</small></p> <p>Ratings and principal characteristics Valeurs nominales et caractéristiques principales</p> <p>Trademark (if any) Marque de fabrique (si elle existe)</p> <p>Type of Manufacturer's Testing Laboratories used Type de programme du laboratoire d'essais constructeur</p> <p>Model / Type Ref. Ref. De type</p> <p>Additional information (if necessary may also be reported on page 2) Les informations complémentaires (si nécessaire, peuvent être indiqués sur la 2^{ème} page</p> <p>A sample of the product was tested and found to be in conformity with Un échantillon de ce produit a été essayé et a été considéré conforme à la</p> <p>As shown in the Test Report Ref. No. which forms part of this Certificate Comme indiqué dans le Rapport d'essais numéro de référence qui constitue partie de ce Certificat</p> </div> <div style="width: 50%;"> <h3 style="text-align: center;">CERTIFICAT D'ESSAI OC</h3> <p>Automatisches Laborgerät für wissenschaftliche Forschungszwecke</p> <p>Cell.Copedia GmbH Bosestraße 4, 04109 Leipzig GERMANY</p> <p>Cell.Copedia GmbH Bosestraße 4, 04109 Leipzig GERMANY</p> <p>Cell.Copedia GmbH Bosestraße 4, 04109 Leipzig GERMANY</p> <p>Ratings: 24V; 0.9A</p> <p>FABian</p> <p>./.</p> <p>FABian®</p> <p>IEC 61010-1:2010 (ed. 3.0) IEC 61010-2-081:2015 (ed. 2.0)</p> <p><i>National differences:</i> CANADA, USA G0M-1509-5104-SCM001N-V01</p> </div> </div>	
<p>This CB Test Certificate is issued by the National Certification Body Ce Certificat d'essai OC est établi par l'Organisme National de Certification</p> <div style="display: flex; justify-content: space-between; align-items: flex-end;"> <div style="width: 40%;">  <p>Eurofins Product Service GmbH Storkower Strasse 38c D-15526 Reichenwalde b. Berlin Germany</p> <p>Date: 2016-01-25</p> </div> <div style="width: 55%; text-align: right;"> <p><i>Signature: Jörg Kusig</i></p>  </div> </div>	

	Ref. Certif. No. DE-6-G5170005
IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME	
<div style="display: flex; justify-content: space-between;"> <div style="width: 35%;"> <p>CB TEST CERTIFICATE</p> <p>Product</p> <p>Name and address of the applicant</p> <p>Name and address of the manufacturer</p> <p>Name and address of the factory</p> <p><small>Note: When more than one factory, please report on page 2</small></p> <p>Ratings and principal characteristics</p> <p>Trademark (if any)</p> <p>Customer Test Facility (CTF) Level used</p> <p>Model / Type Ref.</p> <p>Additional information (if necessary may also be reported on page 2)</p> <p>A sample of the product was tested and found to be in conformity with</p> <p>As shown in the Test Report Ref. No. which forms part of this Certificate</p> </div> <div style="width: 60%; background-color: #f0f0f0; padding: 10px;"> <p>Automatisches Laborgerät für wissenschaftliche Forschungszwecke</p> <p>Cell.Copedia GmbH Bosestraße 4, 04109 Leipzig GERMANY</p> <p>Cell.Copedia GmbH Bosestraße 4, 04109 Leipzig GERMANY</p> <p>Cell.Copedia GmbH Bosestraße 4, 04109 Leipzig GERMANY</p> <p>100-240VAC / 47-63Hz</p> <p>FABian</p> <p>./.</p> <p>FABian®</p> <p>IEC 61326-1:2012</p> <p><i>National differences:</i> Canada, USA</p> <p>G0M-1509-5104-EC02LAB-V01</p> </div> </div>	
<p>This CB Test Certificate is issued by the National Certification Body</p> <div style="display: flex; justify-content: space-between; align-items: flex-end;"> <div style="width: 40%;">  <p>Eurofins Product Service GmbH Storkower Strasse 38c D-15526 Reichenwalde b. Berlin Germany</p> <p>Date: 2017-01-30</p> </div> <div style="width: 55%; text-align: center;">  <p>Signature: Jörg Kusig</p> </div> </div>	