Tuttnauer
Innovation · Legacy · Partnership

Operator's manual

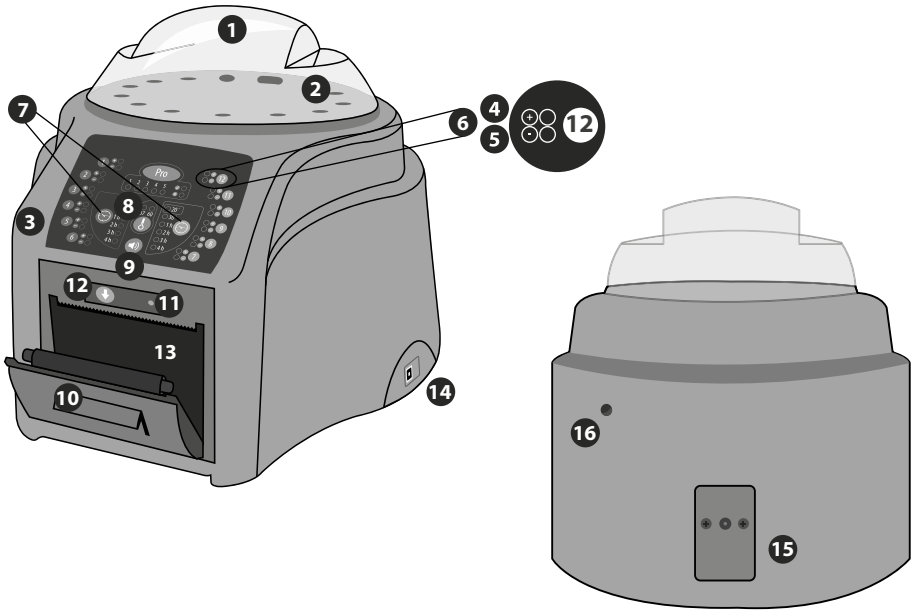
Auto-reader Incubator
for Self-Contained Biological Indicators

Rev.0 FDA | September 2019

Warning: this product contains dry natural rubber

Index

Constituent parts



Description of use

The Auto-reader incubator has been designed for the incubation and automatic readout of Self-Contained Biological Indicators (SCBIs).
The auto-reader allows easy and rapid detection of positive and negative Biological Indicators (BIs). Incubation programs available: 3 hours at 60 ºC, 1 hour at 60 ºC, 30 minutes at 60 ºC .
A positive result can also be evidenced by culture medium color change to yellow, read the instructions for use of each indicator for more information. The choice to perform or not the extended incubation to confirm by color change depends on the internal protocols of each laboratory or hospital.
The auto-reader allows selection of incubation time programs for two zones in an independent way. Zone 1 includes positions 1 to 6, and zone 2 comprises positions 7 to 12.
The incubator not only allows results detection but also provides a printed ticket to record them. In addition, the auto-reader can be connected to a computer by USB. This allows linking the results with the *Traceability Software* for Automatic Reading and Traceability of Rapid Biological Indicators and Hygiene Monitoring Systems.

References

1. Protective cover.
2. Incubation area for 12 BIs. BIs Ampoule crusher.
3. Control Panel.
4. Red light/Positive indicator/Position Light.
5. Green Light/Negative indicator/Position Light.
6. Reading position number.
7. Program selector.
8. Temperature Selector.
9. Alarm Cancellation Button.
10. Thermal printer.
11. Printer's light.
12. Paper's traction button.
13. Cavity for paper.
14. USB port.
15. Input for power source plug (12V DC).
16. Hole for external temperature control.

Symbols

Operating relative humidity.

Operating environmental temperature.

Caution, warning.

Caution: Risk of electric shock.

Caution: Hot surface.

Important, attention.

Manufacturer.

European conformity.

SN Serial number.

Direct current.

REF Product denomination.

To avoid risks and damaging the equipment
-Do not place the auto-reader in an environment exposed to direct sunlight or high intensity light lamps.
-Do not place the auto-reader near devices that emit electromagnetic fields.
-Do not use the equipment on vibrating surfaces.
-Do not pour any liquid inside.
-Do not immerse into any liquid.
-Use indoors only.
-Disconnect the power cord before cleaning.
-Do not use abrasive, corrosive cleaners or disinfectans.
-In case of technical fault, contact the manufacturer for support. Please, do not try to open or repair the auto-reader on your own, since this will imply the loss of product warranty and could lead to a major and irreversible damage.
-Make sure that the auto-reader is connected to a properly rate power cord.

To reduce the risk of using incompletely sterilized loads:
-Make sure to use each BI with its incubation and reading program:
Steam with 3hs. at 60 °C program.
Steam with 1 h. at 60 °C program.
Steam with 30 min. at 60 °C program.

-Check that culture medium completely wets the spore carrier.
-Do not remove the BI until the equipment reports the final readout result, check printed ticke

To avoid the risk of injury, because of glass fragments generated after the glass ampoule inside the BI tube is crushed:
-Cool the BI during the indicated time before crushing the ampoule.
-Do not handle the BI excessively since this might cause the glass ampoule to burst.
-Wear safety glasses and gloves when removing the BI from the sterilizer.
-Wear safety protective glasses and gloves to crush the ampoule and to press the cap of BI.
-Do not use your finger for crushing BI.

To avoid a potencially hazardous situation: avoid contact with the hot surface of the metal auto-reader block.

To avoid BIs from absorbing fluorescent residues: avoid BIs direct contact with chemical indicators or tapes.

Do not use this product in a manner not specified in this manual, otherwise the protection provided by the product might be affected.

Do not replace the power supply cord for other not provided within the product.

Only qualified personnel can access the inside of the incubator and its components. Parts or components inside the machine should not be manipulated by the user.

Power supply specifications

Input parameters	**Operating Condittion**	**Units**
Voltage range	(100-240)	Volts
Frequency	50/60	Hertz
Current	0.2	Ampers
Output parameters	**Values**	**Units**
Voltage	12	DC Volts
Current	4	Ampers

It is recommended to use a UPS instead of stabilizers, since the former has two functions: it stabilizes and provides a continual power source during energy cutoff.

Environment operating conditions

Environmental conds.	Functional conds.	Units.
Altitude	3500 (máx.)	Meters
Operation temperature	10-30	ºC
Relative humidity	30-80	%
Installation/overvoltage	category II	
Degree of contamination	2	
Storage temperature	10-30	°C
Voltage	12	DC volts

Serial/Batch Number

For easy identification, each auto-reader has a unique serial number and a batch number printed on a label found at the bottom of the auto-reader and on its packaging. Please, register your serial number and batch number in this manual for future reference:

Serial Number: _____

Batch Number: _____

Record Table

Use the following table to record firmware updates.

NOTE: manufactury firmware is printed on a label found on the bottom of the auto-reader and on its packaging.

Please, register your manufactory firmware in this manual for future reference:

Manufactury Firmware: _____

Date	Version	Operator

Start-up

All equipment is manufactured with the following settings:
- Time zone: UTC +0:00
- Printing language: English

For changing time zone, refer to *Time zone change mode* section.
For changing printing language, refer to *Printing language* section.

1-Place the auto-reader on a firm surface, free from vibrations, away from sunlight, currents of hot or cold air, chemicals and corrosive or flammable substances. Do not place the equipment in a way that disconnection of the plug from the power supply could be difficult. Leave a gap of at least 10 cm from the wall. Do not move the auto-reader periodically or during its use. Connect the auto-reader to a secure and stable electrical power source.

Do not wet or heat the auto-reader. If liquid is spilled on the auto-reader, disconnect it and dry it immediately. Before turning on, verify that all reading positions are empty.

2-Turn on the machine by connecting the end of the AC power supply to the mains and then connect the other end of the source (plug) on the rear of the unit. The printer's paper indicator light will turn on, if this light becomes intermittent, this means that the thermal paper must be loaded, or that the printer cover is not tightly closed. Otherwise, the light will remain stationary. The machine will start running the last time and temperature set-up.
3-Synchronize the incubator with local time using the auto-reader's Traceability software. For this, connect a PC to the USB plug of the auto-reader and start the program. The incubator will be synchronized with the time in the PC. Synchronization can be done as long as there is not an ongoing reading.
4-The incubator will initiate with the last setup program for temperature and time. To change the incubation temperature, press the button for 3 seconds. Lights corresponding to 60 °C will start blinking, indicating that a temperature program must be selected. For temperature selection, press the button to select 60 ºC. After 4 seconds the temperature modification will be accepted.
For 60 ºC, 30 min., 1 or 3 hrs. program can be selected.
It's possible to select different programs for each half or the same for both, depending on the indicator's final reading characteristics. Check that the time setting is appropriate for the BIs to be incubated in each zone.
To change the time program, press the button of the correspondent zone as many times as needed to choose the right setting.
5- Wait for temperature of the machine to be stable. Once is stable, the indicator of the desired temperature will remain steady.

Do not put any biological indicator in the reading positions until the auto-reader does not confirm temperature stability.

The auto-reader will keep the selected incubation program during the reading process. The system does not allow to modify the incubation program once the reading process has begun, unless the reading is finished.
6-Start readings once the blue temperature selection's light remains stable, this indicates that incubation temperature was reached. Once the selected temperature has been reached and remains stable, after turning on the equipment, a one-time automatic check of the Biological Indicators incubation positions will be carried out. Indicating lights of each well will turn on bringing the result, a green light will show a satisfactory result while a red light will indicate error.
When the equipment detects an error in any position, a ticket indicating the day, time and position involved will be printed. To guarantee the reliability of the results, these positions will be deactivated, thus preventing their use. To evidence this, the red light of that position will remain blinking indefinitely, in order to indicate that the position has been disabled.

For a correct automatic check, the protective cover of the auto-reader should be in its place.

Read BIs instructions for use. Before placing the vials in the auto-reader, press the top to seal the tube. Crush the ampoule (using the ampoule crusher within the box of BIs or the one located within the incubation area of the auto-reader) and make sure that the liquid has completely wet the spore carrier placed at the bottom of the biological indicator plastic tube.

Do not remove or change placement of BI once the reading process has begun. If this occurs, results may be invalidated.

Use a non-sterilized biological indicator as a positive control every time a processed indicator is incubated. For more information refer to the *Positive Control* section of this user guide.

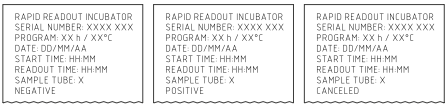
7-Place the rapid BI in a reading position and wait for the result. Reading will start automatically. Immediately after placing the BI in a position, an alarm will sound indicating that reading has successfully began and the position LED will blink until the result is informed.

NOTE: If the auto-reader does not run automatically, it might indicate that the auto-reader temperature is not steady yet (check the temperature indicating light to remain steady) or that the incubation position is disabled due to an error in the initial autotest.

8-If the incubator detects a positive result, the red light and the audible alarm will turn on. This will indicate that the sterilization process to which the BI was subject, has failed. 30 seconds after removing the IB from the incubation position, the alarm and the red

light will turn off automatically and the position will be available to start a new reading.
The negative BIs will be informed with a green light in the corresponding position. This will indicate that the sterilization process to which it was subject has been successful. The green light will remain on for up to 30 seconds after the BI is withdrawn from the reading position.
The incubator will inform results within 30 min. (60 ºC),1 h. (60 ºC) or 3 hs. (60 ºC) according to the program selected. These periods of incubation are the time-limits used by the equipment to inform the fluorescence final readout.
9-Every time a positive result is detected, it will be informed through the printing of the corresponding ticket and with an audible alarm. The alarm can be cancelled by pressing the button .
10-To register the tickets, press paper's traction button, take the paper and press up for the paper to be cut with the serrated edge of the printer.

NOTE: If the paper runs out, printer's blue light will start blinking (see *Replacement of the paper roll in the printer*). The incubator will save the last 12 results, for re-printing, follow the *Reprinting of the last results* instructions.



NEGATIVE **POSITIVE** **CANCELED**

Thermal paper specifications

Recommended paper: JUJO AF50KSE3 or similar (order code ICTP).

Paper width : 58 mm

Maximum paper thickness: 60 g/m2

Maximum diameter size: 50 mm

Replacement of the paper roll

The printer uses thermal paper rolls.

1. To replace the paper roll, pull the handle of the printer's door.

2. Open the printer's cover and remove the spent roll.

3. Place the new paper roll with the outer side up.

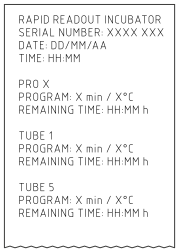
4. Close the printer cover by pressing on the sides of the lid.

Reprinting of results

The auto-reader allows reprinting of the last 12 results by fluorescence readout. To print the results, press the button for 5 seconds.

Remaining incubation time

The auto-Reader also allows verifying the remaining incubation time in every reading position. Whenever a reading process is in course, press and hold the button for five seconds, a ticket will then be printed containing the following information: reading position, incubation program and remaining incubation time.



Positive control

The positive control should belong to the same batch of the processed BI.

Use a non-sterilized biological indicator as a positive control every time a processed indicator is incubated.

Incubate the processed biological indicator and the indicator used as positive control as long as specified in the instructions.

Press the cap to seal the tube and crush the ampoule, make sure the media completely wets the carrier. Write a *C* (for *control*) and the date on the label. The positive control can be placed in any well of the auto-reader.
It is a good practice to use a positive control, this helps ensuring:
- Correct temperature is reached
-Viability of spores has not been altered due to improper storage temperature, humidity, or proximity to chemicals.
-Capability of the media to promote rapid growth.
-Proper functioning of the auto-reader.

Interpretation of results

Rapid Readout

The indicator used as positive control should show a positive result (red light ⊗ ●). The processed BI results are not valid until the biological indicator used as positive control shows a positive result ⊗ ● . A processed BI with a positive result, indicates a failure in the sterilization process. A negative result, (green light √ ●) after 30 min. (60 ºC), 1 h. (60 ºC) or 3 hs. (60ºC) according to the used program, indicates that the sterilization process was effective.
Take action on any positive result inmediately. A positive result indicates a sterilization process failure may have ocurred. Determine the cause of the positive BI following current facility policies and procedures. Always retest the sterilizer and do not use the sterilizer for processing loads until 3 consecutive BI results are negative.

Visual Readout

The Rapid readout system allows the confirmation of results by color change after 48 hours or 7 days incubation analysis (if 7-day readout is made, an humidified environment will be required to avoid media dry out). If the sterilization process was not successful, the growth media contained in the indicator will turn to yellow. If the sterilization process was successful, the media will remain unchanged. Color change to yellow of the growth media shows a failure in the sterilization process. If after the incubation time (see biological indicators directions for use), no color change is noticed in the processed indicators, then the result is negative (the sterilization process was successful).

The color of the growth media in the BI used as positive control must turn to yellow during the process of incubation for the results to be valid. Record the positive ones and discard them immediately as shown in the biological indicators instructions for use.

Disposal

Dispose BIs after use, according to your healthcare and safety regulations (see BIs instructions for use).

Audible alarm

An audible alarm will sound every time a positive result is detected in the auto-reader. The alarm allows the user to immediately detect a positive result without the need to visually control the equipment. The alarm can be cancelled by pressing the button .

Canceling a reading

When a BI is removed from it's position during incubation process, an audible alarm will sound to indicate the tube should be returned to the corresponding position.
If the indicator isn't re-introduced into the reading position after 10 seconds of being withdrawn, the reading will be cancelled and the cancellation will be informed through the printing of a ticket.

Temperature monitoring

The auto-reader contains an internal temperature control. If the temperature falls outside of the specified range (60±2 ºC), the blue temperature led light will start to twinkle.
Temperature can be externally monitored by using a thermometer. The auto-reader has a special hole for placing the thermometer which is located at the back of the device.

Care and cleaning

Clean the exterior surface of the auto-reader with a damp cloth moistened with an small amount of detergent. Do not clean interior components. If additional cleaning of the wells is required, contact your distributor or manufacturer.

Always unplug the auto-reader and allow it to cool before cleaning. Do not immerse the unit in liquid.

NOTE: Auto-reader does not need routine maintenance.

Firmware update

The auto-reader allows updating the firmware periodically (program that controls the device and defines its different features) through the use of a firmware update utility.
This software verifies, by using the internet, the latest firmware version available for the auto-reader; downloads it and installs it in a few seconds without the loss of any device data.

Update procedure

Before starting the process, make sure that the Traceability software is closed. Turn off the incubator for five seconds, then turn it on and follow these steps:
1-Connect the incubator to a PC using a USB cable and make sure to have an internet connection.
2-Open the firmware update utility.
3-Select the device and press Start button to update.
4- Wait until the software indicates that the upgrade process is complete. The auto-reader prints an update confirmation ticket. If it was already up to date, it will print nothing.

NOTE: This process must be repeated every time a new firmware version is available, this will be informed in the website.

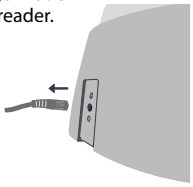
Calibration

The equipment calibration procedure is described in the attached software manual (*Traceability Software* for Automatic Reading and Traceability of Rapid Biological Indicators and Hygiene Monitoring Systems).

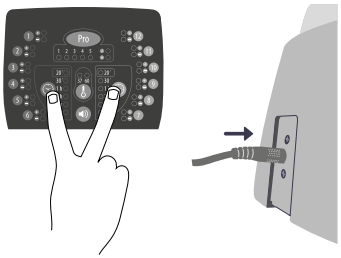
Time zone change mode

This function allows you to advance or delay the internal auto-reader clock in order to adopt a different time zone.

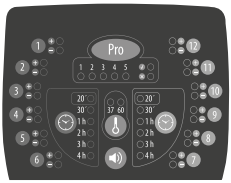
Enter *Time zone change* mode
De-energize the auto-reader.



Press and hold both buttons simultaneously and energize the equipment. A beep will be emitted to indicate access to *Time zone change*.



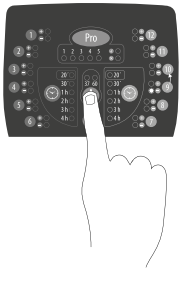
NOTE: when entering *Time zone change* mode a green light will turn on in one of the incubation/ reading position. This number corresponds to the current auto-reader time.



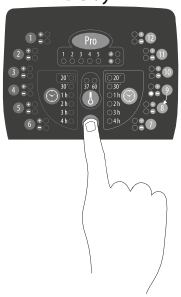
Time zone change

To advance time, press button as many times as hours you need to advance. To delay time press button as many times as hours you need to delay.

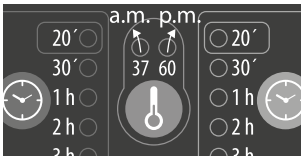
Advance



Delay



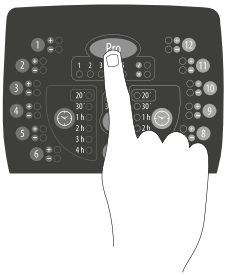
NOTE: 37 °C light indicates a.m. 60 °C light indicates p.m.



Complete time zone change

To save changes press and hold Pro button (Figure 4) for three seconds. A beep will sound indicating that process has been completed successfully. A ticket with the new set time will be printed.

Figure 4



Cancel time zone change

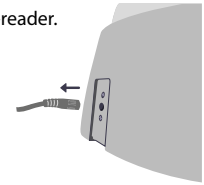
To cancel time zone change process without saving the changes, disconnect power source.

Time setting mode

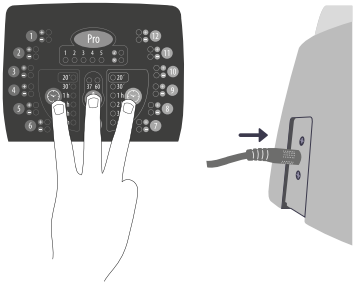
Time setting functionality allows you to establish a specific time regardless of auto-reader current time.

Enter *Time setting* mode

De-energize the auto-reader.



Press and hold both buttons and button simultaneously and energize the equipment. A beep will be emitted to indicate access to *Time setting mode*.



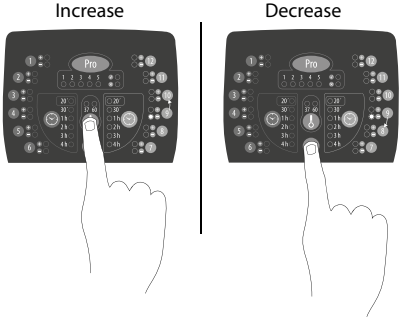
Hours setting

Lights corresponding to 1 to 10 incubation/reading positions indicate the digit value which is set. Lights from 1 to 9 indicate digit value from 1 to 9. Light 10 indicates 0 value.
In time setting mode, light 1 from PRO sector will turn on to indicate ten hour modification and incubation light corresponding to the 10th position will turn on to indicate setting started.

NOTE: 24-hour format.

To **change** hours and minutes digits, use and buttons. To **increase** digit value press ; to **decrease** press (see Figure 5).

Figure 5



- Hours setting: **Ten hours (Hh:mm)**

The blue light number 1 corresponding to PRO sector should be on. If any other light from PRO sector is on, press Pro button as many times as necessary to turn on the blue light number 1. This indicates ten hour setting.

To increase ten hours value, press button. To reduce ten hours value, press button. (See Figure 5).

NOTE: the possible values for ten hour are 0, 1 and 2.

- Hours setting: **Unit hours (hH:mm)**

Press Pro button to turn on the blue light number 2. This indicates unit hours setting. If any other light from PRO sector is on, press Pro button as many times as necessary to turn on the blue light number 2.

To increase unit hours value, press button. To decrease unit hours value, press button. (See Figure 5).

Minutes setting

***- Minutes setting:* Ten minutes (hh:Mm)**

Press Pro button to turn on the blue light number 3. This indicates ten minutes setting. If any other light from PRO sector is on, press Pro button as many times as necessary to turn on the blue light number 3.

To increase ten minutes value, press button. To decrease ten minutes value, press button. (See Figure 5).

NOTE: possible values for ten minutes are 0, 1, 2, 3, 4 y 5.

***- Minutes setting*: Unit minutes (hh:mM)**

Press Pro button to turn on the blue light number 4. This indicates unit minutes setting. If any other light from Pro sector is on, press Pro button as many times as necessary to turn on the blue light number 4.

To increase unit minutes value, press button. To decrease unit minutes value, press button. (See Figure 5).

Finish hours setting

To save changes press and hold Pro button (see Figure 4) for three seconds. A beep will sound, PRO green light will turn on and a ticket with the new set time will be printed to indicate the procedure has been completed successfully.

NOTE: If the modification has not been done correctly, the auto-reader will emit 3 beeps and the red light from PRO sector will turn on. Repeat the procedure.

Cancel hours setting

To cancel hours setting procedure without saving the changes, disconnect power source.

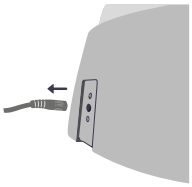
Printing language change mode

This function allows you to change the auto-reader printing language.

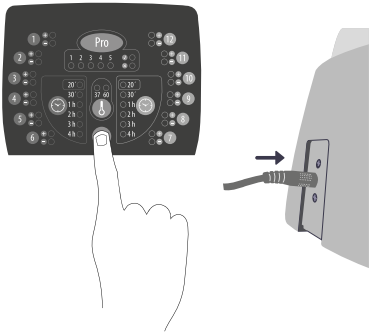
NOTE: each language has a code number assigned:
1 ⟶ English
2 ⟶ Spanish
3 ⟶ Portuguese
4 ⟶ Turkish

Enter to *Printing language change* mode

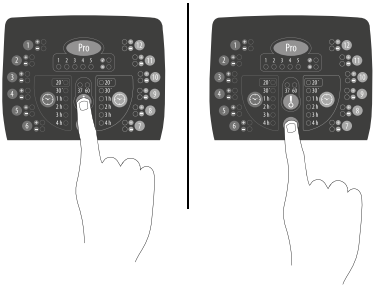
De-energize the auto-reader.



Press and hold button and energize the equipment. A sound will be emitted to indicate Access to *Printing language change* mode.



Use and buttons to select the position number corresponding to language code.



Finish printing language change

To save changes press and hold Pro button for three seconds. A sound will be emitted indicating that process has been completed successfully. A ticket with the new language will be printed.

Troubleshooting chart

Fault	Possible cause	Action
The auto-reader does not start	Power source is not connected.	Check that the power source is connected to the power supply and that the plug is connected to the auto-reader.
The auto-reader gives an error in one position during "Autotest".	A BI is placed in the position at the moment of starting the auto-reader.	Check that every position is empty at the moment of starting the auto-reader.
The auto-reader gives an error in the "Autotest".	Soil particles might be obstructing the light path between the sensors.	Ensure cleanliness of the incubation position. Use of air is recommended. Do not use solid objects that could damage internal components. Restart the auto-reader.
The auto-reader does not run a BI reading. The red light of that position is blinking.	The autotest gives an error in that position, which becomes disabled.	Make sure that the position is empty when starting the auto-reader. Restart the auto-reader.
The auto-reader does not run a BI readout in any position.	The incubation temperature is not stable.	Wait for temperature to be stable.
The auto-reader does not allow to change the incubation program.	Ongoing reading.	Wait for the readings to finish.
The printer does not print and the printer indicating light blinks.	The printer cover is not tightly locked.	Check that the cover is tightly closed.
	Printer without paper.	Place a new paper roll in the right direction.
The printer releases unprinted paper.	Paper roll is placed in the wrong direction.	Check the paper roll direction.
The traceability software does not detect the auto-reader.	The auto-reader is turned off or the USB cable is disconnected.	Check that the auto-reader is turned on, the USB cable is connected and the COM port is correctly installed and accepted by the operative system.
The update of the auto-reader fails.	The auto-reader is connected to the traceability software.	Close the program, restart the auto-reader and try again.