Instructions for SuperFlex™ Automated Chemiluminescence Analyzer

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v 1.0
This manual is proprietary to PerkinElmer, Inc., and intended only for customer use in connection with the product(s) described herein and for no other purpose. This document and its contents shall not be used or distributed for any other purpose without the prior written consent of PerkinElmer. Follow the protocol included with the equipment.

Description of Typeface

- Any precautions, warnings and reminders in any contents of this brochure should be in “black italics.”
- Any function keys and menu items that are right clicked on this brochure should be in “[black italics].”

Precautions

- This device should conform to the requirements of emission and anti-interference specified in IEC 61326-1:2012 and IEC 61326-2-6:2012.
- This device is designed and tested according to class A devices in CISPR 11:2015/AMD1:2016 and its use in places other than those specified for class A devices is prohibited.
- It is recommended to evaluate the electromagnetic field before using this device.
- The use of this device near a strong radiation source (e.g., non-shielded radio source) is prohibited or the normal operations of the device may be interfered with.
- Use of the device must follow the advices of the manufacturer. The repair and maintenance must be performed by manufacturer.
- Refer to the instructions of related reagents for the management method and using method of related reagents and reference substances, etc.
- The brochure must be thoroughly read before using this device and it cannot be used unless the brochure is completely understood.
- Please keep the instructions for use in an easily accessible place for convenient reference.
- Any parts and reagents must be supplied by manufacturer.

The specific antibodies are produced gradually by the immune response system when infected with SARS-CoV-2. A few days to 2 weeks after the onset of symptoms, the specific IgG antibodies can be detected. The results may vary by time when specimens are collected. The presence of IgG antibodies is indicative of patient having been infected in the past, recovered from the disease and possibly become immune.
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Part 1: Device Description

1. Product Overview
The SuperFlex™ Automated Chemiluminescence analyzer is a fully-automatic chemiluminescence immunoassay platform integrating specimen processing, incubation, separation and rinsing and testing. All applicable reagents are in single use aliquots, and must be used immediately after opening to avoid contamination. The test delivers easy operations, no contamination, stable performance, and accurate test results.

2. Description of Functional Mode

2.1 Main Product Structural Composition
The device is composed of sample-loading module, reading module, magnetic bead processing module, reagent strip loading channel, control system and software component (version No.: 1.0)

The device structure is as shown in the following figure:

In addition to the above internal hardware, the outer shell of the instrument is fixed on the internal hardware, and the shell can only be removed by specific tools. All tools shall be kept by the manufacturer, and users shall not remove the shell by themselves. The manufacturer shall not be responsible for the damage of the instrument or other consequences caused by the removal of the shell.

2.2 Intended Use
The product is based on an acridine ester direct chemiluminescence method, which is used with PerkinElmer assays to perform qualitative or quantitative detection of analytes in human serum, plasma, and whole blood samples, including microbial assays (whole blood, serum and plasma), hormone assays (serum) and myocardial diseases assays (serum and plasma).
2.3 Reaction Mechanism
As a very effective chemiluminescence marker, Acridinium ester has the following main advantages:

- Low background luminance and high signal-to-noise ratio
- Less interfering factors against luminance reaction
- Swift and concentrated light emission, efficient and intensive luminance
- Being easily bound to protein, with photon productivity not reduced after the binding
- Stable markers

The SuperFlex™ platform is able to produce magnetic bead-antigen/antibody-test substance-antigen/antibody-acridine marked complex with the magnetic bead coated with an antibody or antigen on the surface as reaction solid-phase carrier and acridinium ester as chemiluminescence marker after going through the “one-step method” (one incubation) or “two-step method” (two incubations) and magnetic separation process according to the important property of the specific/exclusive binding of antigen to the antibody. It is a fully-automatic chemiluminescence platform to assay the contents of specific substance (test substance) in a certain specimen by collecting the signal with a photomultiplier tube according to the relationship between the signal and concentration of test substance (In the sandwich method, the concentration of the test substance is positively correlated to the test signal, and in the competition method, the concentration of test substance is negatively correlated to the test signal).

A strict experimental method must be formulated and followed for the measure to assay trace a substance and the simplified experimental procedure is shown as the following diagram (The steps in the doted box may be repeated for several times according different experimental items):

The SuperFlex™ device automatize the procedure, improving accuracy and reducing the workload.

2.4 Applicable Reagents
This device is used in combination with PerkinElmer assays.
3. Warning Marks

- General Warning Symbol: In vitro diagnostic medical device
- Corrosive substance: Consult instructions for
- Sharp element: Protective earth (ground)
- No reaching in: Manufacturer
- Biological RISKS: Serial number
- Refer to instruction manual/booklet: Authorized representative in the European Community
- Wear protective gloves

4. Technical Specifications & Properties

4.1 Device Parameter
1. Sample loading quantity: 24 samples
2. Testing channels: 12 channels
3. Software operating environment
   - Support software: database SQLite
   - Hardware configuration: CPU basic frequency over 2.9 GHz
   - Internal memory: over 4 G
   - Hardware: over 150 G
4. Footprint (Length × Width × Height): ~ 792 mm × 670 mm × 615 mm
5. Net weight: 78 kg
6. Fuse protector: T5AH 250V
7. Input power: 800 VA
8. Working noise: 55 dB

4.2 Working Environment
1. Indoor use;
2. Atmospheric pressure: 85.0 kPa ~ 106.0kP
3. Power supply voltage: 220 V ~240V;
4. Frequency or frequency range: 50 Hz
5. Voltage fluctuation: the voltage fluctuation of power supply should not be higher than ±10% of nominal voltage;
6. Power or rated electric current: 800 VA;
7. Environment temperature: 15°C - 30°C;
8. Relative humidity: 35% - 70%;
9. The elevation does not exceed 2000 meters;
10. Transient overvoltage class: II;
11. Rated contamination grade: 2;
12. Keep away from strong electromagnetic field interference;
13. Keep away from direct strong sunlight;
14. Have a good grounding environment.
15. Instrument power sockets and computer power sockets need to be independently plugged into different network power supplies
16. Type of device: desktop device
17. The tabletop can bear more than 320 kg
18. Desktop size: 600 mm deep * 1100 mm wide
19. Ventilation conditions: the left, right and rear sides shall be 150 mm or more away from the obstacles.
20. Optional wireless mouse keyboard and touch screen

4.3 Effect of Wastes on the Environment

- This device is equipped with special waste tip carton which is used to store waste tips; the tips cannot be used for a second time, and they should be disposed after use to avoid causing pollution.
- The reagent strips and magnetic rods jackets should not be re-used. They should be disposed of at the end of each experiment to avoid causing pollution.
- During the operations of the device, there may be leakage of a small amount of excitation liquid in the waste box.
- All of the above hazardous waste must be disposed of as infectious waste products! Handle according to local laws and regulations.
- Normal lifespan of this instrument is 10 years (from the delivery from the factory) and it can be prolonged if the device is properly maintained, used, and repaired by the manufacturer or his agent. After the device is declared useless, the manufacturer or his agent should be contacted to be dispatched by specialized personnel for disposal.

4.4 Device Performance

4.4.1 Accuracy and repeatability of sample loading

<table>
<thead>
<tr>
<th>Volume of sample loaded (V)</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bias</td>
</tr>
<tr>
<td>( V \leq 10 , \mu L )</td>
<td>Not beyond ± 1 ( \mu L )</td>
</tr>
<tr>
<td>( 10 , \mu L &lt; V \leq 50 , \mu L )</td>
<td>Not beyond ± 10%</td>
</tr>
<tr>
<td>( V &gt; 50 , \mu L )</td>
<td>Not beyond ± 5%</td>
</tr>
</tbody>
</table>

4.4.2 Accuracy and repeatability of loading of excitation liquid

a. Load 200 \( \mu L \), with the bias not beyond ± 5\%, and coefficient of variance (CV) \( \leq 3\% \).

4.4.3 Accuracy and fluctuation degree of temperature control in reaction area

a. The bias of the temperature of reaction area should be within ± 0.5°C of set value (35°C - 40°C.), and the fluctuation degree should not be higher than 0.5°C.
4.4.4 Device noise
   a. It should not be higher than 200 (after PMT calibration).

4.4.5 Linear range of luminance value
   a. Within the range no less than 3 times other luminance value, the linear coefficient of variance \( r \) is \( \geq 0.99 \).

4.4.6 Repeatability of luminance value
   a. For the luminance reagent method, the coefficient of variance (CV) should not be higher than 5%.
   b. For the reference luminance source method, the coefficient of variance (CV) should not be higher than 3%.

4.4.7 Stability of luminance value
   a. For the luminance reagent method, the change of luminance value should not be higher than 10%.
   b. For the reference luminance source method, the change of luminance value should not be higher than ±5%.

4.4.8 Magnetic bead recovery
   a. Magnetic bead recovery is > 75%.

4.4.9 Intra-batch accuracy of clinical items
   a. Intra-batch measurement repeatability (CV, %) is \( \leq 8\% \).

4.4.10 Warning function of sample loading abnormality
   a. Warning function to detect the existence of tips;
   b. Warning function of tip blockage;
   c. Warning function of the absence of sample.

4.4.11 Warning function of extraction module abnormality
   a. Warning function to detect the existence of the magnetic rod jacket

4.4.12 Warning function of excitation liquid abnormality
   a. Warning function of excitation liquid insufficiency

4.4.13 Function of bar code identification
   a. Function to identify the bar code of reagent strip;
   b. Function to identify the bar code of sample.

4.5 Software Function

4.5.1 User access control function
   a. The software provides a login interface, and the user is unable to operate the device before a successful login;
   b. The software supports both normal user and engineer by providing 2 access rights for the operations user and device manager;
   c. The software supports the correction of password.
4.5.2 Data interface function
   a. It provides LIMS (or HIS, etc.) data interface to support the access to shared folders through standard Ethernet.

4.5.3 Device control function by the software
   a. The software controls the device to carry out item setting, module operation, information inquiry, data process, consumable/waste status reminder, and fault reminder, etc.

4.5.4 Software upgrade and installation
   a. Software upgrade and installation are performed by specialized personnel. Individuals not authorized by PerkinElmer are not allowed to upgrade and install the software.

4.5.5 Software version
   a. Software issuance version 1.0

4.5.6 Precautions for the use of the software
   a. The software should only be operated by specialized personnel. Only qualified properly trained people can operate the software.

4.6 Input and output connections
   a. If 4.3 & 4.4 are met, the input-output connector can be safely operated without additional specifications.

5. Device Installation
The device should only be installed by the manufacturer or authorized agent. Install according to the installation SOP.

**WARNING:** To avoid the risk of electric shock, this instrument must only be connected to a supply main with a ground. An appliance coupler is intended to be used as isolation device from supply mains, do not position the device so that it is difficult to operate the isolation device.
Part 2: Instructions for Use

WARNING:
- The sample area may be biohazardous and the reagents are corrosive. You are strongly encouraged to wear powder-free latex gloves when operating the SuperFlex™ instrument.
- When loading or unloading reagent and samples, if skin comes in contact with liquid, immediately rinse with water for 5 minutes. If the skin is broken also see a doctor. In case of accidental splashing of liquid into the eyes, flush eyes with water immediately for 5 minutes and see a doctor immediately.
- Stop the moving parts before loading or unloading reagents and samples.
- Any waste boxes and their contents used reagent strips and magnetic rod jackets should be disposed of as infectious sources!
- Using the instrument without conforming to these requirements may damage the protector supplied with the device.
- The use of the device is in a manner not specified by the manufacturer may impair the protection provided by the device.

6. Flow Block Diagram for the Use of the Device

Connect properly the device, computer and display

Turn on the SuperFlex software

Successful re-set of the initialization of the device system

Start preparatory work according to the item information

Loading

End of operation

Data query

End of the experiment, unloading and waste disposal

Turn on the main switch of the device, switches of the computer and display

Enter the user’s name and password

Item setting

Item loading

Operation

Operation

Data analysis and uploading

Quit the SUPERFLEX software system
7. Turning on/off the Device

7.1 Confirm Power Supply Signal Input /Output Connection
The power socket and device main switch are as shown in following figure.

When replacing the power cord, the manufacturer or the agent shall be consulted for the specific model. The user shall not replace the power cord by themselves.

If the computer recommended by the company is used, the computer input/output connection method can be as shown in following figure.
• While connecting the instrument, neither the computer nor the instrument should be on.
• Make sure the grounding is reliable when connecting the instrument.
• When the instrument is installed, a power supply board with surge protector shall be used.
• The maintenance department shall check all fasteners of the equipment weekly to ensure they are not loose. The user shall confirm that all fasteners are not loose or abnormal. Then the instrument can be plugged in.

7.2 Turning on the Device
• Turn on the main switch of the SuperFlex™ instrument
• Turn on the computer and display.
• Initiate the software.
Warning: Do remove the fasteners from the moving parts in the device before the instrument is first turned on or the engine may be damaged.

7.3 Turning off the Device
Turn off the SuperFlex™ instrument using the following steps.
• Turn off the software.
• Turn off the main switch of the SuperFlex™ instrument.
• Turn off the computer.
Caution: Please pull out the connector of the power supply line from the device appliance inlet after turning off the device.

8. Prep Work

8.1 Inspection of Device Connection
Check if the electrical connection is properly connected before using the device.

8.2 Waste Box
Empty the waste carton before using the device.
Caution: Dispose of the waste carton and its contents as infectious material! In order to prevent biological hazards and chemical hazards, please put on protective gloves before the operating the instrument. Training should be provided for the prevention of the biological hazards and chemical hazards.

8.3 Excitation Fluid
Check if the excitation fluid is sufficient before using the device.
The assembly of the excitation fluid bottle is as shown in the following figure.
Warning: the excitation fluid is a strong alkali solution. Please wear protective gloves while touching or handling bottle spills or broken containers. Avoid splashing.
8.4 Sample
Check whether the samples are loaded before using the device. And confirm the reagents and calibrations are not expired.

9. Daily Operation and Using the SuperFlex™ Software
Warning: Ensure that all retaining hardware (e.g. screws, fasteners) are in place on removable protective barriers and the removable protective barriers are in place on the instrument during normal operation.

Warning: The device operator should not operate this device before receiving specialized training from PerkinElmer.

Warning: The test specimen should conform to the specimen requirements specified in the instructions for use of the test kits for all test items.

Warning: Loading and changing the excitation fluid, samples, unloading reagent bars and waste liquid boxes is a high-risk operation. Protective gloves must be worn to prevent infection or corrosion.

9.1 Test for Turning on the SuperFlex™ Software and Online Test
Turn on the main switch of the device before turning on the software.

Right click [SuperFlex] on the [Start]-[Program] of Windows, or double click the SuperFlex on desktop.

Click the icon to enter the user login interface (see following figure). Enter the user’s name and password, and then right click [Login]. The user’s name and password are set by the visiting installation engineer of the device.

After successfully logging in, the device will state “Initiating” (see following figure).
In the initiation process, all moving parts will restore in order. The initiation of the device ends after successful restoration and the device enter the main interface (see following figure).

Note: After an engine restoration, all engines should be in a static state. If engines continue moving, the initiation and restoration have not been completed.

In the initiation of excitation fluid, there will be a discharge of a small amount of liquid to the waste collection carton.
9.2 SuperFlex™ Software Main Page

The main page is for the experiment operation and display of main window, including the working area, test tube area, result area, and consumables area.

9.2.1 Working Area

Current testing item

Current operation procedure, including 7 processes, namely, sample loading, mixing, liquid transferring, extracting, eluting, incubating and testing.

Status indicator lamp:
- Grey (Operation stops);
- Green (Normal operation);
- Red (Operation fault or stopping)

Start and stop buttons

Channel ID number
9.2.2 Result Area

![Result Area Diagram]

9.2.3 Consumables Area

![Consumables Area Diagram]

The tip carton is in locking status at present and click locking or unlocking.

- Unlocking
- Locking

- The number of remaining tips; after changing, click to restore to 96
- The area of remaining excitation liquid; after changing, click to restore to 100%
- The number of waste current tips; after emptying the tip carton, click clear for counting.

9.2.4 Specimen Area

![Specimen Area Diagram]

The second line of test tube rack 13-24,
The color displayed has the same meaning as above.

The test tube rack is in locking or unlocking state:

- Unlocking
- Locking

Click to pop up specimen input box to start scanning the specimen information.

The first line of test tube rack 1-12
Color displayed:
White: there is no specimen, or no scanning has been performed;
Grey: The specimen in test tube has been scanned;
Green: The specimen in test tube is being tested.
9.3 Conventional Operation

Warning! Precautions before using the reagents:

- The reagent box should be stored at 2 - 8°C.
- Before use, allow the reagents to warm to room temperature (refer to the instructions for use of the reagent).
- Do not use reagents and calibrations after the expiry date.
- Do not use reagents from different batches together.
- When loading the reagent strip, make sure there is a magnetic rod jacket on the reagent strip.
- Use powder-free gloves.

9.3.1 Operating Steps in the Presence of Data “Double-Pass”

Step 1: Take out the test tube rack and click to change from locked position to change to unlocked position.

Step 2: Place the test specimen in the test tube rack.

Step 3: Click the specimen area to pop up the specimen input box. Click “Confirm” at the end of scanning.

(If the device has been connected to the database system, the device will read the testing items required for the specimen from the database)

Step 4: Place corresponding reagent strips in the corresponding channels according to the software instructions.
Step 5: Click  or  to start the testing procedure for the operating items.

Step 6: At the end of the test, the results will be automatically saved in the database system. The results can also be inquired in the result area (See 9.2.2 for details). The results can also be inquired or exported by clicking (See 9.5 for details).

9.3.2 Operating Steps in the Absence of Data “Double-Pass”

Step 1: Take out the test tube rack and click in case of locking state to change to unlocking state  .

Step 2: Place the test specimen in the test tube rack.

Step 3: Click the place of the test specimen corresponding to the specimen loading area of the software, and the software will pop up a dialogue box. See following figure:

If the test specimen is in the position 1 of No. 1 specimen rack, please also click the corresponding place in the software.

Use code reader or manually input specimen number

Select the testing items required for the test specimen

Click to confirm
Step 4: Place corresponding reagent strip in corresponding channel as instructed by the software.

For example: The software states to place PCT reagent strip in channel 1.

Step 5: Click or  to start running the testing procedure of the operation item.

Step 6: Check the result area (See 9.2.2 for details) or click to inquiry or export the results (See 9.5 for details).

9.3.3 Operation Steps of Batch Input in the Absence of Data “Double-Pass”

Step 1: Take out the test tube rack and click to change from the locked position to change to the unlocked position .

Step 2: Place the test specimen in the test tube rack.

Step 3: Click the specimen area to pop up specimen input box and scan the specimen code. Click “Confirm” at the end of scanning.
Step 4: The software will state if there is no item information for the specimen.

Step 5: Click to pop up batch input window.

Step 6: Place the reagent strip in the corresponding channel as instructed by the software.

For example: The software states to place PCT reagent strip in channel 1.

Step 7: Clock or to start the testing procedure of the operating items.

Step 8: Check the result area (See 9.2.2 for details) or click to inquiry or export the results (See 9.5 for details).
9.4 Calibration Operation

Click in the main page to enter the calibration page.

Click to pop up the curve code input box of standard substance.
Read the 2-D code of the calibration curve on the calibration card with the code reader.

Click “Confirm”.
The software will automatically turn to the page of calibration curve.

**Check the status of the curve: whether the calibration is needed.**

If a calibration is needed for the curve, click \[\text{Curve calibration}\].

Input the S1 bar code information of the standard substance as instructed.
Place the calibration substance S1 to the stated position as instructed.

Input the bar code information of calibration substance as instructed.
Place the calibration substance S2 to the stated position as instructed.

The software will automatically turn to the main page. Place corresponding reagent to the designated channel as instructed by the software and click “Run.”
At the end of the procedure, the software will state that the calibration has succeeded. In the new calibration page, the calibration curve is generated, and the status of the curve is updated. See the following.

9.5 Results Inquiry
The user can enter the results inquiry page to check and export the testing results.
9.6 Log Inquiry
The user can enter the log inquiry page to check the operating information of the device. In case of any faults, the after-sales engineer can be communicated preliminarily according to the log information.

10. Maintenance

!!! NOTE

All maintenance work must be performed after the device is powered off with power cords (the instrument power cord and the computer power cord) pulled out. All shells must be screwed up after maintenance.

The maintenance of this instrument does not need special tools. The required tools and materials are:

A pair of pliers or a medical clamp, 70% ethanol, cotton gauze, distilled water, a cleaning cloth, latex gloves.

Maintenance is divided into daily maintenance, weekly maintenance, yearly maintenance and on-demand maintenance.

<table>
<thead>
<tr>
<th>Maintenance Type</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily maintenance</td>
<td>Maintenance items required at the end of a workday by user</td>
</tr>
<tr>
<td>Weekly maintenance</td>
<td>Maintenance items required at the end of a work week by user</td>
</tr>
<tr>
<td>Yearly maintenance</td>
<td>Maintenance items required at the end of one year by manufacture</td>
</tr>
<tr>
<td>On-demand maintenance</td>
<td>Maintenance items temporarily required for appropriate handling.</td>
</tr>
</tbody>
</table>
10.1 Daily maintenance

Before each experiment, please make sure there is a waste collection box in the instrument!

When the number of waste TIPs collected in the black waste collection box reaches the software setting value (generally 96 pieces), it will prompt you to discard the waste TIPs together with the black waste collection box.

If no prompt appears when there are waste TIPs inside at the end of a workday, the waste TIPs should also be emptied out of the waste collection box or be discarded together with the box.

10.2 Weekly maintenance

1. Make sure to power off the device after all the 12 channels come out and stop at the outermost position. Dip a cotton gauze into distilled water and wring it out. Use the gauze, with a pair of pliers, to wipe the middle and sides of the heating seat.

**NOTE!! The gauze must be twisted dry, and no water droplets or seepage can occur, otherwise it may cause short-circuited.**

2. Make sure to power off the device after all the 12 channels come out and stop at the outermost position. Dip a cotton gauze into distilled water and wring it out. Use the gauze, with a pair of pliers, to wipe the middle and sides of the heating seat.
10.3 Manufacture yearly maintenance

**Recommendation:** replace the trigger solution at least once every month.

The upper cover of the instrument should be opened for the following operations:

When the power is off, the upper cover of the instrument can be opened by unscrewing the two screws on the left and right hinges with a wrench.

1. Make sure to power off the device after all the 12 channels come out and stop at the outermost position. Dip a cotton gauze into distilled water and wring it out. Use the gauze, with a pair of pliers, to wipe the middle and sides of the heating seat.

2. Move the reading module to the suitable cleaning area and wipe the puncher with a gauze with 75% ethanol solution clamped by pliers.

**Note:** The puncher is very sharp, please do not touch directly with your hands!
3. There may be crystals or residual liquid in the drip tray. Wear a pair of protective gloves. Dip the cleaning cloth in 70% ethanol and wring it out. Use it to wipe off the crystals and residual liquid from the groove.

10.4 On-demand maintenance

1. When the instrument is in daily standby status, keep no foreign objects in the storage box.
2. It is recommended to disinfect and clean the user operation area with 75% ethanol solution every two weeks.
3. Generally, it is not necessary to disinfect the linear guide, the rotating shaft, and the roller block of the shaft, unless sample material or buffer solution overflows onto these components. In this case, clean them with 70% ethanol.
4. If the instrument will not be used for a long time (more than seven days), please replace the trigger solution with distilled water.

Click 5 times to thoroughly wash the piping system of the trigger solution. After that, install a clean, empty trigger solution bottle on the instrument, to keep the conduit of the trigger solution clean.
5. Before the device becomes unavailable due to the service or other reasons, disinfection and cleaning are required for the instrument. See the steps above.
6. If a hazardous substance leaks on the device surface or into the device, appropriate disinfection measures should be taken. For detailed operations, please contact the manufacturer or its agent.

11. Trouble Shooting

11.1 Solutions for Common Faults

<table>
<thead>
<tr>
<th>Fault manifestation</th>
<th>Cause analysis</th>
<th>Solution</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>The system cannot be properly connected</td>
<td>The device has not been turned on</td>
<td>Turn on the switch of the device</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Normal communication cannot be maintained between the software and the device</td>
<td>Keep the device on, and restart the software</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Poor contact of the CAN line</td>
<td>Re-insert the CAN line properly</td>
<td></td>
</tr>
<tr>
<td>The device cannot be started</td>
<td>The power line has not been properly connected</td>
<td>Re-connect the power line</td>
<td></td>
</tr>
</tbody>
</table>
11.2 Error Message

11.2.1 Page of Error Box

```
Error code
2102

Error description
MB_DOWNLOAD_Z
Communication timeout
```

Confirm to close the dialogue box

Abort

11.2.2.1 System Error

<table>
<thead>
<tr>
<th>Error code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>-1</td>
<td>Abnormality in reading the database</td>
</tr>
<tr>
<td>-2</td>
<td>Curve fitting failure</td>
</tr>
<tr>
<td>-3</td>
<td>Error in output parameters of curve fitting</td>
</tr>
<tr>
<td>-4</td>
<td>Error in standard curve data of curve fitting</td>
</tr>
<tr>
<td>-5</td>
<td>Abnormality in curve fitting diagram</td>
</tr>
<tr>
<td>-6</td>
<td>Insufficient tip quantity</td>
</tr>
<tr>
<td>-7</td>
<td>Error in specimen tube number</td>
</tr>
<tr>
<td>-8</td>
<td>Erroneous working flow</td>
</tr>
<tr>
<td>-9</td>
<td>Device powered restart</td>
</tr>
<tr>
<td>-10</td>
<td>Failure of initialization of test tube code reader</td>
</tr>
<tr>
<td>-11</td>
<td>Failure of initialization of reagent code reader</td>
</tr>
<tr>
<td>-12</td>
<td>Failure of reading specimen bar code</td>
</tr>
<tr>
<td>-13</td>
<td>Failure of reading reagent bar code</td>
</tr>
<tr>
<td>-14</td>
<td>Failure of reading standards curve bar code</td>
</tr>
<tr>
<td>-15</td>
<td>Failure of reading standards substance bar code</td>
</tr>
<tr>
<td>-16</td>
<td>No match of bar code item number</td>
</tr>
<tr>
<td>-17</td>
<td>User quits</td>
</tr>
<tr>
<td>-18</td>
<td>Insufficient volume of excitation liquid</td>
</tr>
<tr>
<td>-19</td>
<td>Report of position change of limit switch</td>
</tr>
<tr>
<td>-20</td>
<td>Absence of reference curve</td>
</tr>
<tr>
<td>-21</td>
<td>Calibration needed for standard curve</td>
</tr>
</tbody>
</table>
-22  No sufficient calibration points
-23  Failure of curve calibration
-24  The reading is zero
-25  Absence of effective curve
-26  Dark count exceeds the limit

11.2.2.2 Protocol Error
It is composed of 5 digits, the first 3 represent module and command, and the last 2 represent the error:

<table>
<thead>
<tr>
<th>Module</th>
<th>Command</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reading module</td>
<td>100</td>
<td>Read position change of X engine</td>
</tr>
<tr>
<td></td>
<td>101</td>
<td>Read channel change of X engine</td>
</tr>
<tr>
<td></td>
<td>102</td>
<td>Read position change of Z engine</td>
</tr>
<tr>
<td></td>
<td>103</td>
<td>Read drainage pump</td>
</tr>
<tr>
<td></td>
<td>104</td>
<td>Read testing order</td>
</tr>
<tr>
<td></td>
<td>105</td>
<td>Read switching valve</td>
</tr>
<tr>
<td></td>
<td>106</td>
<td>Read pump restoration</td>
</tr>
<tr>
<td></td>
<td>107</td>
<td>Read X engine restoration</td>
</tr>
<tr>
<td></td>
<td>108</td>
<td>Read Z engine restoration</td>
</tr>
<tr>
<td></td>
<td>109</td>
<td>Read acquiring voltage</td>
</tr>
<tr>
<td></td>
<td>110</td>
<td>Read setting voltage</td>
</tr>
<tr>
<td></td>
<td>111</td>
<td>Read acquiring version information</td>
</tr>
<tr>
<td></td>
<td>112</td>
<td>Read module optocoupler status</td>
</tr>
<tr>
<td></td>
<td>113</td>
<td>Read module unlocking X-axis</td>
</tr>
<tr>
<td></td>
<td>114</td>
<td>Read module unlocking Z-axis</td>
</tr>
<tr>
<td></td>
<td>115</td>
<td>Read return of module reset X</td>
</tr>
<tr>
<td></td>
<td>116</td>
<td>Read return of module reset Z</td>
</tr>
<tr>
<td></td>
<td>117</td>
<td>High voltage setting of reading module</td>
</tr>
<tr>
<td></td>
<td>118</td>
<td>High voltage reading of reading module</td>
</tr>
<tr>
<td></td>
<td>119</td>
<td>In-place testing of reading module</td>
</tr>
<tr>
<td></td>
<td>120</td>
<td>Speed governing puncture of reading module</td>
</tr>
<tr>
<td>Channel module</td>
<td>200</td>
<td>Engine restoration</td>
</tr>
<tr>
<td></td>
<td>201</td>
<td>Take magnetic sleeve</td>
</tr>
<tr>
<td></td>
<td>202</td>
<td>Take off magnetic sleeve</td>
</tr>
<tr>
<td></td>
<td>203</td>
<td>Mix magnetic beads</td>
</tr>
<tr>
<td></td>
<td>204</td>
<td>Elute magnetic beads</td>
</tr>
<tr>
<td></td>
<td>205</td>
<td>Extract magnetic beads</td>
</tr>
<tr>
<td>Channel module</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------------</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>206</td>
<td>Hole-site move of Y engine</td>
<td></td>
</tr>
<tr>
<td>207</td>
<td>Step-frequency move of engine</td>
<td></td>
</tr>
<tr>
<td>208</td>
<td>Step-frequency move of Y engine</td>
<td></td>
</tr>
<tr>
<td>209</td>
<td>Step-frequency move of Z engine</td>
<td></td>
</tr>
<tr>
<td>210</td>
<td>Engine control command</td>
<td></td>
</tr>
<tr>
<td>211</td>
<td>Y-axis data download</td>
<td></td>
</tr>
<tr>
<td>212</td>
<td>Z-axis data download</td>
<td></td>
</tr>
<tr>
<td>213</td>
<td>YZ-axis unlocking</td>
<td></td>
</tr>
<tr>
<td>214</td>
<td>Control mode switch</td>
<td></td>
</tr>
<tr>
<td>215</td>
<td>Version query</td>
<td></td>
</tr>
<tr>
<td>216</td>
<td>Magnetic sleeve testing</td>
<td></td>
</tr>
<tr>
<td>Temperature control module</td>
<td></td>
<td></td>
</tr>
<tr>
<td>300</td>
<td>Sensor testing</td>
<td></td>
</tr>
<tr>
<td>301</td>
<td>Multi-channel temperature setting</td>
<td></td>
</tr>
<tr>
<td>302</td>
<td>Temperature control setting</td>
<td></td>
</tr>
<tr>
<td>303</td>
<td>Multi-channel temperature reading</td>
<td></td>
</tr>
<tr>
<td>304</td>
<td>Single-channel temperature reading</td>
<td></td>
</tr>
<tr>
<td>305</td>
<td>Heating rod control</td>
<td></td>
</tr>
<tr>
<td>306</td>
<td>Single-channel temperature setting</td>
<td></td>
</tr>
<tr>
<td>307</td>
<td>Version query</td>
<td></td>
</tr>
<tr>
<td>Specimen-loading module XY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>400</td>
<td>Re-set of specimen-loading XY-axis</td>
<td></td>
</tr>
<tr>
<td>401</td>
<td>Move of specimen-loading XY-axis</td>
<td></td>
</tr>
<tr>
<td>402</td>
<td>Query of specimen-loading version</td>
<td></td>
</tr>
<tr>
<td>Specimen-loading module ZT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>500</td>
<td>Status of sampling module</td>
<td></td>
</tr>
<tr>
<td>501</td>
<td>Restoration of ZT engine</td>
<td></td>
</tr>
<tr>
<td>502</td>
<td>Take tips of sampling module</td>
<td></td>
</tr>
<tr>
<td>503</td>
<td>Take off tips of sampling module</td>
<td></td>
</tr>
<tr>
<td>504</td>
<td>Sampling</td>
<td></td>
</tr>
<tr>
<td>505</td>
<td>Discharge sample</td>
<td></td>
</tr>
<tr>
<td>506</td>
<td>Liquid level testing</td>
<td></td>
</tr>
<tr>
<td>507</td>
<td>Z-axis calibration</td>
<td></td>
</tr>
<tr>
<td>508</td>
<td>Pressure calibration</td>
<td></td>
</tr>
<tr>
<td>509</td>
<td>Liquid dilution</td>
<td></td>
</tr>
<tr>
<td>510</td>
<td>Take diluent</td>
<td></td>
</tr>
<tr>
<td>511</td>
<td>Tip testing</td>
<td></td>
</tr>
<tr>
<td>512</td>
<td>Version query</td>
<td></td>
</tr>
<tr>
<td>Error code</td>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>01</td>
<td>Failure of initialization of communication module</td>
<td></td>
</tr>
<tr>
<td>02</td>
<td>Communication overtime</td>
<td></td>
</tr>
<tr>
<td>03</td>
<td>Tip blockage</td>
<td></td>
</tr>
<tr>
<td>04</td>
<td>No liquid taken in the tip</td>
<td></td>
</tr>
<tr>
<td>05</td>
<td>Alarm of bubble in excitation liquid</td>
<td></td>
</tr>
<tr>
<td>06</td>
<td>Z-axis not properly implemented</td>
<td></td>
</tr>
<tr>
<td>07</td>
<td>Failure of X engine</td>
<td></td>
</tr>
<tr>
<td>08</td>
<td>Failure of Y engine</td>
<td></td>
</tr>
<tr>
<td>09</td>
<td>Failure of Z engine</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Failure of Z26 engine</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Failure of T engine</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Fail to take tip</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Fail to take off tip</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Test tube rack 1 not in place</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Test tube rack 2 not in place</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Tip carton not in place</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Fail to take magnetic sleeve</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Magnetic sleeve fall-off in operation</td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>Ineffective data read</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Fail to detect liquid</td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>Fail to detect tip</td>
<td></td>
</tr>
<tr>
<td>99</td>
<td>Fails</td>
<td></td>
</tr>
</tbody>
</table>
11.3 Solutions for General Faults

**Fault manifestations:**

**Fault cause:**

1. The communication cable plug at the device end becomes loose;
2. The device has not started up.

**Solution:**

1. Re-insert the communication cable plug at the device end;
2. Turn on the power of the device.

**Fault manifestations:**

**Fault cause:**

1. Fail to import information from the database;
2. Item information has not been set for the specimen.

**Solution:**

1. Contact maintenance engine or the management engineer of hospital database;
2. Input manually specimen item information (See 9.3.2 or 9.3.3 for details).

**Fault manifestations:**

**Fault cause:**

1. The bar code is unclear;
2. Code reader fault.

**Solution:**

1. Manually input code bar information;
2. Contact maintenance engineer.
11.4 Fire measures
If the device was burned, remove the power supply immediately, then use dry powder or foam extinguishers to extinguish the fire. If without these things, you can also use thick blankets or wet towels.

11.5 Integration into systems or effects resulting from special conditions
Additional equipment connected to the analyzer must comply with the respective IEC or ISO standards (e.g. IEC60950 for data processing equipment).

When additional equipment is connected to use, the accumulation of leakage current may cause the danger of security. If in doubt, consult your local representative or the technical service department.

Anybody connecting additional equipment to the analyzer is responsible for the configuration of the system and the system.

Local laws take priority over the above-mentioned requirements.

11.6 Maintenance safety
After-sales maintenance engineers, in accordance with the product instruction and maintenance manuals for equipment fault maintenance, will ensure maintenance safety, all shell parts fasteners installed, the fuse is correctly installed, and reliable grounding. After confirming the safety of the instrument, it can be used.

12. Transportation and Storage
Any transport means can be used for the packaged instrument, but make sure to prevent the instrument from being exposed to sunlight and rain, stacked under weights, exposed to chemically corrosive chemicals, exposed to hazardous gases with a temperature of -20°C - 55°C, and a relative humidity not higher than 93%. The instrument may be knocked loose during transportation. The installer shall check the grounding impedance to ensure it is lower than 0.1 Omron and check to see if any of the fasteners are loose. If any are loose, tighten them.

The device should be stored in a clean and well-ventilated site, with an environmental temperature of -20°C - 55°C, relative humidity not higher than 93%, away from the effect of sunlight, rain, corrosive chemicals, and hazardous gases. Generally, the storage period should not be longer than 6 months. Abnormal temperature and humidity fluctuations in the stored procedure may affect the instrument performance. The installer needs to confirm the relevant performance to ensure normal performance.

13. Others
13.1 Information to mitigate residual RISK
Ensure all members of the risk management team assessed the identified risks one by one and take preventive actions. According to the evaluation criteria in the risk management plan, all risks were reduced to an acceptable range. All the estimated risks are evaluated, and the actions are taken for the risks that must be controlled. After the actions are taken, the original risk level is effectively reduced, and all the residual risks are in the acceptable range, after taking measures, the newly introduced risks are effectively controlled and reduced to an acceptable level. The overall residual risks are acceptable. There is no need for users to take additional actions to mitigate residual risks.
13.2 Production Date and Service Life
See label for the manufacturing date.

The service life of the product under normal using conditions is 10 years (from the delivery date from the factory). If the device is properly maintained, used, and repaired, the service life can be extended after being confirmed by PerkinElmer or its agent. If the device is declared useless, contact the PerkinElmer or its agent for disposal. See the following table for the service life of key parts and components.

Note: This service life is determined according to the results of the module aging test. In the using process, the user should operate and store the product according to the requirements in the instructions for use. PerkinElmer should maintain and repair the product. After the maintenance and repair, the product that is confirmed to be able to maintain basic safety and efficacy can be used normally.

13.3 List of Accessories
Please ask the PerkinElmer or its agent for the specific model of the parts in the first table. Users are not allowed to change the parts by themselves. The second list includes required PerkinElmer's reagent kit.

13.4 After-sales Service
In case a machine breaks down, call PerkinElmer for repair; describing the problem in detail. An after-sales service support engineer will provide technical consultation and guidance and evaluate the type of service needed (visiting or delivered).

13.5 Maintenance Precautions
Do not dismantle the machine yourself or you may be hurt!

All parts and components for maintenance must be provided by PerkinElmer or its agent!

*Precautions: The user should not open the device casing!*

*Please contact the company immediately if problems arise!*

13.6 Contact Method
PerkinElmer, Inc
7050 Burleson Rd
Austin, TX 78744
PerkinElmer-AppliedGenomics.com

14. PRODUCT GURANTEE

14.1 GUARANTEE PERIOD
One year since the completion of installation

14.2 Guarantees
Problems caused by the defects in the design and manufacturing within the guarantee period will be repaired free of charge. PerkinElmer will take corresponding measures according to specific defects.
14.3 Not Guaranteed (No Responsibilities Assumed)

- The problem is caused by using the device in an environment other than the environment required in the instructions for use.
- The problem is caused by maloperation of the user.
- The problem is caused by moving, transporting and installation with incorrect method after installation.
- The problem is caused by arbitrary dismantling or remodeling.
- The problem is caused by using the hardware, software or consumables other than those provided by our company.
- The problem is caused by inappropriate maintenance.
- The problem is caused by the aging and failure of the circuit board and original components caused by strongly corrosive gas in the air.
- Please use the device according to the method specified in the instructions for use or the protection provided by the device may be hampered.
- The use of equipment not conforming to the method as required or accessories not provided or recommended by the manufacturer may damage the protection provided by the equipment.

14.4 Rights to Correct the Instructions for Use

The instructions for use may be altered without advanced notice.

Appendix Device Boundary Dimension

(Some sizes may change without notice.)
For more information contact: COVID-19.TechnicalSupport@PerkinElmer.com