Product Manual

Veterinary Chemistry Analyzer

element RC

Thank you for choosing the element RC fully automated dry biochemistry analyzer.

This manual is configured to provide you with the following instructions:

Features, dimensions, principles of measurement, instructions for use, maintenance, packaging, storage, and shipping. Please review this instruction manual carefully before use. To ensure analyzer performance, please note all Warning, Caution and Prompt messages.

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SECTION 1: USING THIS MANUAL

1.1 Scope of Application

Those qualified to use this analyzer include:

1. Users who received operation training from qualified scil personnel.
2. Users who received the operation training from authorized distributors of scil.

scil reserves the right to revise the instructions and issue software updates.

No individual or organization may reproduce, modify or translate the contents of this manual without the written consent of scil.

scil has the final interpretation of the contents of this manual.

The illustrations used in this manual are shown as representative samples, which may differ from the actual products. If there is any difference, the physical product shall prevail.

Be sure to use the analyzer in accordance with the conditions specified in this manual. Failure to do so may result in failure of analyzer or inaccurate test results.

1.2 Warning and Safety Symbols

	WARNING	This information should be followed to avoid potential harm. Please refer to any symbols in this manual.
	CAUTION	All safety precautions and cautions listed in this manual must be followed.
	IMPORTANT	Important prompt message during operation.
	BIOHAZARD	Hazardous blood sample and test kits may be present during operation. Use proper protective gear.
	Grounding Protection	Do not modify the ground.

1.3 element RC Analyzer Use

Follow the instructions below before operation:

- ❖ Please check the analyzer contents and packing list.
- ❖ Please read documents included with the analyzer.

WARNING

The analyzer should be protected from working in humid and corrosive environments. Do not use flammable or explosive gas around the equipment.

Do not remove covers or other parts that are secured with screws to avoid electrical shock that may result from exposure to hazardous voltage or injury from moving parts.

Wear protective gloves, lab coat and safety goggles.

It is the user's responsibility to provide a compatible electromagnetic working environment to ensure the analyzer will perform as intended.

The analyzer complies with the requirement of equipment emission and immunity in GB/T 18268. The analyzer is designed and tested according to Class A equipment in GB 4824.

Do not use this analyzer near strong radiation sources (such as unshielded FR sources), as this may interfere with the normal operation of the analyzer.

CAUTION

Avoid installation locations where water may splash on the equipment.

Plug the power cable into an outlet with a grounding receptacle. Electrical shock may occur if the equipment is not grounded to a protective earth.

Make sure that all cables have been properly connected.

BIOHAZARD

When handling samples (blood) and cleaning or maintaining the analyzer, always follow the biohazard procedures in accordance with the sample handling rules of your facility.

Use proper protective gear (gloves, lab coat, safety goggles).

Used consumables such as rotors, tips, tubes and cloths used to clean the equipment are infectious waste. Process this waste in compliance with any applicable local, state or country regulations.

When discarding the analyzer that may be contaminated with blood samples, follow applicable regulations for your country and dispose of appropriately.

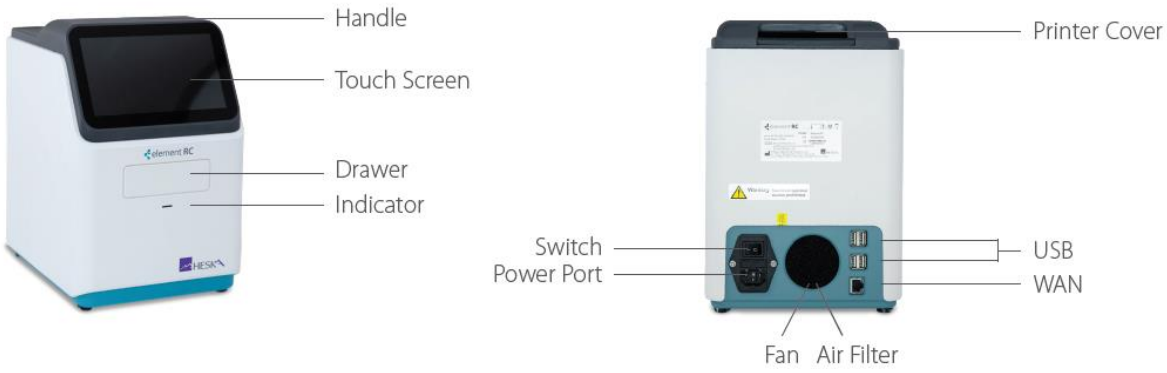
1.4 Compliance with Safety Measures

For using analyzer safely and efficiently, please observe the following precautions:

1. Avoiding failure of analyzer
   The installation environment of the analyzer should meet the requirements of the installation environment in this manual.
2. Preventing electric shock
   Do not open the shell of the analyzer without the authorization of scil and prevent the introduction of liquids into the analyzer. Please contact scil Technical Support Services with any questions. Ensure that the power cord is in good condition before use. Do not use a damaged electric cord to prevent electric shock.
3. Biohazard
   Protective gloves should be worn during biochemical testing operations to prevent biological contamination. If the blood sample is accidently touched, immediately rinse the contaminated area thoroughly under running water and disinfect.
4. Operating reagent rotor
   Reagent beads may contain corrosive substances, follow the instructions strictly in accordance with the manual. The operator will not contact the reagent beads sealed in the reagent rotor during normal use unless the reagent rotor fails. If reagent beads are released, avoid direct contact with reagent rotor and avoid breathing reagent dust.
5. Disposing reagent rotor
   Used reagent rotors should be disposed of in accordance with applicable regulations.

SECTION 2: INTRODUCTION

2.1 Analyzer Appearance



2.2 Basic Introduction

Product name:	Fully automated dry chemistry analyzer
Model:	element RC Veterinary Chemistry Analyzer (element RC Analyzer)
Size:	7.87" (200 mm) width x 9.92" (252 mm) depth x 11.77" (299 mm) height
Weight:	10.1 lbs (4.6 kg)
Accessories:	Power cable, Mini-pipette

The element RC Analyzer features simple operation. The analyzer requires Li-Hep whole blood, Li-Hep plasma or serum sample. Required sample volume is 100µl. Automatic sample analysis is completed by pipetting patient sample in the test rotor and loading into the analyzer.

The element RC Analyzer will report results after 12 minutes of analysis. The analysis results are automatically displayed and printed after the analysis is completed. Furthermore, the results are transmitted to the practice management software if the instrument is connected.

The Analyzer has four USB ports for connecting external printers, a mouse, keyboard, or other supported devices.

2.3 Detection Principle

element RC Analyzer is a bio-based analyzer with microcomputer. It is used in conjunction with the available test rotors to detect the concentration of biochemical substances in the patient sample, and utilizes the corresponding methods of end- point, rate, two-point method, and the eight-segment wavelength synchronous detection.

element RC Analyzer uses the principle of absorption spectroscopy. The absorption spectrum is mainly used for biochemical reaction tests, and its working principle is as follows:

Multiple sets of detection reagents are pre-loaded in the test rotor to form an independent reaction chamber. The patient sample is added to the test rotor, and then the test rotor is placed in the analyzer. The system is controlled by the computer processor, and the biochemical substance in the blood enters the individual reaction chambers and chemically reacts with the corresponding specific reagent to produce a color change. The absorption spectrum is used to detect the change, and the calculation is performed by the analyzer computer to determine the concentration of the biochemical substance present in the patient blood sample. The turbidimetric method is mainly used for detection with immunochemical tests, and the working principle is antigen/antibody complex. After binding, an immune complex is formed, and the turbidity of the complex polymerization occurs within a pre-defined time frame. When light passes through the solution, it can be absorbed by the immune complex. The higher the immune complex, the more light is absorbed. The amount of light absorbed is proportional to the amount of immune complex within a certain range. The absorbance value is measured by the optical path component transmission, and the content of the complex is proportional to the absorbance value. Similarly, when the amount of the antibody is constant, the absorbance value is also proportional to the antigen content, and the concentration and the content of the immune complex are analyzed to determine the concentration of the immune complex.

2.4 Analyzer Structure and Components

The analyzer consists of the machine shell, core components, thermostatic temperature control components, a two- dimensional bar code scanning acquisition component, printer component, optical path component, LCD capacitive display+ touchpad, operating software and a power cord.

The analyzer is compact, lightweight and easy to transport.

Analyzer components:

- An outer plastic shells.
- A variable speed motor that controls the rotation of the test rotor (machine core components).
- A photometer for testing the concentration of substances in a liquid (light path components).

- Two microprocessors for controlling instrument and processing test calculations (Constant temperature, temperature control components, and two-dimensional bar code scanning acquisition component).
- A thermal printer for printing results (printer components).
- 7.0-inch color capacitor multi-touch screen (display screen).
- Multiple selection features related to testing and results processing (operating software).

2.5 Analyzer Function

- 7.0-inch touch screen, Android operation system with multi-language support.
- Single channel test, no cross contamination.
- Advanced optical inspection system, built-in 8 wavelength filters: 340, 405, 450, 505, 546, 600, 630, 850 nm
- Test methods: End point, rate, fixed time.
- Sample information storage can be satisfied with customer information storage demand.
- Intelligent real-time quality control guaranteed accurate test results.
- Support for external mouse and keyboard (USB).
- Built-in thermal printer.

2.6 Scope of Application

The element RC is suitable for biochemical analysis of Li-Hep whole blood, Li-Hep plasma and serum when used in conjunction with the available test rotors. It is for veterinary medicine use only.

2.7 Executive Standard

- The main performance indicators of this product are designed and manufactured in strict accordance with YY/T 0655–2008 "Dry Chemical Analyzer".
- The electrical safety of the product complies with the provisions of GB 4793.1–2007 (Safety requirements for electrical equipment for measurement, control and laboratory - Part 1: General Requirement). The environmental test of the product meets the requirements of GB/T14710–2009 (Environmental Requirements and Test Methods for Medical Electrical Equipment).
- This product meets the special requirements of YY0648–2008 medical equipment Section 2-101 of (Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use).

NOTE: Repeating any of the tests in GB 4793.1–2007 on the equipment may damage equipment and increase the risk of danger!

2.8 Electromagnetic Compatibility Statement

- This equipment complies with GB/T18268.1–2010 (IEC61326–1:2005, IDT) "Electromagnetic compatibility requirements for electrical equipment for measurement, control and laboratory – Part 1: General requirements" and GB/T18268.26–2010 (IEC61326–2–6:2005, IDT) Electromagnetic compatibility requirements for electrical equipment for measurement, control and laboratory use Part 26: Particular requirements for in vitro diagnostic (IVD) medical equipment.
- The following usage requirements should be strictly observed during use, otherwise electromagnetic interference may be caused to other equipment or the electromagnetic interference resistance of the equipment may be reduced or even the basic performance may be lost.
- This equipment is designed and tested according to Class A equipment in GB4824. In a domestic environment, this equipment may cause radio interference and precautions may be required.
- Portable and mobile RF communications equipment may affect the description of medical electrical equipment: Portable and mobile RF communications equipment may affect the normal operation of this equipment, and portable and mobile RF communications equipment should be guaranteed to meet certain spatial distances. See Appendix A, “Recommended Isolation Distances Between Portable and Mobile RF Communications Equipment and Equipment.”
- It is recommended to evaluate the electromagnetic environment before the equipment is used. This equipment should not be used close to or stacked with other equipment. Except for cables, connecting cables and other accessories sold by the manufacturer as spare parts for internal components, the components cannot be replaced or repaired without permission. Otherwise it may cause excessive electromagnetic interference or disturbance.
- Do not use this device near strong radiation sources (such as unshielded RF sources) as this may interfere with proper operation of the device.

2.9 Technical Parameters

Sample type	Lithium heparin whole blood, Lithium heparin plasma and serum
Sample volume	100µl
Bar code	Two-dimensional bar code
Testing time	12 minutes/sample
Testing principle	Absorption spectroscopy, Transmission turbidimetry
Testing method	End point, Rate, Fixed time
Absorbance	0.001 Abs
Cross infection	0
QC & Calibrate	Real time Full-auto finish
Work environment	Temperature: 50ºF–86ºF (10ºC–30ºC) Humidity: 30%-70%
Light source	12 V/20 W, halogen tungsten lamp's life span is over 2500 hours
Power supply	AC 240 V, 50 Hz
Rated power	120 VA
Optic system	Back dividing light technology, 8 band wavelength synchronization detection: 340, 405, 450, 505, 546, 600, 630, 850 nm
Display	7 inch 800*480 multi-touch screen, Android system, Multi-language support
Storage	LAX 500,000 results
Printer	Built-in thermal printer
Connectors	4 USB, one network port
Weight	10.1 lbs. (4.6 kg)

SECTION 3: INSTRUMENT INSTALLATION

3.1 Operating Environment

To ensure optimal performance, the instrument should be installed in accordance with the following environmental conditions:

- Elevation not to exceed 6500 feet (2000 m)
- Temperature: 50ºF–86ºF (10ºC–30ºC)
- Relative humidity: 30%–70%
- Barometric pressure: 860 hPa ~1060 hPa.

The analyzer should be installed according the following conditions:

- Level, stable surface
- Temperature and humidity control
- Avoid direct sunlight or excessive heat
- Avoid sources of vibration or electrical noise and interference (bench top centrifuge)

Do not install the instrument in following conditions:

- Excessively high humidity, in the presence of corrosive gases, in dusty or unfiltered air, or near strong electromagnetic interference
- Without circulating air or adequate ventilation
- In direct sunlight or near other heat sources
- Unsteady or tilted work surface
- Near a centrifuge or other source of vibration or electrical noise

Requirements for power supply:

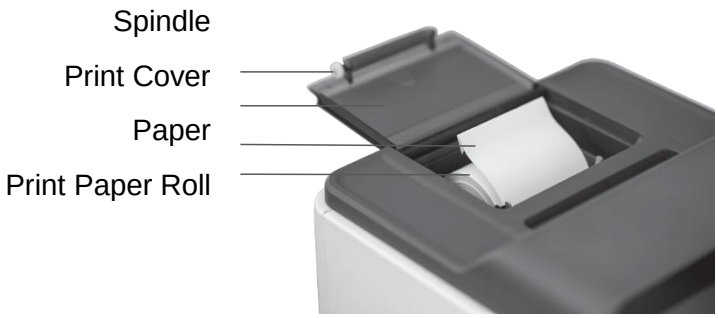
- AC 240 V, 50 Hz, rated power: 120 VA
- The instrument cannot use the same power supply socket with some high-power equipment including centrifugal, refrigerator, oven, *etc*.
- The power supply should earth well and connect the power supply with three-cores wire; the voltage between the neutral line and earth line < 5 V.

3.2 Installation

3.2.1 Installing the instrument

1. Remove the instrument from shipping carton and place it on a stable, level surface.
2. Inspect for any damage.
3. Connect the power cord to the analyzer.
4. Press the power switch at the back of the instrument, the indicator light will illuminate below the screen. The system will enter startup and perform a self-test.

3.2.2 Insert printer paper



NOTE: 50 x 57 mm thermal printer paper has been installed during analyzer installation.

Replacing printer paper

1. Open printer cover.
2. Remove printing paper packaging, then place into analyzer with loose end forward.
3. Hold the loose end and route paper under the outlet on the printer door.
4. Close the printer cover.

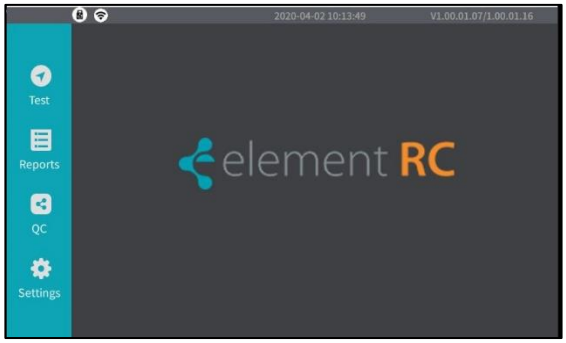
3.2.3 External printer

This analyzer is compatible with printers using HP PCL3 GUI printer language, HP Deskjet or other. Refer to your printer's owner manual for additional information.

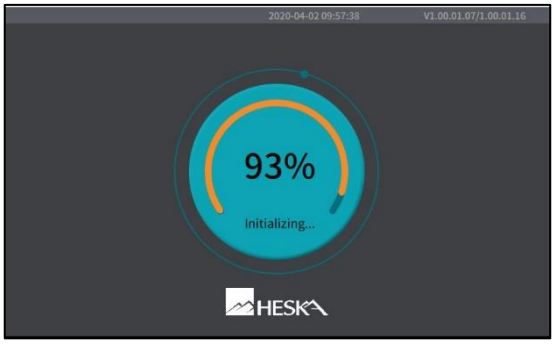
SECTION 4: COMMON OPERATIONS

4.1 Startup

Startup screen:



Initialization screen:

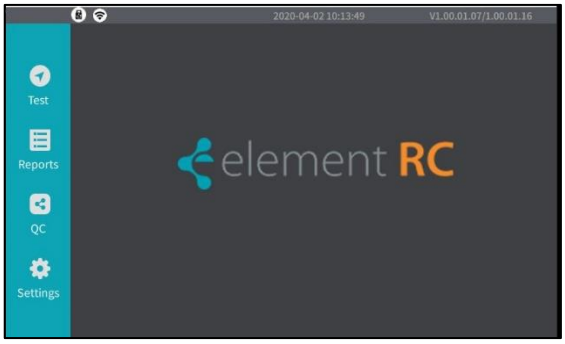


4.2 Commonly Used Buttons

The system will automatically enter the interface as shown below in figure 4-1 after analyzer starts up. Confirm the date and time on the top border is correct.

There are 4 main buttons on the touch screen interface.

1. Test
2. Reports
3. QC
4. Settings

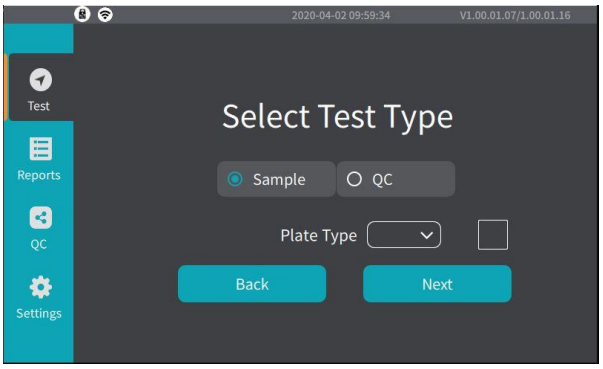


4.2.1 Main Screen Buttons

1. Test

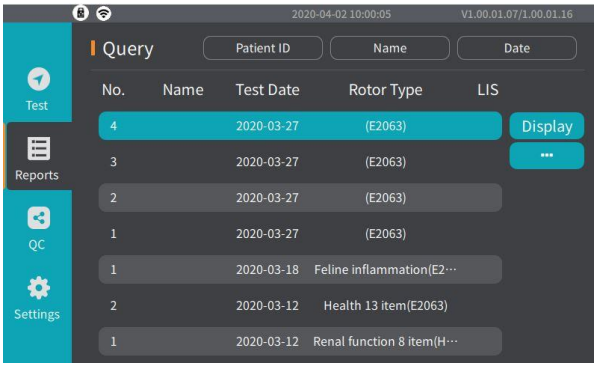
Run patient sample from this screen.

NOTE: Section 5.3 for further information.



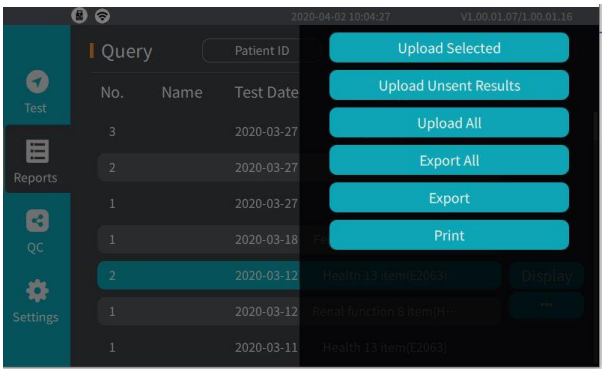
2. Reports

Review prior test results. Select a report and select Display to view results.



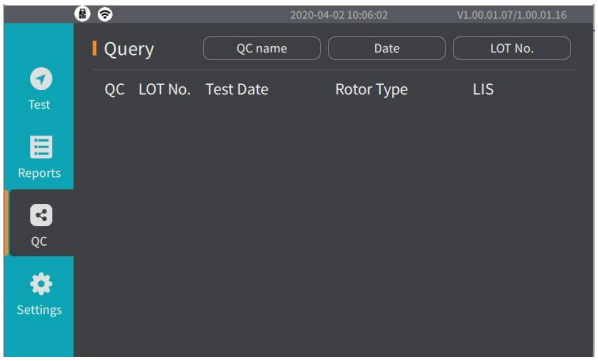
From the Reports screen, select "···" for additional options to the right.

Select Back to exit to Reports screen.



3. QC

Quality control sample lot information and target ranges can be added in the menu.



4. Settings

Configure the element RC Analyzer:

A. Information settings

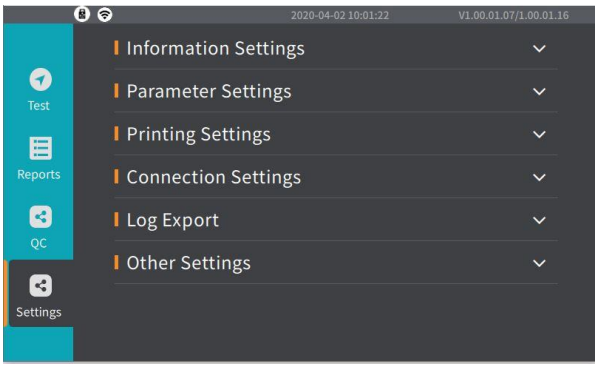
B. Parameter settings

C. Print settings

D. Connection settings

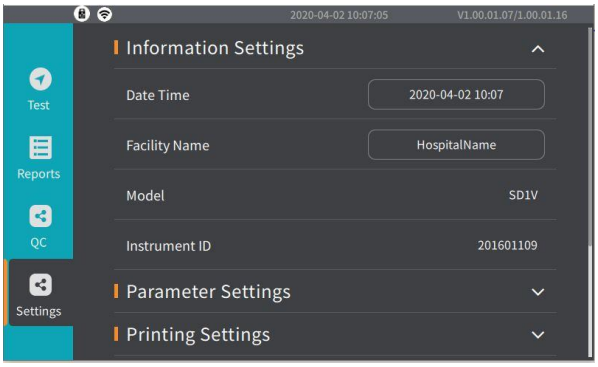
E. Log export

F. Others

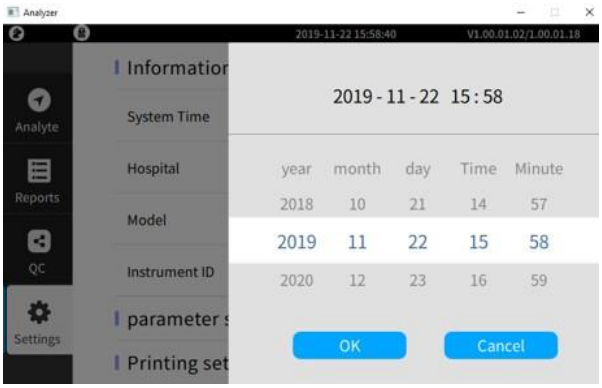


A. Information settings

Set analyzer date/time and enter clinic or hospital name.



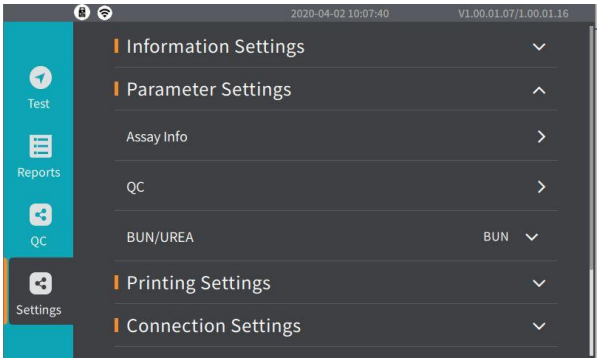
Select the box for System Time to make changes.



B. Parameter settings

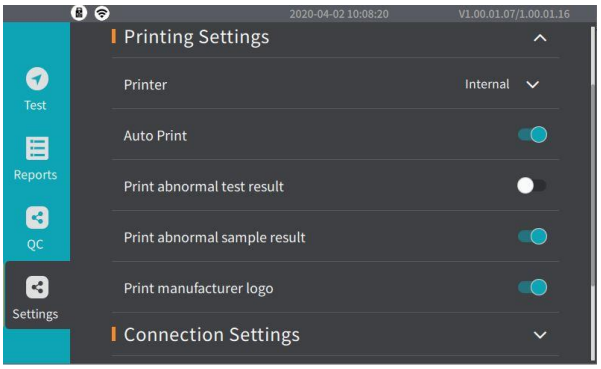
Change individual assays, such as units, reference ranges, *etc.*

NOTE: Do not make changes to parameters unless advised to do so by a scil representative.



C. Printing settings

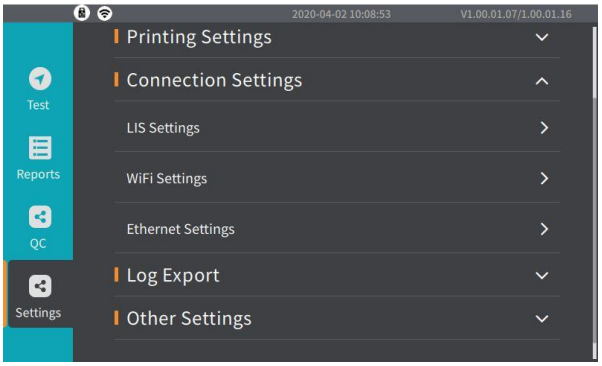
Select the internal printer and turn on automatic results printing.



D. Connection settings

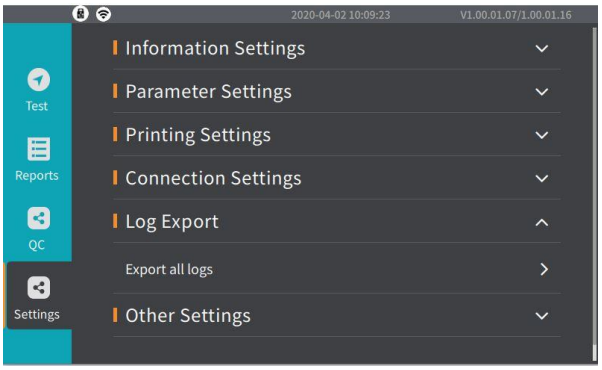
Select data transmission settings.

NOTE: Do not make changes to parameters unless advised to do so by a scil representative.



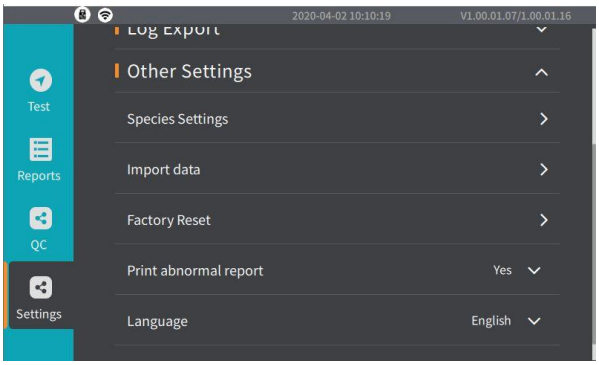
E. Log export

Export test result data to a USB device (U:drive). USB device should be FAT32 formatted.



5. Other settings

Do not make changes to parameters unless advised to do so by a scil representative.



4.2.2 Soft keyboard

The soft keyboard is a built-in keyboard. Users can select the field where information is entered and typed in the window, once the cursor starts blinking and the soft keyboard is activated.

SECTION 5: TESTING AND RESULTS

5.1 Sample Requirements

⚠ WARNING

Always follow biohazard procedures in accordance with the sample handling rules of your facility when handling samples (blood).

5.1.1 Sample handing

1. Collect whole blood sample using 22 g (or larger) needle.
2. Gently invert tube several times to ensure proper mixing of sample with lithium heparin.

⚠ CAUTION

- ❖ Whole blood must be analyzed or transformed to plasma and serum within 30 minutes after collection.
- ❖ Do freeze or shake the sample vigorously, this can hemolyze the sample.
- ❖ If the sample cannot be analyzed immediately after collection, it should be processed into serum or plasma and stored in sealed sample tube at -20°C. Avoid repeated freezing-thawing cycles.
- ❖ The patient should be fasted for 12 hours prior to glucose testing.
- ❖ Check the patient sample for clots or hemolysis. Avoid running icteric or lipemic samples. The analyzer has a built-in centrifugal function - testing will begin after the anticoagulated whole blood has been spun into plasma. Lithium heparin is the only recommended anticoagulant, as it will not interfere with on biochemistry analysis.
- ❖ Always wear proper protective gear when handling patient samples.

5.2 Test Rotor Preparation

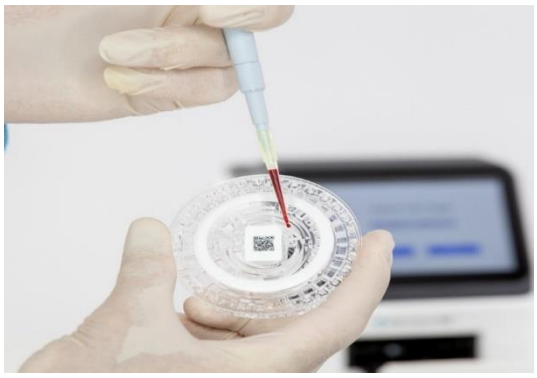
Test rotors are single use only. The rotors contain diluent at the center and separate tunnels leading to cuvettes with individual testing reagents to avoid cross contamination.

5.2.1 Reagent rotor storage and disposal

- Store test rotors in the refrigerator between 2–8°C.
- Remove test rotor from refrigerator and allow to warm up to room temperature for 20 minutes in sealed pouch prior to sample analysis.
- Test rotors in sealed pouches can be stored at room temperature for a maximum of 48 hours.
- Do not expose the test rotor to direct sunlight, or temperatures over 32°C.
- Remove test rotor from sealed pouch, hold the rotor by the edge only to avoid contamination. Test rotors should be used within 10 minutes after opening the sealed pouch. Once test rotors have been removed from the sealed pouch, they should not be returned to the refrigerator.
- Patient information can be written on the test rotor in the grey area.
- Avoid marking or damaging the barcode at the center of the test rotor.
- Insert test rotor into analyzer immediately after pipetting patient sample. Do not shake rotor after patient sample has been pipetted.
- Test rotors are single use only. Used test rotors should be disposed of in accordance with regulations.
- Damaged test rotors should be disposed of immediately. Avoid contact with reagents contained within rotors.

5.2.2 Pipette patient sample

1. Use the supplied 100µl pipette and disposable tip to pipette patient sample into the sample port.
   Fill the sample well to the fill line.



2. Pipette tips are single use, do not re-use to avoid sample contamination.

3. Hold the test rotor horizontally by the edges when insert into the analyzer drawer.

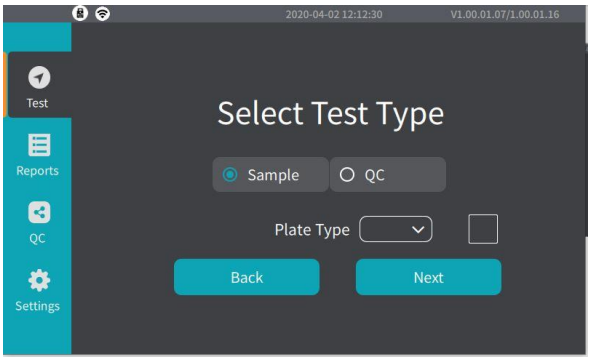
⚠ CAUTION

- ❖ Do not mark or damage QR code on test rotor.
- ❖ Do not touch pipette tip.
- ❖ Place pipette tip approx. 1/16 in (2–3 mm) below the surface of the sample when pipetting.
- ❖ Keep the pipette plunger pressed down until the pipette tip is removed from the sample port on test rotor.
- ❖ Clean any sample on test rotor or around sample port before placing test rotor in analyzer.

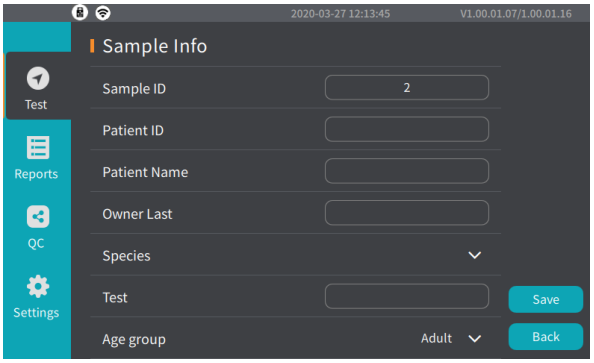
5.3 Sample Test

Turn on the analyzer, if it is not already powered on.

1. The element RC Analyzer will begin a self-check diagnostic.
2. The analyzer will warm the incubator to proper testing temperature, ~5 minutes.
3. From the Welcome screen, tap on **TEST**.
4. Tap on **WORKLIST** or **NEXT** to enter the patient information

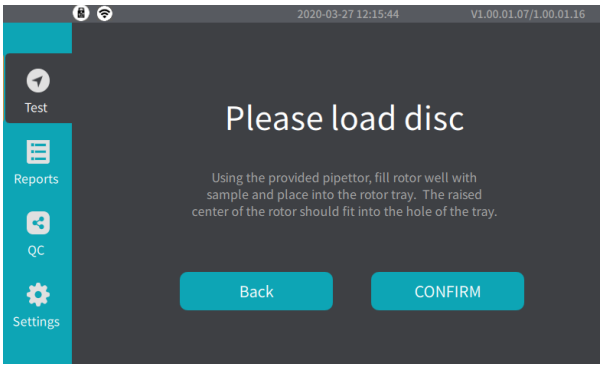


5. Enter the patient ID, select the species and sample type. Tap on **SAVE**

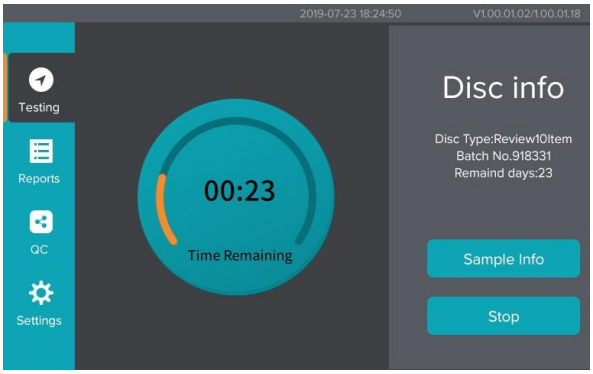


6. The drawer will open and the “Please load disc” page displays on the screen. Insert the rotor. Tap on **CONFIRM** and the drawer will close.

NOTE: Center the test rotor in drawer to avoid errors.



7. The analyzer scans the QR code on the test rotor and begins countdown. Patient information can be added by touching **SAMPLE INFO**.



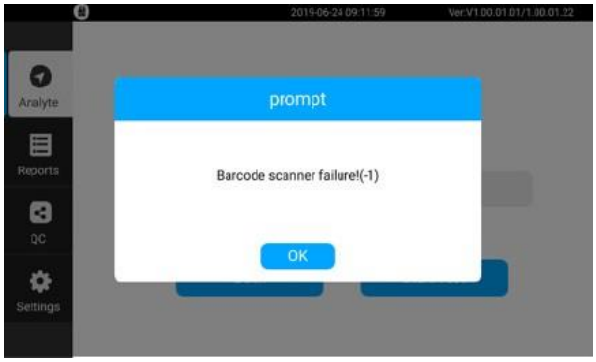
8. Touch **STOP** to terminate current patient sample analysis.
9. Touch **OK** when the test is terminated.

CAUTION

Test rotor and patient sample will no longer be valid after terminating testing.

NOTE: If QR code scanning is unsuccessful, the system will display a pop-up prompt.

If a barcode error prompt pops up, touch **OK** and remove the test rotor to inspect the QR code for damage or contamination. If the QR code is damaged the test rotor must be replaced.



10. When the test time has elapsed, the test is completed, and the test results can be viewed/transmitted/ printed.

5.4 Test Procedure Precautions

Analyzer

- Use grounded power supply and supplied power cord.
- Confirm the ambient temperature of the analyzer is 10ºC–30ºC.
- Do not disconnect power during operation.
- Close the drawer when the analyzer is not in use.
- Pinch hazard – keep fingers clear when analyzer drawer is opening and closing.
- Do not disassemble the analyzer.

Test Rotor

- Do not use expired test rotors. Check expiration date on sealed pouch.
- Store test rotors at 2ºC–8ºC. Use gloves when handling test rotors, handle test rotors by the edges.
- After pipetting patient sample, place horizontally to prevent overflow.
- Test rotors are single use; do not re-use.
- Test rotors must be used within 10 minutes of removal from sealed pouch.
- Analyze test rotor immediately after pipetting patient sample.

Sample

- Whole blood should be used within 30 minutes after sampling to prevent hemolysis.
- Do not place sample in the refrigerator or shake vigorously.

5.5 Print Results

5.5.1 Built-in printer print reports

Sample report

The results of the analysis are automatically stored, and the user can choose to print using the built-in printer.

The header information of the printed report includes: hospital name, patient name, medical record number, sample number, age range, gender, blood sample, test rotor ID, instrument ID, software version and test time.

The printed result section has four columns, profile name, test value result, reference range and units.

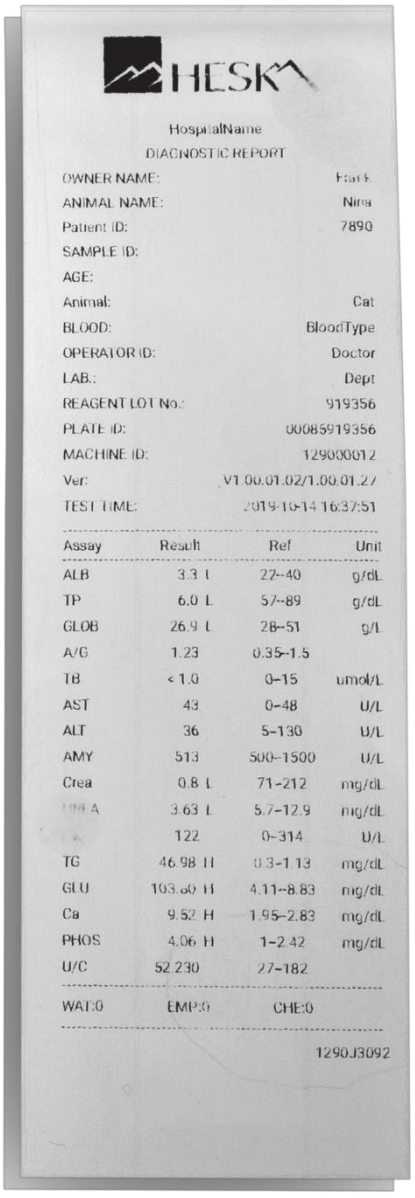
Results outside the reference range will be marked with H (high) and L (low) next to the result and will not be displayed until the header information of the printed report is filled out.

WAT= internal check of the sample volume
EMP= internal self-check
CHE= absorbance monitoring

represents a chemical monitoring hole absorbance. The above indicators are divided into three levels:

0—better 1—general 2—poor

When the WAT, EMP, and CHE indicator value is "2", please contact technical support for assistance.



HESKA

HospitalName
DIAGNOSTIC REPORT

OWNER NAME:	Frank
ANIMAL NAME:	Nina
Patient ID:	7890
SAMPLE ID:	
AGE:	
Animal:	Cat
BLOOD:	BloodType
OPERATOR ID:	Doctor
LAB.:	Dept
REAGENT LOT No.:	919356
PLATE ID:	00085919356
MACHINE ID:	129000012
Ver:	V1.00.01.02/1.00.01.27
TEST TIME:	2019-10-14 16:37:51

Assay	Result	Ref	Unit
ALB	3.3 L	22--40	g/dL
TP	6.0 L	57--89	g/dL
GLOB	26.9 L	28--51	g/L
A/G	1.23	0.35--1.5	
TB	< 1.0	0--15	umol/L
AST	43	0--48	U/L
ALT	36	5--130	U/L
AMY	513	500--1500	U/L
Crea	0.8 L	71--212	mg/dL
UREA	3.63 L	5.7--12.9	mg/dL
[illegible]	122	0--314	U/L
TG	46.98 H	0.3--1.13	mg/dL
GLU	103.60 H	4.11--8.83	mg/dL
Ca	9.52 H	1.95--2.83	mg/dL
PHOS	4.06 H	1--2.42	mg/dL
U/C	52.230	27--182	

WAT:0 EMP:0 CHE:0

1290J3092

SECTION 6: SERVICE AND MAINTENANCE

The element RC Analyzer requires minimal maintenance to ensure optimal performance.

6.1 Analyzer Cleaning

Air filter

Inspect air filter weekly. Clean as needed by removing and rinsing with water. Blot dry and replace.

Casing

Clean the outside of the machine as needed with a mild detergent and a soft wet cloth. Do not spray or pour any detergent or liquid directly onto the instrument. Dry the analyzer with a soft dry cloth.

Display

Wipe the display regularly with a damp, lint-free towel.

NOTE: Clean and maintain the test chamber regularly, based on usage.

6.2 Software Upgrade

The software may require periodic upgrades. This product supports USB flash drive or wireless network upgrade.

Please read the upgrade steps carefully before upgrading software. Confirm that the software upgrade package and software version is correct.

6.2.1 USB flash drive upgrade

1. Prepare a file system for the USB drive in FAT32 format. If the format is incorrect or cannot be confirmed, please format it on the computer and back up the data on the USB flash drive before formatting.
   USB drive formatting process: insert USB drive into the computer ► select the USB drive ► right click ► format ► select "FAT32" file system ► start ► confirm ► format completion prompt ► confirm.
2. Obtain the software compression package from scil's Technical Support Services.
3. Unzip the upgrade package to get the "upgradepackage" directory, which should be placed in the root directory of the USB drive.
4. Unplug the USB flash drive from the computer and plug it into the USB port on the back of the analyzer.
5. Turn on the analyzer or restart the analyzer.
6. The analyzer starts and the software prompts the version upgrade information. Make sure the upgraded version number is consistent with the version number of the software compression package, then touch [Yes]. The software will begin the upgrade.
7. During the software upgrade process, the user will be prompted to complete the upgrade. After the instrument upgrade is complete, the instrument will need to be restarted. Turn the analyzer off and on again.
8. After the software upgrade is completed, it is automatically initialized, and the upgrade is completed.

NOTE: If the upgrade fails [during upgrade], please restart the analyzer. If the upgrade is still unsuccessful, please contact scil Technical Support Services.

6.3 Troubleshooting

Description	Solution
W2021, W2022, W2023, W2024, W2041, W2051	Mixing error, check sample for proper mixing or use serum / plasma to rerun the test
E1002, E1003, E1023	Restart the analyser and rerun the test
E1012, E1024, W2061, W2062	The rotor or QR of the rotor is damaged Restart the analyser and rerun the test
W3001	Used rotor or damaged QC code Rerun the test with a new rotor
W3003	Sample distribution error caused by a severe lipemia or a high HCT Centrifuge the sample and use plasma or serum to rerun the rotor
M4002	The current rotor is not supported due to a low software version Check the date setting of the analyser Please contact the technical service and update the device
M5041	The rotor is expired Check the date setting of the analyser and rerun the test with a new rotor
M5002	Internal printer error check printer for proper loading of paper
M5021, M5022	external printer error check printer connection check printer for proper loading of paper

NOTE: Contact scil Technical Support Services for additional troubleshooting.

SECTION 7: PACKING, STORAGE AND TRANSPORTATION

7.1 Packing, Storage and Transportation

This instrument is packaged in a cardboard box outer shell and high-quality foam for shock protection. Do not stack the analyzer.

Transportation temperature: -20ºC–55ºC

Storage temperature: 0ºC–40ºC

Relative humidity: ≤ 85%.

Carton case symbols:

This Side Up	Fragile	Keep Dry	Stacking Limitation	Humidity UP 85%	Pressure 700-1060 hpa	For Use Within Temperature Limits	Recycled Package

SECTION 8: EXPLANATION AND RISK WARNING ON EMC

8.1 Explanation and Risk Warning on EMC

This product has passed the EMC test and meets GB/T 18268.1–2010 "Electromagnetic compatibility requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements" and GB/T 18268.26–2010 "Measurement, control and laboratory Electromagnetic compatibility requirements for electrical equipment - Part 26: Particular requirements for in vitro diagnostic (IVD) medical devices.

The following usage requirements should be strictly observed during use, otherwise it may cause electromagnetic interference to other equipment or reduce the anti-electromagnetic interference capability of this product, or even lose its basic performance.

This product belongs to Group 1 Class A equipment of GB 4824–2013 and is suitable for use in all facilities that are not directly connected to the public low-voltage power grid of the residential home.

Portable and mobile RF communications equipment may affect the description of medical electrical equipment: Portable and mobile RF communications equipment may affect the normal operation of this product, and portable and mobile RF communications equipment should be guaranteed to meet certain spatial distances and specific requirements. See the requirements in Table 4.

If the equipment cable connection is faulty, please contact our company for repair or replacement, otherwise it may cause excessive electromagnetic interference. If the equipment is faulty, please contact scil's Technical Support Services. Do not repair or replace the components yourself, otherwise it may cause excessive electromagnetic interference.

⚠ WARNING

In addition to the transducers and cables sold by the manufacturer of the equipment or system as spare parts for internal components, the use of accessories, transducers and cables outside the specified regulations may lead to increased emission or reduced immunity of equipment or systems.

⚠ WARNING

Devices or systems should not be used close to or overlay other devices. If they must be used close to or overlay, they should be observed to verify that they can operate normally under the configuration they are using.

This product belongs to professional IVD equipment and needs to pay attention to the following preventive warnings:

- The emission and immunity requirements specified in Tables 1 to 4 shall be met.
- It is recommended to evaluate the electromagnetic environment prior to use.
- Do not use this equipment near strong radiation sources (such as unshielded RF sources), as this may interfere with normal operation of the equipment.

Basic performance

The equipment should work normally, and the bias of glucose (GLU) test results should meet the requirements of 2.3 in the technical requirements.

Test method

Three measurements were made on the same quality control sample of GLU, and the allowable error was calculated according to the method listed in 3.3 in the technical requirements.

8.1.1 Operating Mode

Normal test mode: The device is powered on, and the GLU accuracy reagent disk is loaded for normal testing.

Table 1 – Guide and manufacturer's statement—electromagnetic emissions. The product is intended to be used in the electromagnetic environment specified.

Emission Test	Compliance	Environmental Guidance
Radio frequency emission GB 4824	Group 1	The product uses RF energy only for its internal functions. Therefore, its RF emissions are low and there is little possibility of interference with electronic equipment.
Radio frequency emission GB 4824	Class A	The product is suitable for use in all facilities that are not directly connected to the home and to the public low-voltage grid of the residential home.
Harmonic emission GB 17625.1	Not applicable	
Voltage fluctuation/ Scintillation emission GB 17625.2	Not applicable	

Table 2 – Guide and manufacturer's statement—electromagnetic immunity. The product is intended to be used in the electromagnetic environment specified.

Immunity test	IEC 61326 Test Level Guide	Coincidence level	Environmental Guidance
Electrostatic rotorharge GB/T 17626.2	±4 Kv Contact rotorharge ±8 kV Air rotorharge	±4 kV Contact rotorharge ±8 kV Air rotorharge	The floor should be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic materials, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst GB/T 17626.4	±1 kV to power cord	±1 kV to power cord	Network power supply should have the quality of use in typical commercial or hospital environments.
Electrical surge GB/T 17626.5	±1 kV Line to line ±2 kV Line to ground	±1 kV Line to line ±2 kV Line to ground	Network power supply should have the quality of use in typical commercial or hospital

			environments.
Voltage dip, short interruption and voltage change on the power input line GB/T17626.11	0%Ut, Continue 1 cycle (On Ut, 100% sag)	0%Ut, Continue 1 cycle (On Ut, 100% sag)	Network power supply should have the quality of use in typical commercial or hospital environment. If the users of this product need to run continuously during power interruption, it is recommended to use un-interruptible power supply or battery power supply.
	40%Ut, Continue 5 cycles (On Ut, 60% sag)	40%Ut, Continue 5 cycles (On Ut, 60% sag)	Network power supply should have the quality of use in typical commercial or hospital environment. If the users of this product need to run continuously during power interruption, it is recommended to use un-interruptible power supply or battery power supply.
	70%Ut, Continue 25 cycles (On Ut, 30% sag)	70%Ut, Continue 25 cycles (On Ut, 30% sag)	
	5%Ut, Continue 5s (On Ut, 95% sag)	5%Ut, Continue 5s (On Ut, 95% sag)	
EMF (50/60Hz) GB/T 17626.8	3A/m	3A/m	If abnormal work occurs, it is necessary to keep the product away from the power frequency magnetic field or install a magnetic shield in the place. The power frequency magnetic field in the anticipated installation site should be measured to meet the requirements below the level.

NOTE: Ut refers to the AC network voltage before the voltage is applied.

Table 3 – Guide and manufacturer's statement—electromagnetic immunity. The product is intended to be used in the electromagnetic environment specified.

Immunity test	**IEC 61326 Test Level Guide** **Test Level Guide**	**Coincidence level**	**Environmental Guidance**
Radio frequency conduction GB/T 17626.6	3V (Effective value) 150 kHz~80 MHz	3 V (Effective value)	Portable and mobile radio frequency communication equipment should not be closer to any part of the product than recommended isolation distance, including cables, which should be calculated using a formula corresponding to the transmitter frequency. Recommended isolation distance d=1.2 √P d=1.2 √P 80 MHz~800 MHz d=2.3 √P 800 MHz~2.0 GHz In formula: P—Maximum output rated power of the transmitter provided by the transmitter manufacturer in Watt (W). d—The recommended isolation distance is in meters (m). Fixed RF transmitter field strength, through the electromagnetic field survey to determine, each frequency range B should be lower than the level in line with. Disturbance may occur near equipment marked with the following symbol .
Radiated electromagnetic field GB/T 17626.3	3 V/m 80 MHz~2.0 GHz	3 V/m	

NOTE: For 80 MHz and 800 MHz frequencies, higher frequency band formulas should be used.

NOTE: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies. Fixed

transmitters, such as wireless (cellular/cordless) telephones and ground mobile radio base stations, amateur radios, AM/FM radio broadcasting and television broadcasting, cannot accurately predict their electric field in theory. In order to evaluate the electromagnetic environment of fixed radio frequency transmitter, the survey of electromagnetic field should be considered. If the measured product is located in a place where the electric field is higher than the above RF level, the product should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as reorienting the direction or location of the product. In the whole frequency range from 150 KHz to 80 MHz, the Electric field should be less than 3 V/m.

Table 4 – Recommended isolation distance between portable and mobile radio frequency communication equipment and products.

Maximum rated output power of transmitter W	**Isolation distance corresponding to different frequencies of transmitter/m**		
	150 KHz~80 MHz d=1.2√P	80 MHz~800 MHz d=1.2√P	800 MHz~2.0 GHz d=2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

The product is expected to be used in radio frequency radiation disturbance controlled electromagnetic environment. Depending on the maximum output power of the communication equipment, the buyer or user of the product can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile radio frequency communication equipment (transmitter) and the product.

For the maximum rated power of the transmitter not listed in the table above, the recommended isolation distance (d), in meters (m), can be determined by the formula in the corresponding transmitter frequency bar, where (P) is the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W).

NOTE: At 80 MHz and 800 MHz frequencies, the formula of higher frequency band should be adopted.

NOTE: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.

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