Operator's Manual:

Charm EZ® Lite

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Introduction

The Charm® EZ Lite System is a complete simultaneous incubator and analyzer system specifically designed for use with most Charm 3 and Charm ROSA® test strips. Results are interpreted based on a numerical scale and are stored in the Charm EZ Lite memory. Data can be printed, displayed on the Charm EZ Lite screen, or downloaded to a computer system in a real time or post analysis mode.

Firmware version 0.98 or higher

OM-612-003

Charm Sciences, Inc.

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CHARM SCIENCES INC

General Features

LED Lights:

The LED lights on the front of the unit help indicate several types of status for the unit or the strip run

Charging Light:

On the battery powered models-

- Green indicates External DC power is applied and the battery is being charged.
- Off indicates that the unit is not charging.

On non-battery models-

- It does not turn on.

Power Light:

On the battery powered models-

- Red light indicates the unit is plugged in to 12V power supply or battery voltage is too low.
- Green light indicates the unit is not plugged in and is running of battery power.
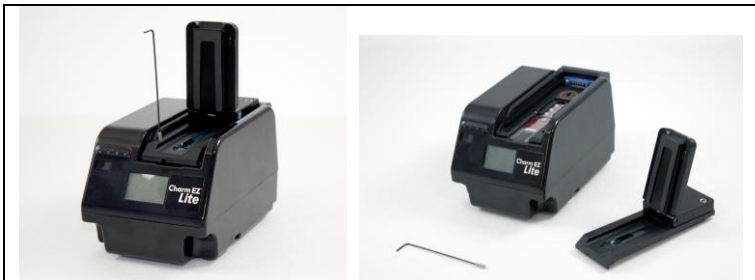- On non-battery units, it's always green.
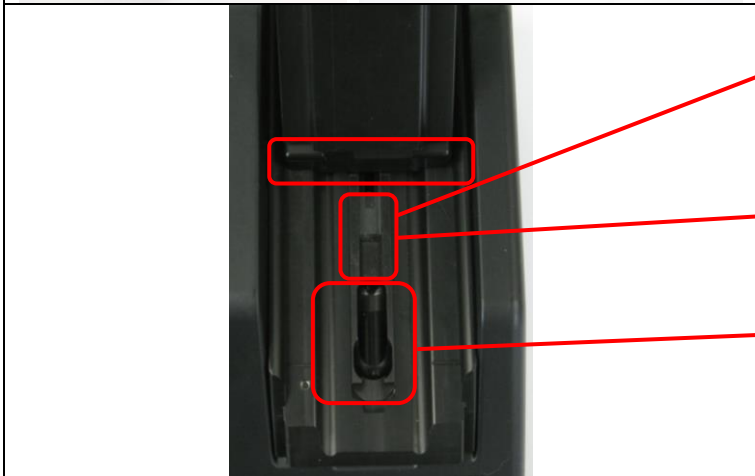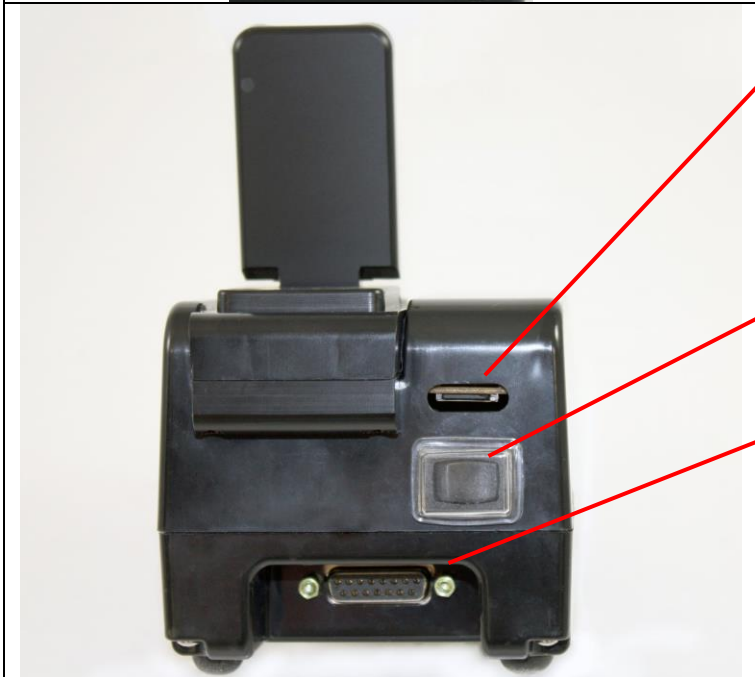
Temperature Light:

- Green light indicates the unit is at the correct temperature for the test strip being run.
- Red light indicates the unit is adjusting its incubation temperature.

Result Light

- Green light indicates the strip run was negative.
- Red light indicates the strip run was positive.

LCD Screen

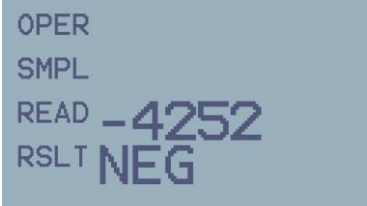|	
	Removable Slide Mechanism: The incubator mechanism can be removed for easy cleaning by removing one set screw.
	Strip Sensor
	Lens
	Sample Compartment
	Micro SD Card Slot **Note:** Power must be off to remove and reinsert the card. Do not power the unit on with the card removed.
	Power Switch
	I/O Connector Port
	Digital Thermometer Port

Getting Started
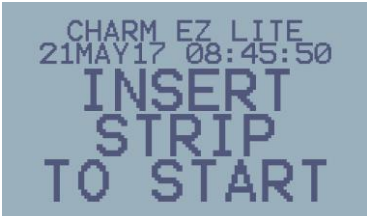
The Charm EZ Lite is factory-calibrated and can be immediately used to run and analyze tests.

1. Turn on the Charm EZ Lite.
2. Connect to printer (optional).
3. Insert valid test strip and follow the on screen instructions.
4. Run test.

Different reader and channel options are factory calibrated and are customized on request. They may also be updated with technical assistance. The different options include read-only or incubate-and-read per channel.

NOTE: The Charm EZ Lite comes with a removable incubator mechanism for easy cleaning. This incubator mechanism MUST BE inserted in the system at all times when running or analyzing test strips. Make sure unit is powered off before removing or inserting the incubator.

Reading a Test

CHARM EZ LITE 21MAY17 08:45:50 **INSERT STRIP TO START**	• **Plug in the Charm EZ Lite** and wait for the "Insert Strip to Start" screen • **Place test strip in Charm EZ Lite.** Do not close door until after sample is added.
OPER SMPL **MRLBL1** ADD MILK/CLOSE DOOR	• The Charm EZ Lite will automatically read the test strip and adjust the assay type and incubator temperature to match the test inserted. • **Wait for incubator temperature indicator to turn green**
	• While holding the test strip flat in the Charm EZ Lite, lift the tab to expose the sample compartment by peeling tape to "Peel to Here" line. • Avoid lifting the test strip and sponge under the tape. • Using a 300 µl pipet, draw up sample, avoiding foam and bubbles. • Holding pipet vertically, slowly pipet a 300 µl (± 15 µl) sample into the sample compartment at indicator line (as shown).
ASSAY IN PROGRESS TIME LEFT :58	• Reseal tape over sample compartment. • Close door on Charm EZ Lite. This will start the test timer. • Do not open the door while the assay is in progress.
OPER SMPL READ -4252 RSLT NEG	• Assay Results will appear on the screen automatically at the end of the incubation period. • Open door, remove test strip from Charm EZ Lite.

All information is stored in memory. Information will automatically print out during analysis if the Charm EZ Lite is connected to a thermal printer. Alternatively, data may be transferred in real time to a computer or later recalled to either a printer or a computer.

Precautions and Error Messages

- Charm EZ Lite must be kept clean and level.
- Keep Charm EZ Lite door open, unless procedure test is in process.
- The Charm EZ Lite may take up to 4 minutes to reach proper temperature, depending on ambient temperature.
- Turning on the Charm EZ Lite without the Micro SD Card or the Slide Mechanism properly inserted will result in an error message. Do not insert these with power on.

THIS STRIP IS NOT CHARM EZ COMPATIBLE INSERT CORRECT TYPE	- The Charm EZ Lite is not compatible with all Charm test strips. - Non-compatible test strips will result in an error message when inserted into the Charm EZ Lite. - For a complete list of Charm EZ Compatible® tests contact your local representative or Charm Sciences at +1.978.687.9200 or support@charm.com.
CHARM EZ LITE 21MAY17 08:45:50 INSERT STRIP TO START	- Only power off the Charm EZ Lite unit from the "Insert Strip" screen. - A loss of power when the unit is performing a task may corrupt the Micro SD card.
DIRTY OPTICS REMOVE STRIP	- Debris on test strips may alter the Charm EZ Lite optics - Keep equipment clean and wipe dust and milk off test strips before inserting in Charm EZ Lite. - At the beginning of each assay the Charm EZ Lite checks to make sure the strip inserted has not been previously run and the optics lens is clean.
DETECTED OPEN DOOR. REMOVE THE STRIP	- Do not open the door while an assay is in progress. - Opening the door will invalidate test results and an error message will display. - Remove the test strip and restart the assay.
FLOW ERROR DETECTED REMOVE STRIP	- The Charm EZ Lite monitors assay progress during incubation to check for proper test development. - Improper flow rates, such as those caused by improper milk volume added, are detected by the system and will result in an error message. - Remove the test strip and restart the assay.

System Settings

Channel Read Only and Incubate Modes, Print Style, SD Card options and Time Settings are all configured by the manufacturer or local representative through the Micro SD card.

Incubate or Read Only Mode

Each test strip channel can be set to Read only Mode or Incubate and Read mode. Read only mode allows the user to incubate test strips in an external incubator and use the Charm EZ Lite as just a reader.

Contact your local representative or Charm Sciences at +1.978.687.9200 or support@charm.com to switch modes on any channel.

OPER SMPL **MRLBL1** ADD MILK/CLOSE DOOR	When in Incubate and Read mode, the screen will prompt the user to add milk.
OPER SMPL **MRLBL1** CLOSE DOOR	When in Read Only mode, the screen will only instruct the user to close door

Print Styles

- The Charm EZ Lite System comes with multiple print style options.
- Print Style 1 provides the data unformatted and only separated by a coma, this style is best used when the information is being exported directly to a computer. See example below.
- Print Style 2 is a fully labeled printout of the values. This style clearly and fully explains the values being printed. See example below.
- Print Style 3 provides an abbreviated version of the information to provide a paper record of results while conserving paper. See example below.
- Print Style 4 contains the same information as print Style 3 except spaced differently
- Contact your local representative or Charm Sciences at +1.978.687.9200 or support@charm.com to switch Print Styles.

Print Style 1	Print Style 2	Print Style 3
MRLBL1 005,01JAN2019,13:27:45,Paul G,BFR02,-1557,Negative	CHARM Sciences EZ Lite Version 0.98 UnitSN= 1234 Date= 01JAN2019 TIME= 13:27:45 Operator ID= Paul G Channel= MRLBL1 LotNumber= 005 Sample ID= BFR02 Answer= -1557 Result= Negative Control= 1657 Test= 2694 Temperature=56.2C	01JAN2019 Oper# Sampl# Read 13:27:45 Paul G BFR02 -1557 MRLBL1 005 Negative 56.2
		Print Style 4 01JAN2019 Oper# Sampl# Read 13:27:45 Paul G BFR02 -1557 MRLBL1 005 Negative 56.2

SD Card Options

- It is important to note that the SD Card should only be removed or inserted when power is not applied to the unit. This can cause improper operation of the reader.
- By default the Charm EZ Lite will have the SD card features enabled.
- With the SD Card features enabled it performs the following security checks:
  - When the System performs its power up initialization it will confirm that all the results saved in the system's internal memory are also saved onto the SD Card.
  - If results are not on the card they will be copied over. If an SD card is lost and a blank card installed, Test Data is automatically written to the Card.
  - The system will also write all the test results to the card as tests are run.
  - The Charm EZ Lite manages the results saved onto the SD card and automatically archives those results into subfolders as needed to maintain the SD card's performance.
- These features can be turned off to speed up the system initialization when the security of the SD Card is not needed (for example, if data is being exported immediately to a computer through the USB port or through network options).
- Contact your local representative or Charm Sciences at +1.978.687.9200 or support@charm.com to change SD Card Options.
- When the SD card is enabled, after every 350 tests the Charm EZ Lite automatically archives the test results. This process may take up to 3 minutes. The Charm EZ Lite cannot be used to read strips when the archive screen is displayed.

Date / Time Settings

- By default the Charm EZ Lite will have date and time set by the manufacturer or local representative.
- Contact your local representative or Charm Sciences at +1.978.687.9200 or support@charm.com to Change Date / Times settings.

Bluetooth Connection

If a Bluetooth enabled EZ Lite is purchased, then the EZ Lite can be used to wirelessly download test data Charm Science's EZ Lite Sim phone app. See the Technical Information section for more details about the Bluetooth module.

Cleaning the Reader Lens

If the Lens or any part of the EZ slide becomes dirty, the entire incubator tray mechanism pulls out for easy cleaning by removing a single set screw.

Please reference TECH-241 for further instructions.

Order Codes

LF-ROSA-EZ-LITE: Charm EZ Lite Calibrated for MRL (EU) Test Strips.

LF-ROSA-EZ-LITE-B: Charm EZ Lite Calibrated for MRL (EU) Test Strips with Bluetooth.

LF-ROSA-EZ-LITE-US: Charm EZ Lite Calibrated for SL (US) Test Strips.

LF-ROSA-EZ-LITE-US-B: Charm EZ Lite Calibrated for SL (US) Test Strips with Bluetooth.

LF-ROSA-EZ-LITE-NB: Charm EZ Lite Calibrated for MRL (EU) Test Strips, Unit has no battery.

LF-ROSA-EZ-LITE-NBB: Charm EZ Lite Calibrated for MRL (EU) Test Strips with Bluetooth, Unit has no battery and Bluetooth included.

LF-ROSA-EZ-LITE-USNB: Charm EZ Lite Calibrated for SL (US) Test Strips, Unit has no battery.

LF-ROSA-EZ-LITEUSNBB: Charm EZ Lite Calibrated for SL (US) Test Strips with Bluetooth, Unit has no battery.

Power

No Bluetooth versions: LF-ROSA-EZ-LITE or LF-ROSA-EZ-LITE-US
Bluetooth versions: LF-ROSA-EZ-LITE-B or LF-ROSA-EZ-LITE-US-B

To supply power to the Charm EZ Lite:

1. Connect the appropriate adapter to the Charm EZ Lite power inlet on the I/O adapter.
2. Connect to a suitable AC outlet (if using AC to DC adapter), or to a 12V vehicle accessory socket (if using the DC automotive power adapter).

CAUTION: Only power adapters supplied by or obtained from Charm Sciences should be used with the Charm EZ Lite. Use of other power sources may result in permanent damage to the unit or personal injury.

No Bluetooth versions: LF-ROSA-EZ-LITE-NB or **LF-ROSA-EZ-LITE-NB-US**
Bluetooth versions: LF-ROSA-EZ-LITE-NBB or **LF-ROSA-EZ-LITEUSNBB**


To supply power to the Charm EZ Lite:

Connect to a suitable AC outlet (if using AC to DC adapter), or to a 12V vehicle accessory socket (if using the DC automotive power adapter).

CAUTION: Only power adapters supplied by or obtained from Charm Sciences should be used with the Charm EZ Lite. Use of other power sources may result in permanent damage to the unit or personal injury.

Printer
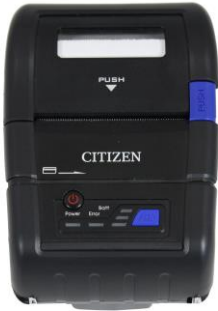
PRN-THERM-CITIZEN

Mini portable thermal printer

Printer method - Thermal line printing
Paper width – 58mm
Paper roll diameter – 30mm
Supported Fonts:(Bitmap) Font A (12 x 24 dot), Font B (9 x 17 dot)
Printing Speed – 80mm/sec
Power requirements – 12 vdc, 2 amps
Dimensions – 5.8cm x 9.6cm x 13.6cm
Battery: Li-ion, 7.4V, 1800mAh, Charging time: 2hrs, Run time: 90 minutes continuous

Digital Thermometer

THERM-DIGITAL-COMARK

Waterproof digital thermometer

Accuracy - ±0.5°C
Response in under 6 seconds
Range - -20° to 200°C
Dishwasher safe
Auto power off
Field Calibratable

Memory

The Charm EZ Lite is equipped with a Micro SD memory card which that can store 100,000 sets of sample information.

Every time a test is successfully run, the assay data is saved to the analyzer's SD Card (Error and Invalid readings are not stored in memory). Stored information includes Date, Time, Lot number, Sample, Operator, Assay, Limit, and Reading.

Once the data is stored in memory, it may be specifically recalled by date and sent to a 32-column printer or a computer spreadsheet for data management.

Exporting Results

Install EZ Export
- Close all open programs and place the Charm USB software stick in the computer's USB slot.
- Click the folder view to view the install setup file.
- Double click on the setup file to launch the installation.
- Once installed, consult the EZ Export Software Operators Manual for further assistance.

Maintenance

General
- Avoid exposure to direct sunlight and water or other liquids.
- The Charm EZ Lite should be cleaned occasionally with a damp cloth, but do not use any harsh cleansers.

Technical Information

Data Port
- Micro SD card slot

Dimensions / Weight

- Screen = 3 x 2 cm LED display
- Unit 9.5 x 9 x 15 cm (W x H x D)
- Weight = 0.7 kg

Ambient Conditions

- Operating temperature: 0°C to +40°C
- Storage temperature: -20°C to +60°C
- Humidity of atmosphere: 10 to 85%, non-condensing

Bluetooth Module

- Bluetooth standard: Version 4.1
- Frequency Band: 2.400 GHZ to 2.500 GHz
- Maximum Raw Data Rate: 1 Mbit/s
- Maximum Application Data Rate: 0.27 Mbit/s
- Modulation Type: DSSS: GFSK (modulation index = 0.5)
- Maximum RF Input: -10 dBm
- Typical Receive Sensitivity: -94 dBm
- Maximum RF Tx Output Power: +4 dBm
- Carrier Frequency Accuracy: +/-20 ppm (24 MHz crystal, +/- 20 ppm stability @ 25°C)

Charm Sciences' Contact Information

Contact the Technical Services staff at Charm Sciences for any questions or concerns about the Charm EZ Lite.

- Twenty-four hour telephone support: **978-687-9200** or **1-800-343-2170**.
- E-mail Address: support@charm.com

Troubleshooting

Do not open the Charm EZ Lite case. *Permanent damage could result. There are no user serviceable parts inside. Opening the case voids any equipment service warranty.*

Contact Charm Sciences at support@charm.com for further information/product support.

Limited Equipment Warranty

1.   WARRANTY; LIMITATION OF REMEDIES: (a) Charm Sciences, Inc. ("Charm") warrants each equipment product to be free from defects in materials and workmanship and to be free from deviations from the specifications and descriptions of Charm's products appearing in Charm's product literature, based upon normal use. The warranty periods are, from the date of delivery:

Days from Date of Delivery	Warranty Coverage
1-30	New replacement unit, shipping
31-90	Parts and labor, shipping
91-180	Parts and labor
181-365	Parts only

Charm shall undertake to correct any such defects in material or workmanship that exist or appear during the warranty periods, provided, however, that Charm shall have no obligation or liability under this warranty unless Charm has been notified of such defect no later than thirty (30) days after such defect is first discovered and, in any case, no later than one year from the date the equipment is shipped to Buyer. Buyer will provide Charm with an opportunity to inspect and test the goods claimed to be defective. Remedial action under this warranty shall require only that Charm at Charm's option, repair or modify the equipment, or replace the same. (b) The foregoing provisions of this paragraph set forth and constitute Charm's sole obligation and liability and Buyer's exclusive remedy under this warranty. Charm's liability shall immediately cease if the seal is broken or the equipment is (i) subjected to accident, misuse, negligence, alteration, improper repair, servicing or maintenance, (ii) installed or used contrary to local, state or federal laws, codes or regulations, (iii) used contrary to Charm warnings, instructions or recommendations or contrary to the purpose or manner for which it was designed, or (iv) used with reagents other than those provided, sold or approved in writing by Charm. In addition, Charm will have no liability if the alleged breach of warranty is due to incomplete information supplied by Buyer or his representative to Charm or if the alleged breach of warranty is due to dirt, debris or other contamination of the equipment.   THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXCEPT TITLE, WHETHER STATUTORY, EXPRESS, IMPLIED (INCLUDING WARRANTIES FOR MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND ALL WARRANTIES ARISING FROM COURSE OF DEALING OR USAGE OF TRADE). Buyer represents that it alone has determined that the equipment purchased is suitable for and will meet the requirements of its intended use.

2.   LIMITATION OF LIABILITY; INDEMNIFICATION: (a) Charm's liability on any claim of any kind, whether based in contract, warranty or tort (including negligence, failure to warn or strict liability) or otherwise, for any expense, injury, loss or damage arising out of, or connected with, or resulting from the design, manufacture, sale, delivery, resale, installation, inspection, repair, reconditioning, operation or use of any equipment, shall in no case exceed the contract price of that equipment. In no event shall Charm be liable for any special, indirect or consequential damages. (b) In the event the equipment is (i) subjected to abuse, misuse, alteration, improper repair, servicing or maintenance, (ii) installed or used contrary to local, state or federal laws, codes or regulations, (iii) used contrary to Charm's warnings, manuals or recommendations, or (iv) used with reagents other than those provided, sold or approved in writing by Charm, Buyer expressly agrees to defend, indemnify and hold Charm harmless from and against all claims, whether based in contract, warranty, or tort (including negligence, failure to warn, or strict liability), losses, expenses, damages, and liabilities which may arise out of the use or alleged use of the equipment to the extent caused by Buyer's negligence.

3.   AMENDMENTS: The warranty provided herein may not be altered except by express written agreement signed by an officer of Charm. Representations, oral or written, which are inconsistent with this warranty are not authorized and if given, should not be relied upon.