

Operator's Manual: novalUM Firmware Version 1.0.4 V20 (English Firmware Release Only)

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Introduction:

The Charm novalUM™ is a portable analyzer used with Charm Lite Series Tests (luminescent assays) including the PocketSwab® Plus (ATP sanitation/hygiene); AllerGiene (ATP hygiene control to allergen detection levels); WaterGiene (sensitive ATP detection in water); PasLite (alkaline phosphatase); CHEF Test (cooking heat efficiency); F-AP (Fast Alkaline Phosphatase); Somalite (somatic cell); Cidelite (pesticides); and Microbial Quality of Water and Wine.

The novalUM is integrated with novalINK™ Software and therefore has maximum flexibility to customize hygiene plans via location, surface type, location groups (plans), and test channel. Test data are stored in memory. Data may be transferred to the instrument display, printer, computer spreadsheet, or to novalINK Software. This allows for on-site sample testing and hard copy printouts or computer data management at another location or time. NovalUM is not compatible with any CharmLink software versions.

OM-266-003



Charm Sciences, Inc.

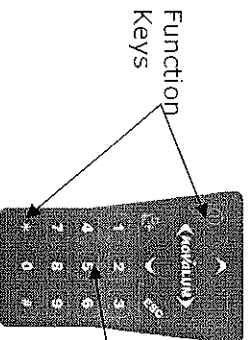
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General Features:



The novalUM uses a set of 10 function keys and 10 numeric keys.
Do not open the novalUM case. Permanent damage could result. There are no user serviceable parts inside.

Function Keys:

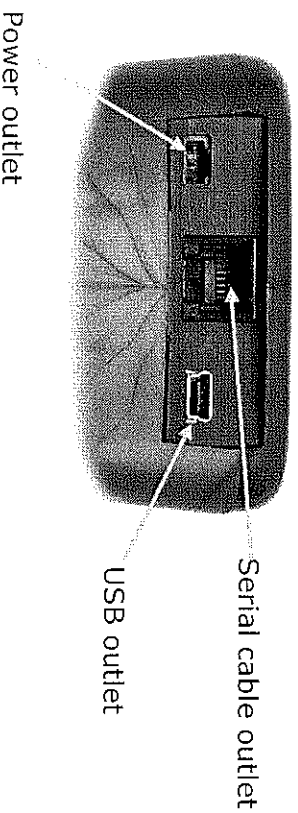
	<ul style="list-style-type: none"> - Turns the analyzer on or off. <p>IMPORTANT: When the unit is powered on (or when disconnecting from novalINK), the unit will restart. DO NOT TURN OFF THE novalUM DURING THIS RESTARTING PROCESS. Please wait until the default Main Menu screen on the novalUM appears before the unit is powered down.</p>
	<ul style="list-style-type: none"> - Activates the instrument with the information currently displayed and blinking on the screen.
	<ul style="list-style-type: none"> - Cancels whatever function is being currently performed. - Returns to a previous menu.
	<ul style="list-style-type: none"> - Moves the blinking cursor up. - Scrolls through data in the Results Menu.
	<ul style="list-style-type: none"> - Moves the blinking cursor down. - Scrolls through data in the Results Menu.
	<ul style="list-style-type: none"> - Moves the blinking cursor to the right - Scrolls up through the location names and numbers.
	<ul style="list-style-type: none"> - Moves the blinking cursor to the left - Scrolls down through the location names and numbers.
	<ul style="list-style-type: none"> - A spare key that does not have a specific function in this version of the novalUM
	<ul style="list-style-type: none"> - Backlight key. Pressing this key will turn the backlight off/on.
	<ul style="list-style-type: none"> - Diagnostics Key When turning analyzer on, hold this key until unit displays "Please connect the printer." The unit will then cycle through a self check to ensure proper functioning. - NOTE: This function can be used only when connected to a printer.
	<ul style="list-style-type: none"> - Used to enter information about sample number, operator number, or date. - Entries by numeric keys should normally be followed by OK which will start the analysis, or ↑ / ↓, which will scroll to the previous or next line.

Getting Started:

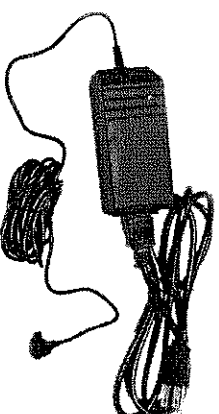
Design a testing program using novalINK and load the plans into the novalUM. (If the instrument was customized by Charm Sciences, this step has already been performed.)

Make sure that the novalUM battery is charged or plug instrument in and run tests while it is charging. Note: The novalUM may not be fully charged upon receipt. Plug the 12V power supply first into the bottom of the unit, and then plug cord into wall outlet, and allow it to charge before the first use. Plugging the unit in using a different order may lead to unit not taking a charge properly. (Due to temperature sensitivity, it is recommended to charge the unit before a running alkaline phosphatase or Allergiene tests. Charging the instrument during use may result in an increase in internal temperature. If the internal temperature is exceeded when running these two types of tests, an error message will appear and the novalUM will not finish the test.)

Bottom View of novalUM



Power Supply



If running PocketSwabs, no further steps are necessary. Tests may be read using the calibrated LUM channel for PocketSwabs. Allergiene and Watergiene tests can be analyzed after the novalUM has been specifically factory calibrated for these tests. Channel 2 is usually designated for Allergiene use and Channel 3 for Watergiene.

For confirmation of Watergiene, and Allergiene calibrations contact Charm Sciences Technical Support.

Refer to novalINK manual to set up programmed plans for testing samples and to name channels.

If running an alkaline phosphatase test, **plug in temperature probe prior to powering up novalUM**. Set up temperature probe in the slot in the stopping solution holder accessory so that it comes in contact with the stopping solution bottle (see photo in Alkaline Phosphatase Temperature Probe section). **Do not put probe directly into Stopping Solution**. See Appendix A for instructions on calibrating channels for PasLite.

If running any other tests, calibrate an open (previously uncalibrated) channel. After calibration, tests may be read on that channel. Refer to novalINK manual to change channel names and to make programmed testing plans.

Reading a test:

PocketSwab, Allergiene or WaterGiene: The novalUM is factory-calibrated and can be immediately used to analyze PocketSwab tests. Please check with Charm Sciences, Inc to verify that novalum is properly calibrated for Allergiene, and Watergiene testing. **Note: To prevent damage and ensure proper function, use only swabs manufactured by Charm Sciences, Inc.**

1. **Choose Plan:** When powering up, the novalUM will perform internal diagnostics. After the diagnostics are complete, the instrument defaults to the Main Menu. Choose option 1, 'Run Test' or choose option 2, 'Programmed Plans'. Run Test - will perform a quick analysis of a test using the settings on the Default Channel (See Preferences section for more information). Programmed Plans - If the channel feature is disabled, the list of available plans will appear. Select the desired plan either by pressing the plan number or scrolling to the plan name and pressing OK.
2. **Choose Channel:** If channels are enabled so that several different types of tests may be analyzed on the novalUM, a list of channels will appear. Choose the channel corresponding to the test being performed. Once the desired channel is selected, a list of available plans will appear for that particular channel. Note: If channels are disabled, the channel list will not appear. The list of available plans will then appear once 'Programmed Plans' is selected. Note: When selecting a channel, either scroll to that channel number and press OK or simply press the number of the desired channel. Use keys 1-9 to select channels 1-9. Press the 0 key to go to directly to channel 10.
3. **Choose location:** The first location number and name in the selected plan is displayed. Use the left/right arrow keys to scroll through locations, or type the number of a location to jump to it directly. The default location is the first, and this will increment as each test is read. Note: When using the arrow keys to scroll through the locations, once the last/final location is reached, the right arrow will advance to the first location number. Pressing the left arrow when the first location is displayed will not display the last/final location.
4. **Enter Test/Site number and Operator ID:** displayed below the location. Use the arrow keys to move to these lines to make changes. These numbers may be up to three digits long. This feature is useful to distinguish data when retesting the same location(s) multiple times or when there are multiple users.
5. **Choose Surface:** As the locations advance with each test, the proper surface for the particular location will also appear. If a different surface type is desired for a location (other than the one that automatically appears for the location), simply scroll down to the surface line and use the left/right arrow keys to scroll through available surfaces until the desired surface appears.
6. **Start the count:** Insert a swab in the sample chamber and immediately press OK. As the reading proceeds, the count time will increment. At the end of the analysis, the result and interpretation will be displayed (the count in RLUs - Relative Light Units - and the interpretation as Pass/Fail). Note: The Allergiene and WaterGiene tests will take slightly longer to begin counting than other channels/assays. This is normal.

All information is stored in memory. Information will automatically print out during analysis if the novalUM is connected to a 32-column printer. Alternatively, the data may be transferred to novalINK and stored in the database for further analysis.

Paslite, Cidelite, Somalite, CHEF and F-AP tests:

- See Appendix A for calibration details.

1. **Choose Plan:** When powering up, the novalUM will perform internal diagnostics. After the diagnostics are complete, the instrument displays the Main Menu.
2. **Choose Channel:** Calibrated and enabled channels may be selected from main menu item 2, 'Programmed Plans', as described above.
3. **Uncalibrated channels** may be calibrated and enabled by scrolling down through the main menu to item 8 'Calibration Menu' or by selecting '8'. Choose the appropriate calibration from the assays menu: Alkaline phosphatase ('Paslite'), Somatic Cells, CHEF/F-AP or Pesticide and press enter. Then select the channel to calibrate. Follow prompts to complete calibration (see Assay Calibration). Note: If the message 'Selection Aborted! Channel has specific test calibration and won't be calibrated' occurs, select a different channel to calibrate. The 'uncalibrate' option (item 5 in the 'calibration menu') may also be used to remove a calibration from a specific channel. Do not 'uncalibrate' the channel unless necessary.
4. **Calibration successful:** After following prompts for each assay calibration and meeting internal performance specifications, a calibration successful message will appear and the novalUM will display the calibrate channel selection screen. Press ESC three times to exit to Main Menu and select option 2 'programmed plans' to run tests/assays. Alternatively, if running an Alkaline Phosphatase, Pesticide or CHEF/F-AP test, select channel from calibrate channel selection screen and select Run tests from the Mode of Operation menu.

The count is expressed in RLU's (Relative Light Units).

In the case of Paslite, FAP and CHEF the RLUs are equivalent to phosphatase enzyme activity and are expressed in miliunits per liter (mU/L). The interpretation (Pass/Fail) for Paslite and FAP is typically based on the limit of 350 mU/L that is set as a channel limit in novalINK software. The interpretation of CHEF is typically set as twice the average RLU of fully cooked tissue. The channel limit is programmed into the novalUM using novalINK software.

CHEF and F-AP share a line on the calibration menu. To display one test or the other requires special configuration through Hyperterminal that will either be factory installed, or programmed by Charm support staff or sales representative.

In the case of Somalite, the RLUs are expressed in SCC x 1000/ml. The pass/fail limits set at 750 or 400 depending on desired screening level. These values should be set as channel limits in novalINK Software.

All information is stored in memory. Information will automatically print out during analysis if the novalUM is connected to a 32-column printer. Alternatively, the data may be transferred to novalINK and stored in the database for further analysis.

Preferences:

To change any of the preference settings:

1. Select option 6, 'Change Preferences', from the Main Menu.
2. Enter password '4000' and press OK. Or press ESC to view preferences without making any changes.
3. Select the desired preference and make changes, pressing OK after each modification.
4. For selections that have Y/N settings, use the right and left arrow keys to switch between Y and N. Press OK once the desired setting appears.
5. A password is required to enter the instrument preferences screen. The password is factory-set to be 4000. Use the up and down arrows to scroll through the list of preferences. Use the number keys or the arrows to change a preference, then press OK.

Note: Many of these preferences may also be controlled using the novalUM Instrument Parameters screen; refer to the novalINK manual for further information.

Print Style:

There are three possible styles that may be used to print data from the novalUM. Print Types 1 and 2 are most commonly used; Print Type 0 is a comma-delimited format used when transferring data real-time to a computer.

Print Type 1 is a condensed 3-line printout (referred to as 'short ticket' in novalINK), and Print Type 2 gives a longer ticket-style printout of results (referred to as 'long ticket' in novalINK). Type 0 is referred to as '80 column' in novalINK. Examples of the three print out styles are as follows:

Print Type 0	Print Type 1	Print Type 2
0001,16SEP2008,13:43:38,0000,000 1,0000,0000,0001,< 000,P 0,0	16-SEP-08 13:43:38 OP 1 0 Count: 000 Channel 1 1 < 0 Location 1 Pass	Company name: Address: ID: NL#### 16-SEP-2008 13:43:38 Channel: Channel 1 Operator: 1 Location: conveyor Plan: Warehouse Surface: rubber Test/Site: 1 Count: 0 Pass/Fail Limit: < 0 Result: Pass

Language: Version 1.0.4 V19 novalUMs have four language options in the 'Change Preferences' menu. However version 1.0.4 V19 is an 'English Only' release. Future versions will be capable of multiple languages. Other languages are included in version 1.0.4 V19 but they are preliminary translations. (Select 0 for English, 1 for French, 2 for Spanish or 3 for German.) See 'Troubleshooting' for step-by-step instructions on how to return the display to English from an unfamiliar language.

Backlight Time: Sets the seconds that the backlight illuminates after the keypad is pressed. Factory setting is 45 seconds.

On Time: The length of time that an inactive novalUM will remain on before turning off to conserve battery power.

Thirty seconds before this shutdown, the instrument will beep to warn the user that a power off is imminent. If any key is pressed in this 30-second window, the timer will reset. If the 30 seconds pass and a key is not pressed, the novalUM will beep two times and immediately turn off.

Factory set at 60: if the novalUM remains idle for 60 minutes, it will automatically turn off.

The On Time may be set anywhere between 000000 (will never automatically turn off, feature disabled) to 000099 (will turn off if inactive for 99 minutes). This setting may be adjusted either in the Change Preferences menu of the novalUM or on the main screen in novalINK.

Password: Allows the password to be changed from the default '4000' to any 4-digit number.

AutoRun: Allows the Run Test option (first option on the Main Menu) to be used as a quick read mode. If AutoRun is enabled (set to 'Y'), selecting Run Test will automatically initiate a test count. The test will be run using the calibration of the Default Channel and will be associated with Plan0 and the first Location and the first Surface loaded into the novalUM. Note: The channel limit value will be the value used when determining pass or fail, regardless of the location or surface that appears on the screen or printout when using "Run Test".

Sample Screen: The Sample Screen appears before a test is run. It displays the plan, sample location, operator number, test/site number and surface. If this screen is disabled (set to 'N'), selecting a plan from the Plan Menu will initiate a test using the first location and first surface in that plan. The second test will be associated with the second location and surface, the third test with the third location and surface, etc.

Note: Disabling the Sample Screen will only affect the programmed plans. To disable the Sample Screen when using the Run Test option, activate the AutoRun feature.

Channels: The list of channels may be displayed before a test is run using a programmed plan. If the Channels setting is enabled (set to 'Y'), the list of channels will appear after option 2, 'Programmed Plans', is selected from the Main Menu. Select the channel appropriate to the type of test being run and then choose the appropriate plan.

Plans: Programmed plans can be disabled so that the novalUM will go directly to the Sample Screen when option 2 'Programmed Plans' is selected from the Main Menu. Plans are disabled when this setting is set to 'N'. A maximum of 99 plans may be programmed into the novalUM. Note: If Sample Screen, Channels and Plans are all disabled, selecting Programmed Plans from the Main Menu will automatically start a test count. Data will be associated with the 'default channel' and 'plan 0' will be applied (first location and surface loaded).

Default Channel: Identifies which channel the novalUM will default to when Run Test is selected from the Main Menu. Any channel between 1 and 10 may be selected. It is recommended to leave the default at 01, the factory setting.

Test/Site: The Sample Screen shows the 'Test/Site#' and is factory-set to default to 001. The number set in this parameter is the default value. The Test/Site# will return to this number after each test is run. This number can be manually changed on the sample screen before running a test but the number that is entered in the 'Change Preferences' screen will be the default setting.

The text string 'Test/Site#' may also be changed by editing the Instrument Parameter field in novalINK software. The novalUM can be programmed to show any wording on this line, e.g. 'Store', 'Dept', 'Area', 'Oper#', etc. Please refer to the novalINK manual for details.

Keypad Tone: The keypad tone can be turned off or on. If turned on (set to Y), then every key will beep when pressed. If turned off (set to N), the keys will not beep when pressed. Regardless of this setting, the unit will still beep when powered off/on and when a test is completed.

Shuffle: When enabled (set to Y), the shuffle feature will randomly change the order of locations in a programmed plan. The shuffling of locations will change on a daily basis. When disabled (set to N), the locations will be in the original order.

Daily Performance: Activates the option for a plan to run and store the negative and positive controls. After enabling (set to Y), press key 0 from the Main Menu to run the Daily Performance tests. See section on Calibration/Controls for running Daily Performance.

Location Check: When enabled (set to Y), this feature stores all the failed locations tested in the Programmed Plans. From the Main Menu, press key 9. The first failed location will appear as a sample screen with its corresponding plan and surface. Use the arrow keys to scroll through the failed locations. A failed location can be retested through this option. If there are no failed locations, the screen will remain on the Main Menu.

Additional Functions/Features:

Print Parameters: Selecting option 7, 'Print Parameters', from the Main Menu will print all of the internal calibration parameters to a 32-column printer.

Statistics: There is a built-in statistical menu on the novalUM. Every time a test is run, the assay data is stored in the novalUM's memory and statistical calculations are performed. The following selections may be accessed by selecting option 3, 'Statistics', from the Main Menu.

Note: Alkaline phosphatase, somatic cell, pesticide and CHEFF/F-AP calibration data will be included in the Test Counter and in the memory status portion of the statistics. However, those data will not be included in the lists of failures.

Test Counter: Lists the total number of tests performed on each channel. The channels listed are the channel numbers, not names as defined by novalINK. The first screen identifies the date and time since that counter was last reset. This is the date and time that the counters began counting tests (starting from 0). This date and time will change when 'reset' is selected. The second screen lists the number of tests run on each channel.

Memory Status: Displays the % of memory space used in the novalUM and the number of tests that may still be stored in memory. Memory pointers identify the position of stored data in memory. The novalUM can store up to 4999 test results in memory.

Reset Test Counter: Sets the test counter to zero. This function requires a password, which has been factory-set to '4000'. After entering the password, the instrument will ask for confirmation before resetting the test counter.

Note: Test counters should be 'reset' before uploading any new plans and channels from novalINK. Test Counter is independent of memory, data deletion, or novalINK downloading. Resetting counters on upload correctly reflects the information that is currently loaded into the instrument (rather than other information that was once loaded but is no longer present).

Print Statistics: Sends all current statistical information to a printer or computer. The memory search performed to gather and analyze the data for this analysis may take several minutes, especially if the memory is full.

Change Date/Time:

Option 5 on the Main Menu is 'Change Date/Time'. This is password-protected, the factory password being set to '4000'. Press the right arrow key to move from year, to month, to day and between hours, minutes and seconds. Use the up and down arrows to change the month.

Printer:

A 32-column printer can be connected for simultaneous printout of results or information can be periodically printed from the novalUM through the SEARCH option.

1. Connect the supplied black communications cable to the novalUM computer/printer port located on the bottom of the novalUM. Connect the other end to the serial printer

2. Plug the adapter into the female port on the printer. Turn on the printer.
3. Results will automatically print as each test is completed/analyzed. If a printout does not occur, call for technical assistance or refer to printer instructions and check communication settings.

There are 3 different printout styles. See 'Preferences' section of this manual for further instructions.

Memory:

The novalUM is equipped with memory that can store approximately 4999 test results. Every time an assay is run, the data are saved to the novalUM's memory. Stored data includes Date, Time, Location/Sample number, Site/Test number, Channel, Plan, Limit, RLU count, Result, Operator and Surface type. Once the data are stored in memory, they may be recalled and sent to the display, to a 32-column printer, or to a computer.

*When the novalUM is connected to novalINK, the program automatically searches for new data and downloads it. It is **not** necessary to perform a Search.*

Searching Memory:

1. Select option 4, 'Search' from the Main Menu.
2. On the next screen, select option 1, 'Search', to define the date, time, channel and location of the desired data.
 - If transferring data to a 32-column printer or to a computer connection other than novalINK, use the date and time at the start of the desired data range.
 - If data will be viewed on the novalUM screen, use the date and time at the end of the desired data range.
3. Enter the date and time for the search.
4. Use the number keys to type in the day, the right arrow key to move from the year field to the month field.
5. Use the up/down arrows to change the month, then press the right arrow to move to the day.
6. Enter the time using the right arrow to move from hours to minutes to seconds. Note: the time is based on a 24-hour clock, so 2pm is expressed as 14:00:00.
7. Use the right arrow key to move to the Channel ID line. Enter the desired channel number, or leave it set to '00' to display all channels' data. Press OK.
8. Select the desired location number, or leave it set to '0000' to display all locations' data. Press OK.
9. Press ESC. Verify that novalUM is connected to printer or computer if printing or downloading. Select the desired destination for the data: Screen, Printer, or Computer. Reminder: The 'search' feature is not needed if sending data to novalINK software.
10. If search is to the display, use up and down arrows to scroll through data. Press ESC to return to the Main Menu when data review is complete. If searching to the display and 'NOT FOUND/END OF MEMORY' appears, press the down arrow once. If data is still not displayed, repeat the search.
11. NOTE: The novalUM is capable of storing 4999 tests in memory. The searching feature will be slower as more assays are stored in memory.

Deleting Memory:

There are two options for memory deletion:

To clear *selected* data from memory:

1. Select option 4, 'Search' from the Main Menu.
2. On the next screen, select option 2, 'Delete Prior To'. Enter password '4000' and press OK.
3. Enter cutoff date for memory deletion. Data will be deleted up to (but not including) the entered date and time. Use the number and left/right arrow keys to enter the desired date and time.
4. Press OK. At the prompt 'CONFIRM DELETE' press OK to confirm the deletion, or ESC to abort the deletion.

To clear *all* data from memory:

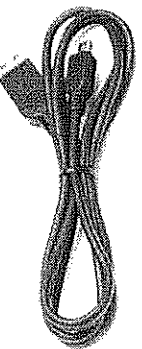
1. Select option 4, 'Search' from the Main Menu.
2. Select option 3, 'Delete All'. Enter password '4000' and press OK.
3. At the prompt 'CONFIRM DELETE ALL' press OK to confirm the deletion, or ESC to abort the deletion.

Computer Setup and Downloading Data:

The novalUM is designed to be customized and download data using novalINK. Refer to the novalINK Operator's Manual for details on how to customize test locations, set limits, build plans, and track stored data.

The novalUM data may be downloaded to other communications programs for data analysis or for real-time data tracking. However, the novalINK software will provide the most detailed and complete storage and analysis of this data. Contact Charm Sciences for the novalUM Operator's Manual Addendum describing how to set up this alternate computer communication connection.

Two different computer communication cables will be supplied with the novalUM. One of them is a USB cable. The other is a serial port cable/adapter. Either one may be used when connecting to a computer. **NOTE: Do NOT use a USB to serial port adapter/connector.** Only use a direct serial cable/adapter OR a direct USB cable.



USB Connector



Serial Connector

Battery:

Charging the Battery:

There are two possible sources of power for the novalUM, an internal rechargeable lithium ion battery pack or the novalUM battery charger.

For optimum battery charge and life, recharge the battery *only* when the novalUM displays the 'Battery Low Recharge Soon' message. The novalUM may be used while recharging. The LED is located on the charger.

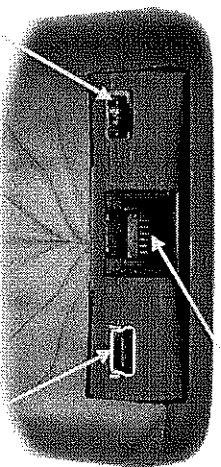
To charge the battery before use:

1. Turn the power off and connect the battery charger to the novalUM charger inlet.
 2. Connect the adapter to a suitable wall power outlet. Note: Only use the supplied charger/adaptor with the novalUM. Use of any other charger can damage the unit.
- Connect the charger to the novalUM before plugging the charger/adaptor into the wall outlet to ensure proper charging.**
3. Recharge time is 2-4 hours. A full charge will last 8-10 hours.
 4. When the battery charge is low and the battery is not recharged immediately, the

- novalUM will operate for a short period of time before automatically shutting off.
- Once connected to the adapter, the LED light on the charger will begin to blink. The unit is charging when the light is blinking (see chart below). The unit is completely charged when the light is steady. If the charger does not function properly, contact Charm Sciences.
 - Disconnect the novalUM from the charger when a full charge is indicated.
 - When connected to novalINK, the novalUM should be either fully charged or plugged in to AC power. This is to prevent shutdown while an instrument update is in process.

novalUM Connections

Serial cable outlet



Power outlet







USB outlet

Battery Charger and Adapter



Battery Charger
3.7 V output
100-240 V, 50-60 Hz, 550 mA power input

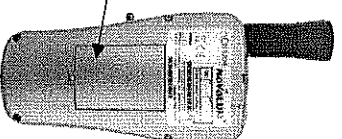
Charging Indicator Label (located on power supply)

Lithium Ion Charger 	
	ON Charge Complete
	Fast Blink Charge Failure
	Flash 50/50 Rapid Charge
	Slow Blink Charge Pending
	OFF No AC or Battery
PART#:	

Replacing the Battery:

Note: Contact Charm Sciences if battery issues occur. If the problem is due to the battery, a new battery may only be purchased from Charm Sciences.

- Turn novalUM off.
- Remove the screw on the back cover covering the battery.
- Unplug the battery connector.
- Insert new battery. Make sure to insert the connector in the same direction as the previous battery connector.
- Replace cover and tighten screw.







Battery Indicator:

A battery charge symbol is displayed in the upper right-hand corner of the screen, showing how much power is left in the rechargeable battery. As the battery power decreases, the level of charge shown also decreases. This indicator is visible on all screens except when a test is in progress.



Indicates charge level of battery.

	Fully charged battery.
	Low charge in battery.
Blinking: 	Battery depleted – recharge immediately.
	Charger has been connected to the novalUM. (Note: This symbol will appear when the charger is plugged into the novalUM regardless if the other end is plugged into a power outlet.)

Memory Battery:

An internal battery is used for memory storage. If this battery is low, a flashing 'L-' indicator will be displayed in the upper right corner of the novalUM screen. Call Charm Sciences Technical Support for further instructions.

Caution: This analyzer utilizes Lithium Ion batteries, and their use should be monitored for optimum life. It is acceptable to leave the unit attached to the charger (AC to DC adapter) for extended periods of time.
Only the battery charger/adapters supplied by or obtained from Charm Sciences should be used with the novalUM. Use of other chargers may result in permanent damage to the unit or personal injury.

Maintenance:

General:

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

Calibration/Controls:

The Charm novalUM analyzer is factory calibrated for 'LUM' or 'PSWAB' (PocketSwab) testing. Customer calibration is not required. Calibration verification is recommended as part of a comprehensive quality assurance program to meet cGMP and HACCP regulations.

The novalUM is specifically designed and calibrated to measure luminescence and interpret pass/fail from Charm PocketSwab single service swabs (PocketSwab Plus, CHEF test, WaterGiene, Allergiene). Inserting swab devices other than those manufactured by Charm Sciences will lead to erroneous and invalid results.

It is recommended that positive and negative controls be run monthly or quarterly to verify calibration. More frequent verification may be required as part of a quality assurance system based on number of tests run (every 100 tests, for example), shift changes, daily or weekly operation. The three-point validation assures that the test and analyzer meet specifications for selectivity as well as sensitivity.

1. **Positive Control:** An ATP Positive Control Tablet is available from Charm Sciences. The PocketSwab Plus is used to test the positive control for calibration validation of the novalUM. This procedure not only validates the calibration of the analyzer but also verifies the performance of the PocketSwab Plus. The specification is listed in the PocketSwab Plus Operator's Manual.
2. **Negative Control:** A negative control (a PocketSwab Plus activated without swabbing a surface) is also run as part of the analyzer calibration validation. The specification for a negative control is 0 RLU on a LUM or PSWAB calibrated channel.
3. **Instrument Blank:** A count of an empty test chamber (no sample inserted in the instrument) should always give 0 RLU.

If specifications are not met, Charm Sciences' Technical Support Department is available (see Troubleshooting) for immediate assistance. ATP Positive Control Tablets, PocketSwab Plus, and loaner novalUM's are available within 24 hours, if necessary.

Technical Information:

Display Specifications (# of characters that will appear on the display):

Channel Name	- The maximum number of characters allowed is 7 (both on the display and in the novalINK software).
Plan Name	- In the 'Plan Menu', up to 19 characters will appear on this screen if fewer than 10 plans have been loaded. If ten or more plans are loaded, then up to 18 characters will appear. On the 'Run Sample Screen', the first 16 characters of the plan name will appear. The novalINK software will allow a maximum of 21 characters, however only 19 or 15 (depending on the screen selected) will appear on the novalUM display.
Location	- Up to 18 characters will appear on the display. This is the same number of characters that the novalINK software will allow.
Surface	- A maximum of 15 characters will appear. This is the same number of characters that the novalINK software will allow.

Reading Time:

- Seven seconds per analysis (5-second count + 2-second display refresh); twenty-seven seconds with Giene channel (20-second count + 7-second display refresh).

Computer Interface:

- RS232 or USB, 115200 baud, 8 bit data, no parity, 1 stop bit.

Dimensions / Weight:

- 9.3 x 3.8 x 2.3 inches.
- 1.0 pound/470 g

Power:

- Battery Charger:
 - Input 100-240VAC, 50/60 Hz,
 - Output 3.7 VDC, 1.8 A maximum.
- Lithium-Ion rechargeable battery: 3.7 V, 1800 mAh (2-4 hr recharge time, charge lasts 8-10 hours).
- Lithium Manganese Dioxide memory cell: 3.0 V, 950 mAh.

Ambient Conditions:

- Operating temperature: 4°C to +40°C.
- Storage temperature: -10°C to +50°C.
- Humidity of atmosphere: 10 to 85%, non-condensing.

Interferences:

Electromagnetic (EM) interference from equipment, including the "Maxi Mix" vortex mixer, may interfere with the result and yield erroneous increased counts. Avoid use of EM generating analytical instruments or equipment within 6 feet, or 2 meters of the luminometer analyzer.

Charm Sciences' Contact Information:

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

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

Troubleshooting:

If liquid spills into the sample chamber try drying with an absorbent swab and allow to air dry. After drying, count a negative control and run an instrument blank (press enter when no swab is in the sample chamber). Both results should be zero. Also run a positive control and make sure the RLU result is as expected. If problems continue, contact Charm Sciences.

If the initial RLU significantly decreases during the 5-second count there may be electrostatic interference from a very dry environment. Wipe the sample with a moist cloth before inserting into the novalUM to count. If problems continue, it may be necessary to extend the count time. Contact Charm Sciences Technical Support for further instructions.

If charging LED indicator does not come on when the unit is plugged in, the internal battery or charging system may not be functioning. Contact Charm Sciences for instructions.

If the novalUM will no longer hold a charge the internal rechargeable battery may need to be replaced. Contact Charm Sciences.

If the "Self-Check Error" appears when the novalUM is turned on, the internal system checks determined the machine is malfunctioning.

- Plug the analyzer into the charger and try turning it back on.
- Turn the instrument off. Fully insert a swab several times (at least 5 times) without pressing any buttons/keys. Remove swab and turn instrument on. If the message continues to appear, contact Charm Sciences.

If a numerical error appears (101, 103, etc.) contact Charm Sciences.

If the novalUM gives all zero results, on positive controls or known positive samples, check that the reagents are within their expiration date and that they have been stored properly. Try reading the control on another calibrated channel. If problems persist, contact Charm Sciences.

If the novalUM gives all high results, even on negative controls, check that the reagents are within their expiration date and that they have been stored properly. Make sure that the test is not being run in direct sunlight. Try reading the control on another calibrated channel. If problems persist, contact Charm Sciences.

If the novalUM shuts off automatically the novalUM turned off to conserve battery or the battery needs to be recharged. Check the "OnTime" setting (refer to 'On Time' portion of the 'Preferences' section of the manual) to adjust the time delay before automatic shutoff, or plug analyzer in to the battery charger and allow time to recharge. *Note: Tests may still be read on the analyzer while it is charging.*

If a flashing "Lr" indicator appears in the upper right corner of the screen, the lithium memory battery needs to be replaced. Contact Charm Sciences immediately for further information.

If the Sample Guide breaks, contact Charm Sciences to arrange repair. A broken Sample Guide is often an indication that the novalUM has been dropped or mishandled and other parts of the analyzer may need repair. Loaner instruments are available overnight.

If the "Warning Memory Almost Full" message appears, make sure all data are recorded, printed or downloaded, and then delete the memory. See section 'Deleting Memory'.

If the "Error Memory Full" message appears, make sure all data are recorded, printed or downloaded, and then delete the memory. See section 'Deleting Memory'.

If the "Internal Temperature exceeds Allergiene acceptable range!" message appears on the screen, the instrument has become too warm and will not run any tests on the Allergiene channel. Allow the novalUM to cool down. It may be turned back on and then used normally.

If the "Instrument Too Warm" message appears on the screen, check that the temperature of the Stopping Solution is 18-24°C. If the temperature is in range and message still appears, power down the novalUM and disconnect the probe. Power up novalUM; the channel will work with probe disconnected. Power down novalUM and re-connect the probe. If the message appears and the temperature range is correct, disconnect the probe and contact Charm Sciences.

If the novalUM is in an unfamiliar language and needs to be reset to English, follow these instructions.

1. Press **ESC** several times (until the display does not change any more).
2. Press **6**.
3. Enter the password "**4000**", press **OK**.
4. Press the **down arrow** once.
5. Press **0** for English.
6. Press **OK**. The screen will immediately flash and reset to English.

If the pass/fail limits shown on a printout or screen do not appear to be the same as the pass/fail limit value assigned to a specific location or sample, the data may have been generated using "Run Test" instead of "Programmed Plans". When using Run Test, the instrument will use the limit associated with the default CHANNEL, rather than the location or surface that appears on the screen or printout.

Warranty:

Charm Sciences, Inc. 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:

<u>Days from Date of Delivery</u>	<u>Warranty Coverage</u>
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.

Appendix A: Channel Calibration

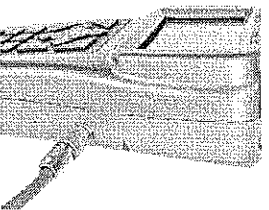
Channels being used for Alkaline Phosphatase, Somalite, CHEF or F-AP, and Cidelite (pesticide) require calibration before first use and with each new lot of test kits (each assay for Cidelite).

1. Select option 8 'Channel Calibration' from the Main Menu.
 2. Select the assay type to be calibrated.
 - PasLite
 - Somatic Cells
 - CHEF or F-AP
 - Pesticide
 - Uncalibrate
 3. Select channel from the menu that will be calibrated. If a channel is unavailable, a message screen will appear. Depending on the assay type selected, a series of prompts will appear as described in the sections of the manual pertaining to each assay type.
 4. If recalibrating for a new lot on the FAP, Pas-Lite, or CHEF test, a prompt for a password will appear before continuing with recalibration. The factory set password is 4000.
- Uncalibrate will reset a calibrated channel for one of these assays and allow that channel to be calibrated for a different assay.

PasLite Calibration:

Temperature Probe:

On the right side of the instrument	- PLUG IN PRIOR TO POWER-UP – The probe is used during alkaline phosphatase assays to measure the temperature of the stopping solution and compensates for any variation in temperature between assays.
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Use novalUM in an upright position (alternatively use stand). Connect the temperature probe and then power on the unit. See step 4 in the 'Getting Started' section of the manual for details. Refer to the section 'Alkaline Phosphatase Temperature Probe' for photo of set up.

1. Calibration results may be viewed on the novalUM screen, printed to a 32-column printer, or viewed in novalINK by filtering a report to 'Status' = calibrator. If using a printer, connect the novalUM to the printer. It is recommended that the 'Print Type' be set to '2', which provides the most detailed information on the printout.
2. Select option 8 'Channel Calibration' from the Main Menu.
3. Select the assay type 'PasLite'.
4. Select the channel to be calibrated. If channel has been previously successfully calibrated for PasLite, skip to step 5b, otherwise proceed to 5a.
5. Matrix selection
 - a. Choose the matrix type to be calibrated (this option appears if the channel has not yet been calibrated)
 - i. Milk (fluid white milks, homogenized, 2%, 1% or skim)
 - ii. Cream (light creams, half and half, heavy and whipping)
 - iii. Flavored (chocolate and other flavored dairy drinks)
 - iv. Other (other liquid products, melted ice cream, ice cream mixes)

v. Note: For solid products such as cheese using 1 part to 4 parts Diluent AP for sample preparation, use CHEF calibration

- vi. Once selected, the novalUM will confirm the matrix selection and ask for confirmation by requesting OK. Press OK to begin calibration (see step 6). Press ESC if desired matrix is different.
- b. Select Calibrate from the menu (this option appears only if the channel has been previously calibrated).
6. Run Test (read a sample using the existing calibration)
7. Calibrate (for a new lot of reagent or for a new product)
8. Control Check (for performance monitoring)
 - a. Once Calibrate is selected, the novalUM will provide message 'This is an AP channel for [matrix]. Recalibrate for [matrix]? OK->Yes or ESC-> No'. If OK is pressed the calibration prompts will begin, see step 6. If ESC is pressed the novalUM will ask for confirmation of desired matrix change and then provide matrix menu, see step 5a.
9. Prepare three negative controls and three 350 calibrators according to the Paslite Operator's Manual. Assay the negative controls in triplicate. Press OK when the tests are ready to be counted, and follow the prompts to count the three negatives. Then assay the 350 mU/L calibrator in triplicate. Follow the prompts to count the three 350 calibrators.
10. Calibrators
 - a. If the novalUM is connected to a printer, the results will print out as they are read
 - b. The initial printed counts are with a background and correction each set to 100. The RLU averages are used by the instrument to determine the correct calibration settings for the matrix. Once accepted the instrument will prompt to repeat the assays, see step 8.
 - c. If there is too much variation between the three replicates of either control/calibrator, the instrument will ask for the assay to be repeated. Press OK to continue, and then count the new tubes, or press ESC to return to the previous menu.
11. The novalUM calculates calibration settings and then prompts to repeat the assays with three negative controls and three 350 mU/L calibrators. Assay the negative controls in triplicate. Press OK when the tests are ready to be counted, and follow the prompts to count the three negatives. Then assay the 350 mU/L calibrator in triplicate. Follow the prompts to count the three 350 calibrators. The average RLUs are compared to the specified ranges. If the values are out of range, the calibration must be repeated (at step 6). If the values are in range, it will proceed to the next step of the calibration.
12. Prepare three 44 (or 88, depending on the product being tested) and three 175 calibrators. Assay the 44 (or 88) calibrator in triplicate. Press OK when the tests are ready to be counted, and follow the prompts. Once accepted, assay the 175 calibrator in triplicate and follow novalUM prompts to count them.
 - a. If there is too much variation between the three replicates of either the 44/88 or 175 calibrator, the instrument will ask for the assay to be repeated.
 - b. If either average is not in the specified range, the instrument may adjust the background and correction settings and prompt for three more replicates of the 44/88 and 175 calibrator.
 - c. If either average is too far out of range, the instrument will return to the start of the calibration (step 4).
13. Once the 44/88 and 175 values have been accepted, the novalUM will display a message that the calibration was successful. Keep the printout of the calibration settings.
14. Press ESC 4 or 5 times to escape to Main Menu.
15. Channel limits for alkaline phosphatase are programmed by connecting to the novalINK software. Typically 350 mU/L is programmed as the action limit for pre-calibrated alkaline

phosphatase channels. Sample plans are also created and loaded using novalINK. At least one plan for each alkaline phosphatase channel is required to perform tests when using option 2 'Programmed Plans' (if channels are disabled). See NovalINK manual for further instructions.

Note: A channel that has been factory-calibrated to run Pocketswabs or Giene tests (AllerGiene, WaterGiene) cannot be calibrated for alkaline phosphatase.

If the temperature probe measures the stopping solution to be outside of the allowable range, a message appears, "Instrument too warm". The novalUM will not allow an alkaline phosphatase assay to be run. Adjust the temperature of the solution and begin again.

Once a channel has been calibrated to run alkaline phosphatase, the channel may be recalibrated to run a different type of assay at a later time if desired. Contact Charm Sciences.

PasLite Control Check:

1. Once a channel has been successfully programmed, select option 8 'Channel Calibration' from the Main Menu. Select PasLite. (Alternatively select option 2 'Programmed Plans' from the Main Menu and then select the proper plan and/or channel.)
2. Select the appropriately calibrated channel. Select option 3, 'Control Check' from the Mode of Operation Menu.
3. Instrument will prompt for one positive AP control or 350 calibrator. Select desired positive control type and press OK when ready.
4. Insert the appropriate positive (positive control or 350 calibrator) and press OK to start the count. If the positive is not in range, the instrument will give the result and then will return to the mode of operation screen. If it is in range, it will prompt for the negative control.
5. Insert negative control and press OK to initiate the count.
6. If the negative control is in range, the control check is completed. If it is out of range, the instrument will display the result and return to the mode of operation screen.

PasLite – MODE OF OPERATION:

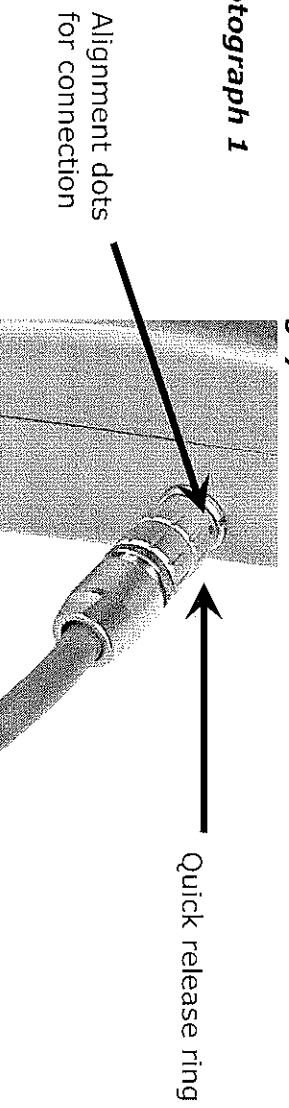
Once a PasLite channel has been calibrated to test alkaline phosphatase on a certain type of product, the mode of operation will appear upon the selection of that channel (when selecting option 8 'Channel Calibration' from the Main Menu, then selecting 'PasLite', and finally selecting the calibrated channel). Alternatively, select 'Programmed Plans' (item 2) from the Main Menu, and select the calibrated channel.

1. Select the appropriate menu item:
 - a. Run Test (from Channel Calibration reads a sample using the existing calibration, from Programmed Plans provides a list of plans in that channel, select plan to enter Run Sample menu, select sample and press enter)
 - b. Calibrate (for a new lot of reagent or for a new matrix calibration)
 - c. Control Check (for performance monitoring)
2. Select Run Test for routine sample analysis. From Programmed Plans, the Plans Menu will appear. If a plan is selected, the Run Sample Screen will appear. The Run Sample Screen information will appear. Appropriate sample information can be selected with arrow keys. Once desired sample information appears on screen, press OK to initiate a count.
3. The instrument will analyze the sample for 5 seconds and then display a Test Result screen. If connected to a printer, all of the result data will print. Otherwise, data may be viewed in novalINK.
4. Press OK to exit the results screen and to return to Run Sample Screen. Press OK a second time to initiate another count.
5. Press ESC to return to Mode of Operation Menu or to the Programmed Plans menu.
6. If a channel is not already calibrated for alkaline phosphatase, selecting the channel from Main Menu item 8, 'Calibration Menu', will immediately put novalUM in calibrate mode, see the section 'PasLite Calibration'. If a channel is not already calibrated for alkaline phosphatase selecting the channel from Main Menu option 2, 'Programmed Plans', will bypass the Mode of Operation Menu and go directly to the plan menu. If a programmed plan does not exist for a channel, a message will appear and the novalUM will go to the Main Menu.

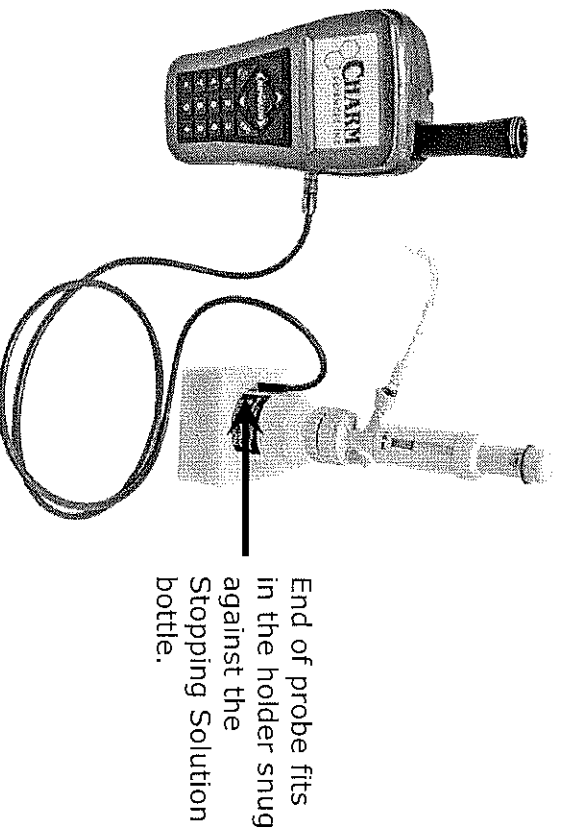
Alkaline Phosphatase Temperature Probe (required for Paslite & F-AP):

1. **Plug probe connector fully into side socket in novalUM prior to power up. Align the red dots as shown in photograph 1, and press in to connect.**
2. Place thermometer end of probe in Stopping Solution holder snug up against Stopping Solution bottle as shown in photograph 2.
3. The probe measures the temperature of the solution and compensates the RLU of the novalUM for temperature variations between 18-24°C. If the temperature is outside of this range, a message appears indicating the temperature is out of range and count was aborted.
4. The temperature probe improves variation of the Paslite and F-AP assays caused by day to day ambient air temperature changes.
5. **Power down instrument prior to un-plugging probe. The probe uses a quick release ring. Pull up on the ring and pull out probe. Do not unscrew the probe (this could cause damage).**

Photograph 1



Photograph 2



Somalite Calibration:

1. Connect the novalUM to a printer (highly recommended). Select option 8 'Channel Calibration' from the Main Menu.
2. Select the assay type 'somatic cells'.
3. Select the channel to be calibrated.
4. Select the type of calibration from 'Calibrate Using' menu.
 - a. Pos. calibrator: This calibrator uses the SCC-ATP calibration tablet.
 - b. Known DMSCC Milk: This uses milk with a known DMSCC in the range of 500 to 1,000 (SCC/ml x 1000). Upon selecting this menu item, the known DMSCC value will be prompted and will need to be entered as SCC/ml x 1000, e.g. a 1000 (SCC/ml x 1000) entry is equivalent to 1,000,000 SCC/ml .
5. Prepare the positive control (SCC-ATP tablet) or test the known DMSCC milk sample according to the Somalite Operator's Manual. Count in novalUM. Repeat this 3 times. Assay the negative control (pasteurized milk). Count in novalUM. Repeat this 3 times.
6. Calibrators
 - a. If the novalUM is connected to a printer, the results will print out as they are read.
 - b. The initial printed counts are with a 100 background and 100 correction value. The RLU averages are used by the instrument to determine the correct calibration settings for the matrix.
 - c. If there is too much variation between the three replicates of either control/calibrator, the instrument will ask for the assay to be repeated. Press OK to continue, and then count the new tubes, or press ESC to return to the previous menu.
7. Once successfully calibrated, the novalUM will calculate calibration settings and deliver a 'Calibration Successful' message.
8. The number delivered after successful calibration is in SCC/ml x1000 units.

CHEF/F-AP Option:

1. The third selection in the calibration menu may appear as either CHEF or F-AP. Switching between channels is accomplished with Hyperterminal commands. Contact support for assistance in converting from one option to the other.
2. The CHEF option is for running the CHEF (Meat Cooking efficiency) Test and the alkaline phosphatase (Paslite) semi-solid assays.
3. The F-AP option is for running a fast and simplified alkaline phosphatase test for liquid dairy products and for the F-AP-M (fast acid phosphatase for meat) test.

CHEF Calibration:

1. Connect the novalUM to a printer (highly recommended). Select option 8 'Channel Calibration' from the Main Menu.
2. Select the assay type 'CHEF'.
3. Select the channel to be calibrated.
4. Select 'Calibrate' from the menu (this option appears if the channel has been calibrated before. If channel has not been calibrated before, the novalUM will skip to Step 8)
 - a. Run Test (from Channel Calibration reads a sample using the existing calibration, from Programmed Plans provides a list of plans in that channel, select plan to enter Run Sample menu, select sample and press enter)
 - b. Calibrate (for a new lot of reagent or for a new product)
 - c. Control Check (for performance monitoring)

5. Prepare three negative controls and three 350 calibrators according to the CHEF Operator's Manual (or Paslite solid/semi-solid procedure). Assay the negative controls in triplicate. Press OK when the tests are ready to be counted, and follow the prompts to count the three negatives. Then assay the 350 mU/L calibrator in triplicate. Follow the instrument prompts to count the three 350 calibrators.
6. Calibrators
 - a. If the novalUM is connected to a printer, the results will print out as they are read.
 - b. The initial printed counts are with a 100 background and 100 correction mode. The RLU averages are used by the instrument to determine the correct calibration settings for the matrix. Once accepted the instrument will prompt to repeat the assays, see step 7.
 - c. If there is too much variation between the three replicates of either control or calibrator, the instrument will ask for the assay to be repeated. Press OK to continue, and then count the new tubes, or press ESC to return to the previous menu.
7. The novalUM calculates calibration settings and then prompts to repeat the assays of three negative controls and three 350 mU/L calibrators. Assay the negative controls in triplicate. Press OK when the tests are ready to be counted, and follow the prompts to count the three negatives. Then assay the 350 mU/L calibrator in triplicate. Follow the instrument prompts to count the three 350 calibrators. The average RLU are compared to the specified ranges. If the values are out of range, the calibration must be repeated (at step 8). If the values are in range (0-5 for negative, 320-400 for 350 mU/L), it will give a 'Calibration Successful' message.
8. Connect to novalINK. Adjust channel limit for CHEF, typically twice the 'negative control average' or 50 RLU which ever is greater (for Paslite applications, 350 mU/L is typically set). Also create and load a sample plan for each CHEF channel. See novalINK manual for further instructions.

CHEF - MODE OF OPERATION:

Once a CHEF channel has been calibrated to test CHEF on a certain type of product, the Mode of Operation will appear on selection of that channel in item 2 'Programmed Plans' or 8 'Channel Calibration' of the Main Menu.

Select the appropriate menu item:

1. Run Test (from Channel Calibration reads a sample using the existing calibration, from Programmed Plans provides a list of plans in that channel, select plan to enter Run Sample menu, select sample and press enter)
2. Calibrate (for a new lot of reagent or for a new matrix calibration)
3. Control Check (for performance monitoring): uses ranges of 0-5 for negative control, 247-453 for positive control.

If a channel is not already calibrated for CHEF, selecting the channel will immediately put you in calibrate mode. See 'CHEF Calibration' section of this manual.

F-AP Calibration:

1. F-AP has different times of incubation depending on matrix: milk, cream or chocolate. The 45 second time for milk and 90 second time for cream and chocolate need to be programmed into specific NovalUM channels designed for the F-AP matrix. If not already programmed, contact technical assistance to perform this set up.
2. Connect the novalUM to a printer (highly recommended). Select option 8 'Channel Calibration' from the Main Menu.
3. Select assay type 'F-AP'.
4. Select the channel, with the appropriate F-AP time/matrix, to be calibrated.

5. Select 'Calibrate' from the menu (this option appears if the channel has been calibrated before. If channel has not been calibrated before, the novalUM will skip to Step 6)
 - a. Run Test (from Channel Calibration reads a sample using the existing calibration, from Programmed Plans provides a list of plans in that channel, select plan to enter Run Sample menu, select sample and press enter)
 - b. Calibrate (for a new lot of reagent or for a new product)
 - c. Control Check (for performance monitoring)
6. Prepare negative control and Positive Control (350 calibrator) according to the F-AP Operator's Manual. Add negative control to vial and Press OK. After negative control counts, then add the Positive Control to vial and press OK.
7. Calibrators
 - a. If the novalUM is connected to a printer, the results will print out as they are read.
 - b. The initial printed counts are with a 100 background and 100 correction mode. The RLU averages are used by the instrument to determine the correct calibration settings for the matrix. Once accepted the instrument will prompt to repeat the assays, see step 7.
8. The novalUM calculates calibration settings and then prompts to repeat the assays of the negative control and Positive Control. Press OK when the tests are ready to be counted. Follow the instrument prompts to count the negative control followed by the positive control. If the values are in range (0-15 for negative, 320-400 for 350 mU/L), it will give a 'Calibration Successful' message. The average RLU are compared to the specified ranges. If the values are out of range, then step 7 will be re-prompted two more times. If out of range after three tries the calibration repeats (at step 5).

F-AP - MODE OF OPERATION:

Once a F-AP channel has been calibrated to test F-AP on a certain type of product, the Mode of Operation will appear on selection of that channel in item 2 'Programmed Plans' or 8 'Channel Calibration' of the Main Menu.

Select the appropriate menu item:

1. Run Test (from Channel Calibration reads a sample using the existing calibration, from Programmed Plans provides a list of plans in that channel, select plan to enter Run Sample menu, select sample and press enter)
2. Calibrate (for a new lot of reagent or for a new matrix calibration)
3. Control Check (for performance monitoring): uses ranges of 0-15 for negative control, 247-453 for positive control.

If a channel is not already calibrated for F-AP, selecting the channel will immediately put you in calibrate mode. See 'F-AP Calibration' section of this manual.

Pesticide Calibration:

1. Connect the novalUM to a printer (highly recommended). Select option 8 'Channel Calibration' from the Main Menu.
2. Select the assay type 'Pesticide'.
3. Select the channel to be calibrated.
4. Select from the 'Mode of Operation' menu.
 - a. Run Test (uses the determined limit from negative control to analyze sample)
 - b. Calibrate (uses the negative control from assay to determine the limit for analyzing samples from that assay).
5. Select 'Calibrate' and the novalUM will prompt for analysis of negative control. If in the specified range (>5000) a limit will automatically be calculated for the channel and 'Calibration Successful' will appear.