





NanoRam[®] Series Handheld Raman System Quick Start Manual



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1. Overview

The NanoRam Series is a handheld Raman instrument designed for rapid identification of sample material based on their Raman spectrum. The instrument has a touch screen operation with intuitive software for easy operation by specialists and non-specialists alike. Identification and Investigation modes of analysis are available based on qualitative analysis of sample spectra that are compared to method and/or library spectra to provide Pass/Fail and Match/No Match results. The operating software (NOS) has different user access levels, and includes a complete audit trail of measurements. Data reporting, management and account management are done by synchronizing the instrument data with the data/library/user/report management software NID, loaded onto a PC. Library and method transfer are supported between same type of units (NanoRam to NanoRam, NanoRam Mini to NanoRam Mini). Both instruments are housed in durable IP6X-rated cases (IP64 for NanoRam and IP65 for NanoRam Mini respectively) that provide different levels of protection from ingress of dust and water.

Note: this quick start manual is applicable to both NanoRam and NanoRam Mini.

1.1. Safety Warning and Cautions

The system contains one Class 3B laser light source. The product complies with 21 CFR 1040.10, Laser products. Please read through this user manual before operating the system.

1.2. Laser Emission Aperture and Beam Shutter

Located at the laser emission aperture, the laser emission label indicates that the laser energy emission occurs at the corresponding port.



The NanoRam unit comes equipped with CDRH-compliant laser safety measures including soft key switch, remote interlock, and emergency laser stop key button.





The laser hazard zone is within 30cm (11.8 inches) to the tip of the point-and-shoot adaptor.

1.3. Remote Interlock (for NanoRam only)

The remote interlock is located at the bottom of the unit next to the Ethernet port. The remote interlock facilitates the laser 'on' and 'off' remote control function. When the laser stop key is inserted into the slot, the interlock is closed and laser emission is enabled. When the key is pulled out, the interlock is open and the laser does not emit and cannot be turned on.



1.4. Laser Warning Label

The laser warning label is located on the rear panel of the system. The label displays the laser safety class, wavelength and power of the laser source.







1.5. Precautions

- Never point the unit directly at a person.
- Never look directly into the laser beam path or scattered laser light from any reflective surface.
- Never look directly into the laser source.
- Maintain low beam level when performing experimental setup to prevent inadvertent beam-eye contact.
- As a precaution against accidental exposures to the laser beam or its reflection, user should always wear laser safety glasses (provided) with sufficient attenuation for the laser.

Sources for additional information and assistance on laser safety:

CDRH-Radiological Health Program

Office of communication, Education and Radiation Programs





Center for Devices and Radiological Health Food and Drug Administration 10903 New Hampshire Avenue W066-4613 Silver Spring, MD 20993 USA

Tel: 1-800-638-2041 Fax: 1-301-847-8149 dsmica@fda.hhs.gov

Laser Institute of America

13501 Ingenuity Drive, Suite 128 Orlando, FL 32826 USA

Toll Free: 1-800-345-2737

Tel: 1-407-380-1553 Fax: 1-407-380-5588

www.lia.org





1. Diagrams of the Instruments

1.1.NanoRam









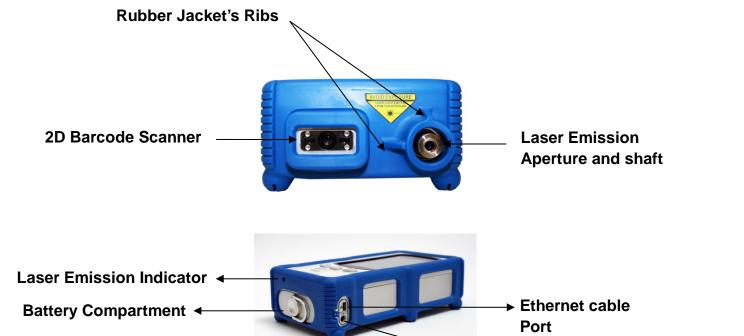


1.2. NanoRam Mini









1.3. Warranty Seal Label

The warranty seal labels are positioned on both sides of the system under the blue jacket. Any attempt to open the panel(s) of this device will break these seals and void the warranty.



1.4. Manufacturer's Identification Label

19 Shea Way, Newark, DE 19713, USA • Tel: +1 (302) 368-7824 • Fax: +1 (302) 368-7830 • Web: www.bwtek.com

★18V DC Power Connector





Located on the rear panel of the system, the manufacturer's general identification label includes warning information and also displays the manufacturer name, address, model number, serial number, and the manufacturing date.

2. Knowing Your Instrument

2.1. Power Supply

The unit can be run on either external power supply or on battery. Before using the unit with the battery, make sure that the battery is fully charged. The battery status can be found on the top right corner of the screen in 'operation' displays, or the center of the screen when in charging only mode. The NanoRam battery can be charged with the 12VDC power adaptor or optional charging cradle. The NanoRam Mini battery can be charged with the 18VDC power adaptor or optional charging cradle.

Note: It is recommended to charge the battery only when the unit is not in use.

2.2. Battery Installation and Charging

Locate and identify the battery cover at the bottom end of the unit.

Note: there are two versions of battery door design: version A and B. To identify: version A does not have any sign on the bottom cover while version B has an unlock sign near the ring. Turn counterclockwise to unlock if you have version A and turn clockwise to unlock if you have version B.



Version A



Version B





Version A:

Hold the ring and turn it counterclockwise 1/8th turn to unlock.



Carefully pull out the battery cover and set aside.



Insert the provided NanoRam Lithium Ion battery pack into the battery compartment as shown. Battery contacts should be facing down (towards the back of the unit) and to the right. The strap attached to the battery pack can be used for battery insertion as well as removal. Assure that the battery is fully inserted.



Install the battery cover back in the same position as removed. Use thumbs and/or fingers to firmly press the cover into place to assure correct positioning and to establish a tight seal.







Turn the ring <u>clockwise</u> 1/8th turn till the ring is in a vertical position.



The cover is now locked.



Version B: Hold the ring. Turn it <u>clockwise</u> 1/8th turn to unlock.



Turn it <u>counterclockwise</u> 1/8th turn till the ring is in a vertical position to lock.



<u>Note</u>: The battery can be charged either through the supplied external power adaptor or using the optional charging cradle.





2.3. Power On/Off

To power on the system, press and hold the power on/off key for at least 3 seconds. An initial screen will display, followed by a NanoRam OS (Operating System) screen indicating that the system initialization is in process with a count up in percentage of completion. After the initialization of the system is completed, the user login screen will be displayed. The unit is now operational.







There are two ways to turn off the system

<u>Soft power down</u>: press the power On/Off key for about one second. A message
appears confirming the shutdown request. Press **OK** to confirm the operation and the
system will turn off. Press **Cancel** to cancel the request and return to the previous
menu.







• Hard power down: press and hold the power On/Off key of for about 3 seconds.

Note: The instrument cannot be hard powered down when it is being charged. Avoid hard powered down unless necessary. An "abnormal power down" error message will be shown if the unit was hard powered down or battery was pulled out during operation.

2.4. User Login

After logging in with the defined user name and password the Home Screen will be displayed.

The Home screen for the NanoRam is displayed here for an Administrator. The same home screen is displayed for an Operator-level user.



2.5. Home Key

Pressing the **Home** key one time on the front panel will:

- return user to the previous screen
- log out and return to the login screen if the user is in the main screen
- cancel the current operation (for example: an acquisition with laser in emission) and return to the Home screen

Pressing the **Home** key <u>twice</u> at any stage of the operation will return user to the Login screen.

2.6. Using the Sampling Accessories

The NanoRam unit standard package comes with four types of sampling accessories which





will facilitate easy and fast sampling. Depending on the type and form of the materials to be measured, the appropriate sampling accessory can be selected. The sample can be placed directly against the adaptor.

Point-and-shoot adaptor	
Liquid vial holder adaptor that	
holds a 15mm(diameter)x 45mm(height) vial	
Bottle adaptor for measurement through	4
a container	
Calibration cap with built-in polystyrene	
Right angle adaptor (optional)	
Tablet holder adaptor (optional)	
Immersion probe adaptor (for use with NanoRam only)	

The user needs to ensure that the sampling adaptor is installed properly before using the NanoRam. Before installing any accessories the NanoRam should be at the log in screen with the laser turned off to ensure safety. No operations are permitted without the lensed shaft in full installed position with standard accessories, or an immersion probe, tablet holder or right-angle adaptor properly installed with their shaft accessory.

For installation of the right angle adaptor, tablet holder or immersion probe please read the guidelines for safe installation and use provided with the accessory. They are included in the Appendix of the user manual as well.

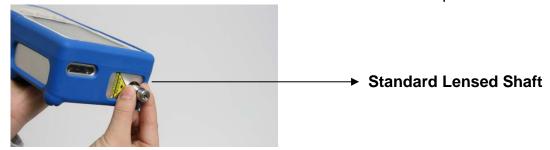




Never remove the lensed shaft when the instrument is on.

The following steps will guide the user to successful installation of the sampling accessory:

Make sure the correct shaft is installed onto the laser emission aperture.



Locate the alignment key on the adaptor and the set pin position at the laser emission aperture.



Push the adaptor onto the shaft until the O-ring just reaches the instrument surface.



Gently turn the adaptor clockwise until a click is felt or the sound of a click is heard, which indicates that the key on the adaptor is set to the set pin at the laser emission aperture. Once the alignment is reached, stop turning the adaptor.







Push the adaptor further in until the O-ring is fully inside the emission port. At this point the adaptor should be positioned firmly into its position.



Precaution: to avoid accidental exposure to the laser beam do not look directly into laser emission aperture.

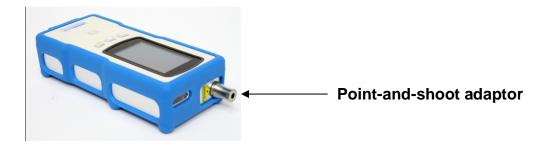
Using the Point-and-Shoot Adaptor

The Point-and-shoot adaptor can be used for powder, solid or liquid sample measurements through a thin and transparent container. With the Point-and-shoot adaptor in place, hold the NanoRam unit so that the adaptor is against the sample container surface.

Note: B&W Tek does not recommend that the adaptor touch <u>powder samples</u> directly, as they may contaminate the lens on the sampling adaptor. The use of a protective transparent plastic film is recommended.







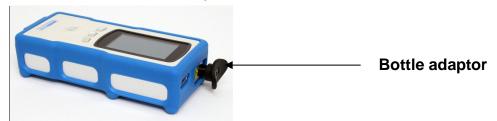
Using the Liquid Vial Holder Adaptor

The liquid vial holder can be used for liquid, gel, or powder samples. The liquid vial holder holds a 15 mm (diameter) x 45mm (height) vial.



Using the Bottle Adaptor

The bottle adaptor can be used for the measurement of samples through transparent containers of less than 5 mm in thickness, such as liquid samples inside bottles, or containers. The bottle or container can be placed directly against this adaptor. The measurement beam will then be ideally focused into the sample over 5 mm away from the surface of the adapter.



The NanoRam Mini unit standard package comes with three types of sampling accessories which will facilitate easy and fast sampling. Depending on the type and form of the materials to be measured, the appropriate sampling accessory can be selected. The sample can be placed directly against the adaptor.





Point-and-shoot adaptor	•
Liquid vial holder adaptor that holds a 15mm(diameter)x 45mm(height) vial	
Performance validation cap with built-in polystyrene	
Right Angle Adapter (optional)	•

The user needs to ensure that the sampling adaptor is installed properly before using the NanoRam Mini. Before installing any accessories, the NanoRam Mini should be at the log in screen with the laser turned off to ensure safety. No operations are permitted without the lensed shaft in full installed position with standard accessories.

<u>Using the Point-and-Shoot Adaptor</u>

The point-and-shoot adaptor can be used for powder and other solid samples. With the point-and-shoot adaptor in place, hold the NanoRam Miniunit so that the adaptor is against the sample container or sample surface.

To install point-and-shoot adaptor, insert the adaptor onto the shaft, gently push it all the way in until the adaptor is installed properly into position and secured by the rubber jacket ribs.





<u>Note</u>: We do not recommend that the adaptor touch <u>powder samples</u> directly, as they may contaminate the lens on the shaft. The use of a protective transparent plastic film is recommended.





Practice caution when measuring dark samples as they may heat up and potentially burn. Lower laser power settings are recommended for dark materials.

Using the Liquid Vial Holder Adaptor

The liquid vial holder can be used for liquid or gel samples. The liquid vial holder holds a 15mm (diameter) X 45mm (height) vial.

To install liquid vial holder adaptor, insert the adaptor onto the shaft at the laser aperture. Make sure the vial holder key is aligned with the jacket rib. Gently push it all the way until the adaptor is now installed properly into position and secured by the rubber jacket ribs.



Align the vial holder key with the rib



Using the Rubber Jacket's Ribs as Bottle Adaptor

The rubber jacket's rib is designed in such a shape that it can be used as a bottle adaptor for the measurement of samples through transparent containers of less than 5mm in thickness, such as liquid samples inside bottle containers. To scan liquid inside the bottle, first remove any sampling adaptor. With only the shaft in place, bottle or container can be placed directly against the shaft. The measurement beam will be ideally focused into the sample over 5mm away from the surface of the adapter.







Using the Right Angle Adapter (optional)

Slide the adapter all the way in with the locating notch aligned with the location pin on the NanoRam Mini measurement port. Carefully rotate as needed to align the adaptor for proper positioning. During measurement operations, place the NanoRam Mini so that its right angle adapter port is in contact with the sample surface.



2.7. Barcode Scanner Key

The barcode scanner functions only in the appropriate displays screens when the system is in the Identification mode, Investigation mode, or while creating new methods. To scan the barcode, place the object in front of the barcode scanner at a distance of ~40 -245 mm, depending on the type of barcode. Press the barcode scanner key for at least 1 second to scan the barcode.

2.8. Laser Switch /Acquisition Key

To turn on the laser, press the laser switch key ...





The laser can be turned on only when the system is in **Identification**, **Investigation**, or **Library and Method building modes**. Pressing the laser button, or Home button during a scan can stop an acquisition. If such an action occurs, the data may not be saved.

Note: In case of emergency, the laser can be turned off any time by pressing the Laser switch button or Home button.

3. Operator User Quick Start

3.1. User Login

The following instructions assume that an Operator account has already been set up by the Administrator.

At the user login screen, enter the user name and password and then press **Login**. The home screen for basic user will be displayed. The user information including user name and user type will be displayed on the upper left of the screen.

The user can select **Remember User Name** to automatically recall the user name. Only the last user name can be remembered. The password is always needed for login attempts.

When the wrong user account information is entered, the system will allow three trials before the system locks out the user. After the system is locked out, the user will be prompted to turn off the system and try again with the correct account information:

"You are not authorized to access this device. The device has been temporarily locked. Please verify your login info and try again at the next power up."







The *Operator* users have access to the functions of select Method, select Operation Preset, perform Identification, perform Investigation, and perform Validation Test, as well as view Library list. The Operator can also perform Data Transfer and thus access the Wireless and Ethernet functions in the Set Up. The rest of the Set Up functions are deactivated for the *Operator* user type, but are accessible for *Developer* and *Administrator* user types. For example, in General setting, an operator can only see following window.



3.2. Perform Material Identification

Press the **Identification** icon on the home screen. The screen for Load Method will be displayed.

Load the method by either scanning barcode or manual selection of the method name from the method list. Enter the number of samples to be tested. When the number of samples is more than one, the identification will be performed in a batch fashion where





the samples within the same Run will carry the same Product name with a suffix of increment of one, starting from #1 (ProductName#1), as the measurement moves to the next sample. Check the option if user chooses to "Use the Method Name as the Product Name". Press **Next** for the page to enter **Run Name**, **Product Name**, and **Sample Info Fields** pre-defined by Administrative user. When running more than one sample in a batch manner, users are required to enter a Run Name.

Press the Laser Switch/Acquisition key $\stackrel{*}{\sim}$ to start acquiring the Raman spectrum. Keep the sample in place until the dark scan is also completed.







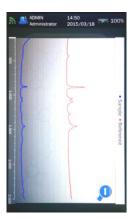
In summary, the Identification test is performed in the following order:

- i. Load the Method.
- ii. Enter product information.
- iii. Acquire a Raman spectrum of the material to be identified.
- iv. A p-value will be calculated by comparing the spectrum acquired from the sample and the spectrum from the method.
- v. A "Pass" or "Fail" result will be declared based on a significance level, which is set in the Method. Therefore, for a p-value greater than or equal to the set value, for example 0.05, the result of "Pass" will be declared; for a p-value less than 0.05, the result of "Fail" will be declared.

For "Pass" results, verified material information and the p-value will be displayed. Press to view the acquired spectrum and the spectrum associated with the method. Press to close the screen and return to the previous screen. For "Fail" results, the probable match suggestion against the library, if available, will be displayed with the corresponding HQI. Press to display the acquired spectrum and the spectrum associated with the probable match.







<u>Single Sample</u>: For identification run with a single sample, the result shows the final result.



<u>Batch Samples</u>: For identification run with more than one sample, the result shows for each of the samples. When any sample(s) within the run **Fail** the Identification test, the user will be asked whether to run another sample. If user chooses **Yes**, a note must be entered (user can either select the default notes or press Add to type in the note) and saved before repeating the test. If user chooses **No**, the current sample will be skipped and the test will proceed to the next sample number.

For identification run with sample number more than one, the user can choose **Pause** to stop the current run and the run will be considered as "unfinished run". The user will be reminded of the unfinished run(s) upon loading another method. User can press **Cancel** to continue loading the method, or press on the name of the unfinished run to resume and finish the unfinished run.













3.3. Perform Material Investigation

Before investigation for unknown materials, the corresponding Operation Preset needs to be selected.

Press the **Set Up** icon on the Home page, and then press **Operation Preset**. The list for the existing Operation Preset will be displayed. Select the desired Operation Preset by tapping on the name. The selected Preset will be marked by a check mark. Press on **View** to view the setting or **Back** to return to the previous screen.







Note: Mixture MinHQI is not available for NanoRam Mini.

The *Operator* is only able to *view* the parameters. If a parameter is changed unintentionally, the change will not be saved, thus the Preset remains intact.

Make sure the appropriate sampling adaptor is properly installed. Place sample correctly





using the sampling adaptor.

Press the **Investigation** icon, and the "ready to scan" page will be displayed. A screen for sample information will be displayed. Enter the necessary information already set in the "Sample Info Field". Press the **Laser Switch /Acquisition** key to start acquiring data.

As a safety warning, the NanoRam will emit intermittent acoustic signals and flash a laser warning symbol on the screen before starting the acquisition. After about 2 seconds as you press the laser acquisition key, laser emission is generated from the instrument.

The system will assign a default initial integration time for the first scan. The integration time will be automatically optimized. A dark scan will follow, accompanied with acoustic signals of a slightly shorter interval.

Note: While the dark scan is being collected, the sample needs to remain at the same position until the dark scan is completed.

After the spectrum is collected, the search for a matching spectrum in the spectral library will start automatically. The investigation result of either "**Match**" or "**No Match**" will be displayed.

For a "Match" result, possible matching compound information and their HQI (Hit Quality Index) will be displayed. Press , to display the aquired spectrum matched with the spectrum of the library. Press to close the screen and return to the previous screen. For a "No Match" result, a message will be displayed. Press , to display the acquired spectrum. Press to close the screen and return to the previous screen.

If the number of hits is >1, and more than one library has an HQI greater than the threshold, the other spectral matches will be displayed in descending order of HQI.





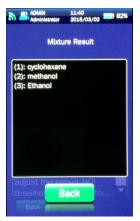




Note: HQI is a measure of the level of correlation of the sample spectrum against a spectrum from the library by use of a predetermined algorithm. HQI=100 indicates a 100% correlation score between the sample spectrum and the spectrum in the library. HQI=0 indicates a 0% correlation score between the sample spectrum and the particular spectrum in the library. While the default setting for minimal HQI is 80, the criteria for "Match" can be set by the user with Administrator or Developer level privileges.

Mixture Analysis (only for NanoRam)

Upon receiving "No Match" result or matched HQI is lower than preset Mixture MinHQI, user can press the **Mixture** button on the result page. The system will run mixture analysis on the given signature to determine possible substance components. The laser does not emit during the mixture analysis. A mixture result will follow.



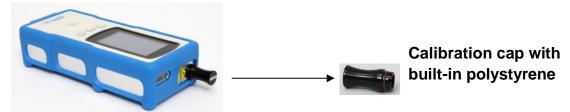




3.4. Performance Validation

Instrument performance validation can be conducted using the performance validation functions. The 'Performance Validate' function is intended to validate the accuracy of the instrument in terms of the Raman shift position and peak intensity within a spectral range as compared to a polystyrene spectrum generated at the factory. A Calibration Cap with a built in traceable Polystyrene Standard is provided for the validation. The frequency on how often the validation test needs to be run should be determined by the user's SOP depending on the requirement of the applications and user quality assurance systems.

Place the Calibration Cap onto the laser emission aperture aligning the key on the adapter with the pin on the emission port. The standard polystyrene material will be at the focal point of the laser beam.



Press the **Set Up** icon on the Home page, then press **Perf. Validation.** The Validation screen will be displayed. Press **Validate** followed by pressing validation scan.

The validation result will be displayed after the scan is done. If the Validation passes, press **Done** to return to the previous screen.













3.5. Enable Data Transfer

To enable Data transfer to the PC with NID Client installed, one must first establish the connection between NanoRam and the PC.

Press the **Set Up** icon on the home screen, then **WLAN & Networks**. Press **Ethernet** for connection via Ethernet, or press **Wi-Fi** for connection via wireless.





After making the connection, return to the Home Screen.

Press the **Data Transfer** icon **u**on the Home screen. The data transfer screen will be displayed with two options available: Ethernet and Wi-Fi.

To enable Ethernet connection, press **Ethernet** button. Once the check mark turns green





the data transfer via Ethernet connection is enabled.

To enable Wi-Fi connection, press the **Wi-Fi** button. Once the check mark turns green the data transfer via Wi-Fi connection is enabled.

See section 5.3 for details on synchronization from NID.





3.6. History Review

To view history scans before syncing to NID, simply swipe down on the NOS display: a Scan History List will appear with Identification or Investigation results. Tap on each result to view details. A mixture analysis (only for NanoRam) can be performed here for investigation scans (if not done earlier in investigation) by pressing Scan button on the instrument. Swipe left and right across the screen can toggle between different scan results. Swipe up to hide the history scan list. All the scan history will disappear after syncing to NID.











4. NID Software

4.1. About NID

NID is a software package included with the NanoRam shipment and is used for management and reporting of data collected with the NanoRam. There are two services designed in the NID software to function on the client's PC and server, respectively:

- NID Client for client PC to access the NanoRam device and manage data
- NID Server for client server for data storage

The connection between the NanoRam device and the PC can be either through Ethernet cable or Wi-Fi network.

When the data on NanoRam device (user account info, test result, library, audit trail data, etc.) is synchronized onto server using NID Client, the data is stored on the NID Server.

4.2. Device Connection on NID

The device connection on NID is done by connecting the NanoRam unit with the computer via Ethernet or Wi-Fi. The connection should be established by the Administrative user.

When an Ethernet cable is used to connect the NanoRam to a PC, make sure:

- Ethernet cable is connected between NanoRam and PC or via an internet router/network port.
- Ethernet connection is enabled in **Data Transfer** menu in NOS software on NanoRam unit.

When Wi-Fi is used to connect the NanoRam to a PC, make sure:

- Both NanoRam unit and the PC are successfully connected to the same Wi-Fi network.
- Wi-Fi connection is enabled in **Data Transfer** menu in NOS software on NanoRam unit.

Note: For data security measure, the Ethernet or Wi-Fi connection will be disconnected automatically under two scenarios: i) if the NanoRam is out of the **Data Transfer** screen;





ii) after screen saver is turned on or the connection has been idle (without any data transfer actions) for 15 minutes. A warning message will appear on the screen. Data could be lost if data is being synchronized at the moment. The user needs to login again and re-enable Ethernet or Wi-Fi in **Data Transfer**.



4.3. Login NID Client

Click on *NID Client* icon on the desktop to start *NID Client* program. At the same time *NID Server* will be open automatically, running in the background.



Enter the NID login info (case sensitive) to login:

User Name: NID Admin

Password: **Password should be set by your Administrative user







Click on in the upper right corner. Six languages are available in display: English, Simplified Chinese, Traditional Chinese, Japanese, Korean and Spanish. Once a different display language is selected, user needs to close and then restart the NID Client for the new setting to take effect.







After the user login to the NID Client program, the PC screen will display the available NanoRam devices that have established connection. The serial number of the system is displayed under the device icon.



Note: NanoRam Mini will appear as a different icon on the login page.



Click on the NanoRam icon with the serial number of the unit you wish to synchronize. The **Login** button will be activated. Enter your login info for the NanoRam device. Click on **Login**. If the unit's clock is different from NID server by more than 10 seconds, a





message prompting the user to "synchronize the unit time to server time" will appear. If "Yes" is selected, the unit's system clock will be synchronized to the server's time. Meanwhile, message "Successfully logged in" will appear. At this stage, the NanoRam device login is completed.



4.4. Data Synchronization

Data synchronization is to transfer data from the NanoRam's memory to the NID server. At this point, user can choose LIMS Report to also have data exported to a set location in a LIMS-compatible format.

Click on **Device** followed by clicking on **Sync** on the left menu bar of the screen. Click **Synchronize** to start the synchronization. Confirmation message appears after synchronization completed.





