NORTHEAST MONITORING, INC.
HOLTER LX REMOTE SOFTWARE

advancing Holter technology

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SCANNING SERVICE INSTRUCTIONS

Welcome to NorthEast Monitoring's Holter LX Remote software. Used in conjunction with a NorthEast Monitoring Digital Holter Recorder, the Holter LX Remote web-site and the Keyless Remote software allows a user to save and send Holter data to a different site for analysis. The Scanning Service or receiving site must use either Holter LX Analysis V5.3 or greater - Pro or Enhanced Plus levels - to retrieve and analyze the Holter data.

Note: This product, like all Holter monitoring products, should be used only under the direct supervision of a licensed physician.

NorthEast Monitoring - FDA Registered Establishment #1224919.

The Holter LX Analysis and LX Remote software - FDA 510K Market Approval Number K930564.

System requirements

This software can only be used in conjunction with a NorthEast Monitoring digital recorder - the DR180+/DR80+Oxy, the DR200/HE or the SD360. It is not compatible with the Holter monitor of any other manufacturer. To run the Holter LX Remote software, your personal computer must include:

- Microsoft Windows XP or Windows 7 operating systems
- a broadband Internet connection
- Internet Explorer or Mozilla Firefox browser application
- Scanning Service site requires at least one copy of the Holter LX Analysis software (Pro or Enhanced Plus)

Operator knowledge

All instructions assume a working knowledge of computers and, specifically, Windows XP or Vista software.

The Users

The Holter LX Remote web-site allows remote users to send Holter data to another site that utilizes the Holter LX Analysis software to analyze and report on Holter recordings. There are three types of users:

1. The Scanning Service Administrator - Will be responsible for customizing the site and setting up and maintaining all of the users.

2. The Remote User - A scanning service customer who records Holter data using NorthEast Monitoring Holter recorder and sends the patient data and Holter file to the Scanning Service via the web-site.

3. The Base Technician - The employee of the scanning service that retrieves the files from the web-site and uses Holter LX Analysis (Pro or Enhanced Plus) to analysis and report on the Holter recording.

The Set up Process

The following steps need to take place in order to get started:

1. First, the Holter Scanning Service contacts NorthEast Monitoring and gets a license to use Holter LX Remote.
2. Once the Scanning Service is licensed, NorthEast Monitoring sets up and notifies the Scanning Service of their web-site location, the Username of the Administrator (admin), their initial password, and their Service (url key) Additionally an encryption key will be given to the scanning service for them to place on the technician desktops.
3. Next, the Scanning Service Administrator logs in, customizes the website and sets up the users - both Remote Users (scanning service customers) and Base Technicians (employees).
4. The Scanning Service administrator then contacts the users providing them with:

   •The address of the Scanning Service web-site

   •Username

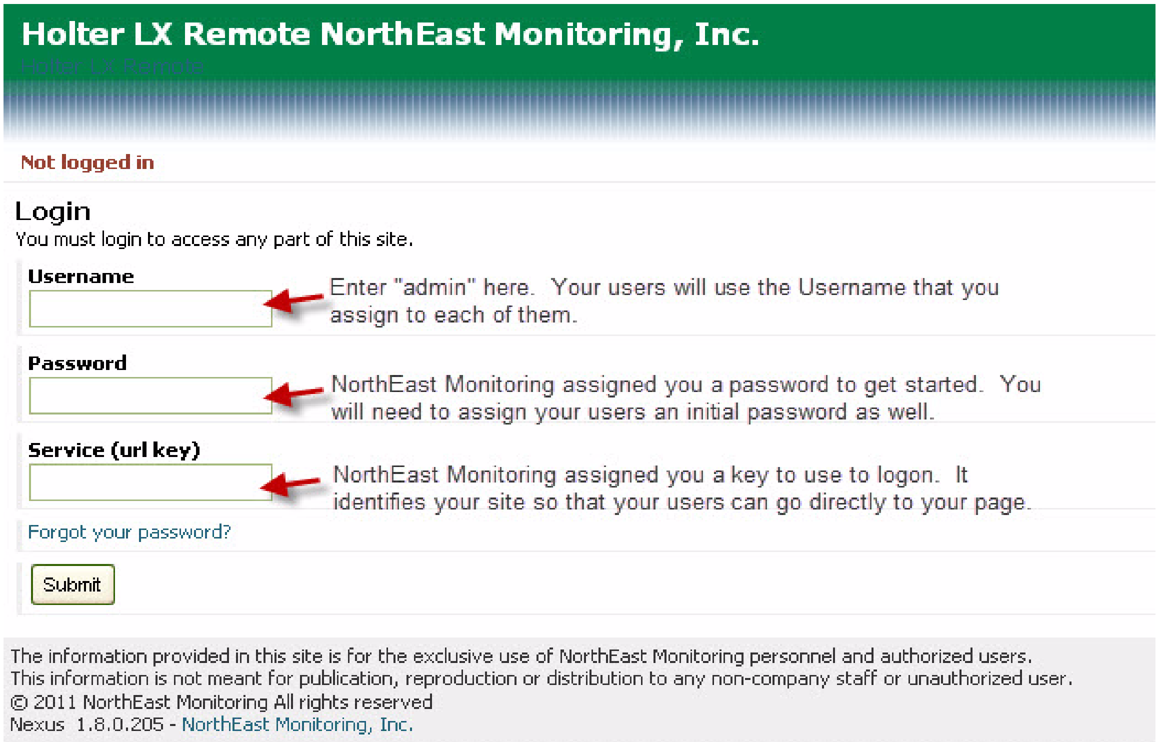
   •Initial password (should be changed by user once logged in)

   •The Service (url key). This is the same for all users - remote and base technicians.

   •For Base Technicians only, an encryption ID that will allow them to view files that are sent by the remote users. This file is called keyring.properites.

Getting Started

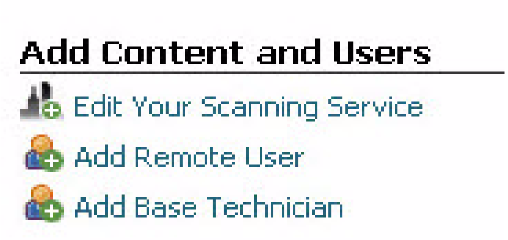
Initially, the Scanning Service administrator should login to customize the web-site and reset their password. When logging in, the administrator will need to know their Username, Password and Service (url key). They will



first have to go to www.HolterLXRemote.com via Internet Explorer or Mozilla Firefox.

Step 1: Edit Your Scanning Service

Once logged in, the administrator can get to their scanning service data by clicking on Edit Your Scanning Service from Add Content and Users.



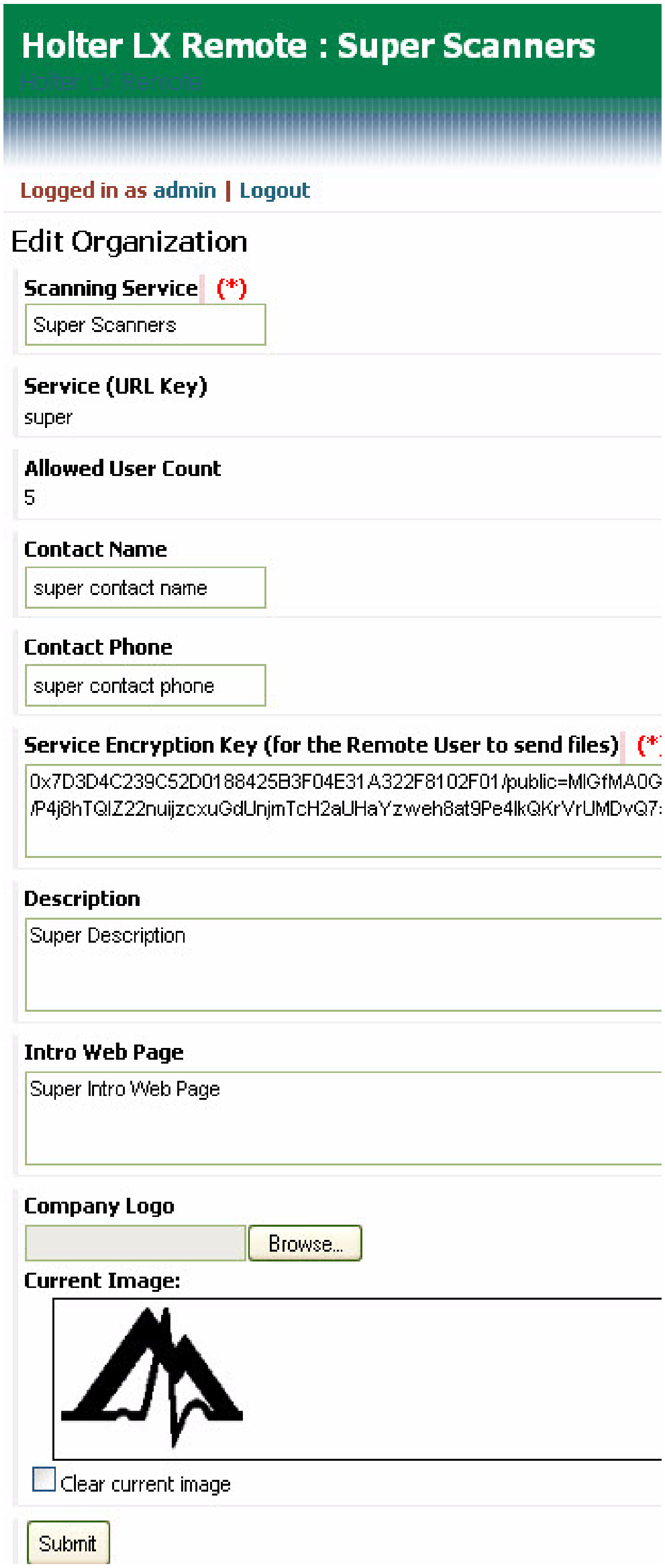
Once you are on the edit screen, fields with the (*) are required. Once on the edit screen, the administrator should review and/or update the following:

Scanning Service - this is the name that will appear when users log into your site. It should be your business name that you want your customers to see.

Allowed User Count - You cannot edit. This is the maximum number of users that you are allowed to have as per your license agreement with NorthEast Monitoring.

Service (URL key) - You cannot edit. This has been set up by NorthEast Monitoring. It is the Service (url Key) that must be present in order to log in to your site. All users for your site use the same Service (URL key).

Contact Name and **Contact Phone** - The administrator's name and contact



for NorthEast Monitoring to use (The users will not see this information.)

Service Encryption key - Do not edit. This is the "key" that will encrypt or lock the data when it is sent from the remote user to your web-site.

Description - This is for your use only.

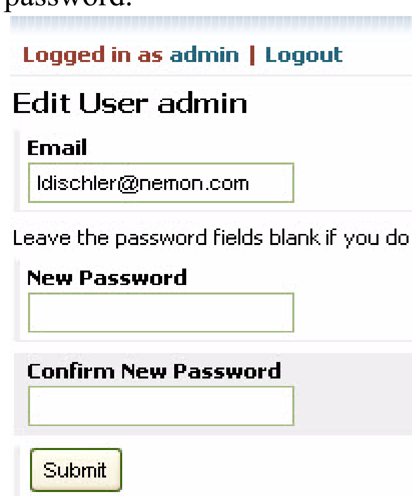
Intro Web Page - This text will be seen by all users who log in to your site.

Logo - For your web site. The files must be a jpg file. Your current image will be shown in the box. If you want to clear it click on the box below.

Submit - Allows you to save your changes. In order to cancel, you can click on "Holter LX Remote" at the top of the screen or "Go Back" using your browser.

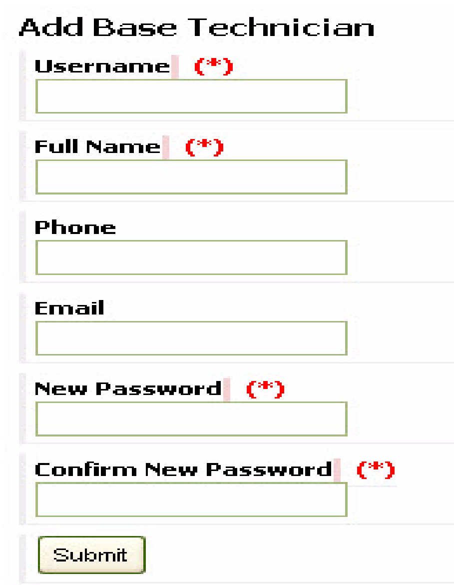
Step 2: Update Admin Information

Click on the "admin" at the top of the screen to update your email address and password.



Note: It is important that you change your password once you first log in so that it is unique and personal to you.

Step 3: Add Base Technicians



Base Technicians are the employees of the scanning service. The Base Technician must also have a Pro or Enhanced Plus level of the Holter LX Analysis version 5.3 or greater software on their desktop in order to analyze the Holter data. The Base Technicians will need to login to Holter LX Remote to retrieve the Holter files that have been placed by the remote users - the Scanning Service customers.

Each Base Technician will need a unique Username. The username must contain no spaces.

Full Name is just to help you identify your users. You can enter anything you like.

Email is not required, but we recommend, as it can be used when a user forgets their password.

New Password and Confirm New Password - these two fields must be identical. Passwords must be at least 6 characters in length.

You will need to tell each Base Technician where to login, their Username, initial password and your service (url key).

Note: You should urge each of your users to reset their password the first time they log in to the system.

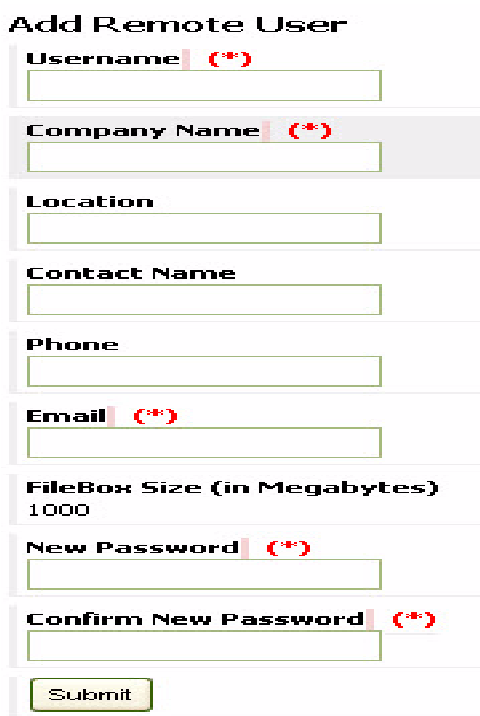
Keyring.Properties file

Every base technician is required to have a file named keyring.properties in their nm\bin directory. This file will be used to decrypt or unlock the remote files once they are received.

NorthEast Monitoring Technical Support will contact you with your file and to help you set up your base technicians. If you have not heard from Technical Support and are ready to get started, you can contact them by calling 866-346-5837 extension 1 or by emailing them at support@nemon.com

The keyring.properites file is not the same key that is on the remote site setup on the web. The key on the web on the remote site “locks” the patient data, while the corresponding Keyring.properites file “unlocks “ it. Do not give the keyring.properties file to the remote sites. It should stay in-house only.

Step 4: Add Remote Users



Remote Users are your customers who send the Holter recordings to be analyzed. They will need to login to save the Patient Information and transfer the Holter recording to the Scanning Service. Each customer must have their own login as they will have access to their files once on the web-site.

Each Remote User must have a unique Username, Company Name, Email address and a password to get started.

The Location, Contact Name and Phone are for your use only. This will help you identify and contact your user moving forward.

Security

Your Holter LX Remote web-site is unique to your scanning service. Only users set up by the Scanning Service administrator will be able to log into the web-site. Holter data sent to the Scanning Service via the Scanning Service web-site will be encrypted so that only the Scanning Service can read and analyze the information. Each base technician must have the special keyring.properties file on their desktop to view the files.

Managing Users and Services

Under Other Actions you will see a button that allows you to Manage Users and Services. This will take you to a location where you can edit, view or delete any existing users.

In order to change a users password, you should choose to edit the user and then enter two passwords in order to reset. All other data, except for Username can be edited via the edit screen.

More about the Service (url Key)

All users affiliated with your web-site will have the same Service (url Key). This “key” tells the Holter LX Remote web-site which scanning service they belong to.

Maximum Allowed Users

Your contract with NorthEast Monitoring has a maximum number of users attached to it. This includes all Base Technicians and Remote Sites combined.

You can view all users affiliated with your contract by going to Other Actions > Manage Users and Services and by pressing View User without selecting a User name. There you will see a count of your current users as well.

Notifying Remote Sites

You will want to send an email to your remote customers with the web-site, their Username, their temporary password and your Service (Key url).

Remind your users to change the password the first time they log on and let them know that the manual is on the web-site. The manual has step-by-step instructions for remote users starting on page 11.

No keyring.properties file is required for remote sites, but they will need to download java and keyless remote to get started.

You may want to have your remote sites send a test file first thing, to ensure that everything is in place before go live.

Linking to your Remote Site

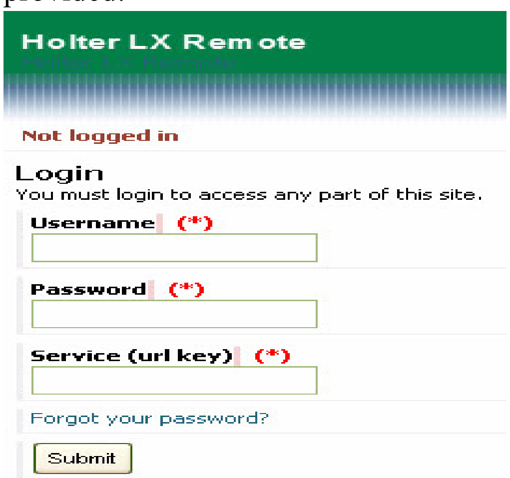
You can create a web address that will point to your site and not require you or your users to enter the Service (url key) every time. The modified web address is as follows: http://www.holterremote.com/nexus/index.php?service=URLKEY, with the URLKEY being replaced with the Service (url key) that was assigned to your organization by NorthEast Monitoring.

Base Technicians: Getting Started

Note: You must have a Pro or Enhanced Plus level of the Holter LX Analysis version 5.3 or greater software on your desktop in order to retrieve remote data for analysis.

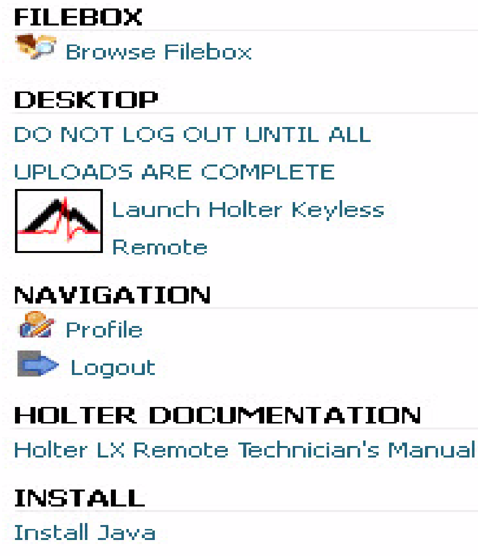
The Scanning Service administrator will provide you with a Username, Password and Service (url key). Start up Internet Explorer or Mozilla Firefox and go to www.HolterLXRemote.com to get log in.

You will see the screen below to log in. Enter the values that you have been provided:



If you have trouble logging in, check with your Administrator to make sure that you have the information correct.

Once logged in, you will be on the Holter LX Remote system. The right-hand side of the screen will look something like this:



Change your password and personal information

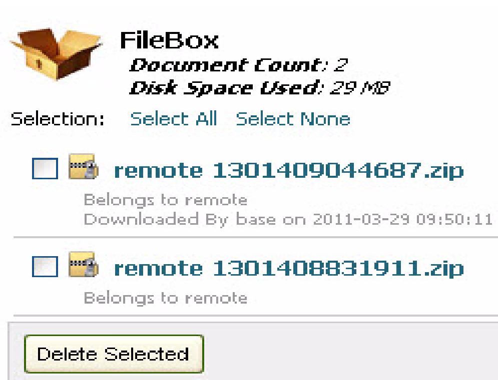
When you log in for the first time, you should change your password to something that you will remember. Your new password needs to be 6 or more character. Do this by clicking on Profile.

At this point, you can also update your name, phone number and email address. Enter an email address if you have one, as this will allow you to reset your password if you ever forget. Enter your new password into the New Password and Confirm new Password fields at the bottom of the screen and press Submit.

The Filebox

In order to download the files that have been sent to you from remote sites, click on Browse Filebox at the top of the screen. Next you will see a list of any files that have been sent. If you see the message “There are no items to display”, this means that there are no new files for you to download.

If files are on your site, you will see a screen that looks like this:



These files are encrypted, but you will know which customer sent them to you as the username of the customer is included with the file name. If a file has already been downloaded, there is a line that shows which user downloaded and when.

To download a file, click on the green box to the right of the file name. You will then be asked to save the file in a directory and you should select the ftp directory associated with your Holter LX Analysis program. This is often found on your desktop at c:\nm\ftp.

Once the files are downloaded you can retrieve them, just as you do now, with the Remote Receive button at the bottom of your Patient Open screen in Holter LX Analysis.

You will want to delete the old files on a regular basis. Newly uploaded files will go to the end of the list, so be sure to check there to ensure that you have retrieved all files from your remote customers.

Important: Keyring.Properties

It is very important that you have the new file named keyring.properties in your c:\nm\bin directory. This file allows you to see and read the encrypted remote files using Holter LX Analysis. If you are unable to see the files, ask your Remote Administrator for the keyring.properties file that was provided to them from NorthEast Monitoring.

Keyless Remote and Java

Keyless Remote is a version of Holter LX software line that is specific to remote sites. It allows your users to save Holter files, set up Patient Information and report headers, and send the information to you. You have access to Keyless Remote, but you do not need it to do your job. It is merely available for you to support your remote users when they have questions.

In order to use Keyless Remote, the user must have a current version of Java saved on their desktop. Be sure to install Java the first time you run the desktop program. After that, you will not need to install again.

Remote User Instructions

You, the remote user, records Holter data using a NorthEast Monitoring Holter recorder. You then send the Holter recording to a scanning service to be analyzed. The scanning service then sends you a report with the analysis complete.

Holter LX Remote consists of two distinct components: 1) Holter LX Remote: On the web - allows for a secure transfer of your patient and Holter data and 2) Keyless Remote: On the desktop - allows you to enter your patient information and initiate the transfer.

Note: This product, like all Holter monitoring products, should be used only under the direct supervision of a licensed physician.

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System requirements

This software can only be used in conjunction with a NorthEast Monitoring digital recorder - the DR180+/DR80+Oxy, the DR200/HE or the SD360. It is not compatible with the Holter monitor of any other manufacturer. To run the Holter LX Remote software, your personal computer must include:

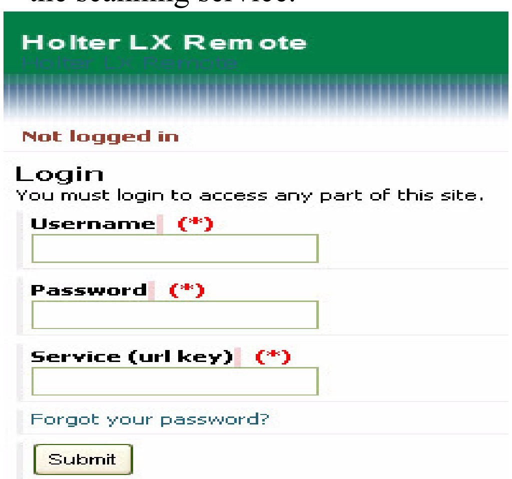
- Microsoft Windows XP or Windows 7 operating systems
- Broadband Internet connection
- Internet Explorer or Mozilla Firefox browser application
- USB flashcard reader or a laptop PC card slot
- Read/write privileges on the c:\nm\remote directory

Holter LX Remote: On the web

The Scanning Service administrator must first provide you with a remote Username, Password and Service (url key) to get started.

Then, start up Internet Explorer or Mozilla Firefox, and go to the secure web-site name: www.HolterLXRemote.com.

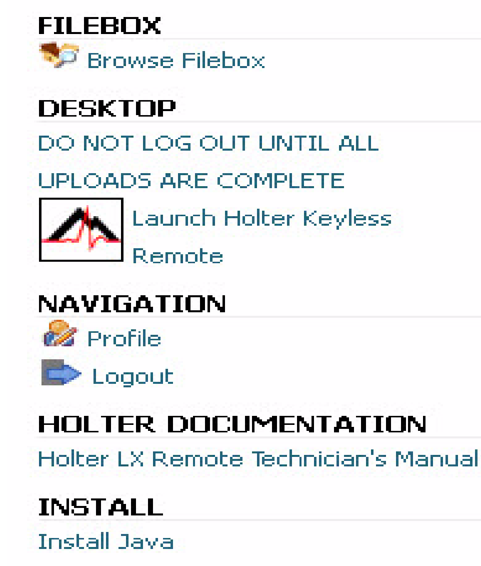
You will then be taken to a login page that looks similar to the right. Here you should enter your Username, Password and the Service (url key) provided by the scanning service.



If you have any trouble logging in, check with the scanning service administrator to make sure that you have the information correct.

At this point you may want to save a bookmark or favorite on your browser to allow you to easily return to the login page the next time you want to use the remote system.

Once logged in, you will be on your scanning service's Holter LX Remote web-site. The right-hand side of the screen will look something like this:



First: Change your password and update personal information

When you login for the first time, you should change your password to something that you will remember. Your new password needs to be 6 or more character. Do this by clicking on Profile and entering your new choice in New Password and Confirm New Password. At this point, you can also update your name, phone number and email address. Enter an email address if you have one, as this will allow you to reset your password if you ever forget.

Second: Install Java

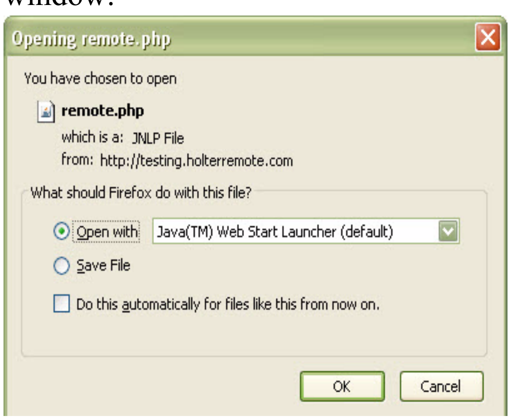
In order to use Keyless Remote on the desktop, you must have a current version of Java installed on your desktop. Install Java before your run Keyless Remote for the first time. After that, you will not need to install again.

Third: Start Keyless Remote

Keyless Remote is a version of Holter LX Analysis that is specific to remote sites. It allows you to save Holter files, set up Patient Information and report headers, and send the information to your scanning service.

You need to stay logged in the Holter LX Remote and the web-site while you are running the Keyless Remote application on your desktop. This will allow the Keyless Remote application to work and your files to be transferred to the web.

When you first click on Keyless Remote you may see the following window:



Select “Open with Java...” to start the software. This window will vary with your operating system and browser, but either way, you will want to choose to “Run” or “Open” the software. There is no need to select “Download”.

If your connection to the web is lost for any reason, not to worry, any data that you entered is saved on your desktop and any file that has not been uploaded will upload the next time you log in to Keyless Remote from the web.

The next time you log in to Holter LX Remote, all you have to do is click on “Keyless Remote” to set up your patients and send your Holter files.

The Filebox

Once you send files to your scanning service, you will be able to see them here. Your scanning service should download and delete your files when they are finished using them, but if you were to send a file in error, you would be able to delete it here if you need to.

Keyless Remote: On The Desktop

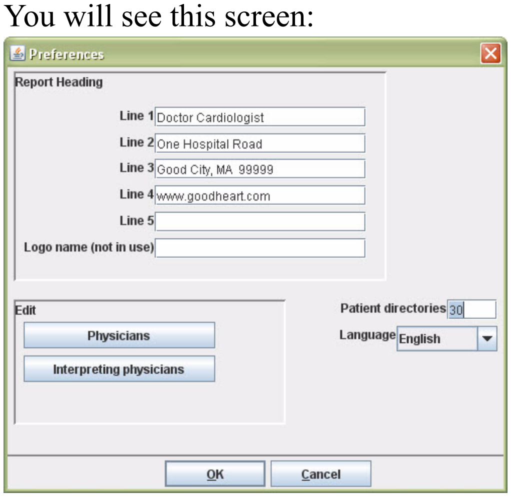
Clicking on Keyless Remote will start a program to download and will automatically open the application for you. Allow this to occur each time.

When Keyless Remote first starts, it will attempt to start a new patient by looking for a flashcard. At this point, you can click on “No” to Confirm that you are not looking for a flashcard, or close the new patient window by clicking on the X. At any point you can start a new patient by clicking on File > New from the toolbar.

Preferences

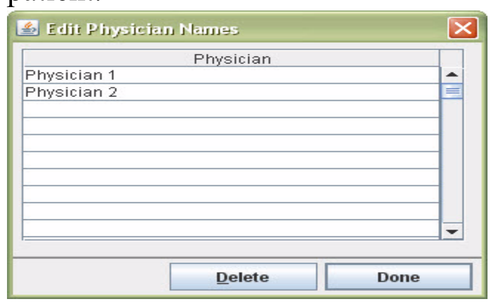
When you first start, you will want to set up your preferences. Preferences allows you to customize your report heading and make it easier to enter physician data on the patient record.

To get to the Preferences, click on File on the toolbar and select Preferences. You will see this screen:



Report Heading Lines 1 through 5 will be sent to the Scanning Service and will populate the report heading on your report. Enter this once and it will be sent with each patient. (The Logo option is not in use, but we plan to implement in the future.) After updating preferences, you may want to close and reopen the current patient before sending so that the new address is assigned to that patient.

Physicians or Interpreting Physicians allows you to add, edit or delete physician names. You can then select from this list while adding a new patient.



Patient Directories. You can increase or decrease the number of your patient directories here. If you decrease directories, you may lose patient data in the directories that you are getting rid of, so be sure that is what you want to do.

Language. Currently Keyless Remote is in English only.

Once this data is all entered and correct, you are now ready to enter patient data and send files. You can come back and edit your preferences at any time.

New Patient

The Keyless Remote software automatically retrieves recording data from the recorder's flashcard, along with the Holter signal, but you are responsible for entering the remaining data. The data saved by the recorder includes the Patient identification number, the recorder number, the date, the start time, and whenever the patient pressed the Event or Diary button.

First insert the patient's flashcard into the card reader and then open the software or select File > New. When the Patient Information window opens for a new patient, the data on the flashcard is immediately read from the card reader.

- If you select File > New before inserting the card, you will see a Confirm window that explains that there is no flashcard in the drive. If this happens, insert the flashcard into the drive and click Retry.
- If you see a message that says, "There are no empty patient..." instead of the New Patient window, see "Making room for new patients" at the end of this chapter.

Once the flash.dat has loaded, the "Copy flashcard" button in the Patient Information window changes to "Copy different flashcard." If the patient information displayed does not match the correct patient, remove the card, insert the correct one and click "Copy different flashcard."

As the Holter data from the card loads onto your computer hard drive, you can start entering the patient information. Once the Patient Information is complete, you can send the file to the remote site. You will not be able to edit Patient Information again, so be sure the data is correct prior to sending.

Enter Patient Information

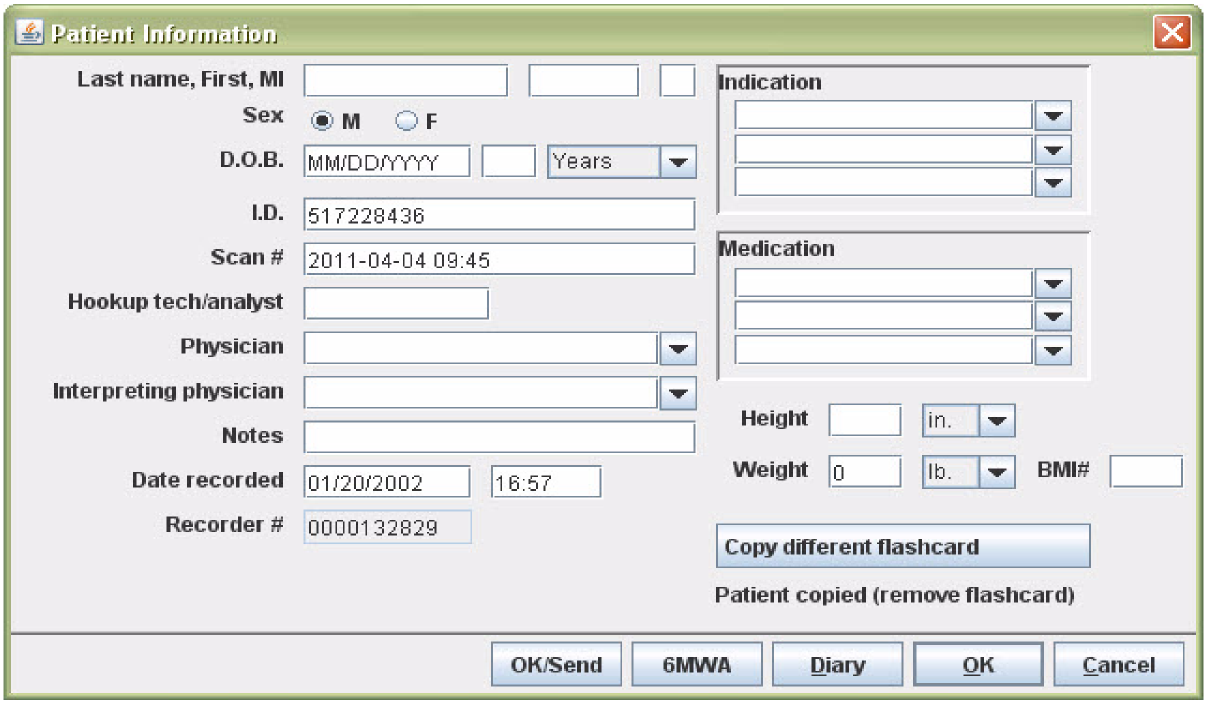
First you will want to enter the patient's name. Starting with the last name, use your cursor or the Tab key to move to the next field. The name in the printed report appears as entered in this window.

Using your cursor or Tab key to move around the screen and fill in the remaining information. There are six types of data fields:

- **Freeform:** These allow you to type alphanumeric characters, limited by the space constraints displayed, e.g., patient name.
- **Radio buttons:** The Sex entry appears as this type. Circles represent the two choices. Click on a circle to select it. Only one choice can be selected.

Example of radio button

- **Formatted:** The entry must be in a specific format. For example, the D.O.B. (date of birth) field must be entered with a valid date format; which one depends on the settings of your system.
- **Automatic:** These are filled in automatically from the flashcard.



- **Check box:** The fields with an empty square can be clicked on to display a check mark. Click again to remove the mark.
- **Combination:** In these, you can either type a freeform entry or make a selection from a predetermined list of choices. To display the list of choices, click on the scroll arrow to the right of the field. In the Indication and Medication fields, the scroll arrow does not appear until you click on the field itself. To select a choice from the list, click on it.

  Some combination boxes have an auto-fill feature. When you start typing an entry, the software will automatically finish typing for you from its list of choices; if the word taken from its list is incorrect, simply keep typing until the correct one appears. If the correct one is not on the list, type the complete entry. These fields have the auto-fill feature: Indication, Medication, Physician, Interpreting physician, and Strip label.

DOB and Age

The D.O.B. and Age fields work together. If you know the patient's date of birth, enter it, and the software automatically calculates the patient's age based on the D.O.B. and the recording date. If you do not know the date of birth, but know the age, type a numeric entry in the Age field, and select the appropriate unit (e.g., years) in the Age Unit field. If you know neither, leave the fields blank. The software does not allow an inconsistent D.O.B. and age; if you enter inconsistent data, it will leave the age and remove the D.O.B.

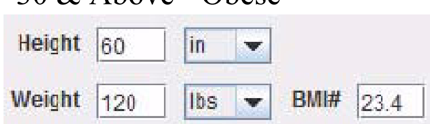
Notes

The Notes field allows an alphanumeric entry that can be used to record information that might be helpful about the Holter test or the patient. It is not printed on the final report. To enter notes to be printed in the final report, use the Comments section of the Report summary.

BMI

Keyless Remote will calculate your patient's Body Mass Index (BMI) if you enter the patient's height and weight and the appropriate units. A patient's weight status can be determined from the BMI as follows:

- Below 18.5 - Underweight
- 18.5 -24.9 - Normal
- 25 - 29.9 - Overweight
- 30 & Above - Obese



BMI on Patient Information Screen

6-Minute Walk Assessment Window

If you have a 6-Minute Walk Assessment patient, you are able to enter 6MWA data using the window that is accessible at the bottom of the Patient Information Screen.

Diary information

While wearing the Holter recorder, the patient can identify symptoms and activities in two ways:

(1) by pressing the Event button on the recorder and, possibly, entering a precoded symptom or activity, or

(2) by keeping a written record of times and symptoms or activities. These entries should be entered into the diary screen at this point. Click on each field to enter and/or edit the data. Date and time will default to the last entry to assist you in entering the required data.

Any diaries saved on the recorder will be seen when the scanning service analyzes the Holter recording.

Send a Patient

Once you are finished entering all patient information and have copied the flashcard, you should send your information to your scanning service.

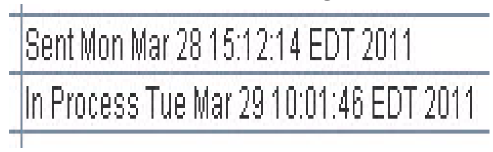
This can be done by clicking OK/Send on the Patient Information screen or Send on Patient Open. It is important to make sure that the patient data is entered correctly before sending the file to the Scanning Service.

If you are not sure, you can always save the patient without sending by clicking OK. If the patient information needs to be changed after sending, you will need to contact your Scanning Service and they will be able to update the information on their end.

Patient Open

You can keep multiple patient Holter records on your computer system. All of the patients currently saved on your desktop appear when you select File >File > Open from the toolbar.

To change the current patient to a different one, either click on the appropriate name on the list and click Open, or double-click on the appropriate line. The Patient Information window for the selected patient will appear on the screen. A column labeled “Sent” shows you when and if the file has already been sent to the Scanning Service.



In Process means that the file is currently being sent or is in the queue to be sent. If a patient has not yet been sent, you can either edit that patient information or press the Send button on the Patient Information or Patient Open screen to send.

Deleting Patients

We highly recommend that you do not delete any patient data until you have received a satisfactory report back from your Scanning Service. This will ensure that you have a back-up of the Holter recording, just in case you need to resend for any reason.

Logout

You will need to keep both your Keyless Remote software and the web-site open while sending files. Once all of your files have finished being sent, you should close Keyless Remote and logout of the web-site.

Making room for new patients

When the software has saved the maximum number of patients allowed by your system, and you choose to not increase the number of directories (see Preferences) you must delete old patients to make room for new ones. If you want to archive an electronic version of each patient record, make sure you back up a patient before you delete it.

To delete a patient from the patient list, go to File > Open to display the list of patient records currently in Keyless Remote. In the Open Patient window, click on a patient name to highlight it and click the Delete button. When the Confirmation window appears, click Yes. That slot in the list will now be available the next time you select File > New.

To delete multiple sequential patients in the Open Patient window, click on the first patient to be deleted, then drag down to the last one you want deleted. With multiple patient names highlighted, click the Delete button. When the Confirmation window appears, click Yes.

To close the Confirmation window without deleting any patients, click No.

The flashcard

ECG data recorded during the Holter period is saved on a removable flashcard. The DR180+/DR180+Oxy recorder uses a compact flashcard, while the DR200/HE and SD360 recorders use an SD flashcard. To input the data from the card to the computer, first remove the flashcard from the recorder, and then insert it into your computer's card reader.

Into a USB SD flashcard reader

To insert an SD flashcard into the drive, hold the card right-side up, with the missing corner away from you and to the right. Insert the opposite edge into the opening of the SD card reader. Push the card in gently until it is fully plugged in. Some card readers have a light indicating when a flashcard is properly inserted; if yours does, make sure the light comes on.

Depending on your computer and your card reader, a window may appear acknowledging that a card has been newly inserted and listing what files are present on the card. A recording saved by a NorthEast Monitoring Recorder is named “flash.dat.” If the window appears, close it.

Into a USB compact flashcard reader

To insert the compact flashcard into the reader, hold onto the card by the edge with the ridge and insert the opposite edge into the opening of the flashcard slot. Push the card in gently until it is fully plugged in. Some card readers have a light indicating when a flashcard is properly inserted; if yours does, make sure the light comes on.

Into a laptop PC card slot

First insert the flashcard into a flashcard adaptor; to do so, hold onto the card by the edge with the ridge and insert the opposite edge into the adapter. Then insert the adaptor, right side up into the laptop's card slot. If a window appears listing what files are on the flashcard, close it.

Formatting a flashcard for the first time

To use a flashcard with a NorthEast Monitoring recorder, it must be formatted properly. Flashcards that come with the recorder are already formatted properly and need only to be initialized before first use. A card from a different source, though, must first be formatted using the FAT file system (not FAT 32) and then initialized using NorthEast's software.

To format a flashcard, insert the card into your computer's card reader, then select My Computer or with Windows 7 go to Start > Computer. In the (My) Computer window, click on the icon designating your card reader, then select File > Format. When the window opens, set the File system to FAT, then click Start. Click Close when formatting is complete.

Initializing a flash card

To use a flashcard with a NorthEast Monitoring recorder, it must first be initialized using the Keyless Remote software. To do so, insert the card into the card reader, close the Explorer window that opens, and using the Keyless Remote software, select File > Flashcard > Initialize. The Initialize Memory Card window opens.

First determine that the correct drive has been selected for your card. The check box should be populated. If drive has not been found, check to be sure that a card is in the slot and the reader is attached to the reader. You will need to Exit and return to this screen to refresh the Drive list.

Once your drive, check to make sure that the correct card format option is selected - the corrected recorder should be selected and the appropriate format should be chosen. If you are sure that your DR200/HE or SD360 recording will be less than 48 hours, you can select that option.

Now press Erase and your card will be initialized for its first use.

Note: If you insert a card into the recorder and get a message that the "Memory card is missing," the card is not formatted or erased properly.

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Into a laptop PC card slot

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