LX Event User's Manual

for use with NorthEast Monitoring's Event Recorders

Version 3.1.1



Maynard, MA 01754 USA www.nemon.com

advancing Holter technology

phone: [+1] 978-461-3992 fax: [+1] 978-461-5991 toll free USA: 866-346-5837

email: info@nemon.com



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LX Event has been developed by NorthEast Monitoring, Inc.

LX Event has FDA 510(k) Market Approval Number K070014.

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

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Technical Support

In addition to the information in this manual, more information and help is available at our web site: www.nemon.com or

Toll Free USA: 866-346-5837 option 1 Phone: [+1] 978-461-3992 option 1 Fax: [+1] 978-461-5991 e-mail: support@nemon.com

The "Technical Support" page on the web-site includes Frequently Asked Questions.

The current version of this manual can be found on our web-site on the "Downloads & Documents" page.

Table of Contents

Chapter 1 Introduction	4
System Requirements 4	
Operator Knowledge 4	
User Specifications 4	
Essential Requirements: 4	
Intended Use 5	
Indications For Use 5	
Utilities 5	
Chapter 2 Procedure Information	6
Find a Procedure/Patient 6	U
New and Patient Info screen 7	
Network Installations 8	
Back-up Procedure Data 8	
Chapter 3 Saving Events and creating Strips	9
The Event Screen 9	
Saving Strips 10	
The Summary Screen 12	
Chapter 4 Reporting	14
To Create a Report 14	•
Customizing Reports 15	
Customizing Reports 13	
Chapter 5 Wireless Files	16
Chapter 6 Known Issues	17

1 Introduction

Welcome to NorthEast Monitoring's LX Event. With LX Event, you can receive ECG recorded events, review the events, save particular ECG strips of interest, create event or procedure summary reports.

System Requirements

LX Event can be used with NorthEast Monitoring DR400 recorders. To run LX Event, your PC should include:

- 1. dedicated PC for LX Event, Event Decoder and Etel, not to be used for other purposes
- 2. Microsoft Windows 10 Operating System
- 3. processor with a speed of 3 GHz or faster
- 4. at least 16 GB of working memory
- 5. monitor with a resolution of at least 1280 x 1024
- 6. disk drive of at least 1 TB HDD or SSD
- 7. laser printer
- 8. internet connection with permissions to make FTP transfers

Operator Knowledge

To use NorthEast Monitoring LX Event, you must have extensive ECG knowledge that allows you to properly identify sinus and paced rhythms, abnormal rhythms, supraventricular and ventricular arrhythmias, artifact, ST segment changes, and pacemaker failures. In addition, all instructions assume a working knowledge of computers and, specifically, Microsoft Windows operating systems.

User Specifications

LX Event is designed to be used by a trained operator under the supervision of a licensed clinician for the purpose of evaluating the ECG captured as part of an automatic or manually saved recording event.

LX Event can only be used with a NorthEast Monitoring, Inc. DR400 recorder in Event mode.

Essential Requirements:

Display capability:

- 1. Display ECG data as individual events.
- 2. Label recordings made from the NorthEast Monitoring recorders with time, date and event type.
- 3. Display in a full disclosure in a scale of from 0.25 to 4x normal with from 3.75 to 60 seconds of data per line of the display.

LX Event Users Manual Intended Use

4. Measure PR, QRS, QT, ST, and HR values using cursors which can be positioned on the ECG data.

Recorder capability:

- 1. Data from recorders can be displayed with all time, date and event labels.
- 2. Data transmission method is wireless using the NorthEast Monitoring Gateway.
- 3. Maximum recording length: No maximum

Intended Use

The LX Event utility is a data management program intended and designed to be used with the DR400 recorders for diagnostic evaluation of transient symptoms such as dizziness, palpitations, syncope and chest pain. The system provides single lead or multiple lead ECG morphology, which may be used to visualize arrhythmias, ST segment changes, SVT, heart block, re-entrant phenomena, and p-waves. The system may be used with pacemaker patients to assess pacemaker activity. The LX Event Software is to be used only on the order of a physician.

Indications For Use

The LX Event utility is intended to be used with the DR400 recorders. LX Event does not analyze data

Utilities

Physician Edit

You will want to create physician files before you start adding patients to LX Event. By setting up physicians, you will able to more easily enter patients when the time comes. In order to do this, go to Utilities > Physician Edit from the toolbar.

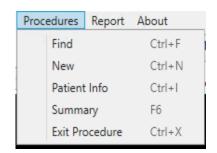
2 PROCEDURE INFORMATION

When the NorthEast Monitoring Event recorder is given to a patient, a new Procedure should be set up in LX Event. Because a recorder number can only exist on one procedure at a time, be sure that the previous procedure for that recorder number has been closed before starting a new procedure with the same recorder number.

When the LX Event utility first opens, it displays a blank screen with a standard toolbar. To create or to work with an existing procedure, select **Procedures** from the toolbar and choose an option.

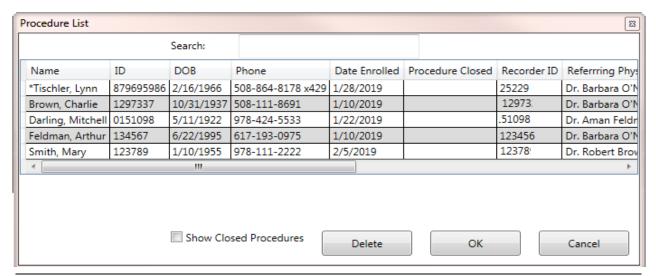
Find a Procedure/ Patient

Go to Procedures > Find. Use the Search box at the top of the screen to search any of the visible items to find your patient. To view Closed Procedures, click on the box at the bottom of the screen. Click on any column to sort that column.



Select a patient by clicking on that line. You can then open that procedure by clicking OK or by double-clicking on the line. From this screen you can also Delete a selected patient. The system will ask you to confirm deleting by typing DELETE to ensure that you are sure you want to delete the selected patient.

Click on the "Show Closed Procedures" box at the bottom to only view Closed Procedures. Scroll to the right to see additional items on the Procedure List.



LX Event User's Manual New and Patient Info screen

New and Patient Info screen

To create a new patient, go to Procedures > New. The Patient Information window will open and enter the new procedure information at this time.

If a procedure is already opened, view the current patient information by going to Procedures > Patient Info. You can update that information at any time.

LX Event requires a Patient to have a Name, an Enrolled Date and a Recorder ID, but we recommend that you also enter the Patient DOB,

Phone and Referring Physician at a minimum. Once you are finished entering a new patient, press **OK** to accept/save or **Cancel** to exit without saving.

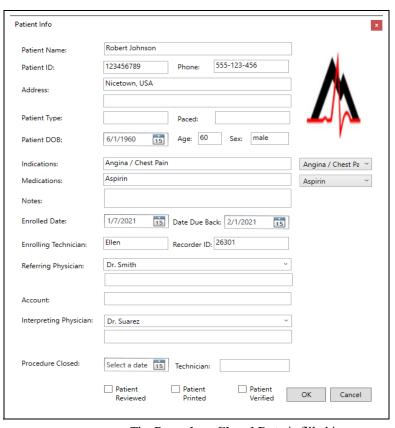
Patient Dates

Enter a date by manually typing or using the calendar.

If you know the patient's Date of Birth - **DOB** - you can enter it and the age will automatically be calculated. You can just enter the age if the date of birth is unknown.

The **Enrolled Date** is the start date of the procedure - when the patient is instructed to begin wearing the event recorder.

The **Due Back Date** is the entered when the procedure has started. It is the date that you expect the procedure to end.



The **Procedure Closed Date** is filled in once the recorder has been returned. Once a procedure has Closed Date, you can no longer save new events for the procedure. The Technician field should be filled in at this time.

Indications and Medications

Each field has a drop-down box where you can select one or more entries. You can also edit the field directly and add or modify what you have entered.

The Recorder ID

Enter the SN number that is found on your recorder.

Status

At the bottom of the Patient Information window, you can update the patient's status by

LX Event User's Manual Network Installations

clicking on the Edited, Reported, or Verified buttons. The status fields are visible from the Patient Found List.

Summary

View the Summary Screen for the currently opened Procedure.

Exit Procedure

Close the current procedure by going to Procedures > Exit Procedure.

Network Installations

The lxevent.ini file located in your installation points to member, provider and other directories. You can customize this file for your purposes as follows:

Incoming Files Directory=c:\nm\ftp. Tells the Incoming Files window where the "Event" folder is located. This is where the wireless files should be saved.

PatientDataDirectory=c:\nm\patients\. The default is on the c: drive, but you can denote a shared directory for network installations.

PhysiciansDataDirectory

=c:\nm\lxevent\Physicians\ The default is on the c: drive, but users can share a single directory for network installations.

Customizing Lists

Lists for medications, indications, diaries and strip labels can be found in the c:\nm\lxevent directory in a typical installation.

DiarySymptom.dat
Indications.dat
Medications.dat
StripLabel.dat

To share these lists, you will need to copy them to each PC. If you customize these lists, you may want to make a copy and save it elsewhere as when and if you update LX Event, your updated lists may get replaced.

Back-up Procedure Data

It is highly recommended that you back-up and save your procedure files separately from your computer on a regular basis. On a typical installation, the Patients directory is found in c:\nm\patients.

Archiving Procedure Data

Data for each procedure is stored in a folder that can be found in the folder name of the year, month and day that the procedure was created. Additionally there is a NMPatients.csv file in the patients folder that acts as the directory for the Patient List in LX Event.

When LX Event is not running, you can archive patient data, by copying and then deleting any year and/or month folder from the Patients folder. To correct the directory file, you will then need to delete the NMPatients.csv file so that it can be rebuilt the next time LX Event is started.

3 SAVING EVENTS AND CREATING STRIPS

A patient must have an open Procedure - a record with no Procedure Closed Date - in order to receive a new event. A procedure may consist of one or more events and you can continue receiving new events for a patient until a Procedure Closed Date is entered onto the Procedure. If a procedure is closed and a new event has arrived, you can either:

- · Open a new Procedure for the patient, or
- Remove the **Procedure Closed Date** from the patient's last record in order to re-open it. (This should only be done if the last procedure should not have been closed.)

The DR400 recorders have the capability to send files via the cellphone network using a Gateway. In order to receive these files you must have NorthEast Monitoring's Event Decoder utility installed in your facility. Information on how to set up and receive files wirelessly can be found in the DR400 manual.

Refer to Chapter 5 for more information on using the Incoming Files window.

The Event Screen

A procedure is composed of one or more events. An event is when the patient experienced a cardiac symptom and either pressed the button or the event was sensed automatically. Settings that you can adjust are on the top row of the screen:

Gain



To change the amplitude of the displayed signal, click on the Gain field and select a different size from the list.

High Pass Filter



To adjust the High Pass filter, click on the drop-down box labeled **HP**. This filter will allow you to reduce baseline wander.



Low Pass Filter



To adjust the Low Pass filter, click on the drop-down box labeled **LP**. This filter will allow you to reduce muscle noise and electrical artifact.

Invert ECG:



To invert the ECG signal, check or uncheck the **Inverted** box.

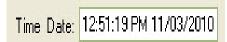
Sec/Row:

To adjust the amount of time in each row of the ECG, click on the drop-down box labeled Sec/Row and choose the amount of seconds in each row.

R-Wave Markers and HR

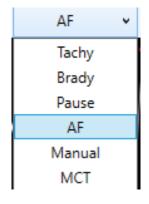
LX Event attempts to label each R-wave with a red dot and then calculates the HR based on the RR-intervals. The HR calculation has a limit of 180 HR.

Time Date



The time at the beginning of the event.

Event Type



The Event Type initially shows the type of event that was captured by the recorder. You can update the event type to be more accurate once the event is reviewed by you.

The drop-down list includes MCT (Mobile Cardiac Telemetry) which is assigned to

ECG data that was not necessarily part of an event, but requested via the ETel utility.

Diary Symptoms

If your patient kept a diary, you may want to enter any symptoms they were experiencing or what they were doing at the time of the Event. You can either select from the drop-down box or add one of your own.

Saving Strips



When an event is open, click on the ECG to identify strips. The blue bull's-eye shows where strips have already been saved. A red bull's-eye appears when the corresponding strip appears at the bottom of the screen. Once the strip appears

on the bottom of the screen, you can place cursors, label and save the strip. Once saved, the bull's-eye will be blue. Use the Previous and Next Strip buttons to switch between and view or edit saved strips.



Cursors

The **Default Cursors** button at the top-left of the strip allows you to place all of the cursors at once in a location determined by LX Event. After pressing Default Cursors, you can move any of the single cursors by pressing the button for the that cursor and then clicking on the screen where you want it to go.

Apply single cursors by first clicking on the appropriate cursor button. LX Event will then place the cursor in the default location, and you are able to move it by clicking elsewhere on the screen. Once the cursor is where you want it, select another button to continue.

In order to remove a cursor, click on the button and then click on the **Delete Cursor** button.

Strip Measurements

The second row of boxes shows the resulting measurements from cursor placement:

PR: Time difference between Q and P.

QRS: Time difference between S and Q.

QT: Time difference between Q and T.

ST: The vertical difference between the values of the I and ST cursors.

HR: The heart rate is calculated based on R1 and R2 being 2 RR intervals apart.

XY: X and Y allow you to measure between any two points on a strip. For screen use only and will not appear on the strip when reporting.

Saving and managing strips

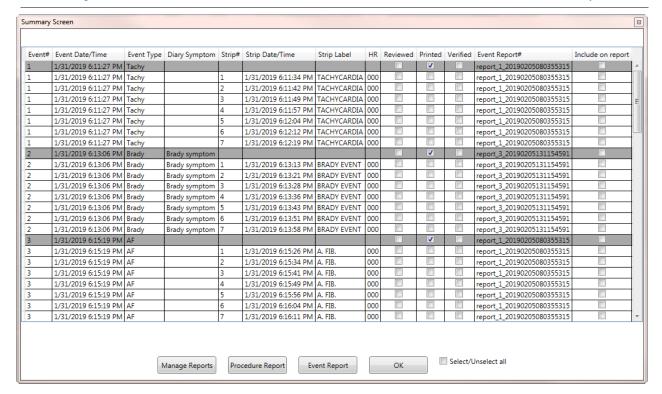
If an event is not significant, you can check the Event Reviewed button to show that it has been reviewed, without saving any strips.

Strip Label. Every strip must have a label to be saved. You can use the pre-formatted labels supplied with LX Event and/or add a label of your own.

Save Strip. Once you assign all of the cursors, you can enter a Strip Label and save the strip by pressing the Save Strip button.

Delete Strip. Delete the strip that you are currently on.

Strip Notes. Once a strip is saved, a gray Notes button will appear. Notes entered here will not be printed on any reports. When Notes exist for a strip, the button will appear green.



Save Event as Strips. If you would like an entire event to be saved as strips, use the Save Event as Strips button. First click on the Event, then add a Strip Label and then click on Save Event as Strips. The label will be applied to all of the strips. You can then go back and edit each strip if desired.

To edit a Strip. To select a previously saved strip, use the **Previous** and **Next Strip** buttons till the strip you want to edit appears on the bottom of the screen. Once the strip appears, you can edit it and the changes will e automatically applied to the strip.

The Summary Screen

The Summary Screen allows you to see a summary list of all events and strips for a procedure in one location. Events appear in gray, and Strips will appear on white lines. You can go to any event or strip by double clicking on that line.

Include in Report (Strips)

This box can be used for Strips only. The "Include in report" check box on the very right is turned on automatically when you Save or edit an existing strip. When one Strip for a given event is selected, either manually or by creating a new strip, all strips within that Event will be included in the report.

You can use the Select/Unselect button at the bottom of the screen to turn on/off all of the Include in report buttons for all events for a procedure.

When an Event report is generated, the report process will then turn off the check boxes and insert the report name that the event was last included on and the Printed box will be populated for that event.

Check boxes:

There are several additional check boxes on the Summary Screen that you can use to manage the procedure as you choose. They are:

Reviewed: This check box is turned on automatically when the Event Reviewed

Event Reviewed

box is checked at the bottom of the screen. This is useful if you decide not to save strips, but want to show that the Event has been seen by a technician.

Printed: Once an Event report is created by the report process, this check box will be populated for the Event.

Verified: Manually check this box after a report is verified and finalized.

Event Report#

This is the file name of the last report that the strip was included on. Click on the Manage Reports button at the bottom of the screen to see a list of all reports that have been created for the procedure. The reports all end in ".odt".

You can also create Event or Procedure reports from the screen. More on that in the next chapter.

4 REPORTING

Once strips are saved for one or more events, you can create a report. There are two types of reports: Event and Procedure. An Event report will include any strips that you saved since the last report you created for this procedure. A Procedure report will include all strips that exist for the patient. Findings for each report can be created and saved in the respective Report windows that can be found on the Summary Screen or Report from the toolbar. Once a report is created, Libre Office will open and at this point you can edit and save the report.

To Create a Report

Reports can be produced or reviewed at any time. In order to create a report:

- 1. Open the procedure.
- 2. Review Events and save strips.
- **3.** Go to Report on the toolbar or the Summary Screen and choose either Event or Procedure Report.
- 4. Enter and/or edit findings.
- 5. Save & Print the report.
- 6. The report will now open for editing and/or printing.

Findings

You can enter and save Findings for either the Event of Procedure report at any time. Just enter the findings and Save until you are ready to create a report.

Include Strips

This check box is turned on by default. Uncheck the box to create a one page report with findings only.

Procedure Report Trend

The Procedure Report will include an HR rend of all strips that were saved during the procedure. The trend will vary in size based upon the duration and can be 1, 3, 7, 14, 21 or 30 days in length. The Max, Min and Mean HR are based upon the strips that have been saved and the %strip values are based upon all saved strips.

Manage Reports

All reports that you created previously have been saved in a directory for that procedure. All reports are saved with the ".odt" suffix. From here you can open and edit reports, but not the strips. If you like you can also delete reports from this screen, but keep in mind that the Summary screen will not update automatically.

LX Event User's Manual Customizing Reports

Note: As of release 3.0.3, all reports are stored in a directory labeled "reports" off of the main patient directory. Previously created reports will still be found in the patients main directory.

report, you should save the file, but it should be an empty file with all blank lines.

Libre Office

Libre Office is word processor that is included with the LX Event install. You can use Libre office, and possibly other word processor, to edit your reports after they have been created by LX Event. You will want to save your report as a PDF file before sending it to its final destination.

Customizing Reports

Two files in the Programs Directory can be updated so that your reports can include your company's logo, name and address.

Report Logo

You can include your organizations's logo on the report. Do this by saving a jpg file, named logo.jpg, of your company logo in c:/nm/ Lxevent/ directory.

Report Name and Address

Your organization's name and address and/or phone can also be added to the report. In order to do this, you will need to edit a file that comes with LX Event with the information that should appear with the report. The file is limited to five lines of text.

You should edit the file with Notepad only. Notepad can be found under All Programs-> Accessories. The file you need to edit is

c:/nm/Lxevent/ServiceAddressHeader.ini.

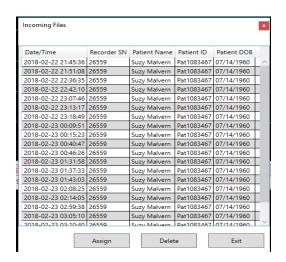
If for some reason you do not want to your organization's name to appear at the top of the

5 WIRELESS FILES

The Incoming Files window allows you to view all event files that have been received wirelessly via the Event Decoder utility.

Incoming Files Window

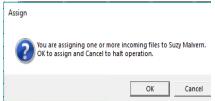
Upon installation, LX Event will look for incoming files in c:\nm\ftp\event. To change this location, you can change the IncomingFilesDirectory in the lxevent.ini file to look to a folder in another location where it can find "Event".



The Incoming Files window automatically matches new event files to open procedures. The matching logic requires that you input the Serial Number from the recorder into the Recorder ID on the Patient Information window. ...

When the Recorder SN on the incoming file matches and open procedure Recorder ID, the Patient Name, Patient ID and DOB will appear columns to the right of the Recorder SN.

Assign Incoming files



When matched, you can select one or more incoming files, and assign them to the Procedure. The system will ask you to confirm the assignment as once assigned the file will be automatically deleted from the incoming files.

If an incoming file is not matching to a patient, you will need to find the Procedure to identify the problem. Most likely the Recorder ID and SN do not match and/or the Procedure has an end date and needs to be reopened for matching to take place.

More information on Wireless

Refer to the DR400 and the Gateway-FTP manuals for instructions on running the Wireless feature which may include MCT (Mobile Cardiac Telemetry). Both manuals can be found at www.nemon.com.

6 KNOWN ISSUES

The following is a list of issues that have been identified in this or a previous version of LX Event:

Release	Bug	Description	Plans to resolve
	#		
3.0.1	1480	Patient DOB on Incoming File Screen wrong date	This may be fixed in a
		format	future release
3.0.1	1519	Invert does not work if ECG not clicked on.	This may be fixed in a
		Always click on the event before saving strips or	future release
		updating the event.	
3.0.1	1521	Strip values are currently affected if the user	This may be fixed in a
		changes the gain.	future release