

NMShow

Instructions for Use Installation and User Guide

X·AVANT
TECHNOLOGY



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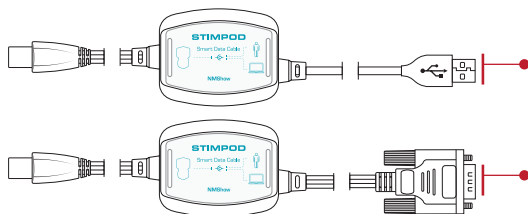
Introduction

The NMShow cable allows a user to connect a STIMPOD NMS450X or NMS450X+ to a PC with the NMShow software (Windows only). The NMShow application allows users to view and record NMT cases. Recorded data can, further, be reviewed and assessed on the program once a case has been concluded.

Intended Use

The Smart Data Cable is used with the STIMPOD NMS450 devices to stream NMT response data to a host monitor or PC, where it can be viewed and stored. It is a non-sterile and re-usable accessory.

Product Codes



Smart Data Cable NMShow USB (XT-45100A-NMS):

Interface AMG/EMG data directly to a PC/Monitor using the NMShow Protocol.

Smart Data Cable NMShow RS232 (XT-45100C-NMS):

Interface AMG/EMG data directly to a PC/monitor using the NMShow protocol.

Figure 1: Smart Data Cable NMShow Codes

Important Notes to User

- ♦ For instructions and information regarding Warning, Caution, Cleaning/ Disinfection, Information on Symbols, Disposal and Warranty, refer to the original STIMPOD NMS450 Device user manual.
- ♦ The NMShow application is not a medical device software.
- ♦ The application works only with designated NMShow cables supplied by Xavant.
- ♦ The application allows users to only view live and/or recorded NMT monitoring data from STIMPOD devices and does not perform any processing of the monitored data itself.
- ♦ Session data created by the user in the application is not collected, stored, accessed or processed by Xavant in any manner.

Privacy and Data Protection

The software allows the user to enter and store patient-related information, such as patient identifier, age, date of birth, and height, together with recorded monitoring data. Patient-related data entered into the software is stored locally on the user's personal computer, as determined by the user. The software does not transmit patient data to the manufacturer or to any external servers, and the manufacturer does not access, collect, process, or store patient-identifiable data.

The user (e.g. healthcare facility or healthcare professional) is responsible for:

- ♦ Ensuring that patient data is entered, stored, and managed in compliance with applicable data protection regulations, including the General Data Protection Regulation (GDPR);
- ♦ Implementing appropriate technical and organizational measures to protect patient data, including access control, data backup, and secure storage;
- ♦ Using patient identifiers that are pseudonymous or non-identifiable, where possible.

The manufacturer has implemented the software in accordance with privacy-by-design and data-minimization principles. Only data necessary for the intended purpose is supported by the software.

Users should ensure that the PC using the NMSHOW software should be virus free and secured in line with facility, FDA and general best practice cybersecurity requirements. Further ensure that the device is up to date, ensuring it has the latest virus protection available to it.

Installation Guide

Online

1. Navigate to Xavant Support page at <https://www.xavant.com/support/>
2. Click the "Download NMSHOW Installer Package" Option to download the .exe file.
3. Once the download is complete, open the file to start installation.
4. The installation should proceed automatically.

USB drive

Insert the supplied USB drive. Open the USB drive from the file manager and double click Nmshow.exe. The installation will proceed automatically.

Updating

Xavant will occasionally release updates to improve or fix the application. When this happens, the application will automatically update if run on a device which is connected to the internet. When the application is opened, it will attempt to connect to the internet to determine whether an update is available. If an update is available, it will be downloaded in the background and installed when the application is closed. When the application is reopened, it should be updated to the latest version. If the application is run on a device which is not connected to the internet, it is the users' responsibility to download the latest version of the software from the Xavant website and install it on the device by following the installation process as above.

Connecting to a PC (USB cable variant)

Step 01: Plug the NMShow Cable into the FireWire port of the STIMPOD.

Step 02: Plug the NMT Monitoring Cable (AMG/EMG) into the FireWire port of the NMShow Cable.

Step 03: Connect the USB end of the NMShow cable to an available USB port on the PC.

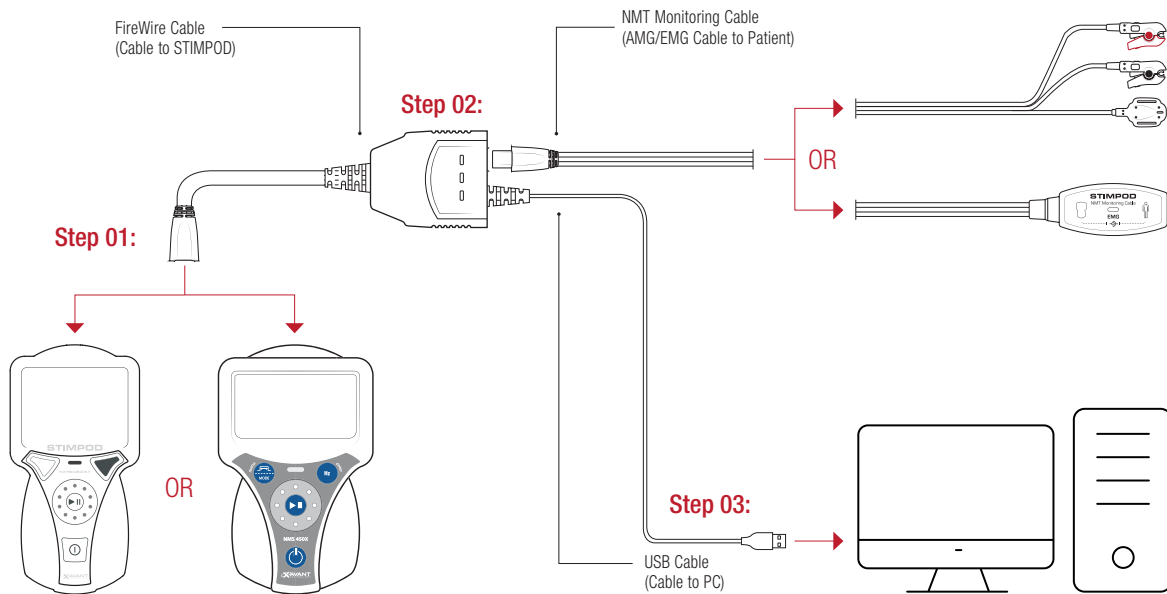


Figure 2: Connecting STIMPOD to a PC - USB Cable

Connecting to a PC (RS232 cable variant)

Step 01: Plug the NMShow Cable into the FireWire port of the STIMPOD.

Step 02: Plug the NMT Monitoring Cable (AMG/EMG) into the FireWire port of the NMShow Cable.

Step 03: Connect the USB end of the NMShow cable to an available USB port on the PC.

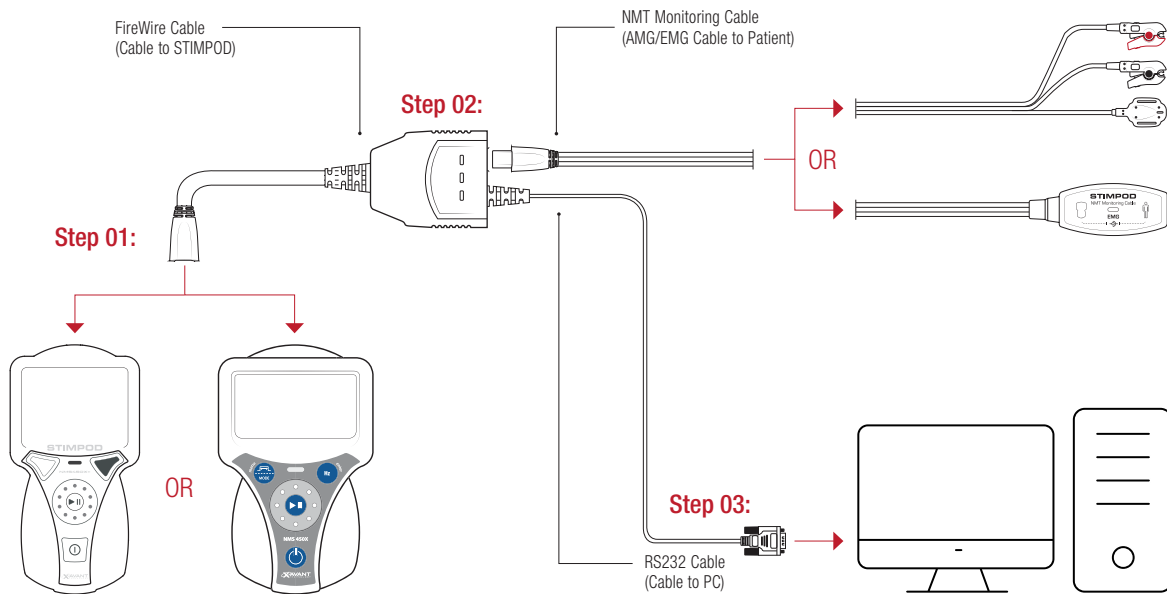
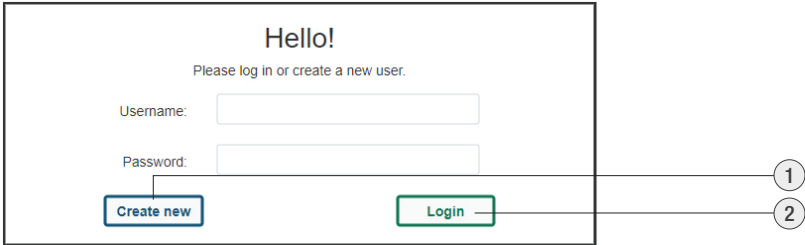


Figure 3: Connecting STIMPOD to a PC - RS232 Cable

Starting NMShow

After the installation is complete run the NMShow application from the desktop icon or the start menu item. The application will open and display the following login screen.



The diagram shows a login window titled "Hello!" with the instruction "Please log in or create a new user." It contains two input fields: "Username:" and "Password:". Below these fields are two buttons: "Create new" (highlighted with a blue border) and "Login" (highlighted with a green border). Two numbered callouts are present: callout 1 points to the "Create new" button, and callout 2 points to the "Login" button.

Figure 4: Log In Window

To start using the application either:

- ① Click on Create new to create a new user account (First time users).
- ② Click Login if you have already created a user account .

Creating a New User

To create a new user, follow the steps below or see the on-screen instructions. Navigate to the **Create New** screen, as shown in Figure 3, by clicking the **Create New** button on the login screen. If a user has already been created, proceed to the Login section.

The screenshot shows a registration form titled "First time user?". Below the title is the instruction: "Please fill in the fields below and click 'create' to create a new account." The form contains four input fields: "Username:" with the text "John01", "Name:" with the text "John Smith", "Password:" with masked characters "*****", and "Repeat:" with masked characters "*****". At the bottom left is a "Go to Login" button, and at the bottom right is a "Create" button. Five numbered callouts (1-5) point to the following elements: 1. Username field, 2. Name field, 3. Password field, 4. Repeat field, and 5. Create button.

Figure 5: Creating New User Window

- 1 Enter a username in the Username field. The username should be at least 4 characters long and may not be the same as another user's username on the same device.

When all the fields are filled in and the Create button is clicked, the application will check if the user already exists and inform the user if this is the case.

- 2 Enter full name in the Name field. This field is not validated and is optional.
- 3 Enter a password in the Password field. The password should be at least 6 characters long. Please be sure to keep the password in a safe place to ensure the user's data is secure as a password cannot be recovered.
- 4 Retype the password in the Repeat field.
- 5 Click the **Create** button. This will create and save the user before returning to the login screen.

User Login

If a user has been created, log in using the steps below. The Login Screen will display when the application is initially opened. It can also be accessed from the Create User screen by clicking the [Go to Login](#) button.

The screenshot shows a login window titled "Hello!" with the instruction "Please log in or create a new user." Below this, there are two input fields: "Username:" with the text "John01" and "Password:" with masked characters "*****". At the bottom, there are two buttons: "Create new" and "Login". Three numbered callouts are present on the right side of the window: 1 points to the Username input field, 2 points to the Password input field, and 3 points to the Login button.

Figure 6: Log In Window (cont.)

- ① Enter your username. This is the unique identifier linking the user to the sessions recorded.
- ② Enter your password.
- ③ Click the Login button. If the correct username and password combination has been entered, the user will be logged in and the Activity Selection screen will be displayed; if not, an error message will be displayed.

Activity Selection

The Activity Selection screen allows the user to select whether to view old sessions in the Archive or Create a New Session to record data from the STIMPOD by using Live mode.

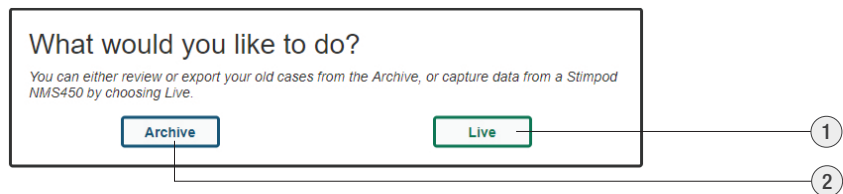


Figure 7: Activity Selection Window

Select either:

- ① Archive - View any of your previous sessions.
- ② Live - View data and record live from STIMPOD.

Creating a live session and recording data

To view data live from the STIMPOD, the device and the monitoring accessory cable needs to be connected to the host device via the NMShow Cable. Click on Live from the Activity selection screen to initiate a new session. Several fields are available which will be attached to the session, however, only the Device and File name fields are required. These fields are annotated below and described on the following page.

The screenshot shows a mobile application window titled "Create a new session". It contains several input fields and buttons. Numbered callouts (1-12) point to specific elements:

- 1: Title bar "Create a new session"
- 2: "Device *" dropdown menu with "Please select..." and a refresh icon
- 3: "File name *" text input field
- 4: "Memo" text area
- 5: "Record Id" text input field
- 6: "Date of birth" text input field with "2018-12-11"
- 7: "Height" section with a text input field and unit buttons "cm", "feet", and "inch"
- 8: "Weight" text input field
- 9: "Gender" dropdown menu with "Please select..."
- 10: "Class" dropdown menu with "Please select..."
- 11: "Create" button
- 12: "Back" button

Figure 8: Creating a New Session Window

- ① Device selection – This allows the user to select the device from the list of devices connected to the PC.
- ② Refresh button – Click this to refresh the list of devices connected to the PC.
- ③ File name – An identifier to help the user distinguish this session when using the archives.
- ④ Memo* – Any general notes or additional information to attach to the session.
- ⑤ Record ID* – A internal record to which this session should be linked.
- ⑥ Date of birth* – Date of birth of the patient.
- ⑦ Height* – The height of the patient, either in centimeters or in feet and inches. The centimeter field will automatically update from the feet and inches and vice versa.
- ⑧ Weight* – The weight of the patient.
- ⑨ Gender* – The patient's gender.
- ⑩ Class* – The patient's ASA (American Society of Anesthetists) physical status classification.
- ⑪  A user should only click this button when the STIMPOD device has been selected, a file name has been entered and the user is satisfied with the information captured. Clicking this button will create the session and open the Live data view screen.
- ⑫ Back Button - This button will clear all fields and return to the Activity selection screen.

* Optional.

Live View

The main components of the Live view are described below. Please note that this functionality works best with the Auto mode of the STIMPOD due to it automatically switching between TOF and PTC stimulation sequences. The various annotated parts of the main screen are described on the next page.

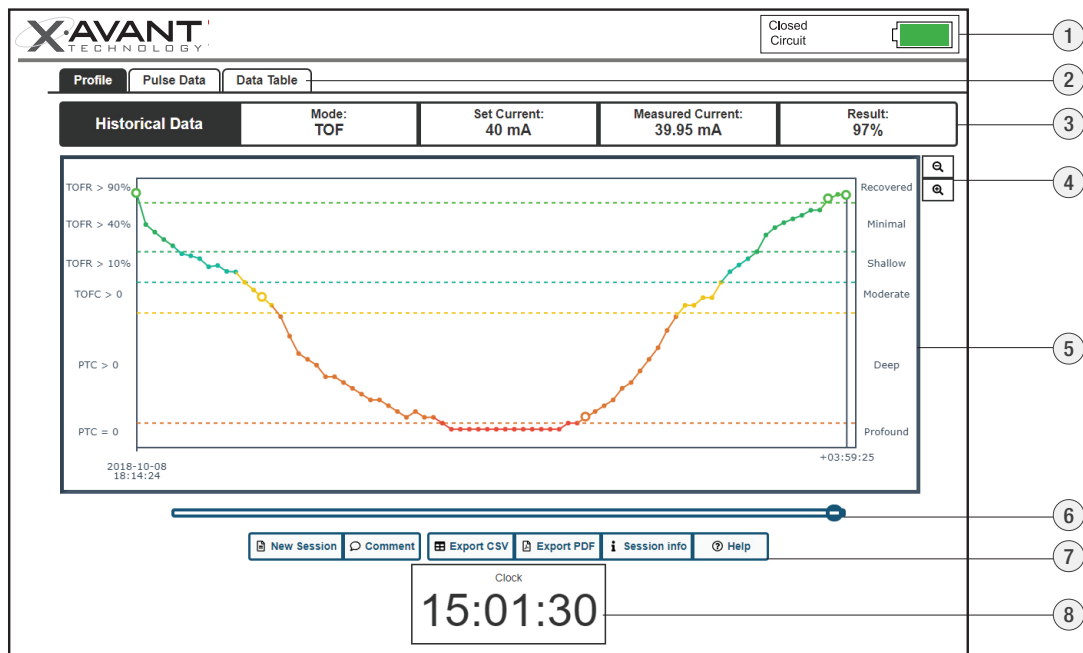


Figure 9: Primary Session Window

- ① STIMPOD Status – Indicates the battery level and whether a closed circuit has been detected.
- ② Tab controls – Change the view to display either the session profile, single stimulation or stimulation data.
- ③ Stimulation details – Display details for the selected stimulation sequence.
- ④ Zoom controls – Investigate a smaller portion of the profile graph, or get a big picture overview.
- ⑤ Main display area – Displays either the historical depth of block graph, the stimulation graph or the stimulation data table.
- ⑥ Stimulation selector - Select the stimulation displayed on the main display area from historical data recorded for the current session.
- ⑦ Toolbar – Start a new session, add a comment, export data and more. See the Toolbar subsection on *page 20* for more info.
- ⑧ Clock – Displays the current time, a stopwatch or a timer indicating the time since the start of the session.

STIMPOD Status

The closed circuit status and battery voltage is displayed at the top of the window. These will be grayed out if no communication has been received from the STIMPOD.

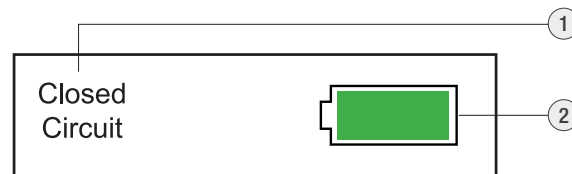


Figure 9.1: Stimpod Status

- ① Closed Circuit indicates whether a closed circuit configuration has been established
- ② Indicates the STIMPOD battery life.

Tab Controls

These controls change the contents of the main display area. Clicking the Profile tab control will display a depth of block graph to visualize the results of all the stimulations for the current session. This presents the results of the session in a single view, allowing for an overview of the full procedure.

The Pulse Data tab displays the results of a single stimulation sequence. This will display the bars for each pulse of the selected stimulation as it is displayed on the STIMPOD.

The third tab controls the Data Table and displays the data for each stimulation of the recorded session in tabular format. The data includes a time stamp, measured and set current, the stimulation result and the stimulation mode.

Stimulation Details

The stimulation details bar indicates the mode, result, set and measured currents for a selected stimulation sequence. This will be shown for both the profile and the pulse data tabs.

Zoom Controls

The zoom controls allow the user to show the depth of block graph in more detail. Click the magnifying glass with the plus or minus sign to zoom in or out respectively. Please note that the zoom is relative and is affected by the number of stimulation sequences which have been recorded.

Main Display Area

Depending on the tab selection made using the tab controls, the content of the main display area is changed to either the profile graph, the pulse data graph or the stimulation data table.

Historical Data	Mode: TOF	Set Current: 40 mA	Measured Current: 39.95 mA	Result: 97%
-----------------	--------------	-----------------------	-------------------------------	----------------

Figure 9.2: Stimulation Details Bar

Profile Graph

The profile graph displays all stimulation results of the current session, indicating the result, depth-of-block zone and the relative time from the start of the session. Only Auto, Train of Four (TOF) and Post Tetanus Count (PTC) modes are supported. Unsupported modes' results will be shown as a grayed-out dot on the graph. The graph is subdivided into the following six depth of block zones:

1. Recovered – Train of four (TOF) ratios over 90% are classified as recovered.
2. Minimal – TOF ratios between 40% and 90% are classified as a minimal block.
3. Shallow – A shallow block corresponds to TOF ratios between 10% and 40%.
4. Moderate – TOF counts between one and three are classified as a moderate block. TOF counts of four with a ratio less than 10% constitutes the boundary between Shallow and Moderate.
5. Deep – A TOF count of zero, or a PTC of one or more are classified as deep.
6. Profound – A PTC of zero is classified as profound.

Please note that occasionally the communication may be interrupted due to electromagnetic noise. Any failed stimulation sequence will be grayed out for this stimulation on the graph and the zone will be set to Failed.

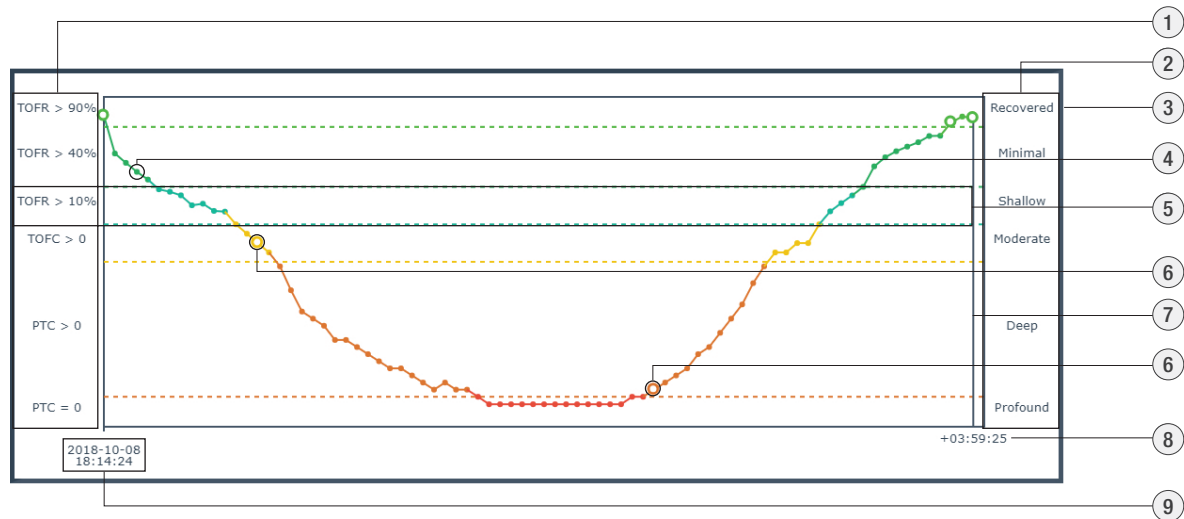


Figure 9.3: Profile Graph

- ① Depth-of-block zone explanations in terms of the mode and result.
- ② ③ Depth of block indication zones, indicated by a dot indicating the recorded data.
- ④ The result of a single stimulation, indicated by a dot indicating the recorded data.
- ⑤ A depth-of-block zone.
- ⑥ Commented stimulation sequences, indicated by a hollow circle.
- ⑦ Bar indicating the currently selected stimulation. This will be the stimulation for which the details in the Stimulation details bar is applicable.
- ⑧ The relative time for the selected stimulation since the start of the session.
- ⑨ The start time of the session.

Pulse Data Graph

The pulse data graph displays the results of the selected stimulation sequence. It will display bars indicating the magnitude of the accelerometer response in a similar way as on the STIMPOD.

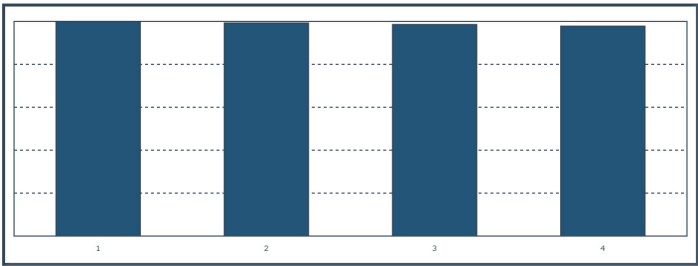


Figure 10: Pulse Data Graph

Stimulation Data Table

The stimulation data table displays: the stimulation results, set and measured currents, the depth-of-block zone, stimulation mode and timestamp for each stimulation sequence. A stimulation can be selected by clicking it once, after which the pulse data graph will be displayed by clicking the selected stimulation result again.

ProfilePulse DataData Table						
Mode	Stim No.	Set Current	Measured Current	Result	Zone	Timestamp
TOF	1	4000 mA	39.94 mA	100%	Recovered	2018-10-08 18:14:24
TOF	2	4000 mA	40.06 mA	72%	Minimal	2018-10-08 18:15:49
TOF	3	4000 mA	39.99 mA	63%	Minimal	2018-10-08 18:17:14
TOF	4	4000 mA	39.98 mA	54%	Minimal	2018-10-08 18:18:39
TOF	5	4000 mA	40.09 mA	47%	Minimal	2018-10-08 18:20:04

Figure 11: Stimulation Data Table Tab

Stimulation Selector

The selected stimulation can be changed by either using the slider below the main display area, scrolling the mouse wheel on one of the graphs or by using the data table as mentioned above.



Figure 9.4: Stimulation Selector

Toolbar

The toolbar consists of some essential functions the user can perform. These functions are described as the following:



Figure 9.5: Toolbar

- ① New Session - This button will open the Activity selection screen, from which the user can once again choose to use the Archive or start a new Live session.
- ② Comment - Add a comment to the current stimulation. See the Adding comments sub-section below.
- ③ Export CSV - Export all the session data on a pulse level to a CSV (comma separated value) file, which can be opened with a text editor or Microsoft Excel. No additional user input is required.
- ④ Export PDF - Open this pop-up window and find the Exporting to PDF sub-section below.
- ⑤ Session info - Open a pop-up window displaying information captured on the Create a Session window.
- ⑥ Help - Initiate a tour of the Live window explaining different sections on the screen.

Adding Comments

One or more comments may be added to each stimulation. Comments will be indicated on the profile graph as an empty circle. Hovering the mouse pointer over these empty circles will display the comment text.

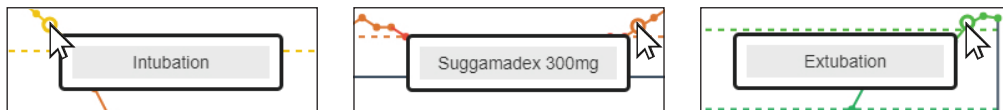


Figure 9.6: Adding Comments Window

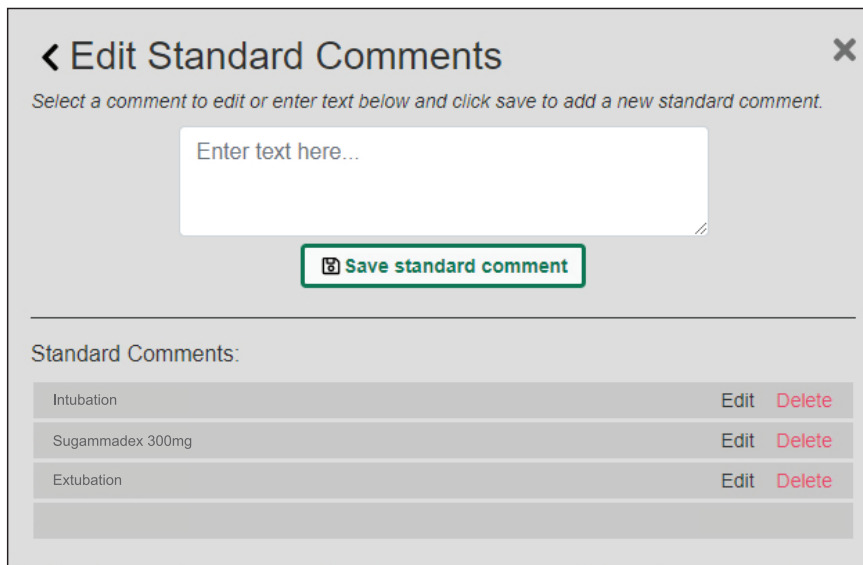
Alternatively, previous comments will also be displayed on the Add Comment screen. Custom comments can be added on the Add Comment screen by entering text into the text area and clicking the Save comment button. Standard comments can be selected from a dropdown menu, after which it can be customized in the text area before saving it using the Save comment button.

The screenshot shows a window titled 'Add Comment' with a close button (X) in the top right corner. Below the title is a instruction: 'Select a standard comment or enter text below and click save to add a comment to the current stimulation.' The main area contains a text input field with the placeholder 'Enter text here...'. Below the text field is a dropdown menu with the text '...or select a standard comment.' and a downward arrow. At the bottom of the main area are two buttons: 'Edit standard comments' (with a magnifying glass icon) and 'Save comment' (with a save icon). Below the main area is a section titled 'Previous Comments:' which contains a list of two comments: 'John01' and 'Jane01'.

Figure 12: Add Comment Window

Standard comments can be added, edited or deleted using the Edit Standard Comments screen, which is opened from the Add Comment screen. Simply enter text into the text area and click **Save standard comment** to add a new standard comment. To edit a standard comment, click the Edit link on the appropriate comment from the list. This will populate the text area, where it can be changed. Remember to save after any changes have been made. Clicking the delete link will remove that comment after confirmation.

Please note that standard comments are shared between all users using the NMShow application on a single host device.



< Edit Standard Comments ✕

Select a comment to edit or enter text below and click save to add a new standard comment.

Enter text here...

Save standard comment

Standard Comments:

Intubation	Edit	Delete
Sugammadex 300mg	Edit	Delete
Extubation	Edit	Delete

Figure 13: Edit Standard Comments Window

Exporting to PDF

A report can be generated from the session data, including: the captured session information, statistics, the profile graph, comments and optionally all the stimulation data as on the data table. Click the Download button to save this report as a PDF file.

PDF Preview

Click the download button to download the pdf as shown in the preview. If the data or graph is not up to date with the current values, you can rebuild the pdf using the 'Rebuild' button.

Include Data? ☐

Session Info:

User	all
Patient Id	AK000921398
Date of birth	02 Jun 1981
Filename	-
Gender	MALE
Height	165 cm (5'5")
Weight	75 kg (165 lb)
ASA Class	2

Memo:

Rebuild

Download

Figure 14: PDF Preview

Clock

The clock can be used as either a real time clock, a stopwatch or as a timer indicating the time since the start of the session.

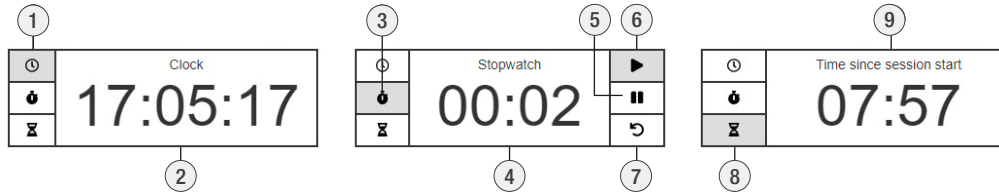


Figure 15: Clock

- ① Select the clock.
- ② The current local time.
- ③ Select the stopwatch.
- ④ The stopwatch time.
- ⑤ The pause button. This will prevent the stopwatch from counting up while keeping the current stopwatch value.
- ⑥ The start button. When clicked, this will cause the stopwatch to continue counting up from the current value (00:00 initially). The start button will have a grey background if the stopwatch is running.
- ⑦ The reset button will clear the current stopwatch value (set to 00:00).
- ⑧ Select the session timer.
- ⑨ The time since the session was created.

Review a Session

You can view any of your previous sessions by using the archive functionality from the Activity selection screen. Clicking on Archive from the Activity selection screen will open the Session select view as shown below.

The screenshot shows a mobile application interface titled "Select a session to review". At the top is a search bar labeled "Enter text to search...". Below it is a table with session information. The table has columns: Record Id, Date of birth, Height (cm), Weight, Gender, and ASA class. The first row contains the values: AK000921398, 1981-06-02, 165, 75, MALE, 2. Below this table is a "Memo" field with the text "Rocuronium 45mg". Under the memo is another table with columns: Date, Session name, and Record Id. The first row contains: 2018-09-25 16:29, demo, and AK000921398. At the bottom of the screen are two buttons: "Back" (outlined in red) and "Next" (outlined in green). Numbered callouts 1 through 6 point to the search bar, the session information table, the memo field, the session details table, the Back button, and the Next button respectively.

Record Id	Date of birth	Height (cm)	Weight	Gender	ASA class
AK000921398	1981-06-02	165	75	MALE	2

Memo
Rocuronium 45mg

Date	Session name	Record Id
2018-09-25 16:29	demo	AK000921398

Back **Next**

Figure 16: Select A Session to Review

- ① Search input – Typing text into this box will filter sessions by any text field of the captured information for each session containing a match to the search input. These fields include: the session name, record id, memo and gender.
- ② Session information – Displays the captured information for the selected session.
- ③ Sessions – Either display the filtered results if a search keyword was typed in or all sessions. Please note that only sessions linked to the current user will be displayed.
- ④ Selected session – Click on a session to select it. The captured information for the selected session will show in the session information section and selecting a session is required to open it by clicking the Next button.
- ⑤ Back button – Click the Back button to return to the Activity selection screen.
- ⑥ Next button – Click the Next button to open the selected session in the Archive view.

Archive View

The Archive View displays the graphs and data of any previous session. The functionality of this screen is the same as the Live view except for the following:

1. The device status is not shown, since the device might not be connected and is not relevant to the archived session.
2. There is no live settings bar for the same reason as above.
3. Only a simple clock is displayed, i.e. no stopwatch and no session timer.
4. Graphs and tables do not update, since the archived session is static.

Please see the Live view section for information on how to use the Archive View. Comments can still be added, and information and data can still be exported as a csv or pdf.

Symbols



Manufacturer



Importer



Warning



WEEE (Disposal of Electronic Waste)



European Representative



Medical Device (Class I)



Product Reference Code/Catalogue Number



Swiss Representative



Prescription Only



Type BF applied part



Non Sterile



Unique Device Identification



CE/EC Conformity Marking EU MDR 2017/745



Refer to Instructions for Use/Accompanying document



Humidity Limitation



Temperature Limits



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