FIRMM® User Manual – Siemens

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Drugs S.L.

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℞ only

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1 Introduction

The FIRMM system is an accessory to an MRI scanner in a hospital radiology department or an outpatient imaging center. FIRMM displays approximate head motion in several types of MRI acquisitions; specifically functional magnetic resonance imaging (fMRI) protocols, diffusion (DWI) protocols and T1/T2 protocols which include volume navigator (vNAV) modifications.

In the case of functional magnetic resonance imaging (fMRI), the MRI scanner acquires time series data and exploits Blood Oxygen Level Dependent (BOLD) contrast effects to visualize brain function. The FIRMM system continuously monitors the MR image data as it is being generated during these exams.

In diffusion MRI (DW), magnetic field gradients are employed to sensitize the image to diffusion in a particular direction and a 4D time series data is acquired. The diffusion patterns can reveal microscopic details about tissue structure and detect potential differences between normal and diseased microanatomy. A specialized form, Diffusion Tensor Imaging (DTI) can be used to generate maps of the white matter and nerve tracts. FIRMM evaluates the individual 3D volumes and quantifies artifacts which may be due to patient motion.

In the case of volume navigator (vNAV) acquisitions the anatomical scan types (such as T1 and T2 weighted MRI) have been modified so that the Siemens MRI scanner can measure patient motion. In some cases, these modifications can also prospectively correct for patient motion and/or reacquire portions of the image data that may have been compromised. The FIRMM system can interpret the motion measurements from the scanner and produce a real time motion graph while the scan slices are being acquired and before a reconstruction has completed. For information about these volume navigator sequences contact your Siemens applications support. To learn more about the FIRMM integration with these special T1/T2 acquisitions; contact Nous Imaging at support@firmm.io or call: +1-844-NOUSIMG (+1-844-668-7464).

Other MR image acquisitions modes or non-product sequences collected during a patient scanning session are ignored by the FIRMM system and no motion data or metrics are displayed.

In general, FIRMM analyzes the images and detects small displacements (roll or translation) of the anatomy along any axis. In the case of volume navigator (vNAV) data the raw motion results are provided by the scanner. FIRMM quantifies these movements and provides the MRI scanner operator with a plot of patient motion displayed as type of 'seismograph', as well as providing a tabulation of the percentage of images that have less motion than a user specified motion threshold, and a tabulation of the total length of image content less than the user-specified motion threshold. This motion information provides the operator with a way to monitor patient movement and may enable them to make more informed decisions about exam management.

Note: The FIRMM Framewise Displacement (FD) data quality measure has been clinically accepted as a strong surrogate for patient motion. The FD metric is generated from patient head movements (translation and rotation) that occur between volumes

The FIRMM DWI quality measures approximate motion that occurs during the instant of individual 3D volume acquisitions.

The FIRMM T1/T2 quality measures are computed by the MRI scanner and measure motion that occurs during the multiple MRI acquisitions that occur within individual MRI 2D slices or 3D volumes.

For instructions on how to install FIRMM please see the "FIRMM Installation Guide".

2 Indications for Use

The Nous FIRMM system is an accessory to an MRI scanner to calculate and display patient motion during a head scan. The motion results are derived from the MR image data as it is being acquired.

MR images can be imported during the scan and analyzed to detect patient motion in real-time. FIRMM enables the operator to become aware of patient motion during the scanning session and can be used to support scanning efficiency.

The device is intended for prescription use only.

3 Safety Considerations

The following section contains the safety considerations associated with FIRMM use. The user needs to become familiar with the following information in order to use FIRMM safely and effectively.

3.1 Definitions

WARNING

WARNING: Indicates a hazardous situation that, if not avoided, could result in death or serious injury.

CAUTION

CAUTION: Indicates a hazardous situation that, if not avoided, may result in property damage, injury, or both.

Note: Is used to alert the user to useful information to operate the device effectively.

3.2 List of Warnings and Cautions

WARNING - The FIRMM tablet and desktop cradle are MR unsafe. Keep them out of the MRI scanner room.

WARNING - Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the FIRMM system and the other equipment should be observed to verify that they are operating normally.

WARNING - Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING - Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the FIRMM system including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

CAUTION - Charge the tablet only using the power cord provided with the system.

CAUTION - Clinicians should be aware that the use of the patient feedback display may interfere with functional MRI measurements.

CAUTION - Clinicians should be aware that only the 'fixation cross' feedback display option has been studied in use with fMRI acquisitions with observations limited to children ages 5-10.

CAUTION – Do not force the tablet to shut down by holding down the tablet power on/off button for more than 1 second. This can cause the disk to become corrupted.

4 Device Description

The FIRMM system is a tablet computer system in a desktop cradle that is permanently networked to the MRI scanner system. The software uses an elegant touch screen interface. If an MRI scan is being performed for which FIRMM can compute motion data, and the MRI scanner is set to transmit the data to FIRMM, the analysis and display begin automatically and provide the operator with a real time motion trace display and motion quality metrics.

FIRMM only stores patient data until the next patient is scanned, or for 24 hours, whichever is shorter. Consequently, it is not possible to review any prior scan data.

FIRMM can be configured to provide visual feedback to the patient on their motion level. To use this feature, you will need to make sure that the HDMI port on the tablet is connected to your existing MRI in-bore projection system.

The FIRMM tablet includes a USB key that has a "DO NOT REMOVE" sticker on it. This USB is used to store utilization data and error logging that may be helpful if Nous Imaging service personnel need to diagnose problems or obtain detailed information about your usage of the system.

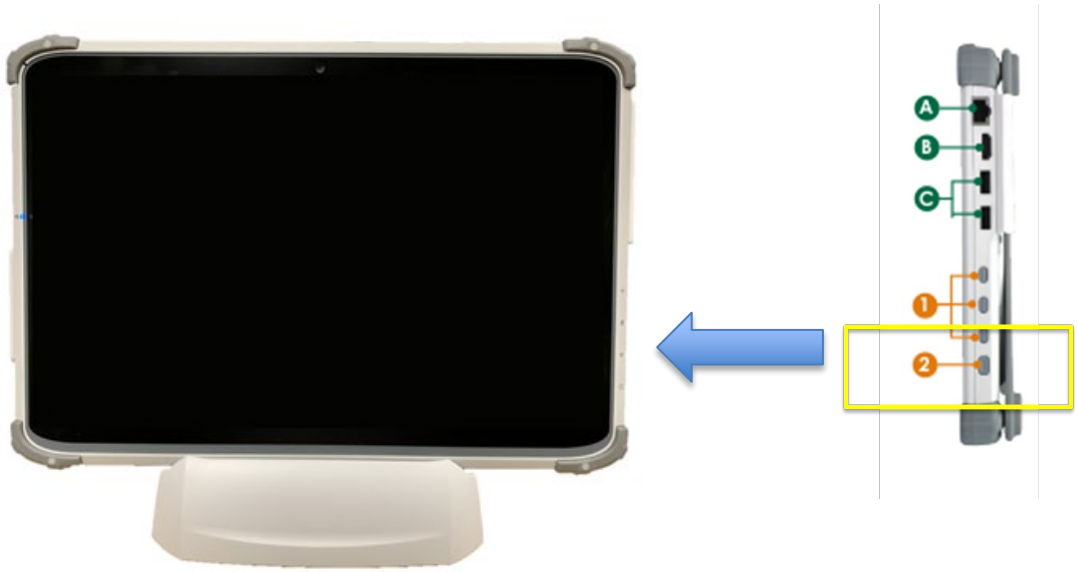
4.1 Performance Characteristics

The following are the technical performance characteristics of FIRMM:

- FIRMM can measure and display movements within 0.3 mm for fMRI scans
- FIRMM Frame Displacement results are updated for each frame received.

4.2 Tablet Computer System

The tablet is powered on by quickly depressing and releasing the power button on the lower right-hand edge of the tablet computer (the number 2 in the figure below). Additional details on the FIRMM tablet computer are provided in the included Basic Operations Guide.



CAUTION - Charge the tablet only using the power cord provided with the system.

Note: The tablet should always be placed in its cradle. The desktop cradle provides power to the tablet and FIRMM will not work without this connection.

When you turn on the tablet the FIRMM software starts automatically. No login is required.

On startup the FIRMM system will display that it is not connected and is waiting to receive data from the MRI scanner.

WARNING - The FIRMM tablet computer and desktop cradle are MR unsafe. Do not take either one into the MRI scanner room. They are intended to remain in the control room.

4.3 Tablet Cleaning Instructions

To clean the Tablet's anti-microbial enclosure:

- Use a soft/non-abrasive cloth moistened with water to clean the enclosure
- To prevent scratching the anti-microbial coating, please wipe gently
- Use alcohol between 68 and 75% to clean the surfaces

5 User Interface Description

The FIRMM user interface has three pages that are described below. Navigate between the pages by selecting the tabs. All pages show a small yellow "i" in the upper right corner of the screen that displays the "about" screen with details about the software (see section 8).

5.1 fMRI

The fMRI tab displays the quality metrics and a trace of the patient motion over time for functional magnetic resonance acquisitions (fMRI).

When FIRMM is receiving fMRI data and calculating motion quality metrics; a small green pip will be displayed on the fMRI tab next to the tab name to indicate that data is being displayed on this interface tab. The green pip will blink briefly when FIRMM starts plotting and disappears shortly after FIRMM completes plotting. FIRMM will also automatically advance to the the active tab except if you are on the settings tab.

Displayed on the fMRI page are:

- The MRI scanner/FIRMM connection status (connected or not connected)
- The series being displayed; clicking the “select series” button provides select and unselect options to enable a different series to be displayed in the motion trace
- Quality time – displays how much data (in minutes and seconds) has been acquired that meets the desired motion threshold. This is the overall scan data time that can be considered “low motion”. Note that if the respiratory filter is on, the quality score is derived from the filtered results.

- Quality score – displays the percentage of low motion data (that is, the percentage of acquired data that is at or below the desired motion threshold). This number is the percentage of frames below the desired motion threshold. Note that, like the quality time, if the respiratory filter is on, the quality score is derived from the filtered results.
- Progress bar (if enabled) – displays progress towards the low motion time goal in both graphic form as well as the percentage value. The total low motion goal time in minutes and seconds is also displayed. See Section 5.3.1.
- Motion trace – a scrollable trace of the acquired motion data. Each data bar is the calculated motion result from the scan frame. The bar color denotes if the motion is low (white) or exceed the user-selected threshold (yellow). If the respiratory filter is on, the bars reflect the filtered results. Pointers indicate the minimum and maximum motion thresholds value (the 0.2 markers in the figure) that has been selected in the fMRI Settings on the Settings tab. This is the threshold used for the quality time and quality score calculation. The trace also shows lower and upper reference limits at 3 times the threshold value (the >0.6 markers in the figure). These reference limits provide an additional amplitude scale and improve the readability of the graph. They are not used for any calculations or results.
    - If you want to review data from earlier in the series you can drag the scroll bar at the bottom of the trace to the left or click on the pointer at the left end of the scroll bar
- A summary of the basic information about the scan being reviewed (series/scan type/motion threshold setting/respiratory filter setting)

5.2 T1/T2

The T1/T2 tab displays the quality metrics and a trace of the patient motion over time for MRI protocols which support vNAV (volume navigator) acquisition sequences. These are most commonly used for T1 or T2 contrast anatomical MR images.

These vNAV (volume navigator) protocols can record patient motion that occurs during the acquisition. In some cases, these protocols can be configured to prospectively correct for patient head movements and/or reacquire portions of the image data that may be affected by motion. Your FIRMM system can display the motion data for these special T1/T2 acquisitions that has been computed by the scanner.

To learn more about the operation of vNAV (volume navigator) modified sequences on your Siemens system you should contact your Siemens applications support.

To learn more about the FIRMM integration with these special T1/T2 acquisitions; contact Nous Imaging at support@firmm.io or call: +1-844-NOUSIMG (+1-844-668-7464).

Displayed on the T1/T2 page are:

- The MRI scanner/FIRMM connection status (connected or not connected)
- The series being displayed; clicking the “select series” button provides the select and unselect options to enable a different series to be displayed in the motion trace

- Quality score – displays the percentage of low motion data (that is, the percentage of acquired data that is at or below the desired motion threshold). This number is calculated by dividing amount of data that met the quality threshold by the total amount of data that has been acquired.
- Motion trace – a scrollable trace of the acquired motion data. Each data bar is the calculated motion result from the scan frame. The bar color denotes if the motion is low (white) or exceeds the user-selected threshold (yellow).

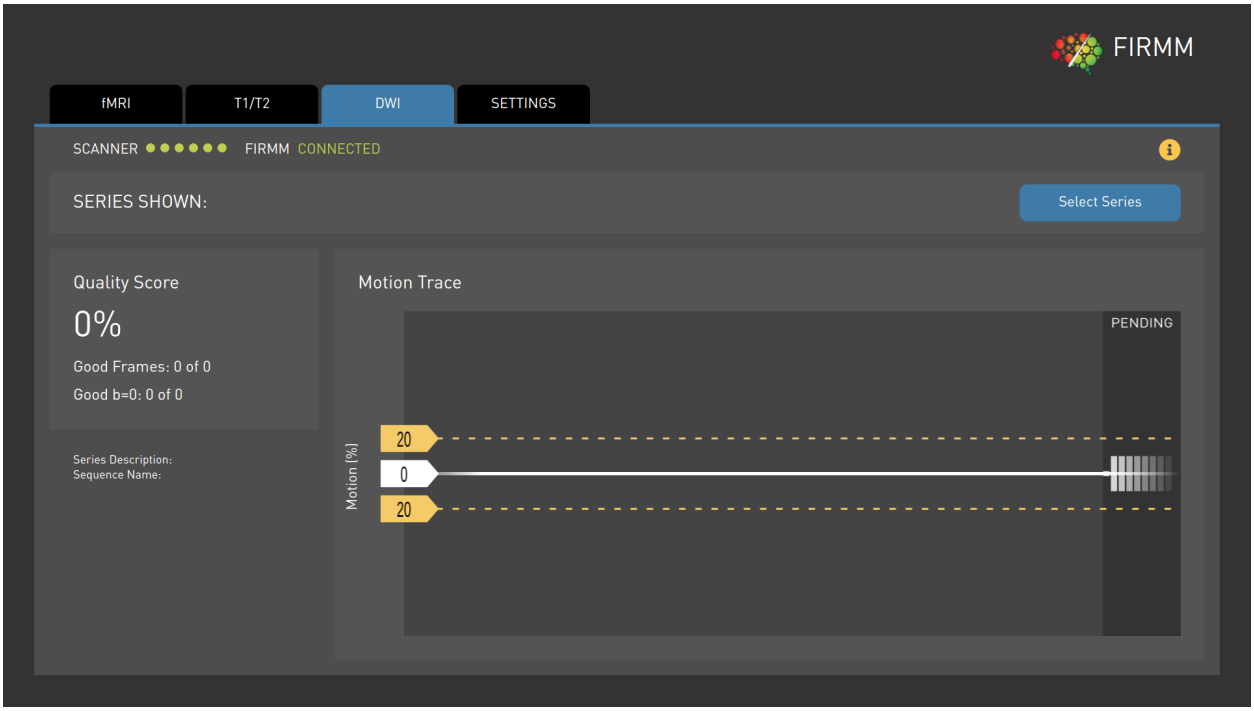
  Pointers indicate the minimum and maximum motion thresholds value (the 0.5 markers in the figure) that has been selected in the Settings.

  The trace also shows lower and upper reference limits at 3 times the threshold value (the >1.5 markers in the figure). These reference limits provide an additional amplitude scale and improve the readability of the graph. They are not used for any calculations or results.

  - If you want to review data from earlier in the series you can drag the scroll bar at the bottom of the trace to the left or click on the pointer at the left end of the scroll bar
- A summary of the basic information about the scan being reviewed such as scan description and sequence name.

5.3 DWI

The DWI tab displays a motion trace and quality metrics for Diffusion Weighted Imaging.



In the case of DWI images FIRMM processes each diffusion volume and characterizes the motion that occurred during each individual time point.

FIRMM represents the motion quality result as the percentage of brain-masked slices which may have been compromised by motion of the total brain-masked slices in the individual diffusion volume.

Displayed on the DWI page are:

- The MRI scanner/FIRMM connection status (connected or not connected)
- The series being displayed; clicking the “select series” button provides the select and unselect options to enable a different series to be displayed in the motion trace

- Quality score – displays the percentage of low motion volumes (e.g., the percentage of acquired DWI volumes that were at or below the within-volume desired motion percentage threshold). This quality is calculated by dividing the number of time points that met the quality threshold by the total number of time points that have been acquired thus far.

    - Good Frames - The number of total good frames out of the frames acquired thus far:

        A clinician or researcher may provide the MRI technologist a value for the approximate number of total good DWI volumes that would maximize the probability of an optimal post processing result.

        The total desired good frames depend on the specific pulse sequence acquisition being performed and the intended post processing that may be performed following the acquisition.

        The MRI technologist may use this figure, together with guidance from the clinician or researcher, to determine if the DWI acquisition is satisfactory.

    - Good b=0 - The number of good b=0 frames out of the b=0 frames acquired thus far.

        A clinician or researcher may provide the MRI technologist a value for the approximate number of total good b=0 DWI volumes acquired which maximize the probability of an optimal post processing result.

        These b=0 time points represent the minimum diffusion coefficient contrast and may be of special significance in some post processing workflows.

        The total desired good b=0 frames depend on the specific pulse sequence acquisition being performed and the intended post processing that may be performed following the acquisition.

        The MRI technologist may use this figure, together with guidance from the clinician or researcher, to determine if the DWI acquisition is satisfactory. d

- Motion trace – a scrollable trace of the acquired motion data. Each data bar is the calculated motion result from the scan frame. The bar color denotes if the motion is below the user-selected threshold (white) or exceeds the user-selected threshold (yellow).

    Pointers indicate the maximum motion thresholds value (the 20% markers in the figure) that has been selected in the Settings.

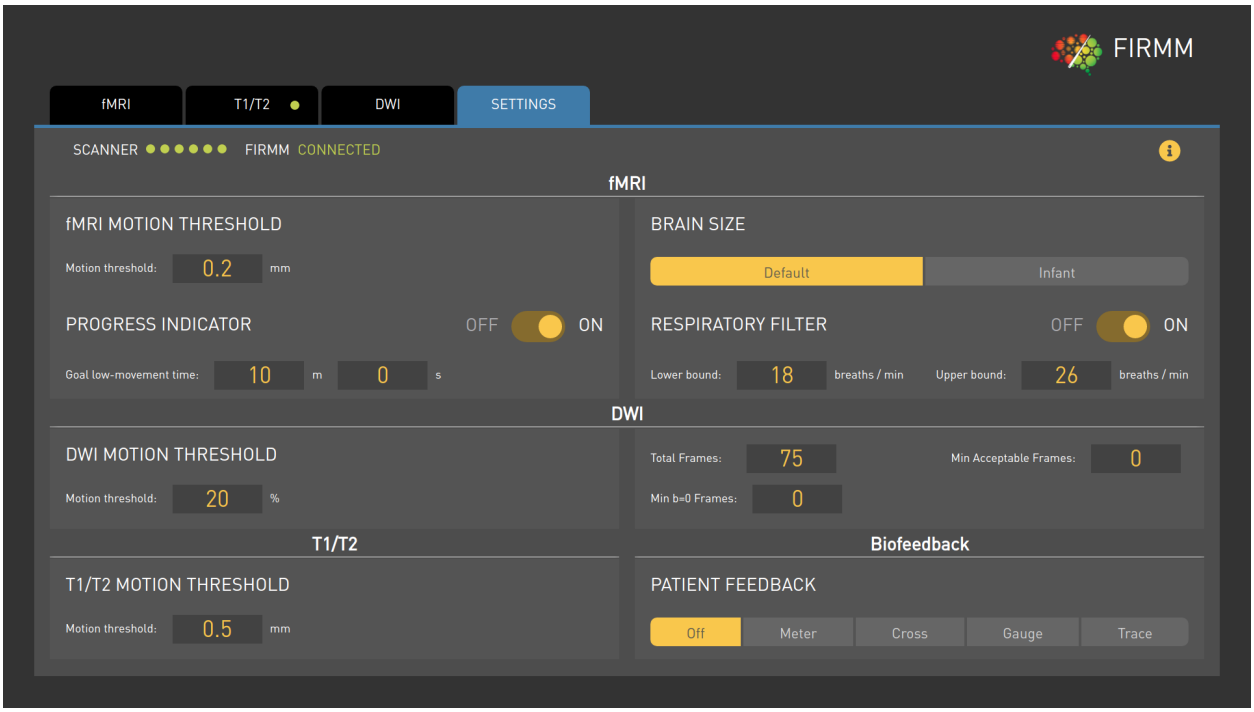
    - If you want to review data from earlier in the series you can drag the scroll bar at the bottom of the trace to the left or click on the pointer at the left end of the scroll bar

- A summary of the basic information about the scan being reviewed such as scan description and sequence name.

5.4 Settings

The Settings page allows you to select the parameters for a scan. These settings may be changed at the start of the scan or at any point during the scan.

Note that no setting changes take effect until you leave the Settings page (that is, go to the fMRI page or T1/T2).



5.4.1 fMRI Settings

For functional magnetic resonance imaging (fMRI) the settings you can modify are:

- Progress Indicator and an associated goal for low movement data – If the progress indicator is turned on, a bar will display on the fMRI screen indicating the scan progress towards the low movement time goal you have set. Some fMRI prescriptions will identify a total amount of low movement data necessary to complete the desired activation analysis in post processing. The "goal low-movement time" in minutes and seconds can be entered if the Progress Indicator is set to "on", otherwise it is not shown.

- fMRI Motion Threshold – Set the motion threshold in mm. Some fMRI prescriptions will identify the desired motion threshold. This is the value used to define "low motion" for the quality time and quality score calculations.
- Respiratory Filtering – If turned on, FIRMM automatically filters out breathing artifacts from the motion plot, quality Score, and quality Time. Because of this, and because the setting is applied to the entire series, if the respiratory filtering is turned on or off during a scan, the plot and the calculated values will change. This approach may be used to determine how much of the overall motion is due to the respiratory artifact versus actual head motion. For more information on how to adjust the filter lower and upper bounds see section 5.3.1.1.
- Brain Size – Select "default" or "infant". This setting affects the scaling of the rotational component of FIRMM FD values, using a typical value for adult or infant head sizes. The "infant" setting should be used with patients 2 years old or younger. Any patients over 2 years of age should use the "default" setting.

Note that these settings are reset to the default values when a new patient is scanned.

The settings relevant to functional magnetic resonance imaging (fMRI) are detailed below:

fMRI Setup Parameter	Default	Minimum	Maximum
Progress Indicator	Off	On/Off	
Goal Low Movement Time	20 minutes	1 second	60 minutes 59 seconds
fMRI Motion Threshold	0.2	0.05 mm	5.0 mm
Respiratory Filter	Off	On/Off	
Respiratory Breaths Per Minute (Low)	18	1	99
Respiratory Breaths Per Minute (High)	26	1	99
Brain Size	Default	Infant	Default

5.4.1.1 Respiratory Filter Adjustments

FIRMM provides the ability to remove respiration-induced artifact motion from fMRI scans. This respiration filtering function may be useful to discriminate between voluntary movements and patient breathing when managing the patient scan.

If breath motion suppression is desired, go to the Settings tab, enable the respiratory filter and enter lower and upper bounds for breaths per minute. The respiratory rate adjustments may be made any time before or during the scan and FIRMM will refresh the motion trace, quality factor, quality time, and progress bar indicator to reflect the new values.

The following table may be used as guidance based on the patient's age. Users should take care that these are generalized values and the stress of the examination, or other factors, can affect the patient's breathing over the course of the study.

Age Range	Cutoff Range (Breaths per Minute)
<1 year	30-60
1-2 years	25-50
2-6 years	20-35
6-12 years	15-25
12-18 years	12-20
19-65 years	12-18
65-80 years	12-28
>80 years	10-30

Note that the respiratory filter will damp computed FD motion values with components in the selected range and it may be necessary to establish different motion threshold expectations when the respiratory filter is applied routinely.

If FIRMM has been installed with the patient feedback display, be aware that the patient will also see the filtered data.

5.4.2 T1/T2 Settings

For vNAV (volume navigator) enabled T1/T2 scans, the settings you can modify are

- T1/T2 Motion Threshold – Set the motion threshold in mm. This is the value used to define "low motion" for the quality time and quality score calculations.

The settings relevant to volume navigator (vNAV) enabled T1/T2 scans are detailed below:

T1/T2 Setup Parameter	Default	Minimum	Maximum
Motion Threshold	0.5	0.05 mm	5.0 mm

5.4.3 DWI Settings

For Diffusion scans, the settings you can modify are

- DWI Motion Threshold Percentage – Set the motion threshold as a percentage of potentially motion corrupted slices over the total brain-masked slices in an individual DWI volume. This is the value used to define "low motion" for the quality time and quality score calculations.
- Min Acceptable Frames - value for the approximate number of total good time points that would maximize the probability of an optimal post processing result for this specific pulse sequence and the intended post processing.
- Min b=0 Frames - The total desired good b=0 frames for this specific pulse sequence acquisition and the intended post processing that may be performed following the acquisition.
- Total Frames – This parameter is not used in the FIRMM user interface today but may be used in future evolutions of the quality score and quality metrics.

The settings relevant to DWI scans are detailed below:

T1/T2 Setup Parameter	Default	Minimum	Maximum
Motion Threshold	20%	1%	100%
Min. Acceptable Frames	0	0	999
Min b=0 Frames	0	0	999
Total Frames	75	0	999

5.4.4 Settings Common to Both fMRI and T1/T2

There are also patient feedback controls which are relevant for both functional magnetic resonance imaging (fMRI) and for vNAV (volume navigator) enabled T1/T2 scans.

- Patient Feedback – Turn off or select a feedback option to display to the patient in the MRI scanner (see section 9 for more details on using this option).

The options under Patient Feedback are OFF, Meter, Fixation Cross, Gauge and Trace. The default value is OFF.

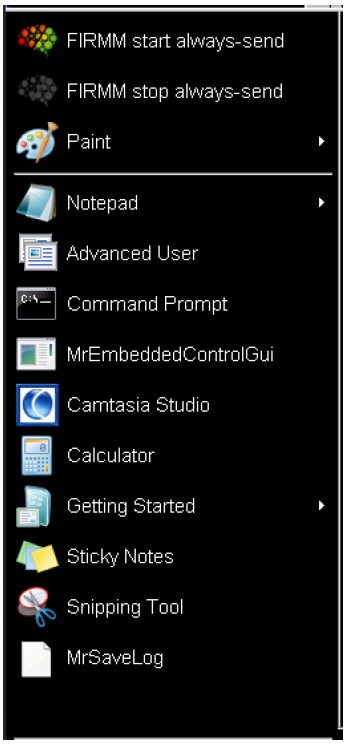
6 Clinical Workflow

Note: If you have a Siemens Numaris X (XA30) and use the BOLD add-in for image transfer from the scanner computer to the FIRMM tablet, skip to **Section 7**. When using BOLD add-in, the image transfer is activated automatically by any series which includes the properly configured BOLD add-in. The use of the BOLD add-in does not require invoking a desktop shortcut to activate FIRMM.

For Siemens Numaris 4 systems, continue with the steps below.

The most common configuration for FIRMM on Siemens systems is to always send every scan data to the FIRMM tablet. This set up is configured during the installation process and does not require you to take any steps to activate FIRMM prior to every exam. If your site has always-send enabled, you can see "FIRMM start always-send" and "FIRMM stop always-send" options in your Siemens scanner computer start menu.

You do not need to use "FIRMM start always-send" before scans if it is already enabled during the installation. But the "FIRMM stop always-send" can be used if the transfer to FIRMM tablet has to be stopped at any point.



Note: The FIRMM tablet should be left on and always connected. If users observe that images are taking longer than expected to be displayed on the console, verify that FIRMM is running or de-activate FIRMM transfers using the FIRMM stop control on the start menu.

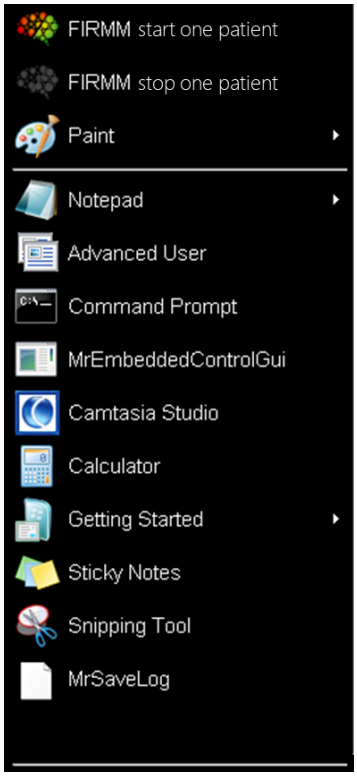
Note: If your Siemens MRI installation is integrated with other research applications which use the real time image transfer mechanism, please contact Nous Imaging technical support at support@firmm.io or call +1-844-NOUSIMG (+1-844-668-7464) for additional guidance before proceeding with the installation.

6.1 Alternative To Always-Send Option

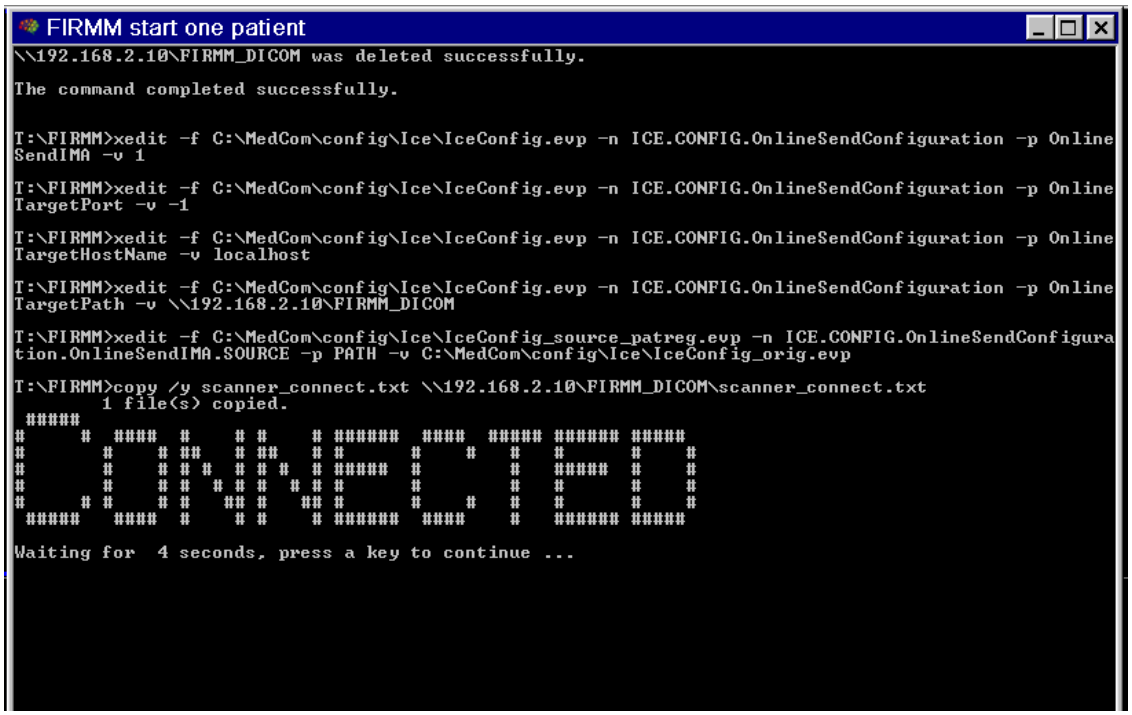
In some facilities it is not possible to set up the Siemens MRI Scanner to always send every MRI scan to the FIRMM tablet. If your FIRMM installation does not have always-send enabled, you will need to activate the transfer from Siemens MRI scanner to FIRMM tablet for every new patient registration.

In this case, to use FIRMM with a Siemens MRI that is appropriate for FIRMM motion monitoring, follow these steps for each patient registration:

1. From the Siemens MRI console – register the patient and select the appropriate exam.
2. From the Siemens MRI console – use Ctrl+Esc to open the Windows Start Menu and display the FIRMM start and stop selections.
3. From the start menu – select the option: "FIRMM start one patient".

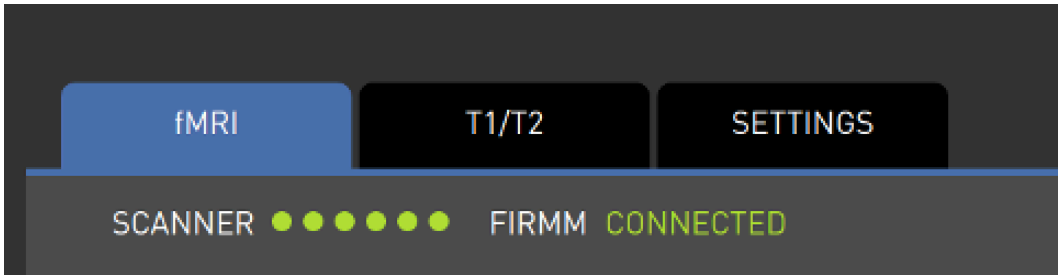


When “FIRMM start one patient” is selected, you will see the following command shell:



Note: To stop the transfer to FIRMM during a scan, select the option “FIRMM stop one patient”. Unless this is option is used, the transfer will continue for the scan duration for the patient and will stop once the scan is completed. You will have to run “FIRMM start one patient” again when registering a new patient.

In addition to the above “Connected” status on the scanner computer, the FIRMM tablet computer indicates that it is connected to the MR scanner in the upper left corner of the fMRI tab or T1/T2 tab, but at this point, it is still waiting for data.



4. Open FIRMM and review the selections on the Settings page
    - If desired, activate the progress indicator and input the desired amount of time of BOLD fMRI data
    - Verify the motion thresholds for fMRI and T1/T2 are correct
    - If desired, turn the fMRI respiratory filter on

- Verify the brain size is set correctly for fMRI motion results.

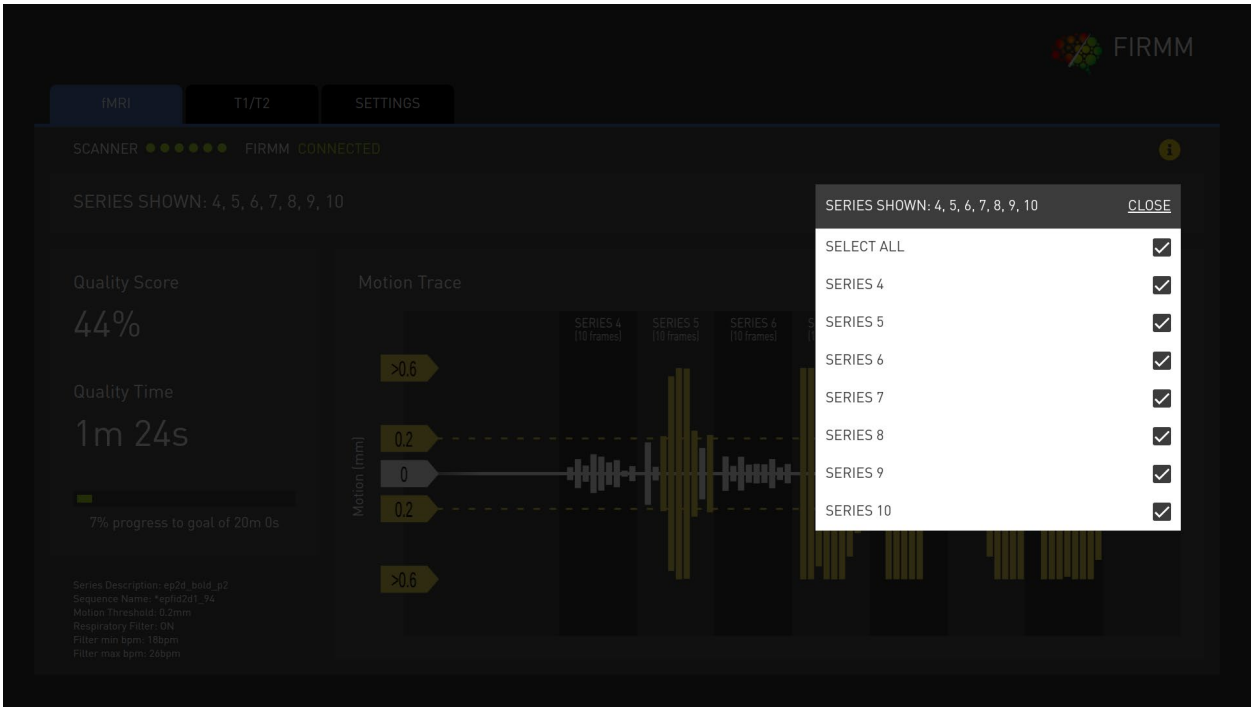
5. Initiate the MRI protocol from the scanner console.
6. On the FIRMM screen, select the fMRI tab and T1/T2 tabs and monitor the scan, when reconstructed MRI data is being transmitted to FIRMM, the motion plot and the quality metrics will display automatically. FIRMM will cue you when new fMRI or new T1/T2 data is being received with a small green pip in the relevant tab that will flash briefly at the beginning of the series.

Note: FIRMM will attempt to process any data that is fMRI BOLD. Whenever data is received, the DICOM header is analyzed to determine if it is appropriate for processing. For this reason, FIRMM may not automatically process research fMRI BOLD acquisition protocols unless you include specific meta data in the DICOM header. Please contact Nous Imaging for assistance in setting up non-product sequences for research.

7 Reviewing Other Series

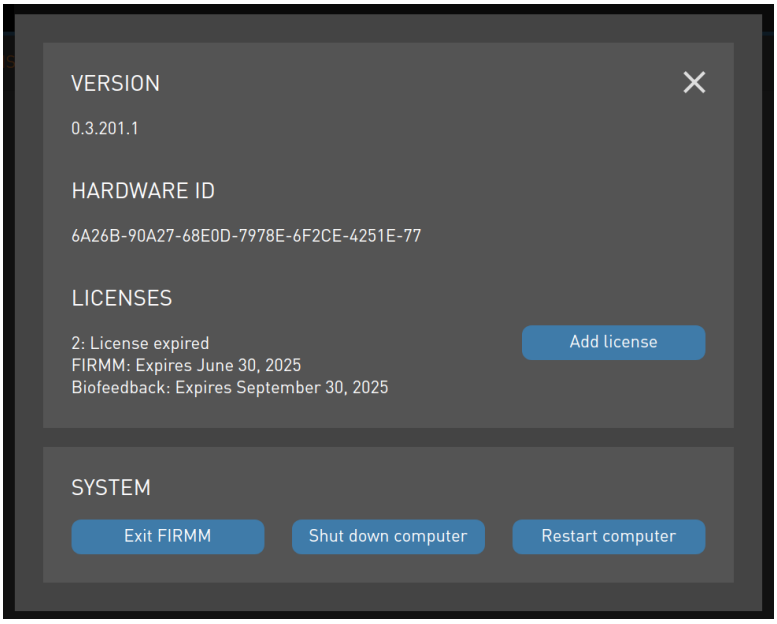
Note: The device removes prior data after 24 hours, or whenever the next patient is scanned.

To review a different fMRI Series and T1/T2 Series in the study, from the fMRI or T1/T2 page click on the “Select Series” button and checkmark the series names from the “Series shown” list.



8 About Screen

Clicking on the yellow “i” at the top right corner of any screen opens the “About” screen, which may be helpful during troubleshooting or when contacting Nous Imaging for Technical Support.



Note: The above is an example screenshot. The actual version and other details will vary based on the unit in your site.

From this screen you can:

- See the software version number
- See the hardware ID number
- See the license expiration date
- Add a new software license (you will be asked to enter a license number)
- Exit the FIRMM software (you will be instructed to contact Nous Imaging for a passcode)
- Shutdown the FIRMM tablet
- Restart the FIRMM tablet

9 Patient Feedback (Optional)

FIRMM has an option for a feedback display in the MRI scanner to give the patient an indication of how much they are moving. In order for the feedback to be used, it must first be connected to the MRI scanner's audio-visual display system. Instructions for how to do this can be found in the Installation Guide and a cable for an HDMI connection is provided with the system.

Note: Only make the connection to the display system in advance of starting the study. FIRMM should be rebooted whenever the connection is changed.

The FIRMM patient feedback option has been tested with the following display modes.

Aspect Ratio	Video Graphic Array Type	Resolution
4:3	SVGA	800x600
4:3	XGA	1024x768
4:3	UXGA	1600x1200
5:4	SXGA	1280x1024
16:9	WXGA	1280x720
16:10	N/A	1920x1200

CAUTION – Clinicians should be aware that the use of the patient feedback display may interfere with functional MRI measurements.

The level of patient head motion can be displayed to the patient using one of four different graphical cues. The selection is made from the Settings page. The feedback setting may be changed to a different option or turned off at any time (including during a scan). These changes take effect only after you navigate to the fMRI or T1/T2 tabs from the Settings tab.

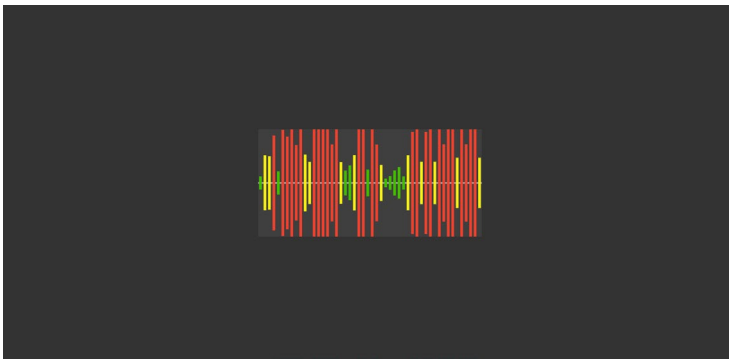
All the feedback displays depict 3 motion zones based on the motion threshold set by the clinician:

- Low motion – green or white – motion ranges from 0 to the set motion threshold
- Medium motion – yellow to light orange – motion ranges from the motion threshold level to two times this level
- High motion – dark orange to red – motion ranges between two and three times the motion threshold

Whenever the motion in a frame exceeds three times the threshold, all modes depict the maximum level of motion in their range.

The patient feedback options are depicted and described below.

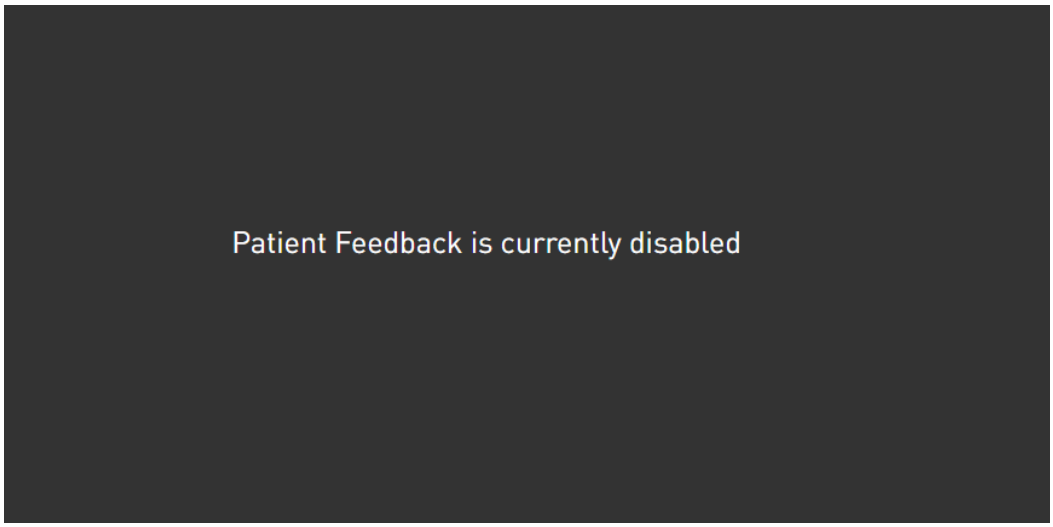
Type	Depiction	Explanation
Meter		The colors and number of colored bars indicate the level of motion in the most recent frame. The more bars that are colored, the higher the motion. When motion is more than three times the threshold, all bars will be colored.
Fixation Cross		The fixation cross changes color (from white to yellow to red) based on the level of motion in the most recent frame.
Gauge		The pointer rotates to reflect the head motion of the most recent frame. The more the pointer rotates to the right, the higher the motion level. When motion is more than three times the threshold, the pointer will be all the way to the right.

Trace		The trace dispays up to the most recent fifty frames. Each bar corresponds to a single frame and indicates the motion value encoded in height and color.

CAUTION – Clinicians should be aware that only the 'fixation cross' feedback display option has been studied in use with fMRI acquisitions with observations limited to children ages 5-10.

The FIRMM software does provide the clinician with alternative meter, gauge and trace patient feedback display modes that have not been formally studied or validated with patient testing.

If the audio-visual system is enabled, and the feedback is turned off, the patient will see this:



10 Compatibility

See the Customer Release Notes for the current list of supported MRI models and operating systems.

The FIRMM system is designed for use with fMRI BOLD acquisition sequences and has been tested with the standard product sequences available with your MRI system.

The FIRMM system also supports use with anatomical sequences that have been modified to include the Siemens volume navigator (vNAV) feature.

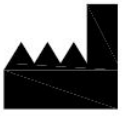
Note: FIRMM will attempt to process any data that is fMRI BOLD or T1/T2 vNAV or Diffusion weighted. Whenever data is received, the DICOM header is analyzed to determine if it is appropriate for processing. For this reason, FIRMM may not automatically process research acquisition protocols unless you include specific meta data in the DICOM header. Please contact Nous Imaging for assistance in setting up non-product sequences for research.

11 Troubleshooting

Issue	Possible Solution
FIRMM is not displaying a motion plot	Verify that you have activated the either the “FIRMM start one patient” or the “FIRMM start always-send” option from the Siemens Console start menu.
FIRMM is not displaying a motion plot for an fMRI sequence	Verify that you are using a production fMRI sequence.
Patient is not seeing any feedback data	Verify that you have activated the patient feedback display on the Settings tab and returned to either fMRI or T1/T2 tabs.
FIRMM motion plot has stopped updating and valid fMRI data is still being acquired	Wait until the current study has finished scanning. Restart the FIRMM tablet using the “Restart Computer” button on the About screen or the tablet on/off button to power off. Verify that you have activated the “FIRMM start one patient” or “FIRMM start always-send” option from the Siemens Console start menu. If the problem persists, contact Nous Imaging technical support.
FIRMM error message indicating licenses have expired	Verify the license status on the About screen. Contact Nous Imaging technical support.
Cannot shut down the FIRMM tablet from the About screen	Wait until the current study has finished scanning. Press the tablet on/off button for one second and confirm the shut down from the popup dialog. If FIRMM does not respond, hold down the on/off button for 4 seconds to shut down, then power up normally. Verify that you have activated the “FIRMM start one patient” or “FIRMM start always-send” from the Siemens Console start menu. If the problem persists, contact Nous Imaging technical support.

12 Symbol Glossary

The following symbols can be found on the device or the device packaging.

Symbol	Title	Definition	Standard, Reference Number
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1, 5.1.7
	Catalog/model number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1, 5.1.6
	Refer to instruction manual/booklet	Indicates the user must read the instructions for use	ISO 7010-M002
	MR Unsafe	To identify an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.	IEC 62570-7.3.3
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself	ISO 15223-1, 5.4.4
	Prescription use only	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.	n/a
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC, and 98/79/EC Includes the manufacturing date	ISO 15223-1, 5.1.1
	Signifies waste from electrical and electronic equipment	Dispose of this equipment according to local regulations for electrical and electronic waste disposal	WEEE Directive 2012/19/EU

Symbol	Title	Definition	Standard, Reference Number
	Authorized Representative in the European Community	The name and address of the authorized representative in the European Community should be adjacent to the symbol.	ISO 15223-1-5.1.2
	EU Certification Mark	Indicates that the medical device can be sold on the European market	MDD 93/42/EEC Annex I Section 13, MDD 93/42/EEC Article 17
	Medical Device	Indicates the item is a medical device.	ISO15223-1:2021, Clause 5.7.7

13 Electromagnetic Compatibility Information

The FIRMM system is intended to be used in the MRI control room (MRI Zone III) only. The FIRMM system should not be used in the MRI scanner room (MRI Zone IV) or near active high frequency surgical equipment, where the intensity of the electromagnetic disturbance is high. The wireless networking and Bluetooth capabilities of the tablet computer are deactivated. There are no essential performances associated with the FIRMM system.

WARNING - Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the FIRMM system and the other equipment should be observed to verify that they are operating normally.

WARNING - Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING - Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the FIRMM system including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Only components described as part of the FIRMM system (the power cable, Ethernet cable, HDMI cable, and USB drives) should be connected to the system. The cables and maximum lengths of cables that are replaceable in the system are:

- Ethernet cable: 150 meters or 328 feet
- HDMI – HDMI cable: 7.6 meters or 25 feet

The FIRMM tablet computer and cradle have been tested and shown to be compliance with IEC 60601-1-2:2004, ("Medical Electrical Equipment Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests"). There were no deviations or allowance used in compliance testing to this standard.

FIRMM is intended for use in the electromagnetic environment specified below in Table 1 and Table 2. The customer or user of FIRMM should ensure that it is used in such an environment and that mains power quality should be that of a typical commercial or hospital environment.

Table 1. Manufacturer's Declarations (Emissions)

Emissions Test	Result
Group 1 or 2	Group 1
Class A or B	Class B
CISPR 11, 14-1, 32 or ISO 7137	CISPR 11
Conducted RF Emissions	Compliant
Radiated RF Emissions	Compliant
Harmonic Distortion per IEC61000-3-2 (Class A, B, C, D)	Compliant
Voltage Fluctuations and Flicker per IEC61000-3-3	Compliant

Table 2. Manufacturer's Declarations (Immunity)

Immunity Test	Compliance Level	Result
Electrostatic Discharges IEC 61000-4-2	±2, 4, 8, 15 kV Air ±8kV Contact	Compliant
Radiated RF EM Fields IEC 61000-4-3	Frequency range 80-2700 MHz 3 V/m	Compliant
Proximity Wireless Fields	Frequency range 385-5785 MHz	Compliant

Immunity Test	Compliance Level	Result
IEC 61000-4-3	9-28 V/m	
Fast Transients IEC 6100-4-4	Input Power Ports ±2kV Signal Input/Output Ports ±1kV	Compliant
Surges IEC 61000-4-5	Input Ports 0.5kV and 1.0 kV (Line to Line) Input Power Ports 0.5kV, 1.0kV and 2.0 kV (Line to Earth) Signal Input/Output 2.0kV (Line to Earth)	Compliant
Conducted Disturbances, induced by RF Fields IEC 61000-4-6	3V RMS outside the ISM band, 6V RMS in the ISM and the amateur radio bands 150kHz to 80MHz	Compliant
Voltage Dips and Interruptions IEC 61000-4-11	<u>Voltage Dips</u> >95% Dip for 0.5 cycle @sync angles 0, 45, 90, 135, 180, 225, 270, 315 >95% Dip for 1 cycle @sync angle 0 30% for 25 cycles (50Hz), 30 cycles (60Hz) @sync angle 0 <u>Voltage Interruption</u> >95% Interruption for 250 cycles (50Hz), 300 cycle (60Hz) @sync angle 0	Compliant
Rated Power-frequency Magnetic Field IEC 61000-4-8	50Hz and 60Hz 30 (A/m)	Compliant

14 Technical Support

We want you to be happy with the FIRMM device. Please contact us with any questions or concerns, or if you encounter a serious incident, by email at: support@firmm.io or call: +1-844-NOUSIMG (+1-844-668-7464). In addition, if you encounter a serious incident, please contact the competent authority in your country.