MYOLEX mScan System User Manual

Contents

MYOLEX mScan System

IMPORTANT NOTE:

THE MYOLEX MSCAN™ IS AN INVESTIGATIONAL DEVICE INTENDED FOR USE BY A TRAINED OPERATOR ACCORDING TO PROTOCOLS APPROVED BY INSTITUTIONAL REVIEW BOARDS. THE MSCAN™ SHOULD NOT BE USED FOR ANY OTHER PURPOSE.

This preliminary App User Manual is prepared with the objective of providing the user all of the information necessary to operate the investigational Myolex mScan™ according to study protocols approved by an Institutional Review Board. The Study Protocol should be read carefully before using the investigational system for the first time, and should be strictly followed.

User Assistance Information

For information and/or issues regarding usage of the Myolex mScan™, please call Myolex at 888.382.8824 x10 or email **support@myolex.com**
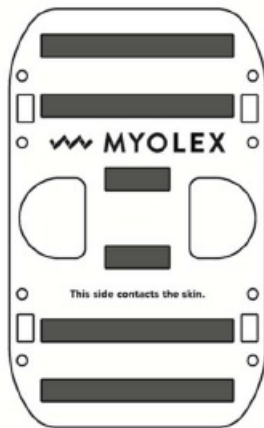
Myolex mScan™ System Overview

What's included

1. Apple iPad and charging cable

2. Myolex mScan™ device, carrying case, and charging cable.

This side contacts the skin.

3. Myolex mScan™ foam electrodes sensor

mScan™ Device

1. LED light indicator: used to indicate device operating status while device is on. It will change color depending on operating status. It will blink or display a steady light for depending on the specific operation.
2. Charge indication LED light: used to indicate device charging status while device is in sleep mode (not turned

on). When it blinks red slowly, it means the device is being charged. When it blinks green slowly, it means the device is at least 80% charged and ready for use.

3. Charge port: used to connect to a charge source via USB C cable for charging the device.
4. Electrode sensor ejection button. Pushing the button will eject the electrode sensor.
5. 5 Power on/off buttons: Press both buttons together to turn on the device; press both buttons again to turn off the device.

mScan™ foam electrodes sensor
The sensor has two sides, one side is be placed against the metal contacts on mScan™ device and the other side contacts the subject's skin. The Myolex label should face out (ie be readable) when being inserted into the device.

Power up

iPad

1. Charge your iPad with the cable provided
2. Press the Home button to enter the iPad
3. Enter the passcode provided
4. Ensure your iPad is connected to a WiFi network

mScan™

1. Charge the device with the cable provided
2. When the charger is plugged in, the device LED lights blinks red slowly if battery is not fully charged. The LED light will change to flashing green when it is charged.
3. Once the device is charged, press and hold the left button to turn on the device until the LED light indicator turns steady green.
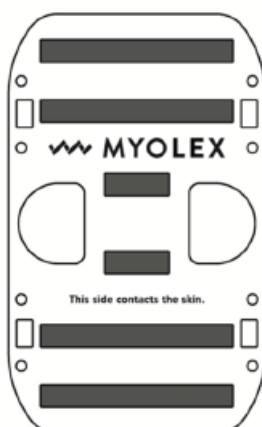
Primary App Actions

Logging in

1. Launch the Myolex mScan™ app on your iPad.

2. Enter your email address and password provided for your log in.

Adding a new patient

1. The first screen that appears after logging in will look like this.

2. To begin, tap the Add a Patient button on the top right corner of the screen.

3. The Save button will become enabled once all the required fields are completed.

Search for a patient

1. Use the search bar at the top to search for a patient by either their name or ID. Tap on Search.
2. Patients will be filtered to show results for your search.

Select a patient
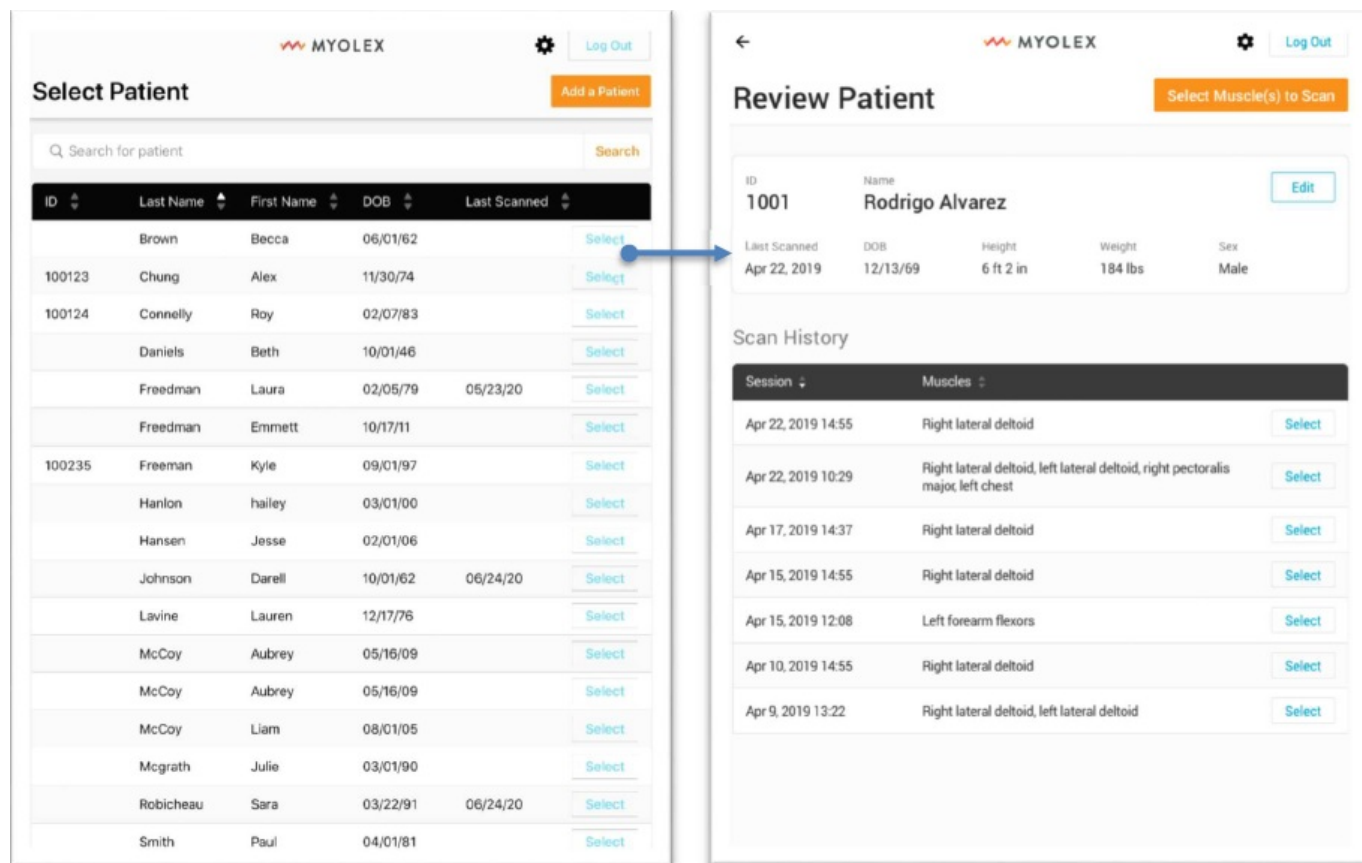
1. T ap on the Select button to view patient information.
2. The Review Patient page is displayed. From here, you can edit patient information, select prior scans, or start a new scan.

Scanning

Load foam electrode to mScan™ device

1. Remove a sensor from sealed bag.
2. Load the sensor into the mScan™ device. Make sure the correct marked side is placed against the device in order for it to click in properly. See image below. The word "Myolex" should face out and should be positioned so that it is in proximity to the on/off buttons.

Select muscles to scan

1. Switch between Anterior and Posterior views to select the muscles you want to measure.
2. Tap the muscle or checkbox next to the muscle name to select. Start Scanning button is enabled once at least one muscle is selected.
3. Tap Start Scanning to start the scan.

Note: Left and right switch sides depending on which view you are using (anterior/posterior).

Scan muscles
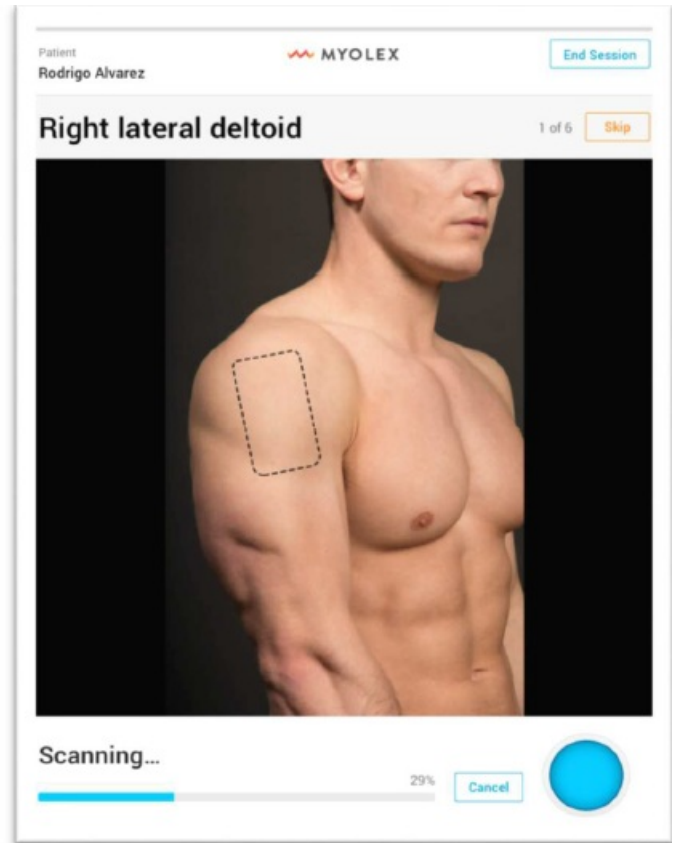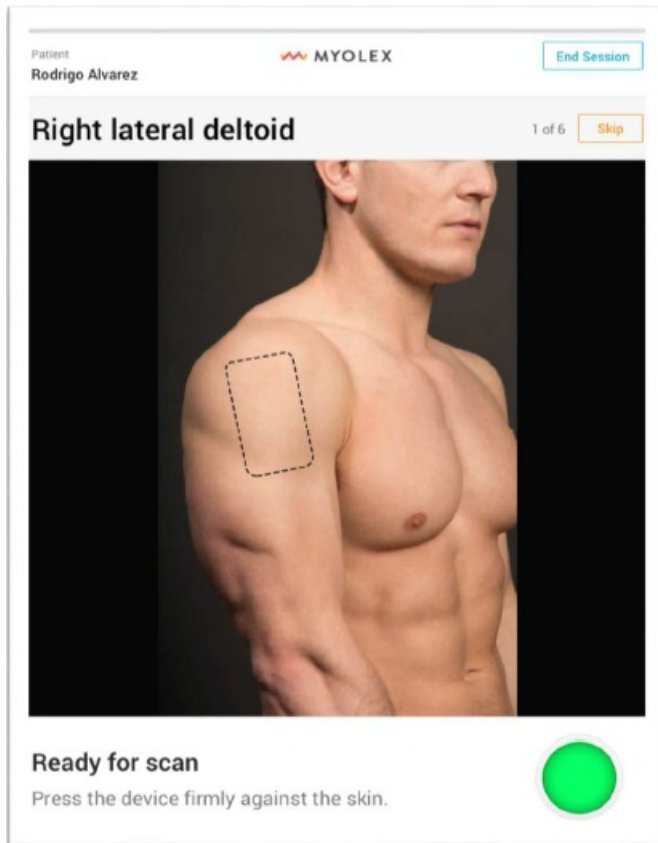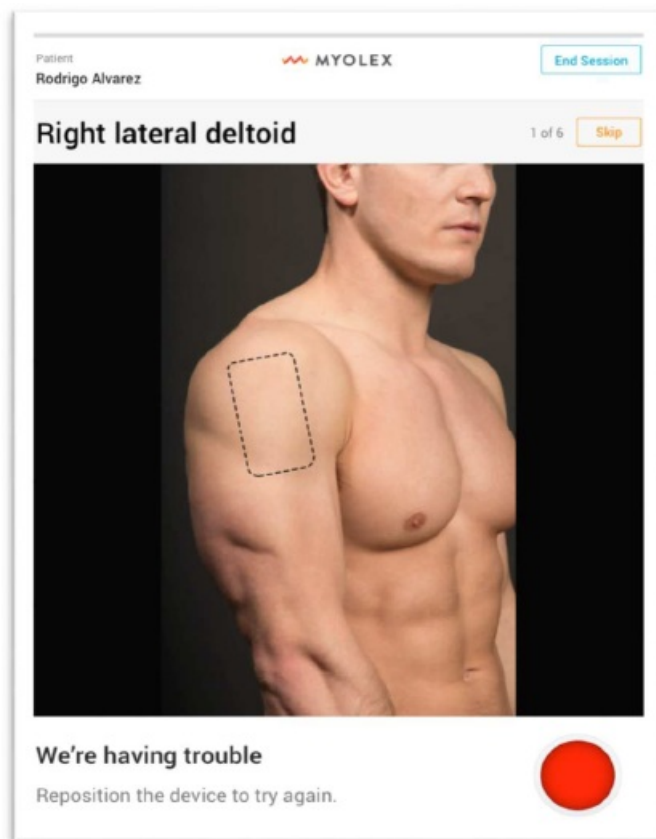
1. View instructions for scanning the muscle. The mScan™ device LEDs change from green to blinking blue when you Start Scan.
2. The mScan™ device LEDs change to a steady blue light when scanning begins and during the scanning process. The iPad will display a Blue circle signifying scanning. The mScan™ app will ping a noise and the mScan™ LED will change to a green light when the scan is complete.
3. An error message will be displayed if the mScan™ is unable to connect to the app or scan the muscle properly. Simply reposition the mScan™ on the muscle and attempt scanning again.

Review Scans

Review results
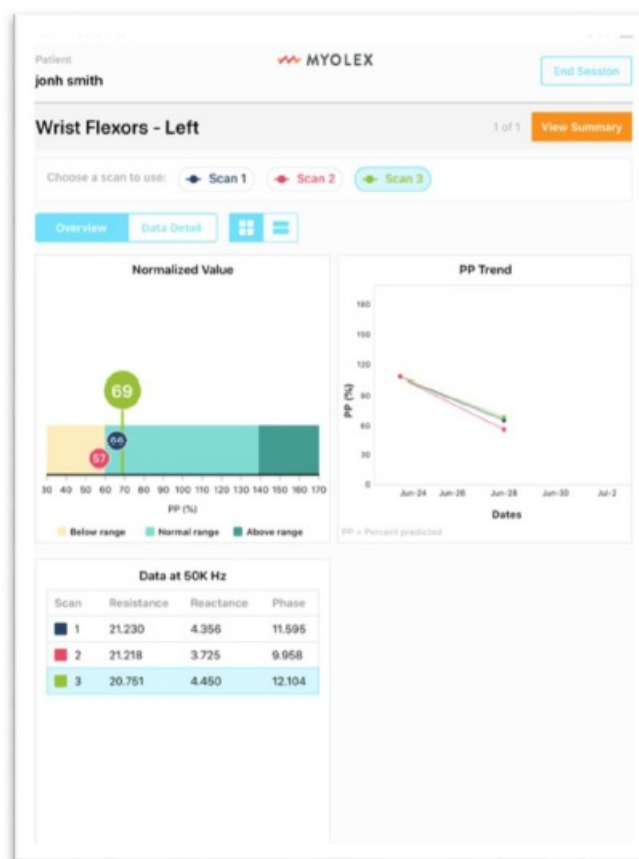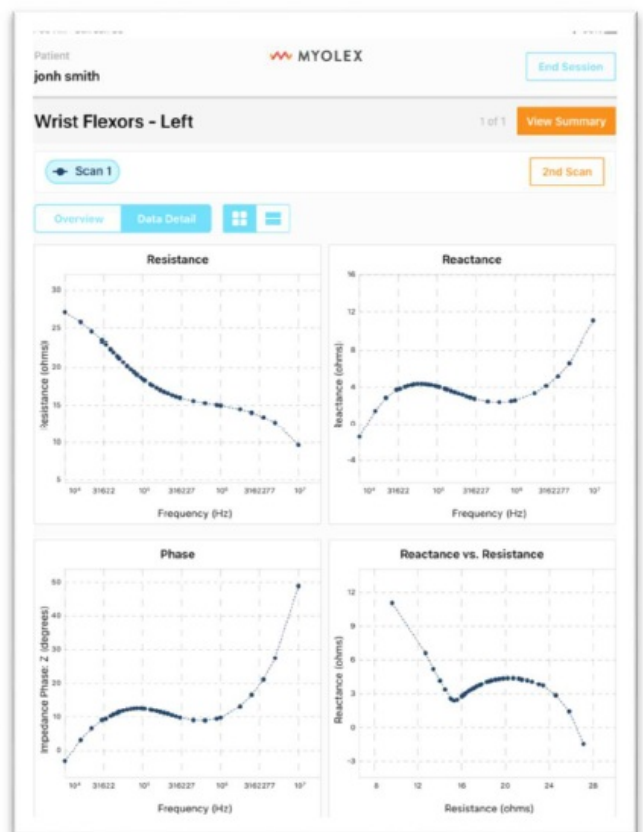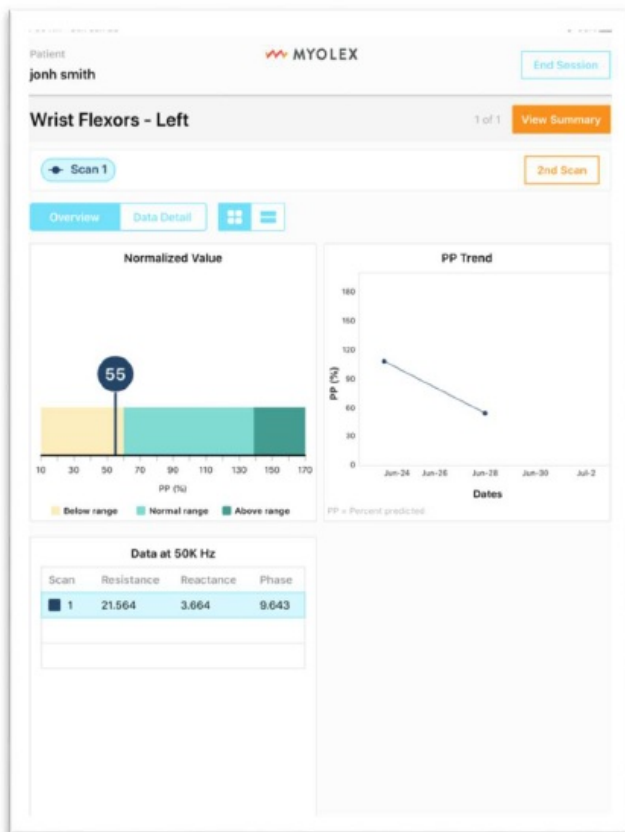
1. After your scan is complete on a single muscle, review your results. Toggle between Overview and Data Detail to view different charts.

2. Choose to either perform another scan on the same muscle by tapping 2nd Scan, or move on by tapping Next Muscle. If it is the last muscle to be measured, tap View Summary.

3. Up to 3 scans can be completed for a single muscle. All scans will be plotted. You will be required to select one scan to keep and the others will be automatically discarded. It will default to keeping the last scan

performed (e.g. second scan if you scanning twice and third scan if you scanned three times). You will have an opportunity to return to this muscle and obtain more data after you have completed scanning all muscles.

Explanation of Results
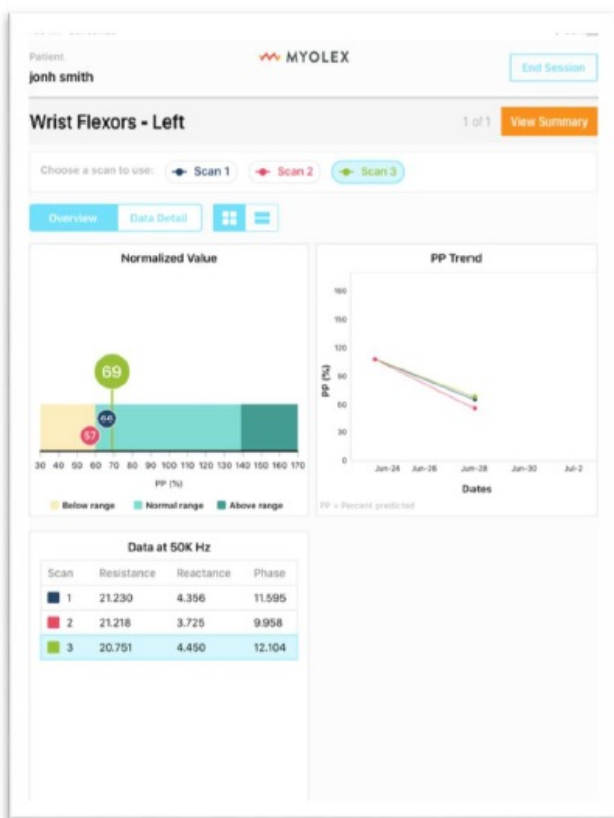
The Overview Tab

1. Normalized Value Provides an image of showing the expected normal range of the muscle for the 50 kHz phase (light green) as a percent predicted of normal values for the subject's sex, height, and weight. Dark green color represents above normal. Maize color shows values below normal. The larger circle represents the most recent measurement during the session; small circles represent the earlier measurements of the session.
2. Data at 50 kHz displays the raw impedance values at 50 kHz for each of the measurements, color coded to match the figure above.
3. Percent predicted (PP) trend shows the percent predicted values comparing the current measurement results to previous measurements.

The Data Detail Tab
1. Four graphs portray the multifrequency values of each of the main impedance parameters between 10 kHz and 10 MHz versus frequency and the Reactance versus Resistance Plot in the lower right (Cole-Cole Plot).

Summary Page
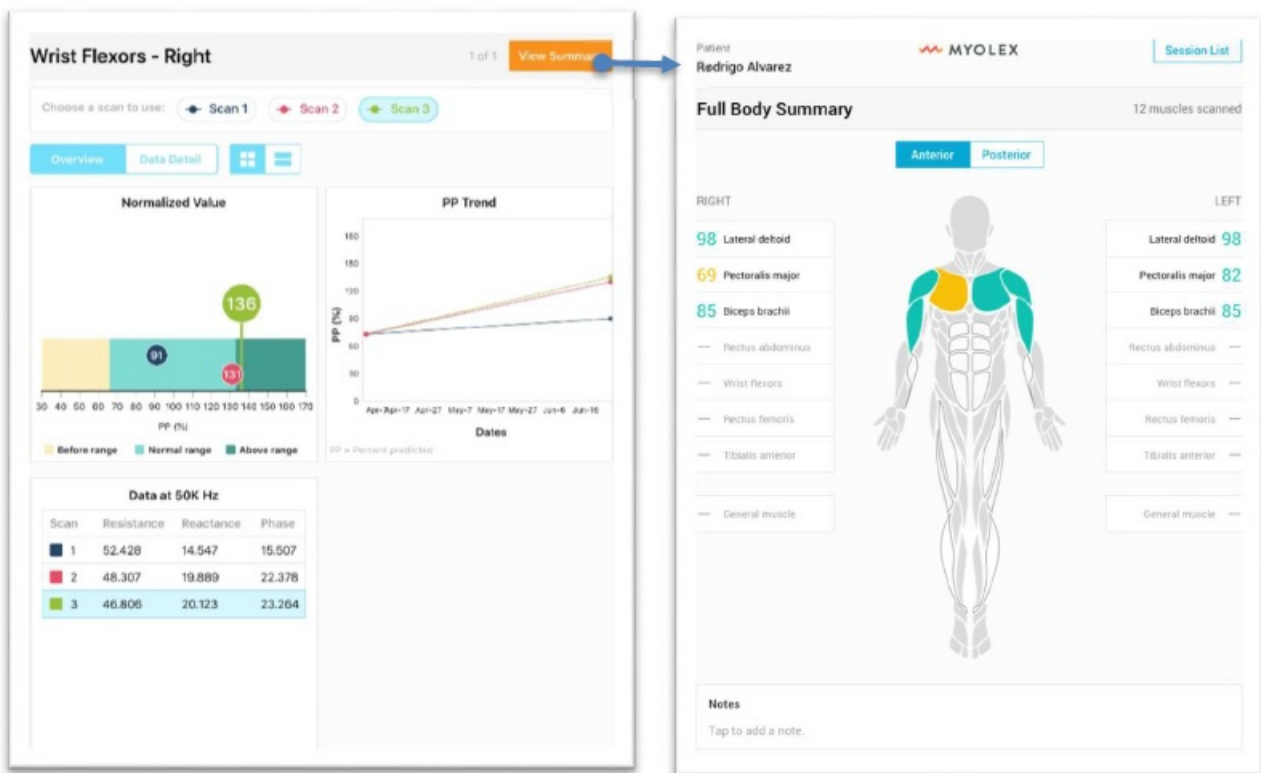
1. After all muscles are scanned, tap on View Summary to see a summary of all muscles scanned.
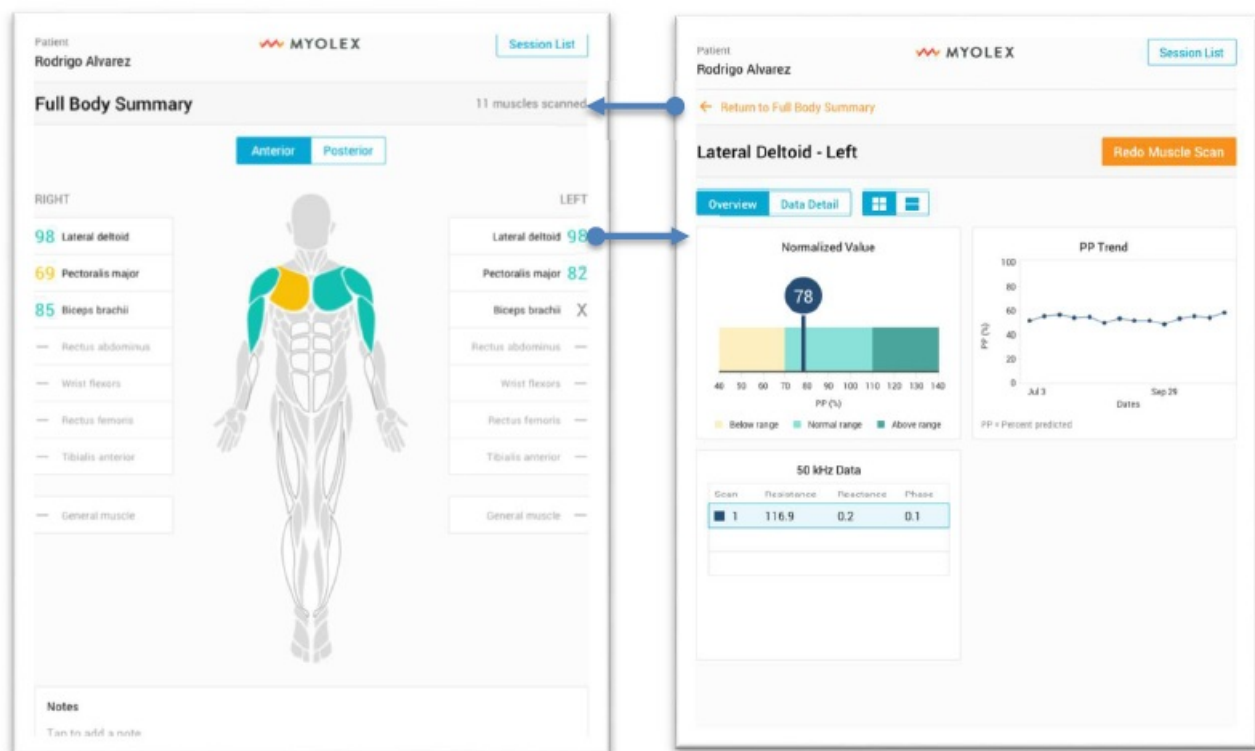
2. Tap on individual muscles to view details in a new page. If user ends a session without performing all scans, unfinished scans appear as an X.
3. Return to patient screen by tapping Session List at the top. (Note: since only one of the three measurements had been selected earlier, the other measurements are no longer visible.) Or tap Redo Muscle Scan to scan the selected muscle again and replace the data you previously collected.

Past scans

After selecting a patient, select a past session and muscles you would like to review.

Review Patient

Select Muscle(s) to Scan

MYOLEX

Log Out

ID
1001

Name
Rodrigo Alvarez

Edit

Last Scanned
Apr 22, 2019

DOB
12/13/69

Height
6 ft 2 in

Weight
184 lbs

Sex
Male

Scan History

Session ↓	Muscles :	
Apr 22, 2019 14:55	Right lateral deltoid	Select
Apr 22, 2019 10:29	Right lateral deltoid, left lateral deltoid, right pectoralis major, left chest	Select
Apr 17, 2019 14:37	Right lateral deltoid	Select
Apr 15, 2019 14:55	Right lateral deltoid	Select
Apr 15, 2019 12:08	Left forearm flexors	Select
Apr 10, 2019 14:55	Right lateral deltoid	Select
Apr 9, 2019 13:22	Right lateral deltoid, left lateral deltoid	Select

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MYOLEX

test94 myolex

Apr 5, 2020 20:05

Full Body Summary

26 muscles scanned

ANTERIOR POSTERIOR

LEFT RIGHT

76	Trapezius	Trapezius	76
85	Triceps brachii	Triceps brachii	83
--	Wrist extensors	Wrist extensors	--
103	Lumbar paraspinals	Lumbar paraspinals	104
90	Gluteus medius	Gluteus medius	78
90	Biceps femoris	Biceps femoris	78
90	Medial gastrocnemius	Medial gastrocnemius	78
--	General muscle	General muscle	--

MYOLEX

test04 myolex

Apr 5, 2020 20:05

Full Body Summary

26 muscles scanned

ANTERIOR POSTERIOR

RIGHT LEFT

76	Lateral deltoid	Lateral deltoid	
76	Pectoralis major	Pectoralis major	76
67	Biceps brachii	Biceps brachii	66
103	Rectus abdominis	Rectus abdominis	102
65	Wrist flexors	Wrist flexors	70
69	Rectus femoris	Rectus femoris	75
77	Tibialis anterior	Tibialis anterior	91
--	General muscle	General muscle	--

Rodrigo Alvarez

Apr 22, 2019 13:45

← Return to Full Body Summary

Lateral Deltoid - Left

Overview Data Detail

Normalized Value

78

40 50 60 70 80 90 100 110 120 130 140
PP (%)

Below range   Normal range   Above range

PP Trend

100
80
60
40
20
0

PP (%)

Jul 3   Sep 29
Dates

PP = Percent predicted

50 kHz Data

Scan	Resistance	Reactance	Phase
■ 1	116.9	0.2	0.1

PP = Percent predicted   ← Scan 1

Settings

Settings page

1. The Settings icon is visible on certain screens before scanning begins.
2. Settings is where you can pair mScan™, check mScan™ battery percentage, and update your mScan™ device firmware and account details.

Pair a device

1. To pair the mScan device with the app, go to Settings and tap on Pair mScan.
2. Follow the directions on the next pair to complete the pairing process.
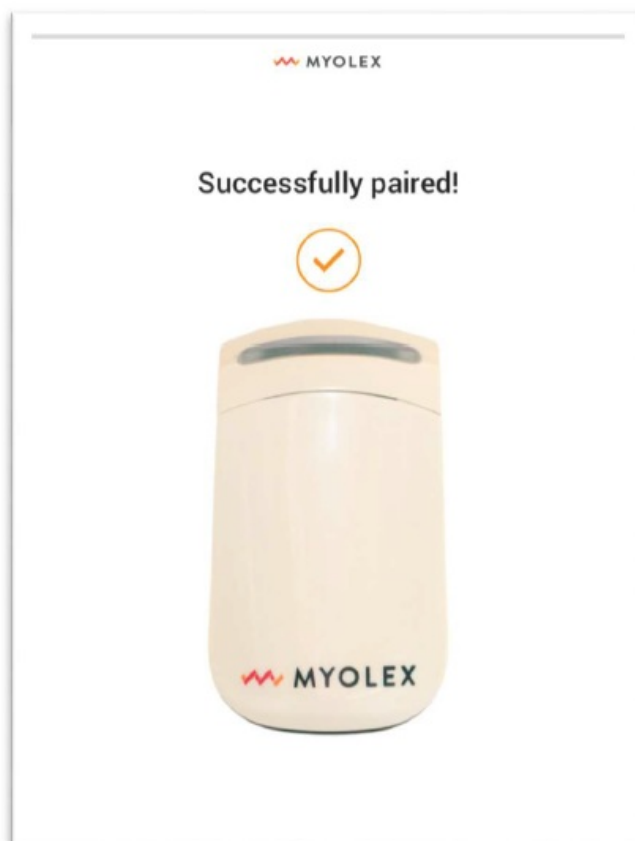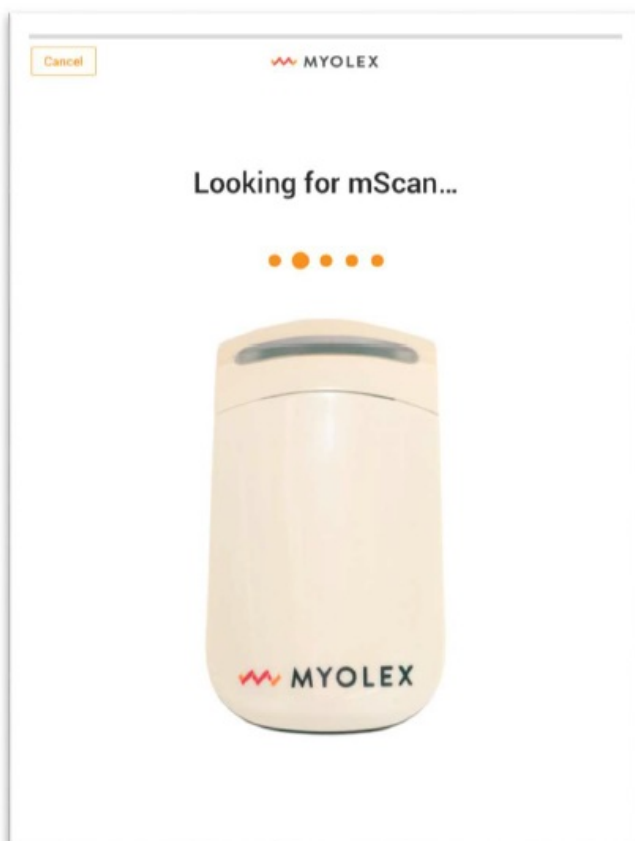
Account details

To change your account email or password, go to Settings and tap on Account.

Firmware update

To update mScan device, go to Settings and follow the instructions after tapping Update mScan.
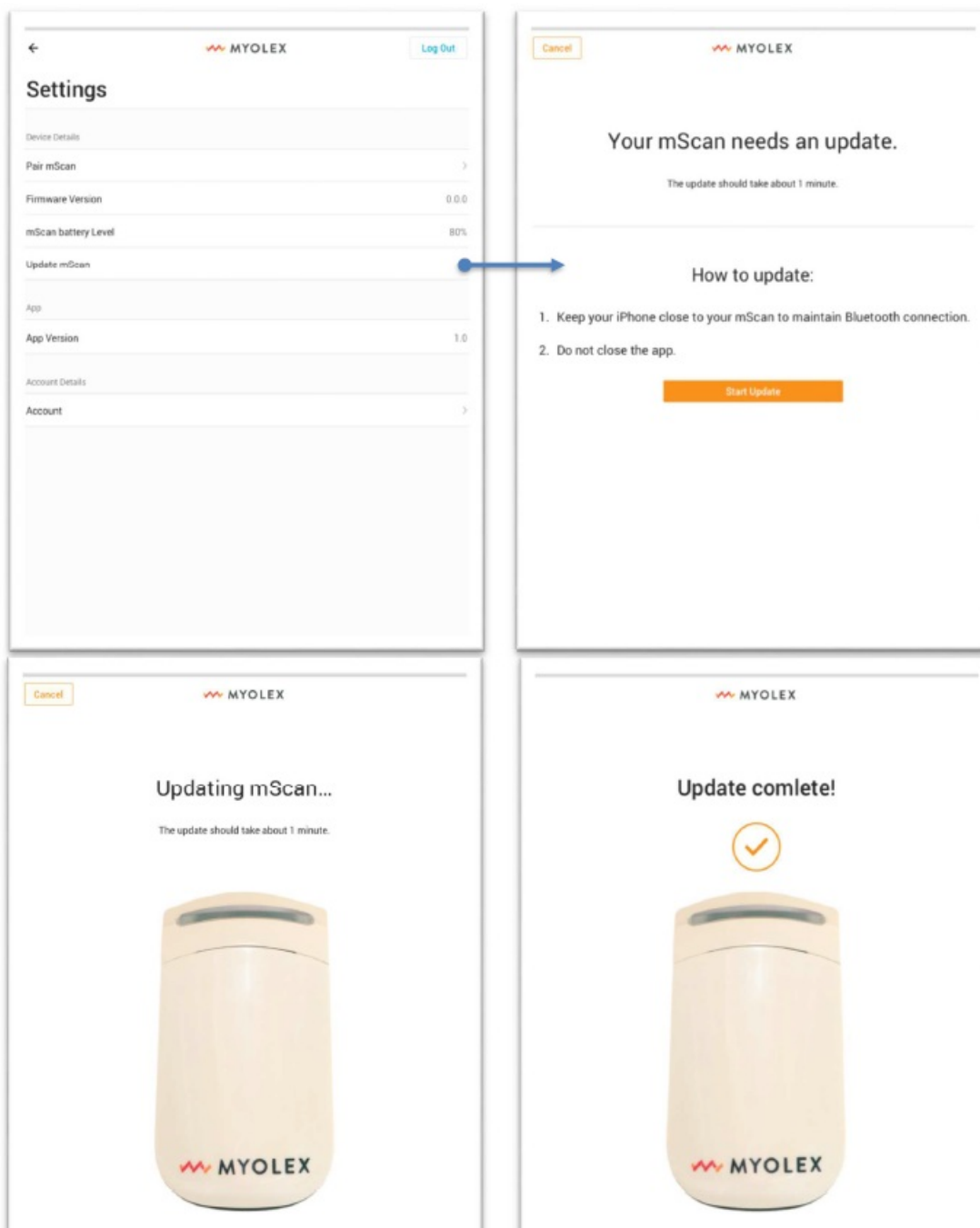
Technical Specification

Electrical Impedance Myography (EIM)
Electrical Impedance Myography (EIM) is a relatively new technology based on the older concept of bioelectrical impedance analysis.1 Whereas many standard bioimpedance approaches utilize electrodes spaced across the body (e.g., placed on the hand and foot), in EIM, the electrodes are placed on a specific location over a muscle or muscle group of interest. A weak electrical current is pas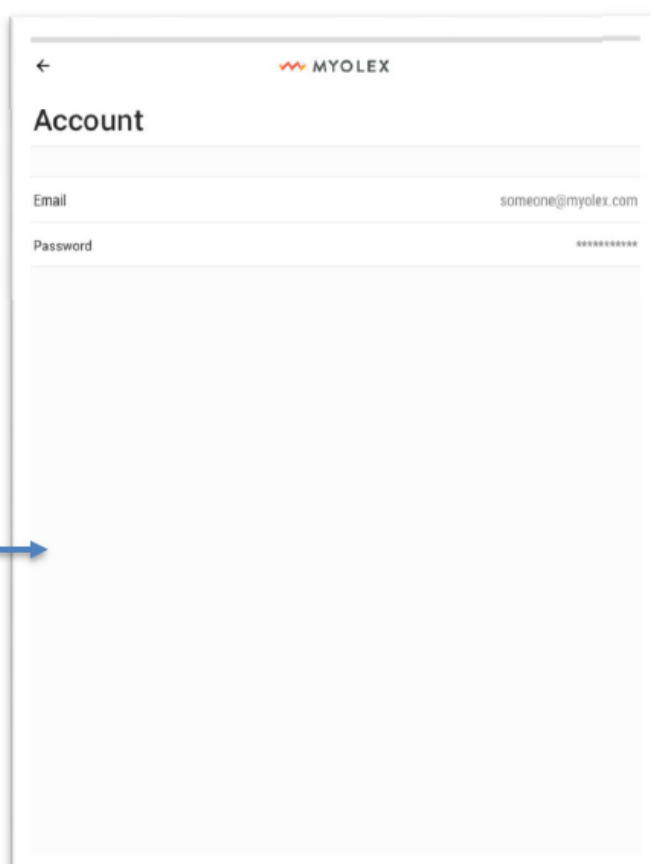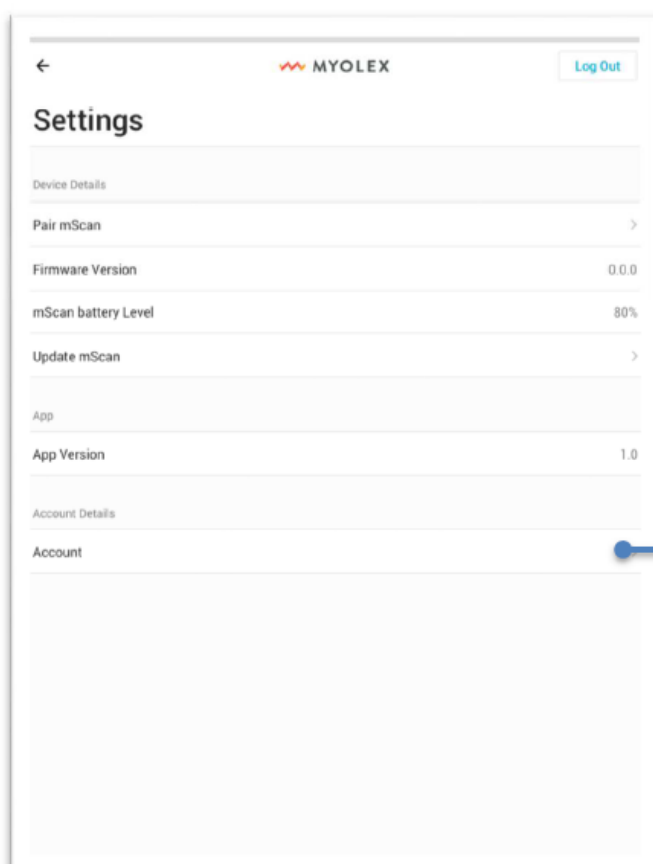sed through the tissue across a wide range of frequencies through one set of electrodes and the resulting voltages are measured via a second set. Alterations in the health of the muscle are reflected in the measured voltages.

Bluetooth®
Bluetooth® is a type of wireless RF (Radio Frequency) communication. Cell phones use Bluetooth® wireless technology as do many other devices. mScan™ device uses Bluetooth® to pair with the iPad to send results to mScan™ App.

Power Requirements

mScan™ is powered by a rechargeable Lithium-polymer battery with 3.7V, 1.2AH. The battery should be charged with provided battery charger which rated as AC input 110-240V, 50/60Hz; 0.6A, Output USB type C DC3.6-6V, 3A. mScan™ battery takes 2 hours to 80% charged from fully discharged, it takes 4 hours to fully charge the battery.

- Warning: Always use the hospital grade, AC power cable delivered with the mScan™ to connect to an AC power source. DO NOT, under any circumstances, use any other cable than the one provided, notably to provide extra cable length. The use of any other cable may result in increased emissions or decreased immunity of the mScan™ with regards to electromagnetic interference.
- Warning: Do not connect the mScan™ to an AC outlet that is controlled using a switch or dimmer.
- Warning: Do not, under any circumstances, remove the grounding conductor from the power plug.
- Warning: Do not use extension cords of any type.
- Warning: The power cable, supply, and plug must be intact and undamaged.

Before starting a patient study:

1. Make sure the iPad and mScan™ device is sufficiently charged (>50%) to conduct the study.
2. Make sure the iPad is connected to a WiFi network with good Internet connection

Electrical Safety and Standards
The mScan™ device has been tested and found to be appropriate for use at home and clinical setting. In most cases, it should not interfere with other devices if used as instructed. However, the device gives off radio frequency (RF) energy from the Bluetooth feature. If not used correctly, the mScan™ device may interfere with TV, radio, or other electronic devices that receive or transmit RF signals.
While mScan™ device is in operation, other electronics wireless devices that are used nearby, such as another mobile device or a wireless network, may prevent or delay the transmission of data between your mScan™ device and your iPad with mScan™ App. Moving away from or turning off these electronic devices may allow communication.
If you experience mScan™ device interference problems, try moving your mScan™ device away from the source of the interference. You can also move the electronic device or its antenna to another location to solve the problem. If you continue to experience interference, contact Customer Service.
This mScan™ device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This mScan™ device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. However, changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the mScan™ device.
FCC guidelines help ensure that the mScan™ device will not affect the operation of other nearby electronic devices. Additionally, other electronic devices should not affect the use of mScan system. mScan™ device has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: (1)Reorient or relocate the receiving antenna; (2) Increase the separation between the equipment and receiver; (3)Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. (4) contact Customer Service for help.

The mScan™ device comply with IEC 60601-1 and IEC 60601-1-2. The mScan™ device is tested to meet requirements of IEC 60601-1 and IEC 60601-1-2.
The recommended wireless security measures include AES encryption.
mScan™ device FCC ID is 2AWC6-1301.

Calibration Requirements

No calibration is required for the mScan™ .

Cleaning

Caution: To avoid transmission of infection, wipe down the mScan™ between each patient use. The mScan™ may be wiped down with alcohol wipes. Under no conditions should the mScan™ be submerged in water or any other fluid. Care should be taken to prevent fluids from coming into contact with any part of the mScan™ .

Storage, Maintenance and Repairs

The mScan™ should be stored in a dry, clean, dust-free environment away from
harmful chemicals, where the temperature never exceeds 95 degrees Fahrenheit.
If the mScan™ appears to be malfunctioning, contact Myolex technical support for assistance by calling 888-382-8824 x10 or emailing support@myolex.com. All repairs to the mScan™ must be carried out by Myolex authorized technicians.

Transport

The mScan™ should always be transported in the case provided to ensure proper protection. When being shipped, the mScan™ should be placed inside the case, ensuring a snug fit, and the case should be placed in a shipping box with bubble wrap or shipping Styrofoam to minimize movement within the box. A label should be placed on the outside of the box indicating that its contents are fragile.

Troubleshooting

1. mScan™ Turns Off: If the mScan™ turns off, simply press the button on the handheld device to turn it back on. The mScan™ will turn off automatically if not used for more than 3 minutes.

2. mScan™ blink red three times rapidly: If the mScan™ blinks red rapidly at turn on, plug in charger to charge the device. This shows that the battery is low on charge.

3. mScan™ does not turn on: If the mScan™ does not turn on, plug in charger to charge the device.

4. Connectivity: If the iPad does not work, check the internet connection to make sure the iPad has good Internet connection. If this does not work, please contact Myolex at 888-382-8824 x10.

Adverse Reaction Information

Warning: Do not use the mScan™ on open wounds, rashes, burns, and other dermatological disorders.

Documents / Resources

	[MYOLEX mScan System](#) [pdf] User Manual 1301, 2AWC6-1301, 2AWC61301, mScan, System, mScan System