

1.0 General System Description

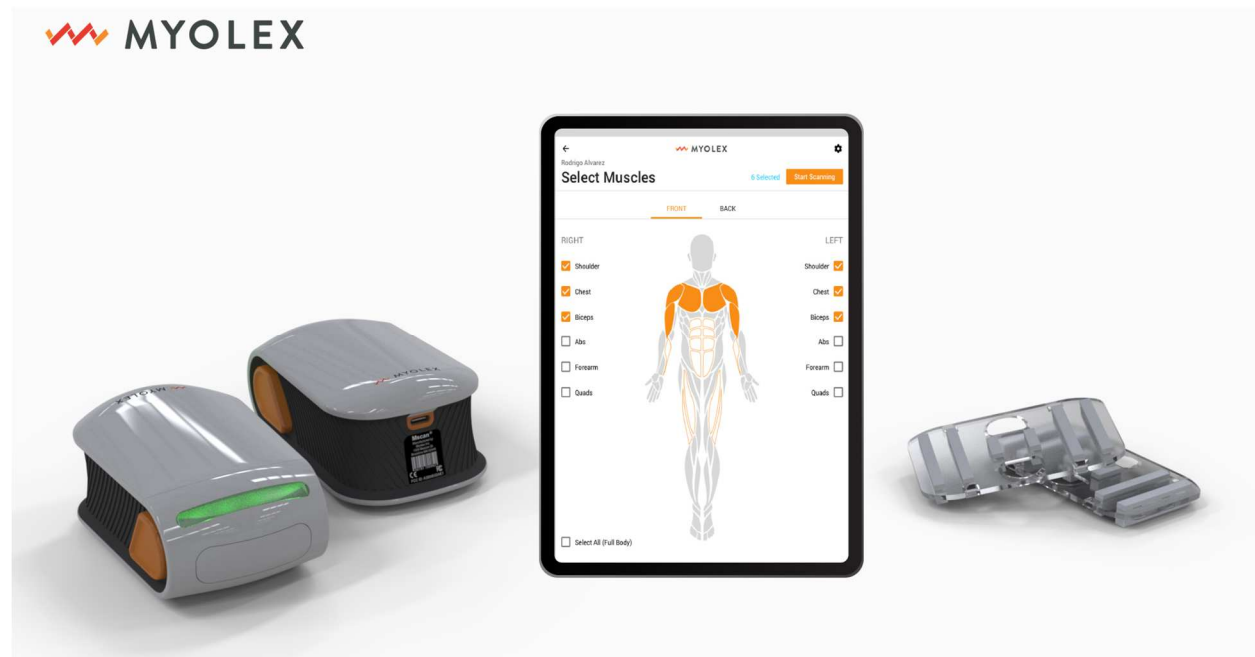
Intended Use: The EIM1301 is intended to measure, monitor and assess muscle status.

Indications for Use: The EIM1301 is indicated as an aid in the diagnosis and monitoring of muscle disorders.

Intended user: The EIM1301 will be used by physical therapist and medical staff including physicians, nurses, technicians, and research assistants

The EIM1301 system comprises the following:

1. A cloud backend for storing data.
2. A mobile device with software for interacting with a user, communicating with the handheld device for acquiring data and communicate with a cloud backend for storing data.
3. A handheld EIM device for measuring localized bioimpedance at one or more angles and frequencies;
4. Disposable sensor which attach to the handheld device and make contact with the patient;



The EIM1301 *Hardware* includes the mobile device, the handheld device, a disposable sensor, the mobile device is a commercial off-the-shelf mobile device requiring no hardware development.

The handheld device includes the following:

1. Electronics
 - a. Analog front end circuitry to measure voltages and currents from multiple electrodes;

- b. Mixed-signal circuitry to generate analog signals based on digital commands, and to convert measured analog signals to digital signals for post-processing, analysis and storage;
 - c. Digital circuitry to generate necessary controls, to acquire data from two analog-to-digital converters, to perform signal processing, and to communicate between the handheld device and the mobile device.
- 2. Mechanical housing with the following features
 - a. Two pushbuttons to initiate EIM tests;
 - b. Mechanisms to mechanically and electrically attach to the electrode array and dispose the electrode array after use.
 - c. LEDs to indicate measurement status and battery charging/Discharge status

The electrode array includes the following:

- 1. Electronics
 - a. An electrode array is made of flexible, biocompatible material adhered to a conformable pad.
 - b. Each electrode array has 6 “landing pads” that electrically connect the electrode array to the handheld.
- 2. Mechanical
 - a. 6 landing pads on top to mechanically and electrically connect to the handheld when loaded into the handheld.

2.0 Technical Description

The EIM1301 applies a swept sinusoid electrical current across two electrodes and measures the resulting voltage across a second set of electrodes. The handheld portion of the device is rechargeable battery powered and could be charged by a USB charger. The handheld device shall be certified to meet the safety standards set by *IEC 60601-1, Ed 2: Medical Electrical Equipment Part 1: General Requirements for Safety*.

3.0 Key Requirements

Specification	Min. Val	Max. Val	Nominal Val	Note
3.0.1 Handheld Device Battery power	3.3V	4.2V	3.7 V	
3.0.2 Handheld Device Battery Charger	4.75V	5.50V	5.0V	Charger maximum current 1.0A
3.0.3 Handheld Device Battery Capacity			1.2AH	
3.0.4 Applied AC current (RMS)	0	1 mA	100 uA	
3.0.5 Applied DC current (RMS)	0	<1 uA	0	N/A (AC coupled)
3.0.6 Resulting AC voltage (RMS)	0	500 mV	10 mV	Measured voltage on skin
3.0.7 Applied differential DC voltage	0	5 mV	0	N/A (AC coupled)
3.0.8 Signal frequency range (Hz)	1 kHz	10 MHz		Applied signal is swept sinusoid with 42 total frequencies
3.0.9 Measurement time	2 sec	8 sec	3 sec	
3.0.10 Impedance range	1 Ω	3000 Ω		
3.0.11 Frequency range	1kHz	10kHz		
3.0.12 Phase range	-180°	+180°		
3.0.13 Phase resolution			0.1°	
3.0.14 Precision Raw Impedance		±3%		for impedance greater than 50 Ω .
3.0.15 Precision Raw Impedance		±1 Ω		for impedance less than 50 Ω
3.0.16 Accuracy Raw Impedance		±1%		between 10KHz to 1MHz for impedance greater than 50 Ω .
3.0.17 Accuracy Raw Impedance		±5%		Less than 10KHz and Greater than 1MHz for impedance greater than 50 Ω .
3.0.18 Accuracy Raw Impedance		±1 Ω		between 10KHz to 1MHz for impedance less than 50 Ω
3.0.19 Accuracy Raw Impedance		±5 Ω		Less than 10KHz and Greater than 1MHz for impedance less than 50 Ω .
3.0.20 Operating Temperatures	10° C		40° C	
3.0.21 Storage Temperatures	-40° C		70° C	
3.0.22 Operating Humidity	10%		90%	

4.0 Radio transmitter

mScan device use Nordic NRF51822 chip as the base with an external chip antenna AMCA31-2R450G-S1F-T made by Abracon LLC.

NRF51822 Bluetooth transmitter brief spec:

- Frequency band: 2.4GHz ISM (2.402– 2.480GHz)
- On air data rate: 250 kbps, 1 Mbps or 2Mbps
- Output power: 0.51dBm
- Sensitivity: -93dBm Bluetooth low energy; -96dBm at 250kb; -90dBm at 1Mbps; -85dBm at 2Mbps
- Oscillators: 16MHz crystal oscillator; 32kHz crystal oscillator

AMCA31-2R450G-S1F-T chip antenna brief spec:

- RF Family/Standard: Bluetooth, WiFi
- Frequency Group: UHF (2GHz ~ 3GHz)
- Frequency (Center/Band): 2.4GHz
- Frequency Range: 2.405GHz ~ 2.495GHz
- Antenna Type: Chip
- Number of Bands: 1
- VSWR: 2
- Gain: 0.5dBi
- Power Max: 3W

Revision History			
Revision	DCO#	Description of Changes	Changed By
2.0.0	DCO 19-007	Initial document release	B. Wei
3.0.0	DCO 20-002	Accuracy spec refined based engineering development	B.We