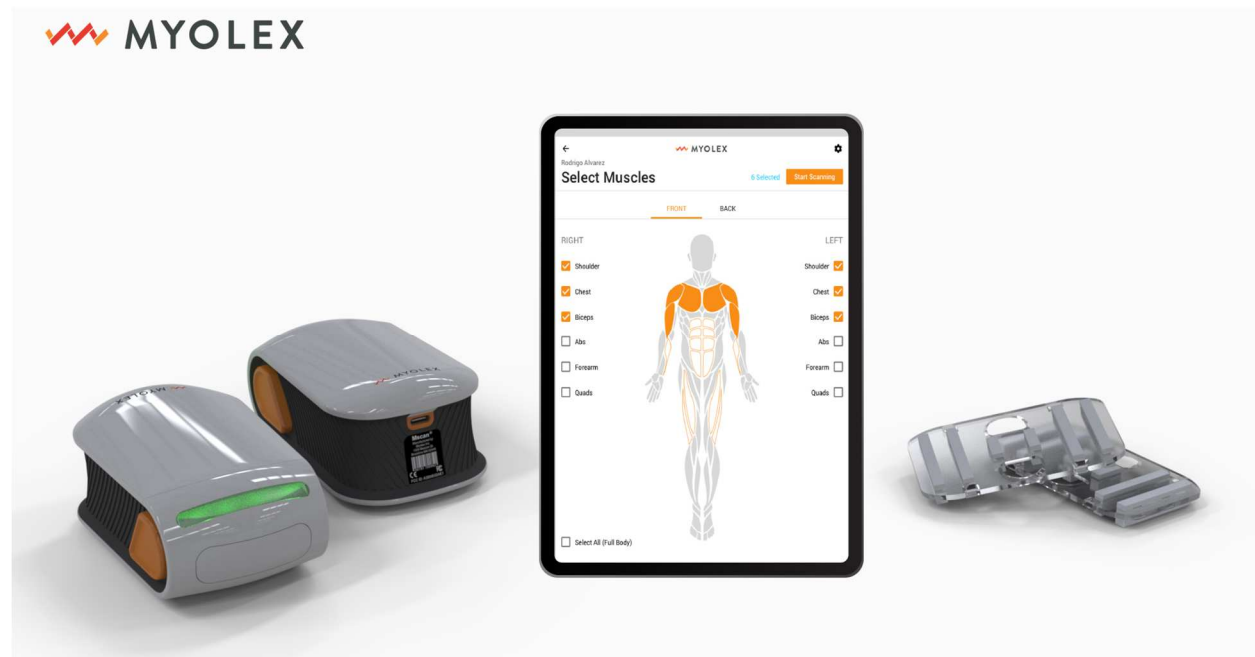## 1.0   General System Description

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	1Ω	3000 Ω		
3.0.11 Frequency range	1kHz	10kkHz		
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	10^0 C		40^0 C	
3.0.21 Storage Temperatures	-40^0 C		70^0 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 1Mbs; -85dBm at 2Mbs
- 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

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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.Wei