

Corbinsoft, The ALM Experts			
Prepared by Merrill, David	Date 2026-06-19 00:51	REVISION 182930	
TITLE Bionic Arm Rotator Joint Spec			

MODIFY, REPLACE OR DELETE ALL TEXT IN BLUE INCLUDING THIS STATEMENT BEFORE
SUBMITTING FOR APPROVALS!

Bionic Arm Rotator Joint Spec

Document Properties

Type:  Mechanical Specification

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1 Purpose

[Example: The purpose of this document is to define the OP Block 79 Requirements for developing the Acme Medical Product®ID Electroporation System]

2 Scope

[Example: The scope of this document is to specify the timing, electrode pattern, and current requirements of OP Block 79. Timing is to include the time delay after trigger press, impedance pulse timing, Electroporation pulse timing, and the time in-between pulses]

3 Background

[Define Mechanical Requirement and explain its functionality]

4 Definitions

4-1 - CFR: Code of Federal Regulations

[This section will auto-populate as the acronyms are used in the document]

4-2 - ID: Intradermal

4-3 - OP Block: Defines the treatment sequence which includes impedance timing, drug delivery timing, pulse timing and associated voltage and current parameters, as well as the Electrode pin configuration

5 References

[Retain blue references only if they are relevant. Add any necessary references.]

5-1 - QA-POL-004 Quality Manual

5-2 - Title 21 CFR Part 820 Quality System Regulation

5-3 - EN ISO 13485:2016 Medical Devices - Quality management systems – Requirements for regulatory purposes

5-4 - ISO 14971:2007 Medical devices - Application of risk management to medical devices

5-5 - EN ISO 14971:2012 Medical devices - Application of risk management to medical devices

5-6 - M11-003704-01 Software Requirement Specification, Acme Medical Product® ID

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6 Document Convention

Each requirement has a requirement ID in the form of OPB ### where OPB indicates that it is a Operational Requirements for Acme Medical Product ID, and ### is a unique number indicating the specific requirement number.

When this document is updated and new requirements are added, the new requirements will begin with the next requirement ID number. The requirement numbers will not be duplicated. For example, if there is a requirement OPB, 12 there will not be another requirement OPB 12.

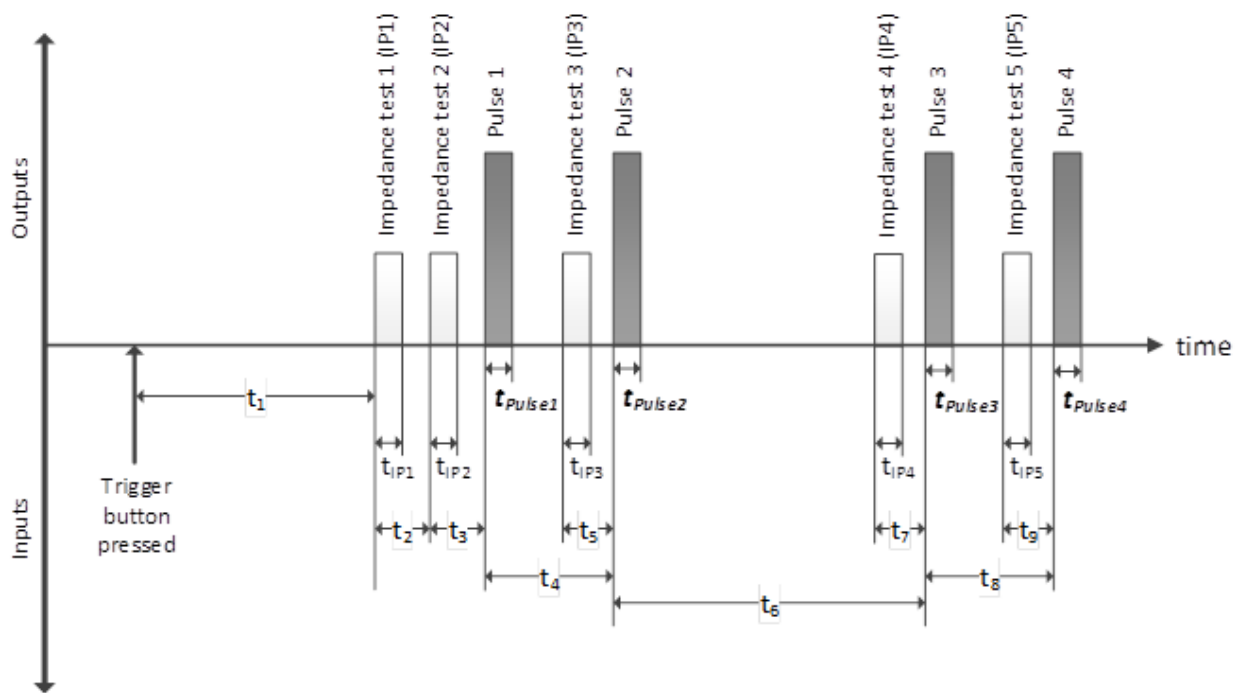
If a requirement is requirement ID is deleted and is not reused.

7 Mechanical Requirement Requirements

[Edit the below categories and turn them into headers as needed]

Note: Mechanical Requirement Requirements DO NOT serve as risk mitigation. There are be no standalone Mechanical Requirement requirements; each is derived from a higher level requirement>

Figure 1 Mechanical Requirement 79 Timing Diagram



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7.1 Impedance Timing

7.1-1 - This impedance will be calculated every 50 ms.

ID	MDT.L-33021
Alternate Id	MDT.L-MER:382
Status	 Draft
Severity	 Should Have

7.1-2 - Contining 33021

ID	MDT.L-36060
Alternate Id	MDT.L-OPM-298
Status	 Draft
Severity	 Should Have

7.2 Drug Delivery Timing

7.3 Pulse Timing

7.3.1 Voltage Parameters

7.3.2 Current Parameters

7.4 Electrode Pin Configuration

Document Revision History

Rev	CO Number	Description	Effective Date

7.4-1 - There shall be a noise filter add on to the microphone.

ID	MDT.L-35005
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Alternate Id	MDT.L-MER:408
Status	 Draft
Severity	 Should Have