



# CERTIFICATE OF ACCREDITATION

## ANSI-ASQ National Accreditation Board

500 Montgomery Street, Suite 625, Alexandria, VA 22314, 877-344-3044

This is to certify that

### Advanced Mechanical Technology, Inc.

176 Waltham Street

Watertown, MA 02472

has been assessed by ANAB  
and meets the requirements of international standard

## ISO/IEC 17025:2005

while demonstrating technical competence in the fields of

## CALIBRATION AND TESTING

Refer to the accompanying Scope of Accreditation for information regarding the types of calibrations and/or tests to which this accreditation applies.

ACT-2511

Certificate Number



ANAB Approval

Certificate Valid: 10/16/2017-10/16/2019  
Version No. 001 Issued: 10/16/2017



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

Advanced Mechanical Technology, Inc.

176 Waltham Street  
Watertown, MA 02472

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CALIBRATION AND TESTING

Valid to: October 16, 2019

Certificate Number: ACT-2511

CALIBRATION

Mechanical / Thermodynamic

Parameter / Equipment	Range	Expanded Uncertainty of Measurement (+/-) <sup>2</sup>	Reference Standard, Method and/or Equipment
<b>AMTI Knee Simulator:<sup>1</sup></b>			
Forces	F <sub>x</sub> = Up to 600 N F <sub>y</sub> = Up to 600 N F <sub>z</sub> = Up to 4500 N	1.0 N 1.7 N 3.5 N	Reference Load Cell
Moments	M <sub>x</sub> = Up to 45.2 N·m M <sub>y</sub> = Up to 45.2 N·m M <sub>z</sub> = Up to 17 N·m	1.1 N·m 1.5 N·m 0.2 N·m	Reference Load Cell and Length Standard Fixture
Vertical Position Sensors	-16.5 mm to 16.5 mm	0.1 mm	Gage blocks
Temperature Probes	(20 to 45) °C	0.1 °C	Digital Thermometer
Vertical Load Actuators	Up to 4500 N	1.2 N	Reference Load Cell
AP Linear Displacement	-25 mm to 25 mm	0.60 mm	Digital Caliper
Internal/External Angular Displacement	-30° to +30°	0.3°	Digital Protractor

**Mechanical / Thermodynamic**

Parameter / Equipment	Range	Expanded Uncertainty of Measurement (+/-) <sup>2</sup>	Reference Standard, Method and/or Equipment
Flexion Angular Displacement	-100° to +100°	1 °	Digital Protractor
<b>AMTI HIP Simulator<sup>1</sup></b>			
Forces	F <sub>x</sub> = Up to 180 N F <sub>y</sub> = Up to 180 N F <sub>z</sub> = Up to 4 500 N	0.1 N 0.1 N 1.9 N	Deadweights  Deadweights Reference Load Cells and Display
Moments (Differential)	ΔM <sub>x</sub> = Up to 7.5 N·m ΔM <sub>y</sub> = Up to 7.5 N·m ΔM <sub>z</sub> = Up to 9 N·m	0.1 N·m 0.1 N·m 0.1 N·m	Deadweights and Display
Vertical Position Sensors	-16.5 mm to 16.5 mm	0.1 mm	Gage blocks
Temperature Probes	(20 to 45) °C	0.1 °C	Digital Thermometer
Vertical Load Actuators	Up to 4 500 N	1.3 N	Reference Load Cell
Internal/External Angular Displacement	-20° to +20°	0.3°	Digital Protractor
Flexion Angular Displacement	-50° to +50°	0.3°	Digital Protractor
Abduction/Adduction Angular Displacement	-20° to + 20°	0.3°	Digital Protractor

**Mechanical / Thermodynamic**

Parameter / Equipment	Range	Expanded Uncertainty of Measurement (+/-) <sup>2</sup>	Reference Standard, Method and/or Equipment
<b>AMTI VIVO Simulator:<sup>1</sup></b>			
Forces	F <sub>x</sub> = (-1 000 to 1 000) N F <sub>y</sub> = (-1 000 to 1 000) N F <sub>z</sub> = (-4 400 to 3 500) N	21 N 21 N 41 N	Multi-Axis Reference Load/Torque Cell and Display
Moments	M <sub>x</sub> = (-80 to 80) N·m M <sub>y</sub> = (-30 to 30) N·m M <sub>z</sub> = (-40 to 40) N·m	1.2 N·m 1.2 N·m 0.6 N·m	Multi-Axis Reference Load/Torque Cell and Display
Vertical Linear Displacement	-22 mm to 22 mm	0.017 mm	Digital Indicator
ML Linear Displacement	-24 mm to 24 mm	0.015 mm	Digital Indicator
AP Linear Displacement	-24 mm to 24 mm	0.033 mm	Digital Indicator
Temperature Probe	(20 to 45) °C	0.1 °C	Digital Thermometer
Flexion/Extension Angular Displacement	-30° to 150°	0.3°	Digital Protractor
Internal/External Rotation	-40° to 40°	0.3°	Digital Protractor
Abduction/Adduction	-25° to 25°	0.4°	Digital Protractor

**Mechanical**

Parameter / Equipment	Range	Expanded Uncertainty of Measurement (+/-) <sup>2</sup>	Reference Standard, Method and/or Equipment
<b>6 Axis Load Cell:</b>			
Forces	F <sub>x</sub> = Up to 2 224 N F <sub>y</sub> = Up to 2 224 N F <sub>z</sub> = Up to 8 896 N	2.5 N 2.6 N 2.4 N	Single Axis Reference Load Cell Length Standard
Moments	M <sub>x</sub> = Up to 113 N·m M <sub>y</sub> = Up to 113 N·m M <sub>z</sub> = Up to 56.5 N·m	0.67 N·m 0.66 N·m 0.33 N·m	Single Axis Reference Load Cell Length Standard

**Mechanical**

<b>FIELD OF TEST</b>	<b>ITEMS, MATERIALS OR PRODUCTS TESTED</b>	<b>SPECIFIC TESTS OR PROPERTIES MEASURED</b>	<b>SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED</b>	<b>*KEY EQUIPMENT OR TECHNOLOGY</b>
Biotribology	Hip Joint replacement components	Weight loss, wear rate	ISO 14242-1 ISO 14242-2 AMTI internal method	AMTI Hip Simulator AMTI VIVO Joint Simulator Balance
Biotribology	Knee Joint replacement components	Weight loss, wear rate	ISO 14243-2 ISO 14243-3 AMTI internal method	AMTI Knee Simulator AMTI VIVO Joint Simulator Balance
Biotribology	Knee Joint replacement components	Weight loss, wear rate	ISO 14243-1 ISO 14243-2 AMTI internal method	AMTI Knee Simulator AMTI VIVO Joint Simulator Balance

Calibration and Measurement Capability (CMC) is expressed in terms of the measurement parameter, measurement range, expanded uncertainty of measurement and reference standard, method, and/or equipment. The expanded uncertainty of measurement is expressed as the standard uncertainty of the measurement multiplied by a coverage factor of 2 ( $k=2$ ), corresponding to a confidence level of approximately 95%.

Notes:

1. On-site calibration or measurement service is available for this parameter, since on-site conditions are typically more variable than those in the laboratory, larger measurement uncertainties are expected on-site than what is reported on the accredited scope.
2. This scope is formatted as part of a single document including Certificate of Accreditation



Vice President