



CERTIFICATE OF ACCREDITATION

ANSI National Accreditation Board

11617 Coldwater Road, Fort Wayne, IN 46845 USA

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 17025:2017

while demonstrating technical competence in the field of

CALIBRATION and TESTING

Refer to the accompanying Scope of Accreditation for information regarding the types of activities to which this accreditation applies

ACT-2511

Certificate Number



ANAB Approval

Certificate Valid Through: 10/16/2021
Version No. 003 Issued: 09/09/2019



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017. 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 17025:2017

Advanced Mechanical Technology, Inc.

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CALIBRATION AND TESTING

Valid to: October 16, 2021

Certificate Number: ACT-2511

CALIBRATION

Mechanical / Thermodynamic

Table with 4 columns: Parameter / Equipment, Range, Expanded Uncertainty of Measurement (+/-) 2, Reference Standard, Method and/or Equipment. Rows include AMTI Knee Simulator, Forces, Moments, Vertical Position Sensors, Temperature Probes, Vertical Load Actuators, AP Linear Displacement, Internal/External Angular Displacement, and Flexion Angular Displacement.



Mechanical / Thermodynamic

Parameter / Equipment	Range	Expanded Uncertainty of Measurement (+/-) ²	Reference Standard, Method and/or Equipment
AMTI HIP Simulator¹			
Forces	F _x = Up to 180 N F _y = Up to 180 N F _z = Up to 4 500 N	0.1 N 0.1 N 1.9 N	Deadweights Deadweights Reference Load Cells and Display
Moments (Differential)	ΔM _x = Up to 7.5 N·m ΔM _y = Up to 7.5 N·m ΔM _z = 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
AMTI VIVO Simulator:¹			
Forces	F _x = (-1 000 to 1 000) N F _y = (-1 000 to 1 000) N F _z = (-4 400 to 3 500) N	21 N 21 N 41 N	Multi-Axis Reference Load/Torque Cell and Display



Mechanical / Thermodynamic

Parameter / Equipment	Range	Expanded Uncertainty of Measurement (+/-) ²	Reference Standard, Method and/or Equipment
Moments	M _x = (-80 to 80) N·m M _y = (-30 to 30) N·m M _z = (-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 (+/-) ²	Reference Standard, Method and/or Equipment
6 Axis Load Cell:			
Forces	F _x = Up to 2 224 N F _y = Up to 2 224 N F _z = Up to 8 896 N	2.5 N 2.6 N 2.4 N	Single Axis Reference Load Cell Length Standard
Moments	M _x = Up to 113 N·m M _y = Up to 113 N·m M _z = 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

Parameter / Equipment	Range	Expanded Uncertainty of Measurement (+/-) ²	Reference Standard, Method and/or Equipment
6 Axis Force Plate:			
Forces	F _x = Up to 4 448N (load cell) F _y = Up to 4 448 N (load cell) F _z = Up to 8 896 N (load cell) F _z = Up to 890 N (deadweights)	2.3 N 2.4 N 1.8 N 0.6 N	Method: ASTM 3109-16 Equipment: Single Axis Reference Load Cells, Deadweights



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Mechanical / Thermodynamic

Parameter / Equipment	Range	Expanded Uncertainty of Measurement (+/-) ²	Reference Standard, Method and/or Equipment
Moments	Mx = Up to 5 423 N-m (load cell) Mx = Up to 542 N-m (deadweights) My = Up to 5 423 N-m (load cell) My = Up to 542 N-m (deadweights) Mz = Up to 2 712 N-m (load cell)	0.9 N-m 0.1 N-m 0.3 N-m 0.1 N-m 0.3 N-m	Method: ASTM 3109-16 Equipment: Single Axis Reference Load Cells, Deadweights

TESTING

Mechanical

FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	*KEY EQUIPMENT OR TECHNOLOGY
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 ACT-2511

Vice President