1. **Purpose:**
   Assure reliability of handheld and cable on the Gen 1B Blood Flow device going to clinical Trial. ASM, Tower Gen 1B 7000-0094

2. **Scope:**
   This document applies to part 7000-0089 ASM, wand 1B bundle and 7000-0122 ASM, Wand 1B

3. **Background (optional):**

According to IEC 60601 handheld devices and cable must be robust to expected usage.

4. **Reference Documents:**

Drop test from IEC 60601-1 drop test for handheld equipment.

5. **Testing**

   1. Drop test

15.3.4.1 HAND-HELD ME EQUIPMENT
HAND-HELD ME EQUIPMENT, ACCESSORIES and ME EQUIPMENT parts that are HAND-HELD shall not
result in an unacceptable RISK as a result of a free fall.

Compliance is checked by the following test.

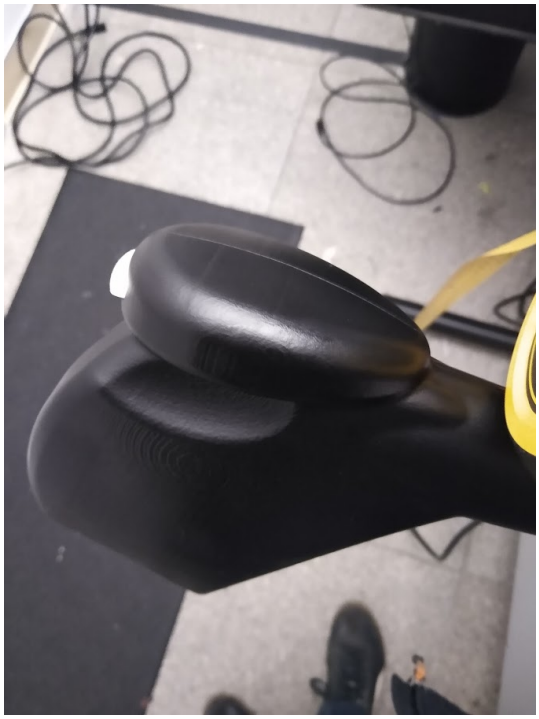
The sample to be tested, with any SAFE WORKING LOAD in place, is allowed to fall freely once from each of three different starting orientations encountered during NORMAL USE from the height at which the ME EQUIPMENT, ACCESSORY or ME EQUIPMENT part is used (as specified in the ACCOMPANYING DOCUMENTS), or

from a height of 1 m, whichever is greater, onto a 50 mm ± 5 mm thick hardwood board (hardwood > 600 kg/m3) lying flat on a concrete or a similar rigid base.

After the test, the HAND-HELD ME EQUIPMENT and, ACCESSORY or ME EQUIPMENT parts shall not result in an unacceptable RISK.

Drop 1 distance

dropped 3 different orientations 3 times each.
9 total drops from 1 meter

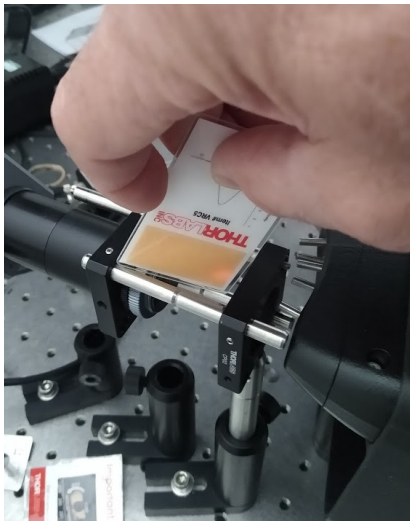


no physical damage

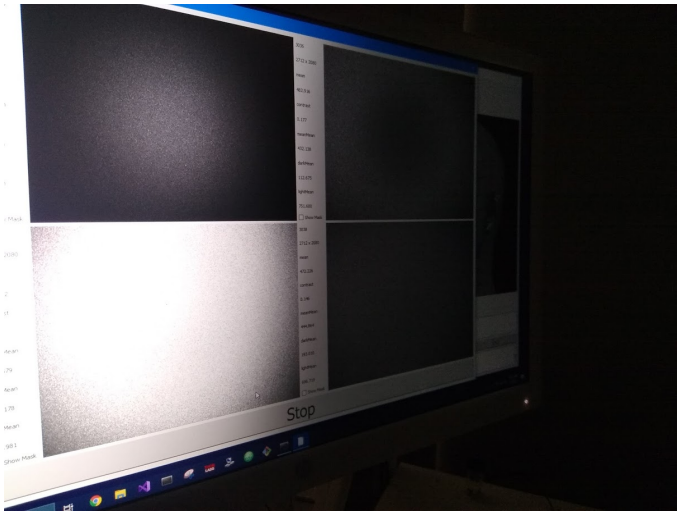
2. rollover crush test
   weigh one wheel of a tower or cart, both are the same weight.
   rollover cable 11 times with a representative tower or cart.
   verify function of cable before and after test by making a blood flow measurement


91.6

No physical damage after the crush test and drop test.



laser beam ok after crush and drop test



all 4 cameras working properly

measurement working properly- OK

3. Pull test

From IEC 60601

The cord is subjected 25 times to a pull on the sheath of the value shown in Table 18. The pulls are applied in the most unfavourable direction without jerks, each time for 1 s.

Immediately afterwards, the cord is subjected for 1 min to a torque of the value shown in Table 18.

Table 18 – Testing of cord anchorages

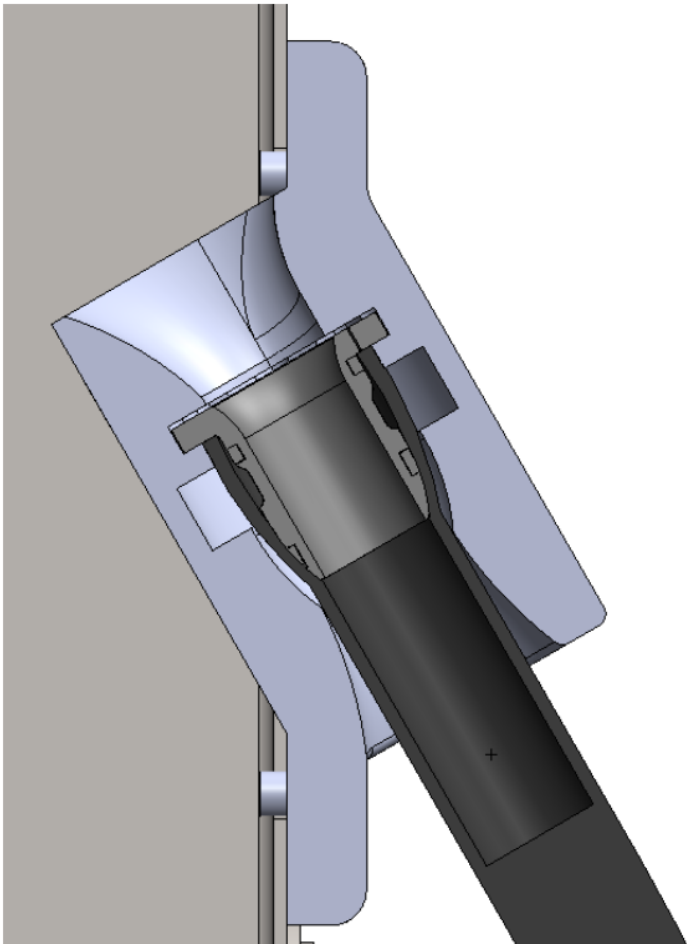
Mass (*m*) of ME EQUIPMENT kg	Pull N	Torque Nm
$m \leq 1$	30	0,1
$1 < m \leq 4$	60	0,25
$m > 4$	100	0,35

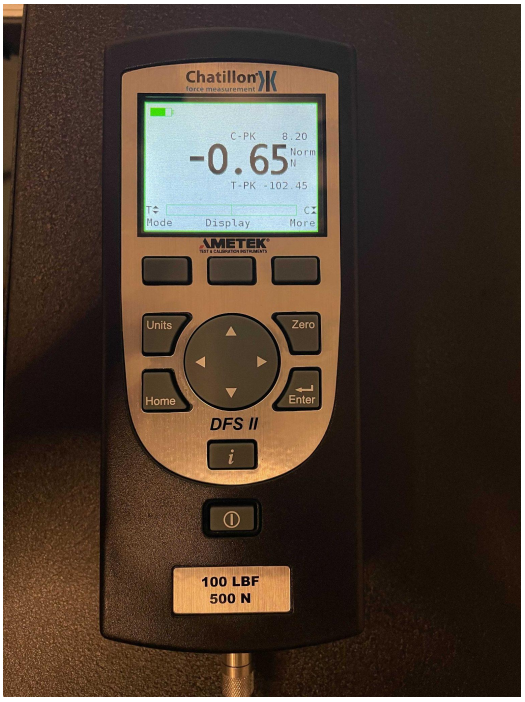
A cord anchorage that allows the cord sheath to be longitudinally displaced by more than 2 mm or the conductor ends to move over a distance of more than 1 mm from their normally connected position is considered to fail.

CREEPAGE DISTANCES and AIR CLEARANCES that are reduced below the values specified in 8.9 constitutes a failure.

Attempt to push the cord into the ME EQUIPMENT or the MAINS CONNECTOR. If the cord can be pushed into the ME EQUIPMENT or the MAINS CONNECTOR to such an extent that the cord or internal parts are damaged, the cord anchorage is considered to fail.

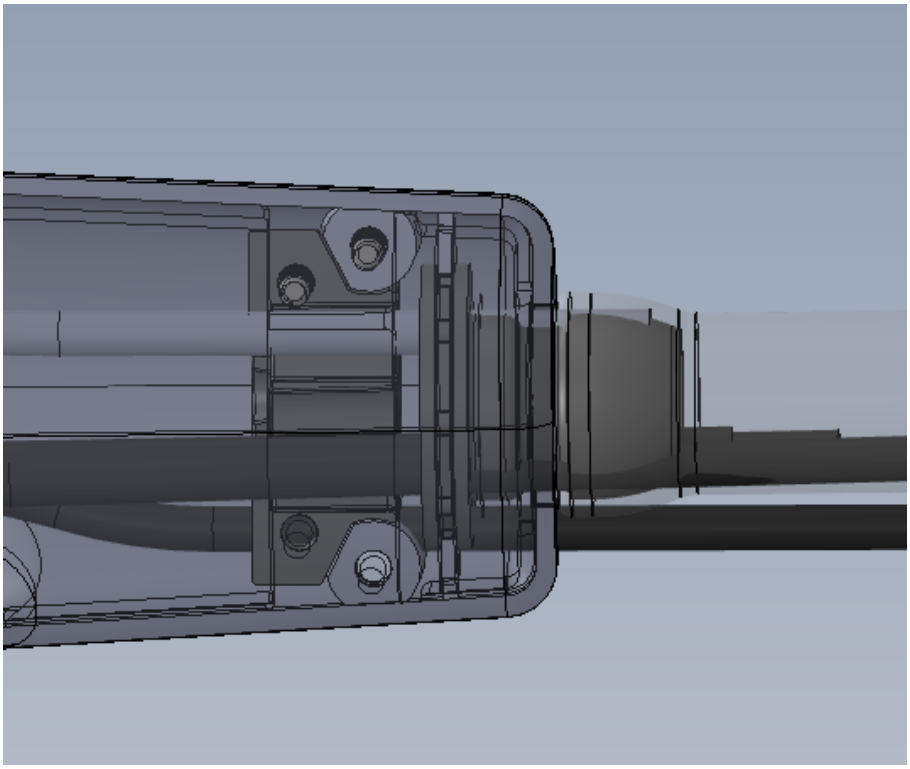
Anchor picture bulkhead side
cross section of model shown below:





102.45N on tower bulkhead,
Passed

Anchor picture handheld side



39.6 N on wand handle, pull test ok.

4. cleaning wipe test-
   pull wipe from CaviWipe container and wipe the entire wand surface and length 4 times.
   CaviWipe recommended by HH IRB

6. Study Summary:

Summary of tests made to the wand and cable

1. drop test hand held

An hand held 7000-0122 dropped from 1 meter onto a wooden board ⅜ thick on the concrete floor 9 times total (3 times, 3 orientations).- no cracking

2. cable roll over

The cable was run over by the cart 11 times- no degradation, visual or functional

3. Pull test
   a. pull test in bulk head to tower 3x
   passed, 100N ok
   b. pull test on handheld 3 x
   passed, 39.6 N ok
4. wipe down/ cleaning
   CaviWipe, 4 wipes handle and cable.
   no degradation seen, wipedown ok

The silicone sheathing and ABS handle were wiped with CaviWipe 4 times - no degradation visual or functional.

6.1. Equipment/Materials

6.1.1. Taylor scale lbs.

6.1.2. Chatillon force gauge DFS2-100 WS2 35955
6.1.3. Gen 1A cart

7. Results and Analysis:

test #	Test	Result
1	Drop test	Pass
2	Crush test	Pass
3	Pull test	Pass
4	Wipe test	Pass

8. Conclusion/Recommendation:

Summary: The wand and cable is low risk for failing foreseen usage

The wand 1B is a passive device, except for the LED and tactile switch.
The tactile dome switch is a very robust design used in millions of consumer and medical devices.
The LED is a very robust solid-state device. The fibers are passive devices; any failure will cause less light to get through the laser.

9. Appendix List: *Chatlillon calibration certification*

Appendix 1

Chatillon
force measurement

AMETEK
8600 Somerset Drive
Largo, FL 33773
(727) 536-7831

CERTIFICATE OF CALIBRATION # WS2 35955

CUSTOMER:

ADDRESS:

CITY/STATE:

TRACEABILITY STATEMENT

TRACEABILITY AS DEFINED BY THIS CERTIFICATE IS TO AN AMETEK TEST AND CALIBRATION INSTRUMENTS DIVISION LABORATORY REFERENCE STANDARD, OR STANDARDS. SAID STANDARDS ARE ULTIMATELY TRACEABLE BY MEANS OF AN UNBROKEN CHAIN OF CALIBRATIONS TO THE INTERNATIONAL SYSTEM OF UNITS (SI-SYSTEME INTERNATIONAL D'UNITES) THROUGH AN ACCREDITED NATIONAL METROLOGY INSTITUTE (SUCH AS NIST, PTB/DKD, BNM, LNE, IGMC, DTI, CENAM, ETC), OR BY REFERENCE TO A NATURAL PHYSICAL CONSTANT ACCEPTED BY CGPM AND CIPM. AMETEK CALIBRATION NORMS ARE IN ACCORDANCE WITH THE BASIC REQUIREMENTS OF ISO 10012 AND ANSI Z540-1.

MODEL: DFS2-100 SERIAL NUMBER: U15719
CALIBRATION PROCEDURE: MGFP-143 DATE CERTIFIED: 3/31/2021

PRODUCT SPECIFICATION

CAPACITY: 100 LBF X 0.01 LBF ACCURACY LIMITS: +/-0.10% OF FULL SCALE
CONDITION: New

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AS RECEIVED
TEST (LBF)
STANDARD
20.00
40.00
60.00
80.00
100.00
110.00
TENSION
COMPRESSION

AS CALIBRATED
TENSION
-19.97
-39.94
-60.00
-79.98
-99.99
-110.00
COMPRESSION
20.01
40.01
60.04
80.03
100.02
110.03

NOTE:
1. THE ABOVE LISTED RESULTS RELATE ONLY TO THE MODEL AND SERIAL NUMBER OF THE UNIT AS SPECIFIED ON THIS CERTIFICATE OF CALIBRATION.
2. CALIBRATION PERFORMED AT 75.56 DEGREES F AND 47.80% R.H.
3. THIS CERTIFICATE OF CALIBRATION SHALL NOT BE REPRODUCED EXCEPT IN FULL, WITHOUT THE WRITTEN APPROVAL OF AMETEK, INC.
4. CALIBRATION STANDARDS HAVE A TWO YEAR CALIBRATION CYCLE.
5. THE CONFIDENCE LEVEL ON UNCERTAINTY STATEMENTS IS 95% (K=2) UNLESS OTHERWISE INDICATED.

CALIBRATION TRACEABILITY

WEIGHT SET	WS8	170-184	07/10/2021
WEIGHT SET	WS8	170-088	05/15/2021

TYPICAL MEASUREMENT UNCERTAINTY = 0.020% OF FULL SCALE

AMETEK Test and Calibration Instruments Division certifies that the product referenced in the Certificate meets specifications; and, further certifies that the referenced instrument was serviced and/or calibrated using quality and manufacturing systems registered to ISO 9001.

Calibrated by: CHANTINA ONG
Date: 3/31/2021

Report Number: WS2 35955

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