PROPRIETARY AND CONFIDENTIAL

AUTHORIZATION				
	NAME	TITEL	SIGNATURE	DATE
Approved by:	Noam Gavriely	CMO CEO		22.09.24
Approved by:	Yifat Baranes	COO		22.09.24
Approved by:	Igor Naroditsky	VP REGULATOIN		22.09.24

Technical specifications of the Hema clear XXL device.

1. General scope: HemaClear XXL device is designed to move blood from the limbs into the central circulation and then block its re-entry for patients with large circumference according to the requirements described beneath. This document includes the technical specifications of the device after lab R&D testing. The next stages should be:
   1.1. Test the units and validate the manufacturing process with 10 to 30 units in order to fine tune the process.
   1.2. Validate the device with a clinical trial
2. Reference
   2.1.1. QC-001 Elastic ring validation test REV15
   2.1.2. QC-002 Elastic sleeve validation test REV 11
   2.1.3. QC-009H Rev 17 HemaClear Mechanical Standard for Assembled Unit
   2.1.4. QC-016H HemaClear Mechanical Standard for Assembled Unit Rev1

3. Abbreviations

SS	Stainless Steel
PVC	Polyvinyl chloride
XXL	Extra extra Large
L	Length
W	Width
H	Hight
OD	Outer diameter

4. General specifications

4.1. Core compression method: Torus Spring: Material: 302 SS

4.2. Elastic sleeve: Material: Woven material with elastic threads (cotton and Lycra threads with pigment)

4.3. Pull straps: Material: Woven material (sateen)

4.4. Pull handles: Material: PVC

4.5. Color: Pull straps will be in Turquoise and white

4.6. 4 pull straps, 2 Turquoise and 2 white.

4.7. The device will be sterilized -

4.8. Application: Two persons will apply on limb, each pulling two of the straps

4.9. Length of Sleeve: 360 cm ± 20 cm

Table 1: Device parameters

HemaClear® Size	**XXL**
1. **Color**	**Turquoise**
2. Patient's Systolic Blood Pressure Limit	<150 mmHg
3. Length of limb	<130 cm
4. Min Circumference	65 cm
5. Max Circumference	99 cm

5. Physical Dimensions

5.1. Device OD*H (mm)= 220*100 ± 2 mm

5.2. Weight (gr)= 970 ± 2

5.3. d – Wire diameter = 2.6 mm ± 0.05 mm

5.4. D – Mean diameter= 33.4 mm ± 0.2 mm

5.5. OD – Outer diameter = 36 mm ± 0.2 mm

5.6. n – Number of active coils= 90 ± 1

5.7. L0 – Free length (initial state) = 240 mm ± 2 mm

5.8. Spring torus OD TOD (sketch below) = 148.4 mm ± 2 mm

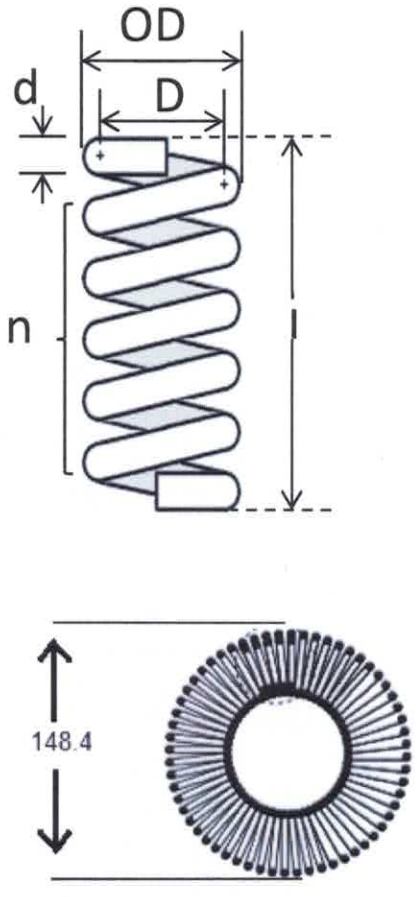

Figure 1:Upper sketch side view of the XXL spring. Lower sketch up view of the spring torus

6. Spring parameters:

In table 2. The spring parameters are detailed.

The K coefficient for steel spring was calculated by the following equation:

$$K\left[\frac{kg}{mm}\right]=\frac{1000\cdot d^4}{D^3\cdot n}$$

Table 2: Spring parameters

XXL	
Spring material	Steel
D [mm] =	36
d [mm]=	**2.6**
n (Active Coils) =	92.308
K [kg/mm] =	0.011
K [N/mm] =	0.104
K [kg/Cm] =	0.106
Lo S (spring) [mm]=	240
ID Torus =L0T (Torus) =	76.4
OD Torus =L0T (Torus) =	148.4

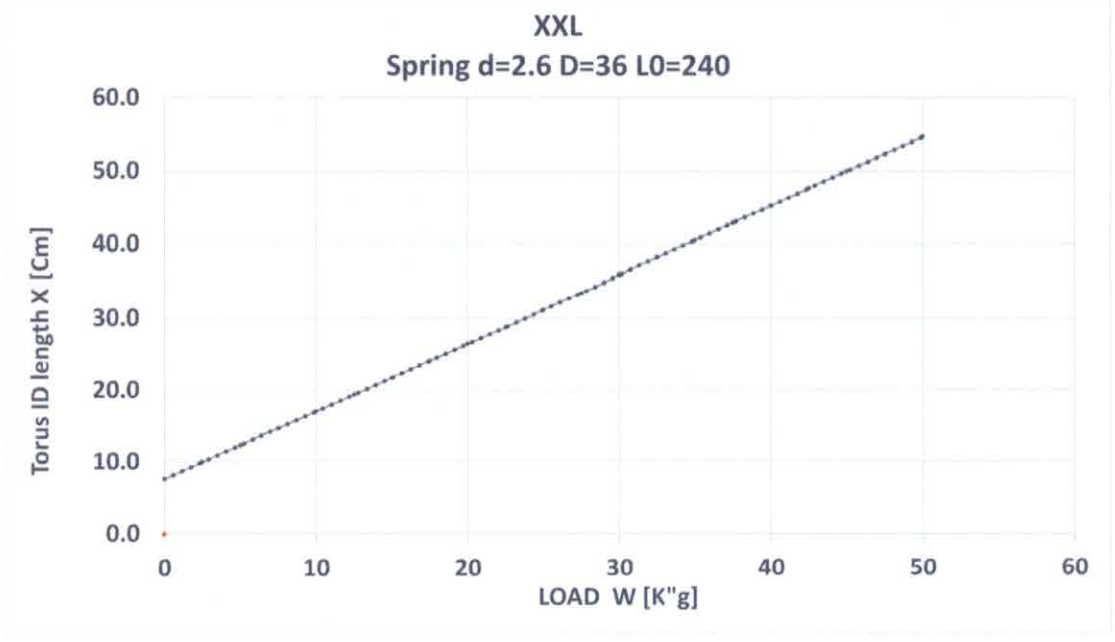

Figure 2: Spring graph of Extension Vs Load. The starting point is L0 of the Torus ID

7. <u>The Mapping of the skin pressure was calculated the following way:</u>

   7.1. A force sensor was set at the Leg simulator device (Legsim). The sensor's location was placed between two Silicon sheets as can be seen in figure 4. The silicone sheets hardness is Shore A of 20 and thickness of 10 mm as shown in Figure 4. These sheets simulate the tissue underneath the skin. The assembled Legsim with the force sensor inside the LegSim can be seen in figure 5.

   7.2. The XXL Device was set at different locations on the Legsim according to Table 3.

   7.3. The integral of the area beneath the curve was calculated as can be seen at Figure 3A for the Force and Figure 3B for the pressure profile. The "tails" were excluded from the integral, hence the integral limit was the width of the device (5.4 cm) ± 2.5 Cm as can be seen in figures 3A and 3B.

   7.4. The ratio between the Average profile area and the Max pressure is the ***Max mean ratio factor (MMRF)***.

$$MMRF = \frac{\text{Average profile area}}{\text{Max pressure}}$$

   7.5. This factor was multiplied with the Max. force measured by the force sensor and was used for calculating the pressure on the skin. The Diameter of the Force sensor is 14.8 mm. To calculate the pressure, the measured force was divided with the area ($A = \pi * R^2 = 172\ mm^2$) see equation of P(Skin). The results of the Pressure profile on the skin - P(Skin) mapping can be seen in table 3.

$$P(Skin) = \frac{F(Sensor) * MMRF}{\pi r^2}$$

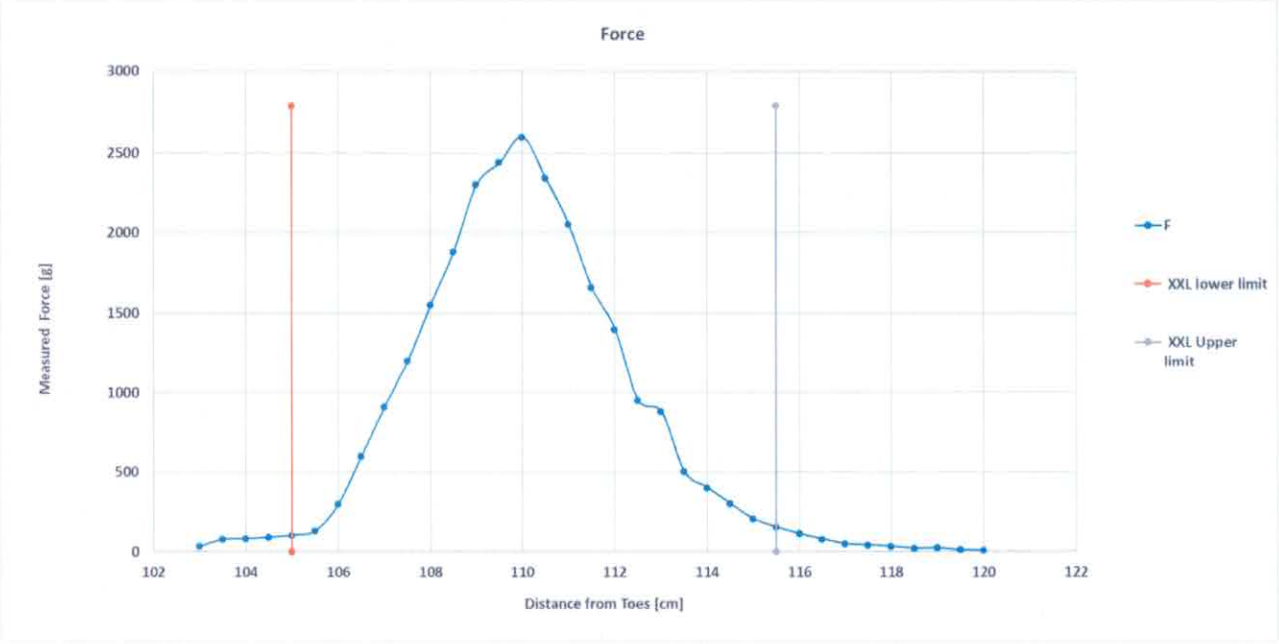

Figure 3A: A force profile of the XXL device was measured the two lines – XXL Lower limit and XXL upper limit shows the width of the XXL device.

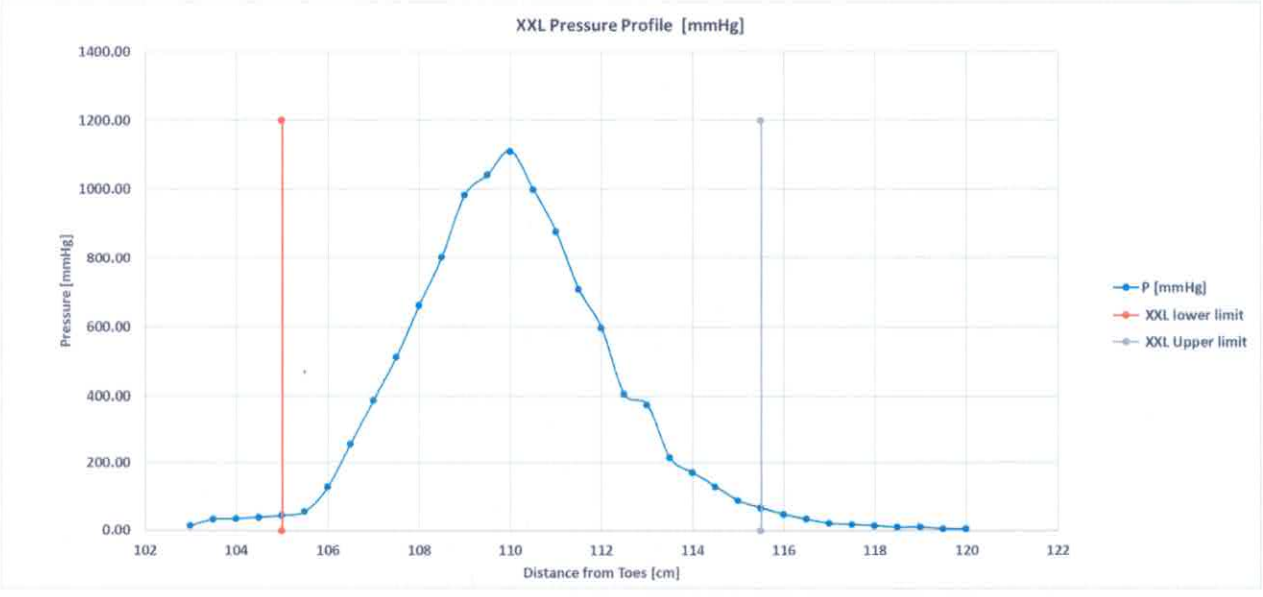

Figure 4B: A pressure profile of the XXL device was measured the two lines – XXL Lower limit and XXL upper limit shows the width of the XXL device.

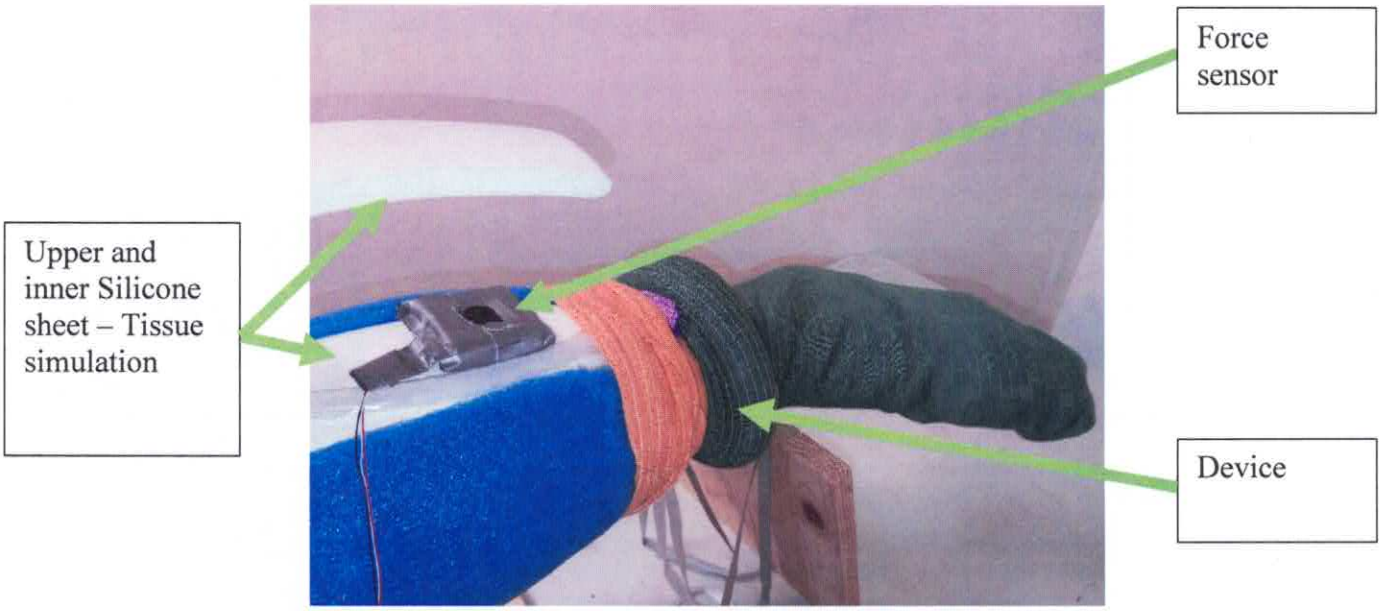

Figure 5: A force sensor placed between two silicone sheets simulating the body tissues.

Figure 6: A Leg simulator – assembled

Table 3: HemaClear® EXTRA- EXTRA-LARGE (XXL) Turquoise, @Skin Pressure, mm Hg

HemaClear® EXTRA EXTRA LARGE (XXL) Turquoise PRH-099-TU01A		Distance from Toes (cm)						
		60-70	71-80	81-90	91-100	101-110	111-120	121-130
LIMB CIRCUMFERENCE (cm)	65-71	274	271	269	266	264	260	256
	72-78	292	286	283	278	276	274	271
	79-85	309	306	302	299	296	293	290
	86-92	326	323	320	317	315	310	308
	93-99	343	340	338	334	331	330	326

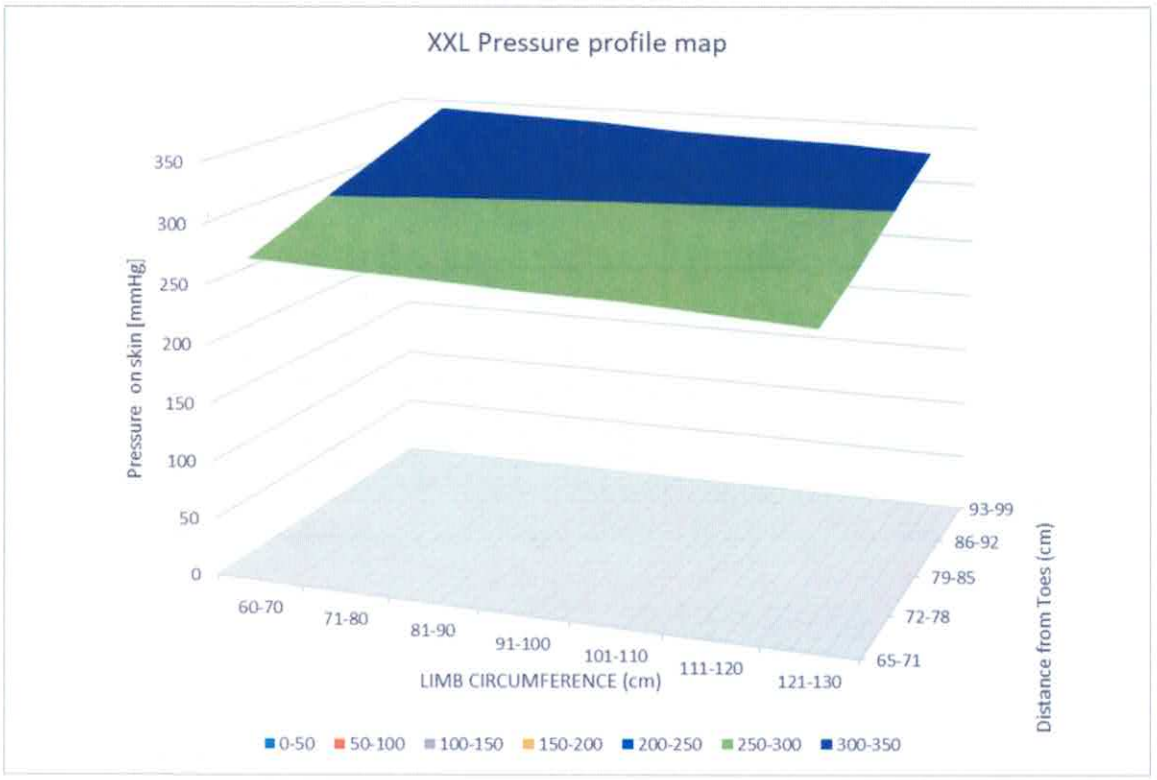

Figure 7: A pressure mapping 3D surface graph can be seen with range of distance from toes (cm) 60 cm to 130; and limb circumference range of 65 to 99 cm.

8. Device blockage testing

The blockage of the device with the **Legsim** open loop simulation device was used to test the blockage of the fluid through a 20 A shore tube and OD = 10 mm, ID = 8 mm. An analog pressure gauge was used to measure the pressures blockage range. The pressure gauge can be seen in figure 7. A solenoid valve simulated a 60 bpm Heart beats. During the pulses the indicator oscillates with a range of ±0.1 bar (± 75 mmHg) and stops for around 0.5 sec at a pressure after the liquid stabilizes. The pressure was controlled manually in an open loop by a potentiometer applying more power to the pump.
The pressure due to the device blockage was measured and the result table is below. The average pressure is 165 mmHg.

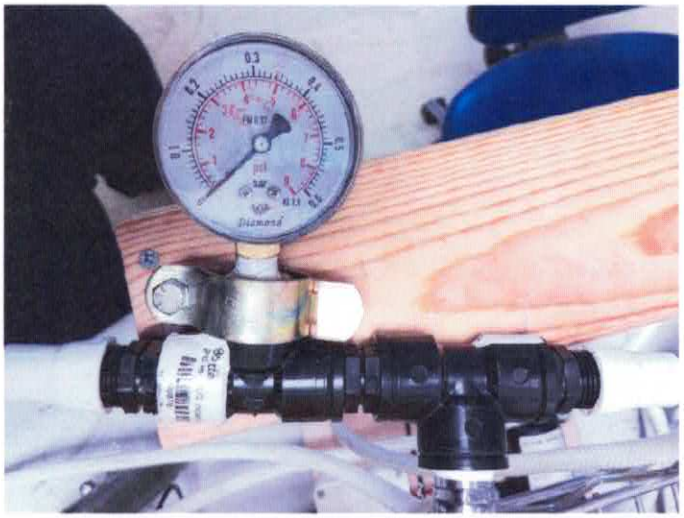

Figure 8: Pressure gauge in the Legsim system measuring the pressure in the system

Table 4: Results of the pressure limit when the device is on the Legsim

XXL								
Blockage Pressure limit [mmHg]								
Distance from Toes (cm)							HemaShock® Orange PRH-80-OR01A	
121-130	111-120	101-110	91-100	81-90	71-80	60-70		
150		150		150		150	65-71	LIMB CIRCUMFERENCE (cm)
150		150		150		160	72-78	
160		160		160		170	79-85	
170		170		180		180	86-92	
180		180		180		190	93-99	

9. Validation testing

9.1. QC-001 - The validation of the spring was made according to Procedure: QC-001 Elastic ring validation test REV15.

The results of the testing can be seen in the following figure 7 and in Table 4:

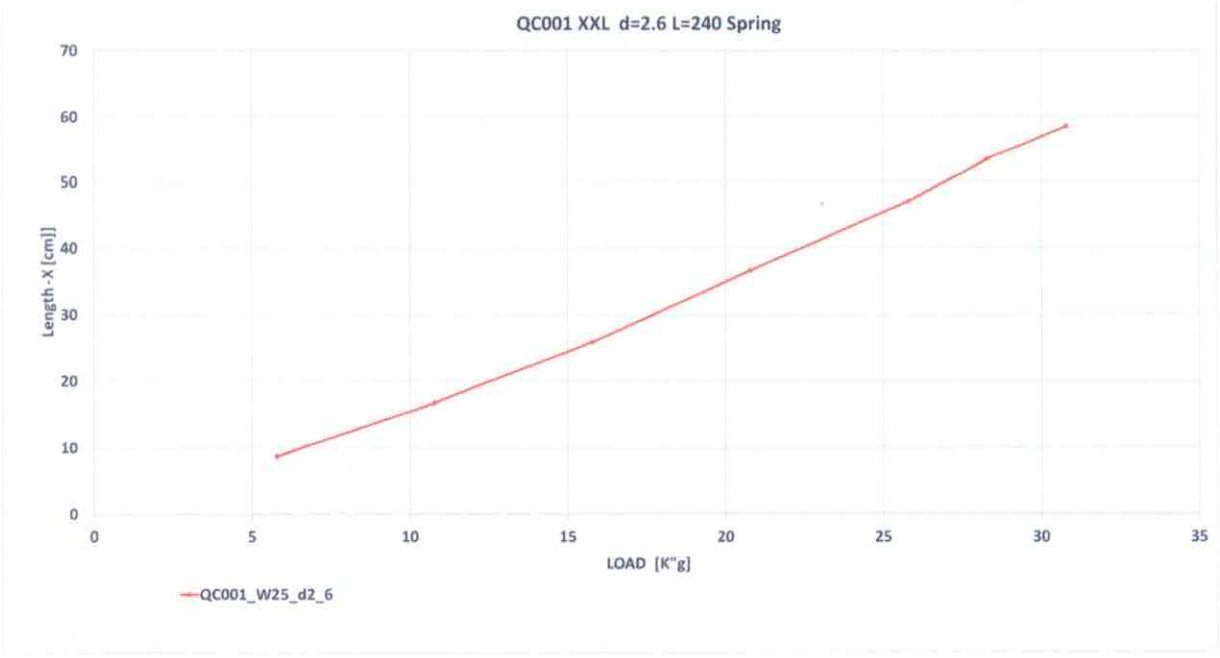

Figure 8: Qc001 Validation testing of the Spring

Table 5: Results of the QC001 testing

Length (cm)	Load (K"G)
8.8	5.8
16.8	10.8
25.9	15.8
36.6	20.8
47	25.8
53.4	28.3
58.7	30.8

9.2. The validation of the sleeve was made according to Procedure: QC-002 Elastic sleeve validation test REV 11

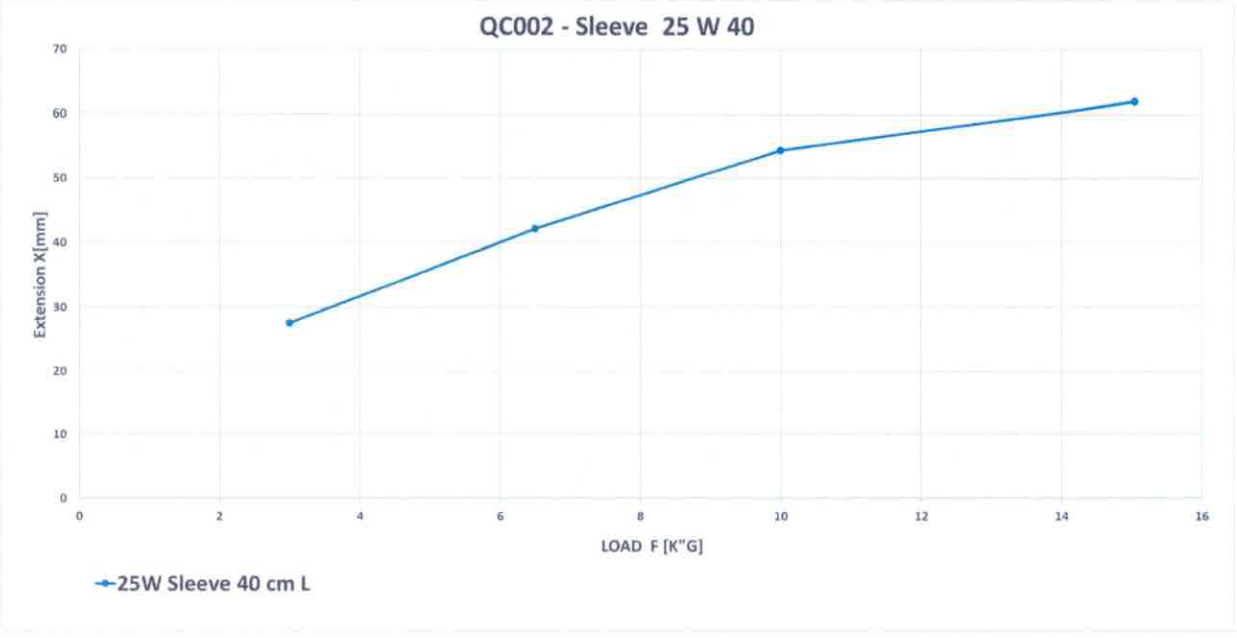

Figure 9: Qc002 Validation testing of the Sleeve with length of 40 cm

Table 6: Results of the QC002 testing

Machine Extension (cm)	Load [K"G]
27.6	3
42.2	6.5
54.4	10
62	15.05

9.3. The validation of the device (product) was made according to Procedure: QC-009H Rev 17 HemaClear Mechanical Standard for Assembled Unit.

The Load was 29.5 K"g.

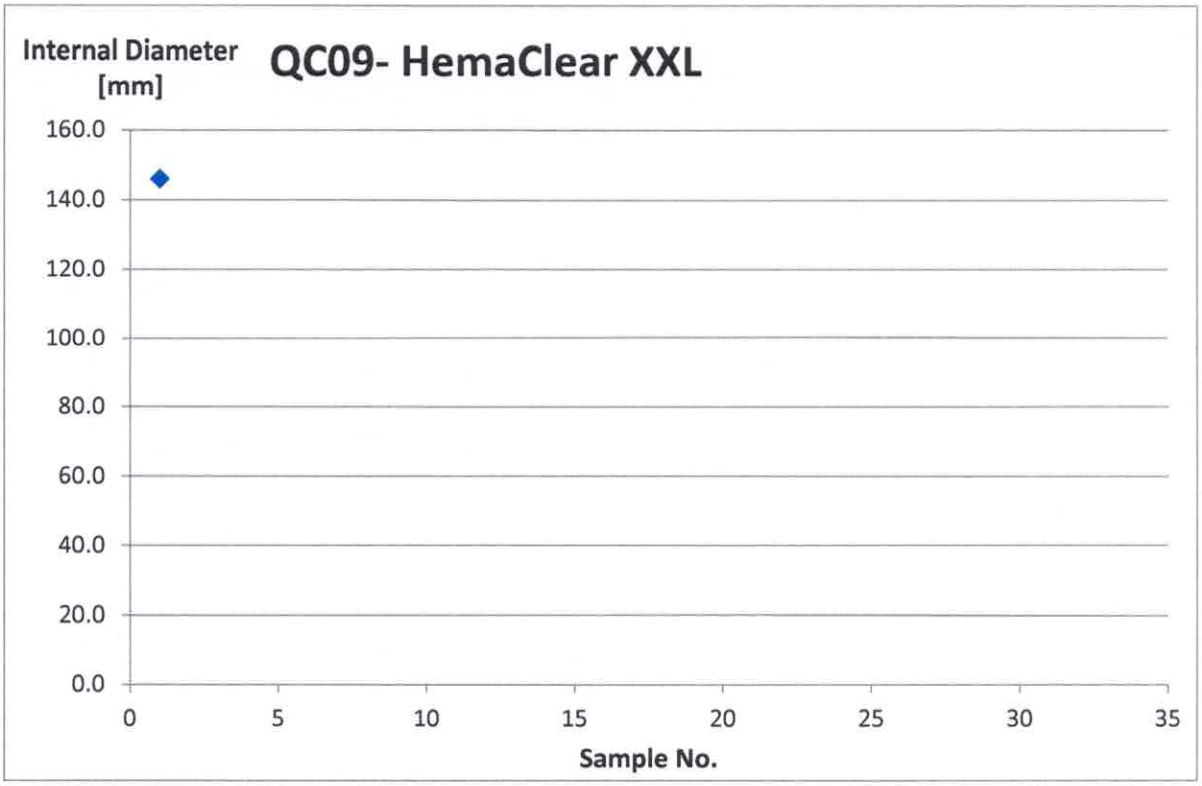

Figure 10: Qc009 Validation testing of the assembled device of HemaClear XXL with Sleeve length of 380 cm

Table 7: Results of the QC009 testing:

Sample #	Internal Diameter - Measured Machine Elongation [mm]
1	146.0

9.4. QC-016H HemaClear Mechanical Standard for Assembled Unit Rev1

Figure 11: Qc016 Validation testing of the assembled device of HemaClear XXL with Sleeve length of 250 cm

Table 8: Results of the QC016 testing:

Length (cm)	Load (K"G)
15	25.8
27.7	45.8
34.4	65.8
38.4	85.8
41.8	95.8
44.2	105.8
47.3	115.8
48.9	123.3
50.5	132.8

10. Appendixes

10.1. Procedure - QC01

10.2. Procedure -QC02

10.3. Procedure -QC09

10.4. Procedure -QC016