

1 Purpose

2 References

2-1 - ISO 60601 for electrified Hospital Beds. [MDT L-39292,  Should Have,  Draft]

3 Definitions

- 3-1 -**
- Activities of Daily Living
- [MDT L-35619,  Should Have,  Draft]
- 3-2 -**
- Approved Server to connect ACME product using WiFi to stream the data relative to the caregiver usage to the Hospital server.
- [MDT L-35620,  Should Have,  Draft]
- 3-3 -**
- The person operating the product to assist in the mobility and care of a patient
- [MDT L-35621,  Should Have,  Draft]
- 3-4 -**
- Central Suspension Point
 - It is the reference point on the hoist to be used for measurements - the reference is the axis of the hooking area.
- [MDT L-35622,  Should Have,  Draft]
- 3-5 -**
- Cumulocity is a unique IoT equipment management tool. Cumulocity allows to manage equipment throughout its lifecycle. Monitor the status of the devices, minimize downtime by visualizing key information, alarms and critical errors in its specific dashboards.
- [MDT L-35623,  Should Have,  Draft]
- 3-6 -**
- Electronic Medical Record - Server managed by the hospital
- [MDT L-35624,  Should Have,  Draft]
- 3-7 -**
- A device used to lift or lower.
- [MDT L-35625,  Should Have,  Draft]
- 3-8 -**
- A charging system installed on straight rails which convert the AC power to DC power to charge the battery in the Hoist.
- [MDT L-35626,  Should Have,  Draft]
- 3-9 -**
- Movement in the horizontal plane parallel to the lifting surface.
- [MDT L-35627,  Should Have,  Draft]
- 3-10 -**
- The time span during which the Product shall serve its intended use.
- [MDT L-35628,  Should Have,  Draft]
- 3-11 -**
- A lift cycle is an up and down movement on the same distance on both sides.
- [MDT L-35629,  Should Have,  Draft]
- 3-12 -**
- Existing Liko Overhead Lift System
- [MDT L-35630,  Should Have,  Draft]
- 3-13 -**
- Existing Liko Overhead LR System
- [MDT L-35631,  Should Have,  Draft]
- 3-14 -**
- Greatest permissible load that can be applied to the hoist system without design margin, equivalent to maximum patient weight.
- [MDT L-35632,  Should Have,  Draft]
- 3-15 -**
- Existing Liko Overhead Lift System
- [MDT L-35633,  Should Have,  Draft]
- 3-16 -**
- SCRM ==> Denotes work in SmartCare Remote Management customer facing portal (cloud based).
 - SCRM On Prem==> Denotes work in SmartCare Remote Management On Premises portal
- [MDT L-35634,  Should Have,  Draft]
- 3-17 -**
- Main user control (first intention).
 - Out of backup control in case of failure.
- [MDT L-35635,  Should Have,  Draft]
- 3-18 -**
- If needed, a redundant interface located on the Hoist.
- [MDT L-35636,  Should Have,  Draft]
- 3-19 -**
- Each side of a connecting interface is connected in such a way that an intended User action is required to disconnect.
- [MDT L-35637,  Should Have,  Draft]
- 3-20 -**
- Existing Liko Slingbar family
- [MDT L-35638,  Should Have,  Draft]
- 3-21 -**
- Safe Working Load
 - The SWL is the user max with additional design margin to cover misuse.
 - The SWL is an R&D value to design - no claim on user documentation.
- [MDT L-35639,  Should Have,  Draft]
- 3-22 -**
- Portable Power Source is another way to name the battery
- [MDT L-35640,  Should Have,  Draft]
- 3-23 -**
- Real Word Usage Profile
- [MDT L-35641,  Should Have,  Draft]
- 3-24 -**
- Optional feature for motorized lateral motion
- [MDT L-35642,  Should Have,  Draft]
- 3-25 -**
- A connection mechanism that connects intersecting rails.
- [MDT L-35643,  Should Have,  Draft]
- 3-26 -**
- Operation mode where the hoist is shutting down some functionalities to optimize its power consumption.
- [MDT L-35644,  Should Have,  Draft]
- 3-27 -**
- Operation mode where the hoist is shutting down more functionalities to further optimize its power consumption.
- [MDT L-35645,  Should Have,  Draft]
- 3-28 -**
- Operation mode for standard use on battery.
- [MDT L-35646,  Should Have,  Draft]
- 3-29 -**
- Operation mode where the hoist is charging its internal battery.
- [MDT L-35647,  Should Have,  Draft]
- 3-30 -**
- Operation mode in which the battery is disconnected from the system to prevent any power consumption. This is used for transport purpose and long-term storage.
- [MDT L-35648,  Should Have,  Draft]
- 3-31 -**
- Command done by the User to either:
 - Start or stop *Vertical Movement*
 - Start or stop *Dynamic Rails* movements
 - Use of or display on the *Hand Control* Screen
- [MDT L-35649,  Should Have,  Draft]
- 3-32 -**
- Current capacity of a battery compared to its nominal capacity (established when it was first created), expressed in percentage.
- [MDT L-35650,  Should Have,  Draft]
- 3-33 -**
- Remaining capacity available in a battery at a given time and regarding its current maximum capacity, expressed in percentage.
- [MDT L-35651,  Should Have,  Draft]
- 3-34 -**
- Missing capacity in a battery at a given time and regarding its current maximum capacity, expressed in percentage. It linked with ELV-4792 - *State of Charge (SoC)* by the formula DoD = 1 - SoC.
- [MDT L-35652,  Should Have,  Draft]
- 3-35 -**
- A system which transfers power to or from Hoist from a Multi Station location either on:
 - End of rail
 - Side Rail Switch
 - Turn Table
- [MDT L-35653,  Should Have,  Draft]
- 3-36 -**
- A charging system in the Hand Control that transfers power from the wall charger to the Hoist.
- [MDT L-35654,  Should Have,  Draft]

4 Sub-System Overview

4.1 Introduction

5 General Non-Functional Requirements

5.1 Physical Constraints

5.1.1 - For all product configuration, the Hoist weights shall respect the following:

1. Tier 2 Hoist: not to exceed 10.0 kg (TBC)
2. Tier 3 Hoist: not to exceed 11.0 kg (TBC)

[MDT.L-35664, (TBC) Should Have, (TBC) Draft]

5.1.1 Hoist Dimensions and position relative to the ceiling

5.1.1.1 - The Tier 2 and 3 Hoists shall have an external dimension of (see figure 2):

1. Length (B) not to exceed 390 mm (TBC)
2. Width (A) not to exceed 245 mm (TBC)
3. Height (C) not to exceed 160 mm
4. Height (Cusp) not to exceed 210 mm

[MDT.L-35666, (TBC) Should Have, (TBC) Draft]

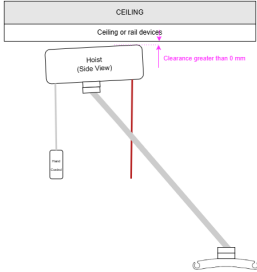
5.1.1.2 - The Hoist length (B) and width (A) shall be symmetric +/-10 (TBC) mm about the Lift Strap. [MDT.L-35667, (TBC) Should Have, (TBC) Draft]

5.1.1.3 - The Hoist shall have a CSP distance (E) from the Upper Lift position to the Lower Lift position of at least 2500 mm illustrated in Figure 2. [MDT.L-35668, (TBC) Should Have, (TBC) Draft]

5.1.1.4 - The clearance between the upper side of the Hoist enclosure and the lower face of the rail/dynamic calls i.e. "D" dimension (see figure 2) shall be 30 0. 2.5 mm.

[MDT.L-35669, (TBC) Should Have, (TBC) Draft]

5.1.1.4 - Where embedded solution apply (rail, turntable), when plays of the Hoist with its carriage are on a side, the clearance between the Hoist enclosure and the ceiling or rail devices shall greater than 0 mm (TBC).



[MDT.L-35670, (TBC) Should Have, (TBC) Draft]

5.2 Performance

5.2.1 Hoist perception and audible feed-backs

5.2.1.1 - When vertical movement is trigger, the Hoist shall be under a perceptible sound level of 52 dBA (TBC) measured from a radial distance of 1 m (TBC need to check the distance between the patient head and the Hoist) starting from the central of the hoist (1 meter sphere starting from the central of the hoist). [MDT.L-35674, (TBC) Should Have, (TBC) Draft]

5.2.1.2 - When vertical or horizontal movement of the product, the vibration level of the Hoist enclosure, per ISO 2631-1, shall be below of 0.015 ms/s (TBC) for the 3 directions ("X,Y,Z" axis).

[MDT.L-35675, (TBC) Should Have, (TBC) Draft]

5.2.1.3 - The usage audible feedback shall be chime type i.e.:

Frequency:

- La - 600 Hz - 0.2 second
- Do - 523 Hz - 0.2 second
- Mi - 659 Hz - 0.1 second

Pulse: 2 pulses in a salve - 200 +/- 50 ms between salve

Sound pressure level: 67.5 +/- 2.5 dB at 1 meter [MDT.L-35676, (TBC) Should Have, (TBC) Draft]

5.2.1.4 - The Error audible feedback audible feedback shall be alarm type i.e.:

Frequency: 800 +/- 50 Hz

Pulse: 3 pulses in a salve

Pulse Duration: td = 200ms +/-50ms

Time between 2 pulses: ts = 125 to 250 ms

Sound pressure level: 67.5 +/- 2.5 dB at 1 meter

[MDT.L-35677, (TBC) Should Have, (TBC) Draft]

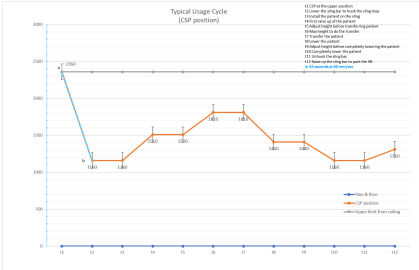
5.2.2 Hoist cycles and Real World Usage Profile

5.2.2.1 - In relation with ELV-1256, the Hoist shall operate 120 seconds mini, in continuous i.e. a complete cycle starting from the top, at the bottom, at the top of vertical lift cycle. [MDT.L-35678, (TBC) Should Have, (TBC) Draft]

5.2.2.2 - Based on ISO EN10535 2021, the Hoists shall achieve the lift cycle defined by § 4.9.2.8. [MDT.L-35679, (TBC) Should Have, (TBC) Draft]

5.2.2.3 - Based on RWUP NFD11646, the Hoists shall achieve at min a usage of:

(To change value, see excel file in attachment)

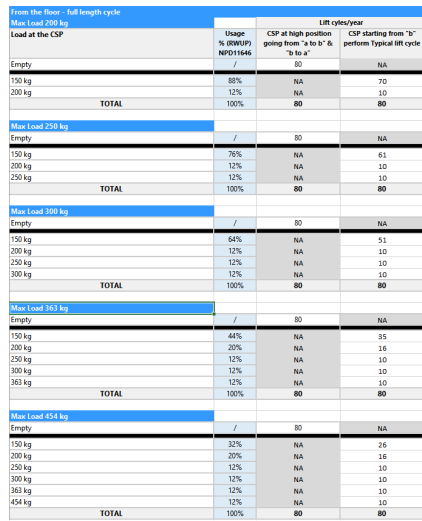


Max Load 200 kg		Lift cycles/year	
Load at the CSP	Usage % (RWUP NFD11646)	CSP at high position going from "a" to "b" (TBC)	CSP starting from "b" perform Typical Lift cycle (TBC)
Empty	0%	3011	N/A
150 kg	96%	NA	3658
200 kg	4%	NA	152
TOTAL	100%	3811	3811
Max Load 250 kg		3011	N/A
Empty	0%	3011	N/A
150 kg	95%	NA	3620
200 kg	4%	NA	152
250 kg	1%	NA	38
TOTAL	100%	3811	3811
Max Load 300 kg		3011	N/A
Empty	0%	3011	N/A
150 kg	89%	NA	3144
200 kg	12%	NA	457
250 kg	4%	NA	152
300 kg	2%	NA	57
TOTAL	100%	3811	3811
Max Load 363 kg		3011	N/A
Empty	0%	3011	N/A
150 kg	70%	NA	2667
200 kg	20%	NA	762
250 kg	7%	NA	257
300 kg	2%	NA	76
363 kg	1%	NA	38
TOTAL	100%	3811	3811
Max Load 454 kg		3011	N/A
Empty	0%	3011	N/A
150 kg	60%	NA	2477
200 kg	20%	NA	762
250 kg	10%	NA	381
300 kg	2%	NA	76
363 kg	2%	NA	76
454 kg	1%	NA	38
TOTAL	100%	3811	3811

[MDT.L-35680, (TBC) Should Have, (TBC) Draft]

5.2.2.4 - Based on RWUP NFD11646 and cycle just below, the Hoists shall achieve a max strap length usage of:

(To change value, see excel file in attachment of ELV-4054)



5.2.2.4 - If the Hoist triggers a High/Low function protection due to lift motor over usage, downward motion shall be allowed. [MOT-L-35682, , 

5.2.2.6 - The Hoist shall manage a margin on over usage protection of High/Low motor to permit a downward & upward motion at the end of a period of 60 (TBC) seconds. [MOT-L-35683, , 

5.2.2.7 - Where [GU] available, when the lift motor over usage protection is active, the Hoist shall provide waiting period and upward motion not available visual feedback. [MOT-L-35684, , 

5.2.3 Emergency function usage profile

5.2.3.1 - When loaded at the Max Load, after a minimum of 400 cycles per year of activations & deactivation, the Emergency Stop shall be operational. [MOT-L-35685, , 

5.2.3.2 - When loaded at the Max Load, after a minimum of 12 emergency lowering per year on at least 40 of unrolled strap per lowering, the Emergency Lowering shall be operational. [MOT-L-35686, , 

5.3-1 - The Hoist shall comply at least with IP34 (TBC) index specify by IEC 60529. (MDT.L-35687, Should Have, Draft)

5.4.1 Interface with Carriage

5.4.1-1 - The Hoist carriage shall be operational when attached / detached from the Lateral Mobility 4 times/year

[MDT.L-35693, Should Have, Draft]

5.4.2.1 - The user control of the Hoist shall be adjustable to be placed between a height "G" of 800 mm to 1200 mm above the floor. [MDT.L-36694, ☐ Should Have, ☐ Draft]

5.4.2.2 - The CSP point of the Hoist shall provide an emplacement to plug the User Control and keep in place when the hoist move for transfer. [MDT.L-36695, ☐ Should Have, ☐ Draft]

5.4.2.3 - The Hoist shall provide a User Control connector:

1. Accessible to plug/unplug without the use of tool
2. Answered the IP constraint of the Hoist (ELV-1309)
3. Support a traction force of 200 N at an angle not to exceed 60 degrees relative to vertical axis.



5.4.4 Interface with Transfer Motor

5.4.5 Interface with the Scale Accessory

5.5 Codes & Standards

5.6 Regulatory

5.7 Design Constraints

5.7-1 - When using the user control, the movements trigger shall

1. Be active only while the corresponding control is active (Hold to Run)
2. For a different movement requests, the second request halts execution of the first while there is more than 1 request in same time.
3. The Emergency stop and lowering control has priority on the other movements.

[MDT.L-35697, Should Have, Draft]

5.7-2 - The Hoist shall trigger an electrical movement:

1. If there is a state change from key release to press
2. While the intended user function pressed
3. Excepted if the intended user function pressed beyond a period of time defined by ELV-3324 (failure management - user control see item 19)

[MDT.L-35698, Should Have, Draft]

5.7.3 - The Hoist shall stop a electrical movement if there is a state change from key press to release. [MDT.L-35699, Should Have, Draft 1]

5.7-4 - When the Hoist generates indication

1. Critical Error
2. Weight Over load
3. Emergency stop
4. Over usage
5. Max angle/Twist of the lift strap
6. Battery recharging needed
7. Service requires

to provide information. IMDT L-35700. Should Have. Draft.

5.7-5 - Except for the lift strap, the emergency lift strap and the user control wire, all moving parts associated of the Hoist shall be enclosed. [MDT.L-35701] Should Have Draft

5.7.6 - When is present, the protections removing shall be only possible by the use of a tool according to ISO 10535:2021 5.4.1.4.1 a. [MDT] - 35702 Should Have Draft 1

5.7.7 - The design of the Hoist shall be in a way that the fasteners and parts cannot be unfixed manually. BMDT-35703 Should Have Draft

5.7.8 - The accessible area of the Hoist i.e. the CSP, Strap, Hoist enclosure shall be smooth to avoid aggressive contact with the user and the patient specify by IEC 60601-1:2005 59.3. IMDT I - 35704 Should Have Draft 1

5.7.1 Moist protection

5.7.1-1 - The exposed parts of the Hoist shall withstand Ultraviolet (UV) light to avoid risk of discoloration or loss of function. [MDT.L-35706, Should Have, Draft 1

5.7.1-2 - The metallic surfaces of the Hoist shall be protected from corrosion to answer:

1. Total of the corroded surface: $\leq 5\%$
2. Protection and Aspect class: $Rp=4; Ra=4$
3. Deterioration degree: $\leq A$

based on ISO 6270, IMDT.L-35707. Should Have. Draft 1

5.7.1-3 - The external ports of Lift Control Board of the Hoist shall have

1. Over-voltage protection
2. Over-current protection
3. Short-circuit protection

[MDT.L-35708,  Should Have,  Draft]

6 Functional Requirements and Associated Non-Functional Requirements

6.1 Support Load

6.1.1 - The fixed HOIST shall manage Safe Working Loads:

1. Tier 2 Hoist: Max Load of 200 kg + accessories supported of 18 kg = 218 kg of load with design margin (TBC)
2. Tier 2 Hoist: Max Load of 250 kg + accessories supported of 18 kg = 268 kg of load with design margin (TBC)
3. Tier 2 Hoist: Max Load of 272 kg + accessories supported of 18 kg = 290 kg of load with design margin (TBC)
4. Tier 3 Hoist: Max Load of 300 kg + accessories supported of 18 kg = 318 kg of load with design margin (TBC)
5. Tier 3 Hoist: Max Load of 350 kg + accessories supported of 18 kg = 368 kg of load with design margin (TBC)
6. Tier 3 Hoist: Max Load of 363 kg + accessories supported of 18 kg = 381 kg of load with design margin (TBC)
7. Tier 3 Hoist: Max Load of 454 kg + accessories supported of 18 kg = 472 kg of load with design margin (TBC)

[MDT.L-35718,  Should Have,  Draft]

6.1.2 - The Hoist shall block the vertical drift within 0.0/+5 mm during 2 hours. [MDT.L-35719,  Should Have,  Draft]

6.1.1 Single Fault Safety of support load function

6.1.1.1 - The Hoist shall guarantee a lifted patient does not fall in the event of a single-fault condition of the drivetrain. [MDT.L-35721,  Should Have,  Draft]

6.1.1.2 - The Single Fault Safety of High/Low function shall not untimely triggering during vertical lift or emergency lowering.

[MDT.L-35722,  Should Have,  Draft]

6.1.1.3 - When the Single Fault Safety mechanism triggers, the Hoist shall stay safe. [MDT.L-35723,  Should Have,  Draft]

6.2 LIR Patient

6.2.1 - When an High/Low command is triggered, the Hoist shall accelerate to achieve the vertical speed (ELV-1256) in $2.5 \text{ (TBC)} \pm 0.5 \text{ seconds}$ without joggle. [MDT.L-35724,  Should Have,  Draft]

6.2.2 - The Hoist CSP shall have vertical movement speeds of $50 \pm 15 \text{ mm/sec}$ (TBC) without joggle & be the same on the way down or on the way up $\pm 5 \text{ mm/sec}$ (TBC) [MDT.L-35725,  Should Have,  Draft]

6.2.3 - When these events occur prior the High/Low activation:

1. Lift motor over usage protection triggered
2. Reach Angle of the lift exceeded (ELV-2009, ELV-2010)
3. Twist of the strap (ELV-3049)
4. Battery in low level situation (ELV-4776)
5. Battery in empty level situation (ELV-4777)
6. Emergency stop

the Hoist shall prevent the vertical upward movement & manage Emergency stop by specification of §6.4. [MDT.L-35726,  Should Have,  Draft]

6.2.4 - When these events occurs during vertical movement:

1. Halt High/Low command
2. Load exceeds $1.5 \text{ (TBC)} \pm 0.20 \times \text{Max Load}$ (TBC)
3. Lift motor over usage protection triggered
4. Reach Angle of the lift exceeded (ELV-2009, ELV-2010, ELV-3049)
5. Twist of the strap (see ELV-ELV-3049)

the Hoist shall halt the vertical movement within 1 seconds and $\pm 20 \text{ mm}$ without joggle. [MDT.L-35727,  Should Have,  Draft]

6.2.5 - When the upper or lower end of the vertical lifting range is going to be reach, even if user requests the intended control, the product shall:

1. Slowdown and halt vertical movement 20 mm ± 5 prior the end stop in within 1.5 seconds ± 0.5 without shock
2. Avoid constraint on the end stop.

[MDT.L-35728,  Should Have,  Draft]

6.2.6 - Exclusively from 0° to 22° angle of the load gravity center at the CSP point, illustrate by Figure 3 "Max Lateral Angle "a"", the Hoist shall permit a lift movement. [MDT.L-35729,  Should Have,  Draft]

6.2.7 - Exclusively from 0° to 3° angle of the load gravity center at the CSP point, illustrate by Figure 5 "Max Front Angle "b"", the Hoist shall permit a lift movement. [MDT.L-35730,  Should Have,  Draft]

6.2.8 - The Hoist shall :

1. guide the lift strap to prevent to enter twist/folding in the lift housing for a strap twisted under 89° in a distance specify by figure 3 "c"
2. stop the rewind of the strap when twisted more than 89° in a distance specify by figure 3 "c".

[MDT.L-35731,  Should Have,  Draft]

6.2.9 - The Hoist shall prevent the lift strap from folding when entering the Hoist housing. [MDT.L-35732,  Should Have,  Draft]

6.2.10 - When the strap reached the fully extended position, the Hoist shall prevent to wind up the strap in the wrong direction. [MDT.L-35733,  Should Have,  Draft]

6.2.11 - When the vertical movement speeds is above than 250 mm/sec (TBC) the Hoist shall generate a error code specify by ELV-3324 "24"

[MDT.L-35734,  Should Have,  Draft]

6.2.12 - The geometry of the Hoist CSP point shall prevent object hooking. [MDT.L-35735,  Should Have,  Draft]

6.2.1 Lift Patient User Interface

6.2.1.1 - The Hoist access to up and down function shall be in 1 action max. [MDT.L-35737,  Should Have,  Draft]

6.3 Transport Patient

6.4 Emergency function management

6.4.1 - When the emergency function triggered, the angle management of the strap ELV-2009 ELV-2010 ELV-3049 shall be shutdown to permit emergency lowering even if there is a strap angle. [MDT.L-35738,  Should Have,  Draft]

6.4.1 Emergency Interface

6.4.1.1 - The emergency Interface of the Hoist shall be:

1. In red color
2. Specific
3. Electrically independent.

[MDT.L-35743,  Should Have,  Draft]

6.4.1.2 - The Hoist shall contain the following symbols placed on the Hoist near the Emergency Stop / Emergency Lowering & on the Emergency Stop / Emergency Lowering user controls:



[MDT.L-35744,  Should Have,  Draft]

6.4.1.3 - The Emergency Interface shall be:

1. At the lower side of the Hoist cover,
2. Centered under the rail,
3. At a distance from the nearest edge of the lift strap to the Emergency control more than 100 mm

[MDT.L-35745,  Should Have,  Draft]

6.4.1.4 - The user control shall provide indications when the emergency stop is activated. [MDT.L-35746,  Should Have,  Draft]

6.4.1.5 - Where the [GU] equipped the Hoist, the Hoist shall display an information to pull down the sling if no more battery and patient weight below than 20 kg (TBC) [MDT.L-35747,  Should Have,  Draft]

6.4.1.6 - Up to a vertical downward force of 80 N (TBC), the Emergency control shall be operational and have no observable damage. [MDT.L-35748,  Should Have,  Draft]

6.4.1.7 - Starting from 81 N (TBC relative to the motor break control at 50 N), the Emergency Stop strap shall detach from the Hoist. [MDT.L-35749,  Should Have,  Draft]

6.4.1.8 - The Hoist Emergency Interface shall be adjustable to be placed between a height "Y" (Figure 2) of $1650 \pm 50 \text{ mm}$ above the floor. [MDT.L-35750,  Should Have,  Draft]

6.4.1.9 - To differentiate the Emergency stop position from the Emergency lowering, the Emergency interface shall provide an additional effort index point of $3.5 \pm 1 \text{ N}$ (TBC) for the 2 positions & a safety stroke of 15 mm (TBC) between these 2 functions. [MDT.L-35751,  Should Have,  Draft]

6.4.2 Emergency Stop

6.4.2.1 - An Emergency Stop activation shall break and isolate the main circuit to stop all movement produced electrically (High/Low, Dynamic Rails) excluded emergency lowering. [MDT.L-35752,  Should Have,  Draft]

6.4.2.2 - While the Emergency interface (stop and lowering) is activated, the Hoist shall:

1. Disregard any electrical movement requests
2. Not cause interruption of Hoist charging (ELV-3327)

[MDT.L-35753,  Should Have,  Draft]

6.4.2.3 - While the Emergency stop is activated, the Hoist shall forbid the vertical drift within 0.0/+5 mm during 2 hours. [MDT.L-35754,  Should Have,  Draft]

6.4.2.4 - When an Emergency stop occurs, the Hoist shall halt vertical movement within 15 mm of strap length. [MDT.L-35755,  Should Have,  Draft]

6.4.2.5 - When resetting the Emergency stop, the hoist shall not restart but only permit restarting.

[MDT.L-35756,  Should Have,  Draft]

6.4.2.6 - The Emergency Stop

1. User on the floor
2. Without the need of tool

shall:

3. Activate with an applied force between 5 N and 10 N
4. Deactivate with a different action than used for activation
5. Deactivate with an applied force between 5 N and 10 N

at an angle of $\pm 25 \text{ degrees}$ (TBC) from the vertical plane illustrated Figure 4.

[MDT.L-35757,  Should Have,  Draft]

6.4.3 Emergency Lowering

6.4.3.1 - The emergency lowering shall be operable if and only if the Emergency stop is in progress. [MDT.L-35758,  Should Have,  Draft]

6.4.3.2 - The Emergency Lowering

1. User on the ground
2. Without the need of tool

shall:

3. Provide a step feeling between emergency stop & emergency lowering activation
4. Activate with an applied force between 5 N to 70 N
5. Deactivate with a different action than used for activation
6. Deactivate with an applied force between 5 N to 70 N

at an angle of +/-25 degrees from the vertical plane illustrated figure 4. [MDT.L-35759,  Should Have,  Draft]

6.4.3.3 - From a load of 25 kg (TBC) to 454 kg, the Emergency Lowering speed shall fit the same downward speed than the main usage i.e. ELV-1256 without joggle. [MDT.L-35760,  Should Have,  Draft]

6.4.3.4 - From a load of 13 kg to 20 kg, the pulling effort on the sling to lower the patient on the floor shall be under 7..10 kg (TBC) within an Emergency Lowering speed with the main usage downward speed ELV-1256. [MDT.L-35761,  Should Have,  Draft]

6.4.3.6 - When an Emergency lowering is stopped, the Hoist shall halt vertical movement within 1 second and 20 mm. [MDT L-35762, Should Have, Draft]

6.4.3.6 - When the lift strap reached the fully extended position due to emergency lowering event, the Hoist shall prevent to wind up the strap in the improper direction. [MDT L-35763, Should Have, Draft]

6.4.4 Specificity of lateral movement

6.4.4.1 - When an Emergency stop occurs, the Hoist shall stop to power lateral movement [MDT L-35764, Should Have, Draft]

6.5 Scale function management

6.5.1 Scale performance

6.5.1.1 - Weighing performance (ramp up, ramp down).

Tolerated differences between results:

Whatever the maximum permissible variation between results, each weighing result must not exceed the maximum permissible error for the load in question.
Over the entire measurement range, the result must not exceed the maximum permissible error.

Test condition

The test must be performed 0 to Max weight with 5 steps in the ramp up and with a symmetrical descent (weight and load) back to 0.

Test acceptance criterion:

The error measured for each of the 5 steps must not exceed the MPE.

Note:

- EN45501 §3.8
[MDT L-35773, Should Have, Draft]

6.5.1.2 - Digital indication subject to overload.

Removing or depositing an overload equal to 1.4 times the actual scale interval, i.e. 1.4 * 100 = 140 g, on the instrument in equilibrium without impact, must unambiguously modify the indication.

Note:

- EN45501 §3.8.2.2
- For user
[MDT L-35774, Should Have, Draft]

6.5.1.3 - Effect of temperature on zero load indication

The zero or near-zero indication must not vary by more than one verification step for an ambient temperature difference of 5°C.

Note:

- EN45501 §3.9.2.3
[MDT L-35775, Should Have, Draft]

6.5.1.4 - Creep

For any load held on an instrument, the difference between the indication obtained immediately after the load has been deposited and the indication observed during the following 30 min must not exceed 0.5 e, i.e. 50g.

However, the difference between the indication obtained after 15 min and that obtained after 30 min must not exceed 0.2 e, or 20g.

If these conditions are not met, the difference between the indication obtained immediately after the load has been deposited on the instrument and the indication observed during the following four hours must not exceed the absolute value of the maximum error tolerated at the load applied.

Note:

- EN45501 §3.9.4.1 [MDT L-35776, Should Have, Draft]

6.5.1.6 - Durability

The error in durability due to wear and tear must not exceed the absolute value of the maximum tolerated error.

Note:

- EN45501 §3.9.4.3
[MDT L-35777, Should Have, Draft]

6.5.1.6 - Humidity conditions

The product must satisfy relative humidity conditions of 85% at the maximum value of the temperature range.

Note:

- EN45501 §5.3.2 [MDT L-35778, Should Have, Draft]

6.5.1.7 - Measuring weight on the rail

It must be possible to measure the weight correctly along the entire length of the rail (curvature...)

[MDT L-35779, Should Have, Draft]

6.5.2 Scale status

6.5.2.1 - Out of range

The product must be able to display the Out of range status calculated from the displayed weight.

- Minimum Patent Weight 13 kg

- Max : max+ 9e

PAR RAPPORT A LA TARE -> TBD [MDT L-35780, Should Have, Draft]

6.5.2.2 - Return zero status

The product must be able have the "Zero accuracy" status when the weight displayed is +/- 14 e = 25 g.

[MDT L-35781, Should Have, Draft]

6.5.2.3 - Stability status

The product must be able to inform about the Stability status.

TBD.

[MDT L-35782, Should Have, Draft]

6.5.2.4 - Tilt status

The product must be able to inform about the Tilt status.

- Tilt is correct: when the angle of the measuring device is less than TBD

- Tilt not correct: otherwise.

[MDT L-35783, Should Have, Draft]

6.5.3 Scale Calibration and verification Process

6.5.3.1 - Scale calibration

The product shall be able to do an OIML scale calibration.

- PAS MAX / 2 -> 100 Kg

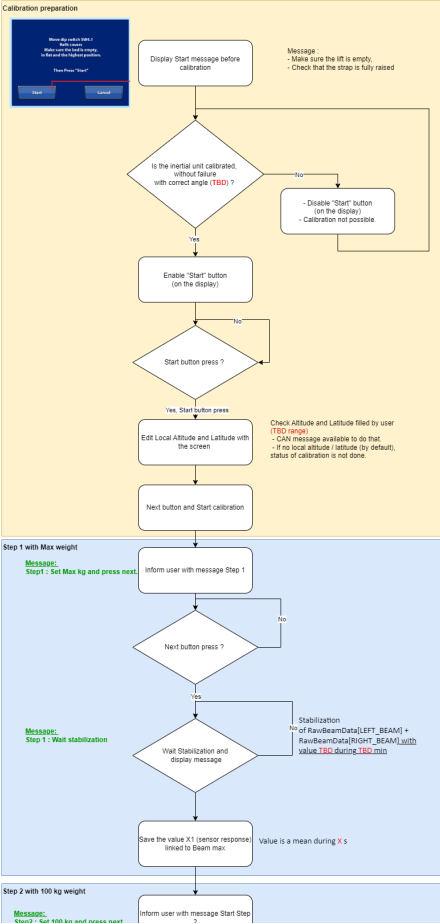
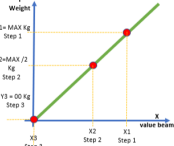
$$y = \text{beam_constant} * x + \text{beam_offset}$$

$$y = W \text{ weight (Eg)}$$

$$x = \text{Value beam (Eg = 92)}$$

$$\text{beam_constant} = (Y1 - Y3) / (X1 - X3)$$

$$\text{beam_offset} = Y1 - (\text{beam_constant} * X1)$$



Enter Calibration SDO 0x3041

Read PDO 189 0x01 CALIBRATION STARTED

Read PDO 189 0x02 STEP 1 - ADD WEIGHT

Next SDO 0x3041

Read PDO 189 0x03 wait stabilization

Read PDO 189 0x04 Add next weight (step 2)

0x3041 0 0 0 23 41 30 00 00 00 00

0x3042 0 0 0 40 41 30 00 00 00 00

189 0 0 0 8 00 00 00 00 04 20 70 00

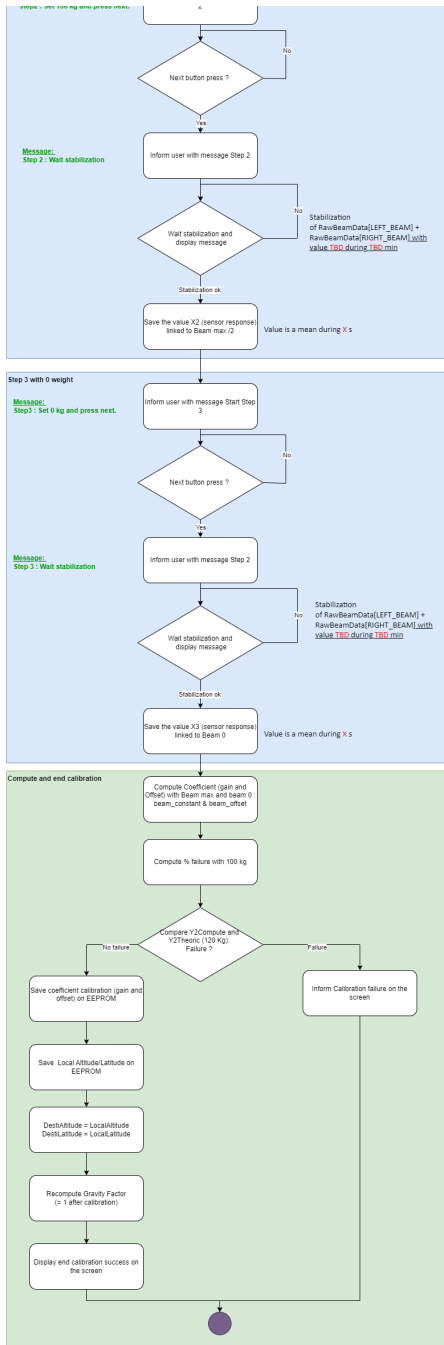
189 0 0 0 8 00 00 00 00 00 00 70 20

0x3041 0 0 0 23 41 30 00 00 00 00

0x3042 0 0 0 40 41 30 00 00 00 00

189 0 0 0 8 00 00 00 00 04 30 50 00

189 0 0 0 8 00 00 00 00 04 40 70 00



Note:-

Calibration will only be done with the Service tool

[MDT.L-35794, Should Have, Draft]

6.5.3.2 - Calibration and safe working load.

Calibration must be possible for each Safe working load.

Consequently, the "maximum" weight of the first calibration step is the value of the product's safe working load.

Note:-

- 7 SWL = 7 maximum calibration

[MDT.L-35785, Should Have, Draft]

6.5.3.3 - Altitude and latitude of destination.

Product shall have the ability to set or retrieve destination altitude and latitude information for use with the OIML scale.

Note:-

- Read on GUI / Service tool

- Write with service tool.

[MDT.L-35786, Should Have, Draft]

6.5.3.4 - Gravity constant G.

The product must be able to calculate and retrieve (for display) the G constant from destination altitude and latitude and local altitude and latitude.

This G constant must be taken into account when calculating the scale's OIML weight.

The product must be able to display the G interval.

Note:-

- Compute of G is : $G = 9.780318 * (1 + (0.0053024 * \sin(\text{LatitudeDestination} * 3.1415927 / 180) * \sin(\text{LatitudeDestination} * 3.1415927 / 180))) + (0.0000058 * (\sin(2 * \text{LatitudeDestination} * 3.1415927 / 180) * \sin(2 * \text{LatitudeDestination} * 3.1415927 / 180))) + 0.000003085 * \text{LatitudeDestination}$

- Range variation is : $[(\text{MaxWeight} * \text{Tolerance}) / G / \text{MaxWeight} * (\text{MaxWeight} * \text{Tolerance}) / G / \text{MaxWeight}]$

with OIML Tolerance -> 1/3 e = 0.033.

[MDT.L-35787, Should Have, Draft]

6.5.3.4 - Scale verification.

It must be possible to verify the lift's OIML scale with a scale display weight with a details e (= 100g)

Note:-

Scale verification must be done on a Service Tool and on Hand remote Screen.

On Hand remote and Service tool, weight must be easily displayed/switched on User mode or Technician mode.

[MDT.L-35788, Should Have, Draft]

6.5.3.4 - Scale verification date.

The product must be able to edit and save the OIML scale verification date.

Note:-

- This will be done on the GUI (read and write) and on the service tool (read and write).

- The verification date format is day, month, year [MDT.L-35789, Should Have, Draft]

6.5.3.7 - Calibration and verification date.

When a calibration is carried out and completed in success, the verification date must be deleted (product = unverified). [MDT.L-35790, Should Have, Draft]

6.5.3.4 - Calibration interface.

Product shall have the interface to do a calibration.

Note:-

Calibration will be done on Service tool and not on the GUI.

[MDT.L-35791, Should Have, Draft]

679 0 0 8 23 41 30 00 03 00 00 00
5F9 0 0 8 60 41 30 00 00 00 00 00

189 0 0 8 00 00 00 00 04 50 00 00

189 0 0 8 00 00 00 00 04 60 70 00

679 0 0 8 23 41 30 00 03 00 00 00
5F9 0 0 8 60 41 30 00 00 00 00 00

189 0 0 8 00 00 00 00 04 70 70 00

6.5.4 Saved Weight
6.5.4.1 - Save Weight process.
The product shall be able to save the Displayed Weight.
In case of already patient weight saved, the product shall be able to erase previous Weight (and replace it with new weight)

Requirements for saving a weight:

- Hoist angle must be correct
- The weight must be stable
- No technical errors on the scale (sensor, communication...)
- Weight must be between min and max. Weight out of weighing capacity : Out of range scale (max + 9e or min). While on saving weight screen, the scale shall indicate if the Applied Weight is below the Minimum Patient Weight (13 kg) for the lift.

[MDT L-35792,  Should Have,  Draft]

6.5.5 Zero/Tare process
6.5.5.1 - Product and Tare process.
The product shall only be able to zero/tare the product Scale when the product is without patient.
Repeated operation of a tare device is permitted.

Note:

- EN45501 §4.6.10 [MDT L-35793,  Should Have,  Draft]

6.5.5.2 - Tare process.
The product shall be able to tare the OIML Scale.

Requirements for taring:

- Hoist angle must be correct
- The weight must be stable
- No technical errors on the scale (sensor, communication...)
- Weight must be between minTare and maxTare.

[MDT L-35794,  Should Have,  Draft]

6.5.5.3 - Tare/Zero performance.
Whatever the tare, the product must be able to return to zero with the associated tolerance.

The deviation back to zero, once the indication has stabilized, after removal of any load that has been held on the instrument for thirty minutes, must not exceed 0.5 e, i.e. 50 g.

In addition, after returning to zero from any load greater than Max and immediately switching to the lowest weighing range, the indication near zero must not vary by more than e for the next 5 min.

Note:

- EN45501 §3.5.3.3 [MDT L-35795,  Should Have,  Draft]

6.5.5.4 - Tare process and maximum value.
The effect of any zeroing device must not alter the maximum range of the instrument.

The total effect of zeroing devices and the zero hold device must not exceed 4% of the Maximum range (200 kg) -> 8 kg, with the effect of the initial zeroing device not exceeding 20%.

We need to be able to hook something to the end of the strap, which must weigh a maximum of 30 Kg (this should allow us to measure up to 500 Kg). For calibration (only the hanging system)
Tare/zero values below -30 Kg (< 20% max) are prohibited.

Note:

- EN45501 §4.5.1
- TODO : lien avec le terrain / Service. Comment ils ont l'information ? -> A inclure dans la doc technicien. Impact aussi sur l'indus (choix du dispositif). NMI -> Doc à disposition des vérificateurs
- Delete after

4.5.1 Effet maximal

L'effet d'un dispositif de mise à zéro quelconque ne doit pas modifier la portée maximale de l'instrument.

L'effet total des dispositifs de mise à zéro et du dispositif de maintien du zéro ne doit pas dépasser 4 % de la portée maximale, l'effet du dispositif de mise à zéro initiale ne devant pas dépasser 20 %. Cette disposition ne concerne pas les instruments de classe IIII, sauf s'ils sont utilisés pour des transactions commerciales.

Une étendue plus large est autorisée pour le dispositif de mise à zéro initiale si l'instrument satisfait à 3.5, 3.6, 3.8 et 3.9 pour toute charge compensée par ce dispositif dans l'étendue spécifiée.

4.5.1 Effet maximal

L'effet d'un dispositif de mise à zéro quelconque ne doit pas modifier la portée maximale de l'instrument.

L'effet total des dispositifs de mise à zéro et du dispositif de maintien du zéro ne doit pas dépasser 4 % de la portée maximale, l'effet du dispositif de mise à zéro initiale ne devant pas dépasser 20 %. Cette disposition ne concerne pas les instruments de classe IIII, sauf s'ils sont utilisés pour des transactions commerciales.

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Une étendue plus large est autorisée pour le dispositif de mise à zéro initiale si l'instrument satisfait à 3.5, 3.6, 3.8 et 3.9 pour toute charge compensée par ce dispositif dans l'étendue spécifiée.

4.6.2 Echelon

L'échelon d'un dispositif de pesage de la tare doit être égal à l'échelon de l'instrument pour toute valeur donnée de la charge.

4.6.4 Plage de fonctionnement

Le dispositif de tare doit être tel qu'il ne puisse pas être utilisé à ou en deçà de son effet zéro, ou au-delà de son effet maximal indiqué.

[MDT L-35796,  Should Have,  Draft]

6.5.5.4 - Usage Maximum Tare.
The product must have a maximum possible tare weight of 40 kg.
This information must be included in the user documentation.

Note:

- The tare is subtractive
- EN45501 §3.5.3.4
- Delete after

3.5.3.4 Dispositif de pesage de la tare

Les erreurs maximales tolérées sur un dispositif de pesage de la tare sont, pour toute valeur de tare, les mêmes que celles tolérées sur l'instrument pour la même valeur de charge.

4.6.6 Dispositifs soustractifs de tare

Lorsque l'utilisation d'un dispositif soustractif de tare ne permet pas de connaître la valeur du reliquat de l'étendue de pesage, un dispositif doit interdire l'emploi de l'instrument au-delà de sa portée maximale ou signaler que cette portée est atteinte.

[MDT L-35797,  Should Have,  Draft]

6.5.5.6 - Zero et tenue du zero Accuracy

After zeroing, the influence of the zero deviation on the weighing result must not exceeds 0,25 e = 25g within **TBD** min.

Note :
- EN45501 §4.5.2 and 4.6.3 [MDT L-35798,  Should Have,  Draft]

6.5.6 Scale Product integration

6.5.6.1 Electrical integration

6.5.6.1-1 - Using the scale in the lift

When using the scale, the product must disconnect the charger/any power supply other than the battery.

Note :
- Specification in accordance with using the lift in battery -> SSRD4495
[MDT L-35804,  Should Have,  Draft]

6.5.6.1-2 - Electrical power supply

The product must comply with the recommendations for power supply defined in the standard EN45501 §3.9.3
Input voltage must not affect measurement or weight calculation

Note :
- EN45501 §3.9.3 / A.5.4
- Scale Lift is used only in DC mode (input of the scale)
[MDT L-35805,  Should Have,  Draft]

6.5.6.1-3 - Electrical integration

The product must comply electronically with everything in the standard Chapter Appendix B (OIML D11 / IEC 61000-4-4 / IEC 61000-4-2 / IEC 61000-4-5 / IEC 61000-4-6).

Note :
- EN45501 §5.5.3 [MDT L-35806,  Should Have,  Draft]

6.5.6.1-4 - Electronic Scale test

The product must satisfy all applicable tests in appendix B of standard EN45501 (except B 3.7) and EN45501 §5.3.4.

Note :
- Already included ISO61000-4 (no new test)

Note :
- EN45501 §5.3.4
[MDT L-35807,  Should Have,  Draft]

6.5.6.2 Software integration

6.5.6.2-1 - Initialization

During initialization, there must be no indication or transmission of the weighing result.

Note :
- EN45501 §5.3.5
- Transmission is done with CAN (particular value while init is not completed). [MDT L-35808,  Should Have,  Draft]

6.5.6.2-2 - Impact of external tools on scale

The Service tool, or any other external tool, must not have any impact on the weight measurement or display.

Note :
- EN45501 §5.3.6.1 / 5.3.6.2
- Electronical CAN with or without External tool / Weight PDO is not sent with Service Tool. [MDT L-35809,  Should Have,  Draft]

6.5.6.2-3 - Scale software version and identification

The product must be able to give or display the software version of the OIML Scale part.

Note :
- EN45501 §5.5.1
[MDT L-35810,  Should Have,  Draft]

6.5.6.2-4 - Software documentation

Software documentation must be provided to the OIML Notify body, containing all the information required to review the software.

Note :
- EN45501 §G2.1
- SRS / S2D Software documentation.
[MDT L-35811,  Should Have,  Draft]

6.5.6.2-5 - Scale and memory

Software memory must have sufficient storage capacity for the intended purpose.

When saved, the data must include all the information required to recall a previous weighing operation:

- decimal point(s);
- unit(s) of measure (can be encoded);
- identification of stored data
- a checksum or other signature of the stored data.

Note

- EN45501 §5.5.3
- No decimal point because saved in g unit on the Memory / unit(s) of measure & identification of stored data describe on the SRS EEPROM
- CRC will be done in software on scale memory EEPROM (see SRS) [MDT L-35812,  Should Have,  Draft]

6.5.6.2-6 - OIML Software integration

Scheduling and runtime of the measuring process shall not be influenced by not legally relevant software [MDT L-35813,  Should Have,  Draft]

6.5.6.2-7 - Scale Parameter save

The following scale parameters shall be stored in a nonvolatile manner:

- Saved Weight
- Calibration parameters
- Current Zero weight
- Scale Error Codes

[MDT L-35814,  Should Have,  Draft]

6.5.6.2-8 - Scale and date

The date used to memorize the scale records needs to be secure.

In case of failure (battery failure, battery level too low) the user needs to be clearly informed before about a failure of the battery managing the date and hour.
The error must be enabled until a new date has been entered. [MDT L-35815,  Should Have,  Draft]

6.5.6.2-9 - Software and IEC 62304

The software must be compatible and tested in accordance with IEC 62304 (tests and associated documentation). [MDT L-35816,  Should Have,  Draft]

6.5.6.3 Mechanical integration

6.5.6.3-1 - Mechanical integration

The scale module hardware board must be closed.

Note :
- EN45501 §G2.2.1 [MDT L-35817,  Should Have,  Draft]

6.5.6.3-2 - Seal between load cell and support

The mechanical attachment of the load cell (screw) to its support must be protected by a seal.

[MDT L-35818,  Should Have,  Draft]

6.5.6.4 Failures

6.5.6.4-1 - Failures on scale

The product must be able to report potential errors on the scale (reported on a screen or on a technician's tool).

TBD

Note :
- EN45501 §4.1.2.2 and 5.1.1 [MDT L-35819,  Should Have,  Draft]

6.5.6.4-2 - Failure scale and weight

When a significant fault has been detected (a scale error), the scale functionality must shut down and no longer display weights.

As long as the error is active, it should be visible to the user when he/she tries to use the scale.

Note :
- EN45501 §5.2 [MDT L-35820,  Should Have,  Draft]

6.5.6.5 Security Scale

6.5.6.5-1 - Security scale for intrusion or modification

The product must have means of protection on the components.

The product's software must include this protection (software protection), with the possibility of winding up an intrusion counter, or an intrusion test (available with a technician tool).

This applies to:

- calibration commands (calibration coef + factory zero) done or attempt
- altitude or latitude adjustment (destination)
- any software update.
- Scale memory erase

The product must maintain a history of any intrusion.

Note :
- EN45501 §4.1.2.4, §5.5.1
[MDT L-35821,  Should Have,  Draft]

6.5.6.5-2 - Installation of seats

The product must not have replaced load cells without breaking the seal.

The product must be sealed for any access to or modification of the load cells.

Note :

- EN45501 §4.1.2.4
[MDT L-35822,  Should Have,  Draft]

6.5.6.5-3 - Data protection.

Transmission or storage of patient weight data must be protected against accidental or intentional modification.

When saving, a checksum must be applied to the memory write.

Note :

- EN45501 §5.5.3.3
- On software : CRC on memory + CRC CAN.
- [MDT L-35823,  Should Have,  Draft]

6.5.6.5-4 - Software security.

The scale software must be protected against external (pirate) updates. If this is not the case, the scale software must not be able to start if the code is falsified (CRC fail).

Note :

- EN45501 §G2.2.2
- Le logiciel au niveau cybersécurité sera testé régulièrement (timing défini dans le SPMP...)
- Software impact: use of CRC on LCB Software, Cybersecurity for LCM Software. SRS on version consistency between LCB and LCM and error generation otherwise.
- [MDT L-35824,  Should Have,  Draft]

6.5.6.5-5 - Confidential data.

The product must never, without being secured, record a weight associated with a patient ID.

Note :

- Software impact: In LCB no patient identifier / On the LCM side, always cyber security (no memory reading).
- WELMEC 7.2 / 8.2 T5
- [MDT L-35825,  Should Have,  Draft]

6.5.7 Scale test and verification

6.5.7-1 - Creep test.

The product must be able to withstand a creep test as specified in Annex A EN45501 §Annex A A.4.11.1.

Note :

- EN45501 §Annex A
- Test done on development. [MDT L-35826,  Should Have,  Draft]

6.5.7-2 - Standard Weight for verification.

Standard weights or masses used for type examination or verification of an instrument must comply with the metrological requirements of OIML Recommendation R 111

Note :

- EN45501 §3.7
- EN45501 §Annex A
- [MDT L-35827,  Should Have,  Draft]

6.5.7-3 - Ramp up/down test and weighing test.

The product must undergo a ramp up/down test.

The error close to the maximum range must not exceed the maximum tolerated error, and the absolute value of the difference between the errors obtained for all the measurements taken in pairs must not exceed the greater of half the verification scale interval or half the absolute value of the maximum tolerated error.

Note :

- EN45501 §5.3.3 and 5.4.2
- OIML R76-1 A.4.4 / A.4.8
- EN45501 §Annex A
- Test done on production, development and on field.
- [MDT L-35828,  Should Have,  Draft]

6.5.7-4 - Repeatability .

The product must be able to measure the same mass several times (5 times) and each time the value must be consistent.

The measurement must be close to 80% of the maximum.

You must wait for the return to zero between measurements without saving the value. The max values will be saved (not the return to zero values).

Note :

- EN45501 §3.6
- EN45501 §Annex A
- OIML R76-1 A.4.10 / R76-1 3.6.1

[MDT L-35829,  Should Have,  Draft]

6.5.7-5 - Zeroing accuracy test.

The product must be able to do Zeroing accuracy test.

Note :

- OIML R76-1 A4.2.3
- EN45501 §Annex A
- Test done on production, development and on field.

[MDT L-35830,  Should Have,  Draft]

6.5.7-6 - Scale indication limit test.

The product must be able to do Zeroing accuracy test.

Note :

- OIML R76-1 4.2.3 page 32)
- Test done on production, development and on field [MDT L-35831,  Should Have,  Draft]

6.5.7-7 - Tare Accuracy Test

The product must be able to do test a Tare Accuracy Test.

Note :

- OIML R76-1 A.4.6.2 / R76-2 §9
- EN45501 §Annex A
- Test done on production, development and on field [MDT L-35832,  Should Have,  Draft]

6.5.8 Scale display

6.5.8.1 Continuous weight

6.5.8.1-1 - Continuous weight display .

The primary user control Integrated Scale user interface shall display a continuously-updating weight measurement. [MDT L-35839,  Should Have,  Draft]

6.5.8.1-2 - Digital indication format

- Any decimal part must be separated from the corresponding integer part by a decimal comma, with one digit to the left of the decimal point and all digits to the right.
- The decimal point must be aligned with the bottom of the digits (e.g. 0.3 kg).
- On an analog indicating device, the zones on either side of zero must be distinguished by the “+” (in case f positive value) and “-” signs. Minimum Displayed Scale Value: indication below zero with minus sign possible when a tare device is in operation.

Note :

- EN45501 §4.2.2.2 [MDT L-35840,  Should Have,  Draft]

6.5.8.1-3 - Increment display.

The primary user control EN45501 Integrated Scale user interface shall display weight in increments of 0.1 kg by default. [MDT L-35841,  Should Have,  Draft]

6.5.8.1-4 - Indication limit.

Max value: Indication must be made impossible above Max + 9 e.

Min value : An indication below zero (with minus sign) is possible when the tare device is active and the tare load has been removed from the load receptor. It is also possible for negative values of up to -20 d = -2 kg may be displayed, even if the tare device is not active.

TBD

Note :

- The values above the Maximum Scale Capacity are for margin and to ease testing
- Reference EN45501 § 4.2.3 Limits of Indication for 0.9 kg. It is based on 9e where e is the verification scale interval. The value of e is given in the EN45501 scale section of this document.
- Note: Reference EN45501 Limits of Indication
- [MDT L-35842,  Should Have,  Draft]

6.5.8.1-5 - Unit.

The scale user interface shall display the units (kg) of measurement for weight displayed on the GUI (EN45501 §2.1).

The product must also be able to display the weight in Pounds while retaining the weight in kg (configured by user configuration).

Note :

Configuration to have or no pounds is done thanks to the Service tool and configuration file.

[MDT L-35843,  Should Have,  Draft]

6.5.8.1-6 - Weight display limitation.

The product shall be able to display the weight only if LRI is in Recommended LRI Position:

- Hoist angle must be correct -> See ELV-4279
- No technical errors on the scale (sensor, communication, beam failure...)
- Weight must be between min and max. -> See ELV-4280

The scale shall display a message “---” instead of a weight if the product is unable to measure or display the Weight [MDT L-35844,  Should Have,  Draft]

6.5.8.2 Scale Normative display

6.5.8.2-1 - Display normative information

The following markings shall be displayed either on or near the EN45501 scale user interface exactly as shown below when the continuously updated scale is displayed:

- Max (Maximum Scale Capacity)
- Min
- e
- Class

Note :

- For min and max, spaces before and after the “v” may be removed.
- No additional symbols can be added after any of the markings including “=”, “1” and “:”.
- Reference EN45501 Presentation of descriptive markings [MDT L-35845,  Should Have,  Draft]

6.5.8.2-2 - G Display.

The product shall display the value of G computed and G interval (on user access).

Note :

- See SSRD 4345 about G compute. [MDT L-35846,  Should Have,  Draft]

6.5.8.3 Display status

6.5.8.3-1 - Zero indicator status.

The product shall display the zero indicator with this symbol (>0<) (See ELV-4281 - Return zero status: The product must be able have the “Zero accuracy” status wh...)

Note :

- Reference EN45501 §4.5.5 [MDT L-35847,  Should Have,  Draft]

6.5.8.3-2 - Equilibrium status.

The product shall display Stable Equilibrium status. The product must be able to display if the scale is stabilized or no (See ELV-4873 - Stability status: The product must be able to inform about the Stability status ...).

[MDT L-35848,  Should Have,  Draft]

6.5.8.4 Patient Weight saved process Display

6.5.8.4-1 - Display the saved weight :

The product shall display the most recent saved weight. [MDT.L-35849, (T) Should Have, ✓ Draft]

6.5.8.4-2 - Display saved weight process :

Display Weight saved function:

During the Saved Weight function the user interface shall include the following features:

- Visual message or image telling user to not touch the product. The user control Integrated Scale interface shall provide a visual indication when weight saving is in process, including a "hands off" instruction.
- Product waits the weight stability (see ELV-4873)
- When stability is ok :
 - audible indicator that a weight has been measured and saved
 - Display of saved weight
 - Time & date of the saved weight

Problem to save weight:

In case of issue to saved weight, product must abort the saved weight process.

[MDT.L-35850, (T) Should Have, ✓ Draft]

6.5.8.4-3 - Stability status:

The product must be able to display the Stability status.

[MDT.L-35851, (T) Should Have, ✓ Draft]

6.5.8.4.4 - Display when weight cannot be displayed or measured:

The product must display information when the weight cannot be displayed or measured with an error message indicating the cause.

- In case of no stability (See ELV-4873) during more X s (timeout), the user control Integrated Scale interface shall provide a visual indication that stability is not correct to saved weight.
- In case of hoist angle is not correct, the user control Integrated Scale interface shall provide a visual indication that angle is not correct to display or saved weight.(see ELV-4279)
- In case of technical scale feature (due to sensor, communication...), the user control Integrated Scale interface shall provide a visual indication that scale is on error to display or saved weight.
- In case of scale is out of range, the user control Integrated Scale interface shall provide a visual indication that scale is out of range to display or saved weight. (see ELV-4280)

[MDT.L-35852, (T) Should Have, ✓ Draft]

6.5.8.5 Tare process Display:

6.5.8.5-1 - Display Tare process :

Message Before :

Before Zero the product, the user interface shall provide an information like:

- "The lift must not be occupied to perform zeroing",
- "Place all standard element before zeroing the lift",
- "Verify lift is with correct sling bar"

AND request confirmation before zeroing the product.

Message during tare proces :

Visual message or image telling user to not touch the product. The user control Integrated Scale interface shall provide a visual indication when tare is in process, including a "hands off" instruction.

Product waits the weight stability (see ELV-4873).

Message after tare:

When stability is ok, Tare process is done on the scale module.

The user interface shall provide an information like tare is done: Scale Zeroed/Tared

Display problem to tare (see SSRD 4958):

In case of issue (stability timeout, scale failure, angle or range) to tare, product must abort the tare process and display the cause.

Note :

Tare / Zero. Quel mot ?

[MDT.L-35853, (T) Should Have, ✓ Draft]

6.5.8.5-2 - Zeroing and Tare :

Product tare and zero are combined. The product must show the "0/T" symbol. [MDT.L-35854, (T) Should Have, ✓ Draft]

6.5.8.6 Technician Scale oiml Display:

6.5.8.6-1 - Technician scale OIML Display :

Product shall have the display for technician:

- Altitude and latitude of destination (GUI: read / Interface Service tool: read & write)
- Altitude and latitude of local (GUI: read / Interface Service tool: read & write)
- G computed and G interval (GUI: read / Interface Service tool: read)
- Current Weight computed with Technician mode (see OIML scale) and User mode (GUI: read / Interface Service tool: read)
- Possibility to read/write OIML verification date (GUI: read & write / Interface Service tool: read & write)

[MDT.L-35855, (T) Should Have, ✓ Draft]

6.6 Power management of the Hoist

6.6-1 - **Not to be used**

[MDT.L-35856, (T) Should Have, ✓ Draft]

6.6-2 - A utiliser [MDT.L-35857, (T) Should Have, ✓ Draft]

6.6-3 - A utiliser [MDT.L-35858, (T) Should Have, ✓ Draft]

6.6-4 - A utiliser [MDT.L-35859, (T) Should Have, ✓ Draft]

6.6.1 General power operation of the Hoist

6.6.1-1 - When battery charges on In-Rail Charging or End of Rail battery chargers, the electrical function (High_Low, Emergency lowering, electrical movements or function display on user control) on& lateral movement of the Hoist shall:

1. Stop the battery charge to prevent to draw current from any connected charging power supply
2. Use the battery power to perform the movement
3. Permit associated electrical movement

[MDT.L-35868, (T) Should Have, ✓ Draft]

6.6.1-2 - When battery charges through Hand Control chargers, the electrical function (High_Low, Emergency lowering, electrical movements or function display on user control) of the Hoist shall:

1. Stop the battery charge to prevent to draw current from any connected charging power supply
2. Use the battery power to perform the movement
3. Permit associated electrical movement

[MDT.L-35869, (T) Should Have, ✓ Draft]

6.6.1-3 - While there is battery charged, the Hoist shall remain operational in the event:

1. Loss of AC mains power
2. Interruption of AC mains power
3. Restoration of AC mains power

[MDT.L-35870, (T) Should Have, ✓ Draft]

6.6.1-4 - The Emergency Stop activation or reset shall cause no interruption to charging of the Hoist. [MDT.L-35871, (T) Should Have, ✓ Draft]

6.6.2 Charging systems

6.6.2-1 - When charged through the End of rail or Hand Control, the interface between the battery and power supply shall integrate **10 (TBC)** connections/disconnections min per day combined with 3 years of use without impact on battery performance (cycle numbers ELV-1651 & SOH of **80% min (TBC)**).

[MDT.L-35872, (T) Should Have, ✓ Draft]

6.6.2.1 In-Rail charging system

6.6.2.1-1 - The battery of the Hoist shall integrate the possibility to be charged by In-Rail Charging System. [MDT.L-35876, (T) Should Have, ✓ Draft]

6.6.2.1-2 - When charged by In-Rail Charging System, the battery of the Hoist shall charge from 0 % to 100 % in 16 hours max. [MDT.L-35877, (T) Should Have, ✓ Draft]

6.6.2.2 Hand Control charging system

6.6.2.2-1 - The Hoist battery shall integrate the possibility to be charged through the Hand Control. [MDT.L-35878, (T) Should Have, ✓ Draft]

6.6.2.2-2 - When charged through the Hand Control, the battery of the Hoist shall charge from 0 % to 100 % in 6 hours max. [MDT.L-35879, (T) Should Have, ✓ Draft]

6.6.2.3 End of Rail charging system

6.6.2.3-1 - The Hoist battery shall integrate the possibility to be charged by the Multi-station through the Hoist Multi-connector. [MDT.L-35880, (T) Should Have, ✓ Draft]

6.6.2.3-2 - When charged by the End of Rail charging station, the battery of the Hoist shall charge from 0 % to 100 % in 6 hours max. [MDT.L-35881, (T) Should Have, ✓ Draft]

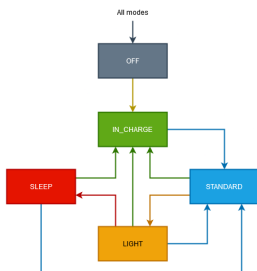
6.6.3 Power modes and transitions

6.6.3.1 Power modes

6.6.3.1-1 - To save power consumption, the Hoist shall have Power Modes:

- ELV-4765 - Off Power Mode
- ELV-4770 - In-Charge Power Mode
- ELV-4769 - Standard Power Mode
- ELV-4767 - Light Power Mode
- ELV-4768 - Sleep Power Mode

working following below diagram:



[MDT.L-35884, (T) Should Have, ✓ Draft]

6.6.3.1.1 Behavior in Off Power Mode

6.6.3.1.1.1 - While in **ELV-4765 - Off Power Mode**, the Hoist shall disable the following features:

1. Ready to use
2. Screen hand remote
3. Membrane hand remote
4. Scale
5. SCRM connectivity
6. Emergency status
7. Vertical Motor movements
8. Dynamic Rails movements
9. Battery management
10. Service

[MDT.L-35890,  Should Have,  Draft]

6.6.3.1.2 Behavior in In-Charge Power Mode

6.6.3.1.2.1 - When in **ELV-4770 - In-Charge Power Mode**, the Hoist shall enable the following features with their own management:

1. Ready to Use
2. Screen hand remote
3. Membrane hand remote
4. SCRM connectivity
5. Emergency function
6. Battery management
7. **Service (TBC)**

and the following features are disabled:

8. Scale
9. Vertical Motor movement
10. Dynamic Rails movement

[MDT.L-35891,  Should Have,  Draft]

6.6.3.1.3 Behavior in Standard Power Mode

6.6.3.1.3.1 - When in **ELV-4769 - Standard Power Mode**, the Hoist shall enable all features with their own management:

1. Ready to Use
2. Screen hand remote
3. Membrane hand remote
4. Scale
5. SCRM connectivity
6. Emergency function
7. Battery management
8. Vertical Motor movement
9. Dynamic Rails movement
10. **Service (TBC)**

[MDT.L-35892,  Should Have,  Draft]

6.6.3.1.4 Behavior in Light Power Mode

6.6.3.1.4.1 - When in **ELV-4767 - Light Power Mode**, the Hoist shall disable the following features:

1. Ready to use
2. Screen hand remote
3. Membrane hand remote
4. Scale
5. Vertical Motor movements
6. Dynamic Rails movements

and

7. SCRM connectivity feature is enabled but shall reduce its activity
8. Battery management is enabled
9. emergency function is enabled
10. **Service** functions is enabled

[MDT.L-35893,  Should Have,  Draft]

6.6.3.1.5 Behavior in Sleep Power Mode

6.6.3.1.5.1 - The Hoist, when in **ELV-4768 - Sleep Power Mode**, shall disable the following features:

1. Ready to use
2. Screen hand remote
3. Membrane hand remote
4. Scale
5. SCRM connectivity
6. Vertical Motor movements
7. Dynamic Rails movement
8. **Service**

and

9. Battery management is enabled
10. Emergency functions is enabled

[MDT.L-35894,  Should Have,  Draft]

6.6.3.2 Power mode transitions

6.6.3.2.1 - Excepted for ELV-5032, the Hoist shall transition between power modes in **less than 1.5s (TBC)** [MDT.L-35895,  Should Have,  Draft]

6.6.3.2.2 - While in **ELV-4769 - Standard Power Mode**, **ELV-4767 - Light Power Mode** or **ELV-4768 - Sleep Power Mode**, when a charging power is available via the **ELV-2436 - Hand Control Charging System** and when there is no **ELV-4784 - User Request**, the Hoist shall transition to **ELV-4770 - In-Charge Power Mode** [MDT.L-35896,  Should Have,  Draft]

6.6.3.2.3 - While in **ELV-4769 - Standard Power Mode**, **ELV-4767 - Light Power Mode** or **ELV-4768 - Sleep Power Mode**, when a charging power is available via the **ELV-2438 - Multi Station Charging System** and when there is no **ELV-4784 - User Request**, the Hoist shall transition to **ELV-4770 - In-Charge Power Mode**.

VC: I feel like a **Lateral Movement** should stop the battery charge (to protect the electrical contacts from sparks damage) but not make the system switch to **Standard Power Mode** or prevent it from switching to **In-Charge Power Mode** [MDT.L-35897,  Should Have,  Draft]

6.6.3.2.4 - While in **ELV-4769 - Standard Power Mode**, **ELV-4767 - Light Power Mode** or **ELV-4768 - Sleep Power Mode**, when a charging power is available via the **ELV-1073 - In-Rail Charging System** and when there is no **ELV-4784 - User Request** for **more than 5 min**, the Hoist shall transition to **ELV-4770 - In-Charge Power Mode**.

VC: I feel like a **Lateral Movement** should stop the battery charge (to protect the electrical contacts from sparks damage) but not make the system switch to **Standard Power Mode** or prevent it from switching to **In-Charge Power Mode** [MDT.L-35898,  Should Have,  Draft]

6.6.3.2.5 - While in **ELV-4770 - In-Charge Power Mode**, when there is a **ELV-4784 - User Request** or when the charging over is disconnected, the Hoist shall transition to **ELV-4769 - Standard Power Mode**.

VC: Since **Lateral Movement** only interrupts the battery charging in **IRC** or **EOR** systems, there is no need to switch to **Standard Power Mode**. [MDT.L-35899,  Should Have,  Draft]

6.6.3.2.6 - While in **ELV-4767 - Light Power Mode** or **ELV-4768 - Sleep Power Mode**, when there is a **ELV-4784 - User Request** or **Lateral Movement**, the Hoist, out of the user control display of the Hoist defined by NP051278 ELV-6034, shall transition to **ELV-4769 - Standard Power Mode** in less than **1 second (TBC)** [MDT.L-35900,  Should Have,  Draft]

6.6.3.2.7 - While in **ELV-4769 - Standard Power Mode**, when there is no **ELV-4784 - User Request** or **ELV-843 - Lateral Movement** for more than 10 min, the Hoist shall transition to **ELV-4767 - Light Power Mode**. [MDT.L-35901,  Should Have,  Draft]

6.6.3.2.8 - While in **ELV-4767 - Light Power Mode**, when there is no **ELV-4784 - User Request** or **ELV-843 - Lateral Movement** for more than 24h, the Hoist shall transition to **ELV-4768 - Sleep Power Mode**. [MDT.L-35902,  Should Have,  Draft]

6.6.3.2.9 - While in **ELV-4770 - In-Charge Power Mode** or **ELV-4769 - Standard Power Mode**, when the battery **ELV-4792 - State of Charge (SoC)** drops below **2% (TBC)** or when a specific message from technician tool is received, the Hoist shall transition to **ELV-4765 - Off Power Mode**.

VC: Can the electronics/software systems swap to **Off Mode** even if a power source is connected ? [MDT.L-35903,  Should Have,  Draft]

6.6.3.2.10 - While in **ELV-4767 - Light Power Mode** or **ELV-4768 - Sleep Power Mode**, when the battery **ELV-4792 - State of Charge (SoC)** drops below **2%**, the Hoist shall transition to **ELV-4765 - Off Power Mode**. [MDT.L-35904,  Should Have,  Draft]

6.6.3.2.11 - While in **ELV-4765 - Off Power Mode**, when a charging power is detected, the Hoist shall transition to **ELV-4770 - In-Charge Power Mode** and initiates its startup sequence. [MDT.L-35905,  Should Have,  Draft]

6.6.4 Battery performances

6.6.4.1 - Following the "Cycle of ELV-4054", battery 100 % charged, with an State of Health (SOH) level of 80 %, per Max Load configuration & for each specific single load cases, the Hoist shall guarantee in excel:

(to change the value of the spreadsheet below, used the excel file in attachment into ELV-4054)

Battery		
Max Load 200 kg		
Load at the CSP	Usage %	Number of cycle
150 kg	65%	80
200 kg	4%	71
Max Load 250 kg		
150 kg	60%	80
250 kg	3%	63
Max Load 300 kg		
150 kg	50%	80
300 kg	3%	55
Max Load 363 kg		
150 kg	40%	80
363 kg	3%	45
Max Load 454 kg		
150 kg	30%	80
454 kg	1%	30

[MDT.L-35906,  Should Have,  Draft]

6.6.4.2 - The battery charge shall manage 3 years of charge/discharge without impact on battery performance (cycle numbers following ELV-1651 & SOH of **80% min (TBC)**) [MDT.L-35907,  Should Have,  Draft]

6.6.4.3 - The Hoist shall calculate the State of Health (SOH) % of the battery i.e. the ratio of real battery capacity / the initial battery capacity. [MDT.L-35908,  Should Have,  Draft]

6.6.4.4 - The Hoist shall provide information of the SOH in a specific menu only accessible by service technician. [MDT.L-35909,  Should Have,  Draft]

6.6.4.5 - After 24 months of storage, the battery of the Hoist shall guarantee a degradation of its max capacity less or equal than 20 %.

VC: max capacity means SOH ? The battery manufacturer states that a battery becomes unusable when SOH goes below 80%, so this spec means the battery must be replaced after 2 years of storage, that's a bit strange. [MDT.L-35910,  Should Have,  Draft]

6.6.4.6 - After 24 months of storage, the Hoist battery shall always be rechargeable. [MDT.L-35911,  Should Have,  Draft]

6.6.5 Battery levels

6.6.5.1 - The Hoist shall transition to Full battery level when the **ELV-4792 - State of Charge (SoC)** is **above 80%** [MDT.L-35912,  Should Have,  Draft]

6.6.5.2 - The Hoist shall transition to High battery level when the **ELV-4792 - State of Charge (SoC)** is **between 50% and 90%** [MDT.L-35913,  Should Have,  Draft]

6.6.5.3 - The Hoist shall transition to Medium battery level when the **ELV-4792 - State of Charge (SoC)** is **between 50% and 30 % allowing 50 % of the cycle number defined by ELV-1651** [MDT.L-35914,  Should Have,  Draft]

6.6.5.4 - When battery charge level shall only achieve 1 complete way up/down cycle with the max load, the Hoist shall transition to Low battery level. [MDT.L-35915,  Should Have,  Draft]

6.6.5.5 - When the remaining battery capacity is lower than 1 complete way up/down cycle with the max load (ELV-4776), the Hoist shall transition to Empty battery level [MDT.L-35916,  Should Have,  Draft]

6.6.6 Power supply coming from Hoist

6.6.6.1 To Dynamic Rails

6.6.6.1-1 - The battery of the Hoist, through multi-Connector, shall supply power to the motor of dynamic rails (turntable, switch). [MDT L-35919,  Should Have,  Draft]

6.6.6.1-2 - Exclusively when an electric dynamic rails user request is request, the Hoist shall supply power to the multi-connector.
[MDT L-35920,  Should Have,  Draft]

6.6.6.1-3 - Where the hoist integrated a multi-connector, when the Hoist powered an electric dynamic rails (turn table or switch rail), the electrical movement of the dynamic rails shall be triggered if and only if the carriage of the Hoist is fully engaged on the fix part of the dynamic rail to avoid shear point. [MDT L-35921,  Should Have,  Draft]

6.6.6.2 To Transfer Motor

6.6.6.2-1 - The Hoist shall provide an interface to supply power to a motorized transfer motor. [MDT L-35922,  Should Have,  Draft]

6.6.7 Safety characteristic of the battery

6.6.7-1 - The battery of the Hoist shall have an internal protection that works independently of the electronic of the IIR if battery is exposed to a critical conditions i.e.:

1. A cannot charge situation due to its low level of charge
2. Over charging
3. To be completed

[MDT L-35923,  Should Have,  Draft]

6.6.7-2 - When dropped from a installation height (see explanation into the context) & table height defined by IEC 62133-2 §7.3.3, the Hoist with the battery shall be protected from leakage or fire hazard to prevent explosion. [MDT L-35924,  Should Have,  Draft]

6.6.7-3 - When dropped from a installation height (see explanation into the context) & table height defined by IEC 62133-2 §7.3.3, the battery installation shall prevent leakage or fire hazard to prevent explosion. [MDT L-35925,  Should Have,  Draft]

6.6.7-4 - The LIR Control Board shall be protected:

1. from a polarity inversion
2. from incompatible battery connection

[MDT L-35926,  Should Have,  Draft]

6.6.7-5 - The Hoist shall:

1. charge the battery with 1 charging system at the time
2. provide the remaining duration to to have a 100% of the battery charged.

VC: Je n'ai pas compris le point 2 (formulation à changer pour être plus clair ?)

[MDT L-35927,  Should Have,  Draft]

6.6.7-6 - The Hoist shall charge the battery if the intended power supply is detected and no electrical movement engaged.

VC: doublet d'autre specs ?

[MDT L-35928,  Should Have,  Draft]

6.6.8 Battery user Feedbacks

6.6.8-1 - The Hoist shall provide a power related visual feedback for:

1. Battery in charge mode
2. Battery charge level
3. Low battery
4. Empty battery
5. Defective battery (see §6.8.1 error management)

VC: Seulement pour la télécommande écran ? Si oui, à préciser. Si non, certaines info ne peuvent pas être affichées (ou pas prévues pour l'instant) sur la télécommande membrane.

[MDT L-35929,  Should Have,  Draft]

6.6.8-2 - When Low battery level (ELV-4776) detected, the Hoist shall

1. Inform by visual indicator ELV-3173
2. While a High_Low key press is detected inform through audible ELV-3222 indicators.

[MDT L-35930,  Should Have,  Draft]

6.6.8-3 - When Empty battery level (ELV-4777) detected, the Hoist shall:

1. Inhibit the up function
2. Permit a complete lowering for the load range
3. Support the storage constraint of ELV-3202
4. Inform by visual ELV-3173
5. While a High_Low key press is detected inform through audible ELV-3222 indicators.

[MDT L-35931,  Should Have,  Draft]

6.7 Maintain the product

6.7-1 - When a software update event pushed to the Hoist, the Hoist shall download software updates if and only if battery has at least 25% capacity remaining **(185)** [MDT L-35932,  Should Have,  Draft]

6.7.1 Set credential

6.7.2 Exchange data (Wifi/bluetooth)

6.7.3 Manage configuration

6.7.4 Diagnose

6.7.5 Calibrate

6.7.6 Manage periodic inspection

6.7.7 Install/Remove soft

6.7.7.1 Software update

6.7.7.1-1 - Software update

The product shall be able to update product software with a technician tool, either wired or wireless when permitted by the product configuration. [MDT L-35942,  Should Have,  Draft]

6.7.8 SCRM

6.7.8.1 General requirement

6.7.8.1-1 - Enable/Disable SCRM option.

The product provides a possibility to enable or disable the Remote Service feature.
The Remote Service feature is disabled by default.

Note:

- Settings on the customer configuration file [MDT L-35947,  Should Have,  Draft]

6.7.8.1-2 - Identification Product and SCRM.

TODO

Requete Certificate with Product ID ? When and how ?

Hypotheses: no impact when Product ID In Certificat

[MDT L-35948,  Should Have,  Draft]

6.7.8.2 Secured Server communication

6.7.8.2-1 - Server connection.

When the Remote Service feature is enabled SCRM, the product shall connect securely to the Remote Service server.

Note:

Done with product information:

- Tenant Information (from Customer configuration file) with Certificate
- Organization Name (from Customer configuration file)
- Facility Name (from Customer configuration file)

[MDT L-35949,  Should Have,  Draft]

6.7.8.2-2 - Secure communication with Server.

The device shall be capable of communicating securely with an trusted remote server using TLS 1.2 with 256-bit encryption as a minimum. [MDT L-35950,  Should Have,  Draft]

6.7.8.2-3 - Server disconnection/reconnection.

The device, with [AEWD] connection test (see note), shall have a recovery process to automatically reconnect the [AEWD] as soon as the connection failure is solved.

The product shall attempt disconnection/reconnection when the product loose the Remote Service Server during more **T60** minutes.

Note:

1) Lost of Server connection can be because of Device failure or Server failure. [MDT L-35951,  Should Have,  Draft]

6.7.8.2-4 - Secure communication :

The product shall support installation of EAP-TLS client certificates and CA certificate through local and remote interfaces.
The SOM shall support updating of existing EAP-TLS client certificates and CA certificates through local and remote interfaces.

Note:

- Certificate update with Service Tool or SCRM.

[MDT L-35952,  Should Have,  Draft]

6.7.8.3 Operations

6.7.8.3.1 Software update

6.7.8.3.1-1 - Update software.

The product shall be able to update product software from SCRM request with/without last manual technician step **(T60)** [MDT L-35958,  Should Have,  Draft]

6.7.8.3.1-2 - Update software process.

When commanded by the Remote Service Server and the product is not processing a SW update, the product shall download the software package.

When the product is processing a SW update, and the product receives a command to update from the Remote Service Server, the product shall:

1. reject the latest SW update request.
2. send a rejection message to the Remote Service Server corresponding to the latest SW update request.

When commanded by the Remote Service Server AND the SOM is not processing a SW update, the SOM shall send a downloading message to Remote Service Server

When the product detects an error in the downloaded software package, the product shall retry attempt to download up to 5 times.

Note :

SRS ?

[MDT L-35959,  Should Have,  Draft]

6.7.8.3.1-3 - Update communication verification.

When the product downloads the software package, the product shall perform a verification of the downloaded software package.

Note:

- Done by SHA [MDT L-35960,  Should Have,  Draft]

6.7.8.3.1-4 - When the SOM fails to download the software package 5 times, the SOM shall send a download failure message to Remote Service Server [MDT L-35961,  Should Have,  Draft]

6.7.8.3.1-5 - When the SOM detects an uncorrupted software package, the SOM shall send a Staging message to Remote Service Server [MDT L-35962,  Should Have,  Draft]

6.7.8.3.1-6 - The SOM shall initiate distributing the SW package to the boards upto 3 times where:

1. Bed is on AC power
2. SOM determines that received SW package is not corrupted. [MDT L-35963,  Should Have,  Draft]

6.7.8.3.1.7 - The SOM shall continue the SW package to the boards available on bed battery power when:

1. SW staging process was initiated
2. Bed is on battery

[MDT.L-35964, Should Have, Draft]

6.7.8.3.1.8 - When the staging of the firmware to a board is interrupted by a power loss of the SOM, the SOM shall re-stage the firmware for the impacted board for upto 3 times, when SOM recovers from power loss. [MDT.L-35965, Should Have, Draft]

6.7.8.3.1.9 - When the SOM fails to stage a board for 3 times the SOM shall send a message to Remote Service Server. [MDT.L-35966, Should Have, Draft]

6.7.8.3.1.10 - When the MCB determines that the staging is consistent, the MCB shall attempt toggling the boards upto 3 times, under the following conditions:

1. AC power is connected, AND
2. Battery charge is >= 50%

[MDT.L-35967, Should Have, Draft]

6.7.8.3.1.11 - When the SOM receives a toggle failure message from MCB, the SOM shall send a message to Remote Service. [MDT.L-35968, Should Have, Draft]

6.7.8.3.1.12 - When the MCB receives a successful toggle message from all the boards, AND if the SOM OS update is pending the MCB shall send a message to the FUD to present the **finalize software installation with OS update** screen. [MDT.L-35969, Should Have, Draft]

6.7.8.3.1.13 - When the MCB receives a successful toggle message from all the boards, the MCB shall send a message to the SOM to inform the Remote Service server of toggle completion. [MDT.L-35970, Should Have, Draft]

6.7.8.3.1.14 - When the MCB updates the boards following a power cycle, the MCB shall display the home screen till the MCB receives a loading success or loading failure message from the SideCom micro controller

[MDT.L-35971, Should Have, Draft]

6.7.8.3.1.15 - When the MCB receives a loading failure message from the SideCom micro controller, the MCB shall

1. send a staging_inconsistent message to SOM
2. create critical error: ERR_MCB_INCONSISTENT_SW.

[MDT.L-35972, Should Have, Draft]

6.7.8.3.1.16 - When MCB receives a successful toggle message AND the software update is pending, the MCB shall send a message to FUD to display a visual indicator on

1. the home screen,
 2. settings screen
- suggesting the software update is pending.

[MDT.L-35973, Should Have, Draft]

6.7.8.3.1.17 - The Remote Service OS Update process on the SOM shall have a demonstrated reliability of 99% with 90% Confidence. [MDT.L-35974, Should Have, Draft]

6.7.8.3.1.18 - When the MCB determines that the Firmware update initiated by the Remote Service is upgraded to the bed, the MCB shall send a message to SOM to inform Firmware Update success to the Remote Server. [MDT.L-35975, Should Have, Draft]

6.7.8.3.1.19 - After the bed restarts to complete the firmware update process, if the SOM succeeds in upgrading itself to the staged SOM application software, the SOM shall send a Firmware Update success message to the Remote Server. [MDT.L-35976, Should Have, Draft]

6.7.8.3.1.20 - After the bed restarts to complete the firmware update process, if the SOM fails to upgrade itself to the staged SOM application software, the SOM shall send a Firmware Update Failure message to the Remote Server [MDT.L-35977, Should Have, Draft]

6.7.8.3.1.21 - The SOM shall support encrypted firmware package for remote upgrade. [MDT.L-35978, Should Have, Draft]

6.7.8.3.2 Configuration update

6.7.8.3.2.1 - Configuration update with SCRM.

The product shall be able to change the customer configuration from SCRM request.

Note:

A customer configuration is an encrypted file, created with Service tool to configure:

- Display configuration (default language, date/time format, technician password, time zone used)
 - Scale configuration (Unit ? Hide patient weight ?..
 - Mobility score format (next release)
 - Connectivity profile (SSID, Password..
 - SCRM and BDHP (next release) parameter
 - Many others configuration (reminder for maintenance expiration, patient name HIPPAA encrypted
- This configuration file can be edited once and then sent to the entire product fleet

[MDT.L-35979, Should Have, Draft]

6.7.8.3.3 Logs

6.7.8.3.3.1 - The product shall be able to send log file to SCRM Server.

Log files could be used for all history requests

Note :

2 possibilities to get log:

- SCRM: Logbook
- Cumulocity : other logs

[MDT.L-35980, Should Have, Draft]

6.7.8.3.3.2 - When the SOM receives a fetch log message from the Remote service, the SOM shall send the SOM logs to RemoteService. [MDT.L-35981, Should Have, Draft]

6.7.8.3.4 Data

6.7.8.3.4.1 - When the SOM contains a stored Remote Service External ID AND the SOM establishes connection with Remote Service, the SOM shall send the following data to the Remote Service:

- Service_Required_Status
 - Active_Error_Codes
 - Access_Point_Information
 - Location_Information
 - WIFI_Configuration
 - Hardware_Information
 - Firmware_Version
 - Software_List
- [MDT.L-35982, Should Have, Draft]

6.7.8.3.4.2 - When the SOM receives an Active_Error_Code, the SOM shall initiate an Inhibit Timer with a resolution of 5s for the detected Active_Error_Code.

When the bed powers UP AND SOM receives an Active_Error_Code, the SOM shall initiate an Inhibit Timer with a resolution of 5s for the detected Active_Error_Code.

[MDT.L-35983, Should Have, Draft]

6.7.8.3.4.3 - When a Status_Change occurs on the Service_Required_Status, AND the SOM contains the stored Remote Service External ID, the SOM shall send the Service_Required_Status to Remote Service Server. [MDT.L-35984, Should Have, Draft]

6.7.8.3.4.4 - When a Status_Change occurs on the Firmware_Version, AND the SOM contains the stored Remote Service External ID, the SOM shall send the Firmware_Version to Remote Service Server. When a Status_Change occurs on the Software_List AND the SOM contains the stored Remote Service External ID, the SOM shall send the Software_List to Remote Service Server. [MDT.L-35985, Should Have, Draft]

6.7.8.3.4.5 - When a Status_Change occurs on the Patient Presence AND the SOM contains the stored Remote Service External ID, the SOM shall send the Patient Presence to Remote Service Server. [MDT.L-35986, Should Have, Draft]

6.7.8.3.4.6 - When a MQTT_Config command is received from the Remote Service Server, the SOM shall create an MQTT profile.

When a WIFI_Config command is received from the Remote Service Server, the SOM shall create an WIFI_profile [MDT.L-35987, Should Have, Draft]

6.7.8.3.4.7 - The SOM shall send a heartbeat to the Remote Service Server every 5 +/- 1 min. [MDT.L-35988, Should Have, Draft]

6.7.8.3.4.8 - The MCB shall send the Remote Service message time stamp to be displayed on the Remote Service Credentialed_Service_User interface of the FUD in the following format: [MDT.L-35989, Should Have, Draft]

6.7.8.3.4.9 - Link with ICD Data.

If data points supported by the device, the data supplied by the wireless module, including exception values if applicable, shall comply with "NPD35311 Device Data Dictionary for **MQTT** Protocol" to support HR Digital Health Gateway system. [MDT.L-35990, Should Have, Draft]

6.7.8.3.4.10 - Timeout data transmission.

For all data streaming on **MQTT**, when their status change, streamed on **MQTT** in less than 3 seconds, the BDHP gateway shall be able to timestamp (date/hours/minutes/seconds) this data. [MDT.L-35991, Should Have, Draft]

6.7.8.3.4.11 - Maintenance date.

For Preventive maintenance, the device shall be able to transmit, in less than 3 seconds after a change occur to Approved External Wireless Device [AEWD]:

- Installation date
- Periodic inspection...

[MDT.L-35992, Should Have, Draft]

6.7.8.3.4.12 - Data connection to server.

The lift sends data to SCRM to find out **how it will connect** (Thin-edge), and which operations are supported. (download configuration file, softa update, log recovery...).

The lift sends data to SCRM to monitor the state of the wifinetwork and its use (between the lift and SCRM):

- Product IP address
- MAC address (product).
- Access Point used
- RSSI (signal strength)
- SSID (Wi-Fi profile used, on which network)...

[MDT.L-35993, Should Have, Draft]

6.7.8.3.4.13 - Device Logs

The product shall be able to sent Device log from SCRM request.

Product log could be:

- Debug log file
- Maintenance date and history
- Connectivity history
- Scale access
- Failure history and occurrence

[MDT.L-35994, Should Have, Draft]

6.7.8.3.4.14 - Failure Logs

The product shall be able to sent current active failure to SCRM in order to view alert and information for error code.

[MDT.L-35995, Should Have, Draft]

6.7.8.3.4.15 - Product data

The product shall be able to sent this product data to SCRM:

- Overweight status + count
- Emergency Status + count
- Last patient weight saved + count
- Status of power state [Charging, normal use, standby, standby deep, critical battery]
- Status of the battery: Battery Health, type of battery , capacity, voltage... No possibility to have all data (topic with Electronic team to have this data)

[MDT.L-35996, Should Have, Draft]

6.7.8.3.4.16 - Product version

The product shall be able to sent this product version to SCRM:

- Software revision
- Product identification (Model name and Serial Number)
- Detail list of software version
- Name of the configuration ("Friendly name")

[MDT.L-35997, Should Have, Draft]

6.7.8.3.4.17 - Detail usage data.

The product shall be able to sent this detailed usage to SCRM:

Data : Last Lift activity (Date / up_in_charge (cm), down un charge (cm); up empty (cm), down empty (cm), horizontal (m) / declared activity). In this case, we save a complete movement [MDT.L-35998, Should Have, Draft]

6.7.8.3.4.18 - Location.

The product shall be able to sent this location to SCRM:

- Static localization (Service Tool)
- Dynamic localization (AP localization)

[MDT.L-35999, Should Have, Draft]

6.7.8.3.5 SCRM configuration

6.7.8.3.5.1 - Configuration

The product shall be able to be configured with configuration file and external technician service [MDT.L-36000, (1) Should Have, (2) Draft]

6.7.8.3.5.2 - Configuration and security

When decrypting Wi-Fi credentials for use, the product shall only store the decrypted credentials in volatile memory

Note:

- A part of encrypt key is on LCB module, others are on LCM module. [MDT.L-36001, (1) Should Have, (2) Draft]

6.7.8.3.5.3 - Update SCRM Configuration

When the product receives an update to the existing SCRM profile over the local and remote interfaces, the product shall store the update in persistent memory [MDT.L-36002, (1) Should Have, (2) Draft]

6.7.8.4 Link with User Interface

6.8.1.4-1 - Each time a Wireless process (connection, wait for gateway response), has been engaged between the device and HR Gateway, needs a waiting period to be completed, the device shall display "a living information" to inform user that a process is in progress ELSE the display of "a living information" shall stop as soon as the process is ended. [MDT.L-36003, (1) Should Have, (2) Draft]

6.7.8.4.2 - The product shall have an interface to ON or OFF (power down WIFI radio emission) the WIFI module AND provide associated visual feed-back.

Note:

- OFF/ON interface based on recommendations 1999/519/EC, Wi-Fi network ANSSI No DAT-NT-005/ANSSI/SDE/INP (Anses n° 2012-SA-009),
- OFF meaning power down WIFI radio emission.
- By default, the WIFI shall be OFF. [MDT.L-36004, (1) Should Have, (2) Draft]

6.8 Connectivity

6.8.1 Wireless Communication (if Option available)

6.8.1.1 - Even if the product is connected through its Wireless function to an Approved External Wireless Device, it shall continue to provide all local alerts through the defined visual and audible indicators. [MDT.L-36008, (1) Should Have, (2) Draft]

6.8.2 Wireless module of the device

6.8.2.1 - With a 802.11 compliant wireless access point transmitting 25mW at 2.4Ghz or at 5Ghz, with patient on the device, with device in worst case position (see note) i.e. preventing as much as possible the diffusion of the WIFI signal (bell effect), the device shall measure a receive level, i.e. record the receive signal strength at the WIFI module antenna, of at least -65 dBm at a line-of-sight distance of:

- 16 m from the transmitter in free space and at any angle for 2.4 GHz,
- 8 m from the transmitter in free space and at any angle for 5 GHz.

Note:

- Worst case condition for a bed is in flat and in low position.
- Calculation of 8 meters for 5 GHz Frequency

Distance

In free transmission a radio wave is naturally attenuated according to the distance that separates it from its transmitter.

This attenuation is proportional to the square of the distance. Each time the distance doubles, the signal is divided by 4 which corresponds to an attenuation of 6 dB.

Example: for a distance of 50 m the attenuation is 74 dB, it increases to 80 dB for 100 m.

Frequency

The higher the frequency, the greater the attenuation. Here again, the damping will be proportional to the square of the frequency. For the same transmission power, a frequency twice as high therefore implies a signal 4 times weaker (6 dB gap between 2.4 GHz and 5 GHz).

However, the higher the frequency, the higher the achievable throughput.

Calculation

For 2.4 GHz / 16 m / -65 dBm

For 5 GHz / 16 m / -71 dBm

For 5 GHz / 8 m / -65 dBm [MDT.L-36009, (1) Should Have, (2) Draft]

6.8.2.2 - Device on AC power, with patient on the device, with all electrical features of the device operating, with device in worst case position (see note) i.e. preventing as much as possible the diffusion of the WIFI signal (bell effect) as a starting position, the signal-to-noise ratio (SNR) at the WIFI module antenna shall be at 15 dB at minimum during all operating mode.

Note:

Worst case condition for a bed is in flat and in low position. [MDT.L-36010, (1) Should Have, (2) Draft]

6.8.2.3 - To protect the device from attacker, the WIFI chipset shall be located in an enclosure with a cover attached to force to have a tool to access it. [MDT.L-36011, (1) Should Have, (2) Draft]

6.8.2.4 - On Main power, in case of WIFI module failure, the product shall log the error and inform the user [MDT.L-36012, (1) Should Have, (2) Draft]

6.8.3 General WIFI characteristics to interface the Gateway

6.8.3.1 - The Wireless communication of the WIFI Connected Product to the Approved External Wireless Device [AEWD] shall be compatible with IEEE 802.11 a/b/g/n. [MDT.L-36013, (1) Should Have, (2) Draft]

6.8.3.2 - The product shall have the possibility to retrieve network time to update the product. [MDT.L-36014, (1) Should Have, (2) Draft]

6.8.3.3 - EPPs

The SCM shall store any Wi-Fi credentials with a FIPS 140-2 compliant encryption

To do in security chapter ? [MDT.L-36015, (1) Should Have, (2) Draft]

6.9 Functional Interactions

6.9.1 Provide caregiver efficiency (ready to use, feed-backs)

6.9.1.1 - Where the hoist equipped with [Membrane] user control, when activated, the Hoist shall display a status of:

1. Weight overload & Exceeded Max reach angle
2. Emergency Stop activation (ELV-4128)
3. Battery states (red, orange, green)
4. Failure (see ELV-3324)

[MDT.L-36017, (1) Should Have, (2) Draft]

6.9.1.2 - Where the Hoist equipped with [GUI] user control, when there are actives, the Hoist shall display explanation of:

1. Weight overload
2. Emergency Stop activation (ELV-4128)
3. Battery states (red, orange, green)
4. Failure (see ELV-3324)
5. Exceeded Max reach angle
6. Lift motor over usage (ELV-1952)

[MDT.L-36018, (1) Should Have, (2) Draft]

6.9.1.3 - The Hoist enclosure shall display a Red, Safety Yellow and Green indication relative to the Hoist "ready to use" status (see ELV-1786 - When The Hoist is wake up, its "ready to use" status shall: " switch on 1 of its...).

1. User in standup position, visible at a distance of 10 m around the Hoist enclosure,
2. With least ambient illuminance favorable level in the range of 100 lx to 1 500 lx
3. The observer having a visual acuity of 0 on the log min Angle of Resolution (log MAR) scale or 6/6 (20/20) corrected.

Can we say the Hoist display a "visual/light/colored indication" instead of re-stating the specific colors green/yellow/red that are already defined in ELV-1786 ?

[MDT.L-36019, (1) Should Have, (2) Draft]

6.9.1.4 - When The Hoist is wake up, its "ready to use" status shall:

1. switch on 1 of its 3 colors (ELV-3178 - The Hoist enclosure shall display a Red, Safety Yellow and Green indication rela...) within 1.1 sec of detection
2. following "display priority" specify in table just below
3. following trigger specify in table just below

MEANING >>	Ready to use		Ready to use
	Feed-back in case of wrong usage		Feed-back in case of Hoist failure
STATES	Battery not charging: Constant light	Battery charging mode: Blink passing through a dim display at 0.2 Hz	Blink at 1000 Hz (TBC)
GREEN	Display Priority 4 All OK and Full battery level (ELV-4773) & High battery level (ELV-4774)	When the battery is in charging mode, while the battery level is under X % (TBC - see § Battery management)	NA
SAFETY YELLOW	Display Priority 3 1) Medium battery level (ELV-4775) 2) Over usage (ELV-3328)	When the battery is in charging mode, while the battery level is under X % (TBC - see § Battery management)	NA
RED	Display Priority 2 1) Weight Overload 2) Emergency Stop activates 3) Low battery level (ELV-4776) 4) Empty battery level (ELV-4777) 4) Exceeded Hoist strap angle (ELV-2009, ELV-2010, ELV-3048)	When the battery is in charging mode, while the battery level is under (see battery level (TBC - see § Battery management)	Display Priority 1 In case of critical failure defined by ELV-3324 and ELV-3142

[MDT.L-36020, (1) Should Have, (2) Draft]

6.9.1.4 - The ready to use fonction of the Hoist shall switch on in case of :

1. Key press of the Hoist user control
2. A Hoist movement
3. Hoist status change defined by ELV-1786 - When The Hoist is wake up, its "ready to use" status shall: " switch on 1 of its... -between "Red", "Safety Yellow", "Green" displays-

[MDT.L-36021, (1) Should Have, (2) Draft]

6.9.1.4 - While the Hoist is not in power saving mode, the ready to use fonction shall stay ON.

Link to Power modes definitions (par. 6.6) when properly defined. [MDT.L-36022, (1) Should Have, (2) Draft]

6.9.1.7 - The Hoist shall produce a usage audible indicator (specify by ELV-3222 - The usage audible feedback shall be chime type i.e.: Frequency: La - 600 Hz - 0...) for:

- a.1 Upward Movement requested whereas weight overload triggered
- a.2 Upward Movement requested whereas lift motor over usage protection triggered
- a.3 Upward Movement requested whereas vertical upper stop reached
- b.1 Lower movement requested whereas vertical lower stop reached
- c.1 Movements requested whereas Emergency Stop Activated
- d.1 Movements requested whereas Exceeded max reach angle of the strap or twist of the strap (ELV-2009, ELV-2010, ELV-3049, ELV-1326)
- e.1 Movements requested whereas the "Low battery capacity" detected (ELV-4776)
- f.1 Movements requested whereas the "Empty battery" detected (ELV-4777)

[MDT.L-36023, (1) Should Have, (2) Draft]

7 Labeling

7.1 - The Hoist shall have a label with:

1. CE marking
2. Medical Device manufacturer
3. Authorized representative in the European Community
4. Date of manufacture.
5. Manufacturer's Part number
6. Manufacturer's Serial number
7. Model definition
8. Recycling necessary. Do not dispose

9. Class II mark for protection against electric shock
10. "Read instruction guide" symbol

[MDT.L-36024, Should Have, Draft]

7-2 - The Hoist shall be marked with Unique Device Identifier (UDI) in accordance with GS1 Data Matrix format as specified in FDA UDI Guidance documents #69-1-1 and 89-4203. [MDT.L-36025, Should Have, Draft]
7-3 - The Hoist shall be marked with:

1. the min load in kg and lbs unit
2. the max load in kg and lbs unit

visible by a user specify by ELV-3493. [MDT.L-36026, Should Have, Draft]

7.1 Label relative to battery function

7.1-1 - The part of the Hoist intended to deliver power shall be marked with the following information when applicable:

1. Rated output voltages
2. Rated current or power
3. Output frequency

[MDT.L-36029, Should Have, Draft]

7.1-2 - The battery location shall have a label visible when the user access with the following information:

1. Battery type
2. Battery feature
3. Caution: "Only qualified Service Personnel to change the Battery"
4. Mode of insertion of the battery
5. Warning sign indicating the Hazard if applicable
6. Warn not use different batteries else risk of restult in a HAZARD of high temperatures, fire or explosion
7. The life duration.

[MDT.L-36030, Should Have, Draft]

7.1-3 - The battery access cover shall be protected by a seal label. [MDT.L-36031, Should Have, Draft]

7.1-4 - The Over-voltage, Over-current and Short-circuit protection shall have a characteristics label on the Lift Control Board near from their location. [MDT.L-36032, Should Have, Draft]

7.2 Packaging

7.2-1 - [«Requirement Text»](#) [MDT.L-36033, Should Have, Draft]

8 Logistical Requirements

8.1 Packaging

8.1-1 - [«Requirement Text»](#) [MDT.L-36040, Should Have, Draft]

8.2 Transport & Storage

8.2-1 - [«Requirement Text»](#) [MDT.L-36041, Should Have, Draft]

8.3 Material Handling

8.3-1 - [«Requirement Text»](#) [MDT.L-36042, Should Have, Draft]

8.4 Installation/Removal

8.4-1 - [«Requirement Text»](#) [MDT.L-36043, Should Have, Draft]

8.5 Reprocessing

8.5-1 - The system shall reprocess changes to work items in updated documents submitted to DRIM. [MDT.L-36044, Should Have, Draft]

8.5-2 - The system shall allow new workitems in updated documents submitted to DRIM. [MDT.L-36293, Should Have, Draft]

8.6 Service and Maintenance

8.6.1 Calibration

8.6.1-1 - When the Hoist requires calibration process, the calibration event shall be timestamped. [MDT.L-36048, Should Have, Draft]

8.6.1-2 - Using the service menu, the Hoist shall permit the calibration of high/low movement to guarantee these criteria:

XXX

XXX

XXX [MDT.L-36049, Should Have, Draft]

8.6.2 General Error Management

8.6.2-1 - The Hoist shall store the failures information replacing the oldest code with a newly created code on a sliding window of 70 values. [MDT.L-36050, Should Have, Draft]

8.6.2-2 - The Hoist shall log failures to support 2 ways to display i.e.:

A) List of error with the information:

1. Triggered hour & date of active status - Failure Code - Active/Non Active
2. Trigger hour & date of non-active status - Failure Code - Active/Non Active

B) Occurrence historical of error code per error code with the information:

1. Triggered hour & date - Disappeared hour & date (if available) - Critical/Non-Critical - Failure Code - Active/Non-Active - Number of occurrence per failur

[MDT.L-36051, Should Have, Draft]

8.6.2-3 - The hoist shall handle the following breakdowns:

[MDT.L-36052, Should Have, Draft]

8.6.2-4 - When the failure is no more active, the Hoist shall update the user visual and audible feed-back accordingly.

[MDT.L-36053, Should Have, Draft]

8.6.2.1 Error management - users feedbacks

8.6.2.1-1 - The primary user control shall display or remove an error within 1.1 sec of detection.

[MDT.L-36055, Should Have, Draft]

8.6.2.1-2 - When an error activates, the Hoist shall generate a user feed-back i.e.:

1. For critical, non-critical failure:

a. Switch on failure indicator on user control

b. Where a Graphical Unit Interface available, display a pop-up:

1. With date & hour when error generates
2. With failure code & active/non active status
3. Interface to acknowledge the information

c. While the error activates, when the error triggers & when the function relative to the failure used (see ELV-3324), generate an audible feed-back (see ELV-3223).

3. For critical failure (ELV-3324):

While the error activates, when the error triggers and when the Hoist is wake-up, switch on the red light of "Ready to Use" at a frequency of **1000 Hz (1Bc)** for 30 seconds.

[MDT.L-36056, Should Have, Draft]

8.6.2.1-3 - Where Graphical Unit Interface available, while there is an active failure, a press on failure pictogram shall display the pop-up specify on ELV-3142 "2.a." [MDT.L-36057, Should Have, Draft]

8.6.3 Interface with Service Tool

8.6.3-1 - The **Service Menu** shall provide a user access to read:

1) The MAC and the physical IP address of Wifi Module of the product. [MDT.L-36058, Should Have, Draft]

9 Revision History

10 Approvals