

### 1 Purpose / Scope

This document is to control and check the preparation, execution, and follow-up process for a corrective maintenance or an inspection of a LokomatPro V6.

<b>Device Serial Number</b> L60163	<b>Service Request Number</b>  
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**(Optional) Customer Contact (E-Mail, Phone)**

### 2 Preparation

No	Description	Check	
1.	Clarified all open points with the customer, appointment for customer visit made	<input checked="" type="checkbox"/> Ok	
2.	Check for valid Hocoma LokomatPro V6 "Repair Technician" certificate / Date of certificate: <u>10/2013</u>	<input checked="" type="checkbox"/> Ok	
3.	Remote repair: Inform engineer about skill set, electrical safety test requirements and responsibility for proactive reporting about performed tests. Only fully tested devices and released by DIH may be put back in operation. (All relevant tests passed)	<input checked="" type="checkbox"/> Ok	<input type="checkbox"/> N/A
4.	<b>Service Request</b> 1. Check "Service Requests" and follow up with the responsible ticket owner (if necessary) 2. Check open "Service Requests" on other devices at this customer (if available) <input type="checkbox"/> <b>DIH-Service</b> (Oracle > Service > Service Request) <input type="checkbox"/> <b>DIH-Service Partner</b> (Contact your responsible DIH-Service)	<input type="checkbox"/> Ok	<input checked="" type="checkbox"/> N/A
5.	<b>Pending Points</b> <b>number of open pending points:</b> _____ Check pending points for the product above also for the other Hocoma products at customer site <input type="checkbox"/> <b>DIH-Service</b> (Oracle > Maintenance Management > Manage Asset > Pending Points And Issues) <input type="checkbox"/> <b>DIH-Service Partner</b> (Contact your responsible DIH-Service)	<input checked="" type="checkbox"/> Ok	<input type="checkbox"/> N/A
6.	<b>Corrective Maintenance Material</b> 1. Check if all needed parts for corrective maintenance (including pending point parts) have been sent 2. Check if the parts arrived at customer side (e.g. Tracking number, confirmation by recipient...) <input type="checkbox"/> <b>DIH-Service</b> (Oracle > Service > Service Requests > Parts) <input type="checkbox"/> <b>DIH-Service Partner</b> (Contact your responsible DIH-Service)	<input checked="" type="checkbox"/> Ok	<input type="checkbox"/> N/A
7.	Book flights, car and hotels	<input checked="" type="checkbox"/> Ok	<input type="checkbox"/> N/A
8.	Clarify visa and valid ID status	<input type="checkbox"/> Ok	<input checked="" type="checkbox"/> N/A
9.	Clarify security situation in the country (Travel restrictions due to health or political issues)	<input type="checkbox"/> Ok	<input checked="" type="checkbox"/> N/A
10.	Medical clarification (vaccination)	<input type="checkbox"/> Ok	<input checked="" type="checkbox"/> N/A
11.	Print / Fill out "QF3401 Customer Service Order" (acc. Part 9)	<input checked="" type="checkbox"/> Ok	
12.	Copy instructions (acc. Part 10) and latest released software to the USB Stick	<input type="checkbox"/> Ok	<input checked="" type="checkbox"/> N/A

### 3 On site

*As a personal safety measure, to prevent infection and to avoid cross-contamination, precautions must be taken. Make sure to comply to the general hygienic rules in the clinic. Before performing any work on the device, make sure it is cleaned and disinfected according to user manual. The use of hygienic gloves and masks is recommended. If no gloves are being used, wash and disinfect your hands accordingly.*

No	Description	Check
1.	Performed corrective maintenance according to marked options (mark applicable): <input type="checkbox"/> Latest released "Service Manual LokomatPro V6" (L6-SA-01) <input type="checkbox"/> Instructions: _____ Parts replacement: <input type="checkbox"/> Parts have been replaced, listed on "Customer Service Order", section "Parts Exchanged / Traceability" <input type="checkbox"/> No parts have been replaced	<input checked="" type="checkbox"/> Ok
2.	Checked, performed and closed all pending points/issues / number of closed pending points: _____	<input checked="" type="checkbox"/> Ok

#### 4 Function Check

**Corrective Maintenance Report:** Only replaced or affected components need to be tested. Choose check points below accordingly

**Inspection Report:** All checkpoints need to be performed / filled out

No	Checkpoint	Instruction (select at least one for affected component check)	Pass	Fail	N/A		
1.	Power On	<input type="checkbox"/> Press the "Power on" button, system starts without errors <input type="checkbox"/> Lokocontrol software starts automatically	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
2.	Control Software Version	<table border="1" style="width: 100%;"> <tr> <td style="width: 50%;"><b>LokoControl SW-Version (Current Version)</b> 6.5.2.12</td> <td style="width: 50%;"><b>LokoControl SW-Version (Updated Version)</b></td> </tr> </table>	<b>LokoControl SW-Version (Current Version)</b> 6.5.2.12	<b>LokoControl SW-Version (Updated Version)</b>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>LokoControl SW-Version (Current Version)</b> 6.5.2.12	<b>LokoControl SW-Version (Updated Version)</b>						
3.	Electronics / Cables / Screens	Cables- and/or ground connections/fixations are connected according to "Service Manual": <input type="checkbox"/> Power Electronics <input type="checkbox"/> Lokomaster Interface <input type="checkbox"/> Motor Controller <input type="checkbox"/> Lokocontrol-PC <input type="checkbox"/> FreeD Electronics <input type="checkbox"/> Treadmill Electronics <input type="checkbox"/> Therapist Screen <input type="checkbox"/> Patient Screen <input type="checkbox"/> Force Sensor Patient <input type="checkbox"/> Force Sensor Lokomat <input type="checkbox"/> Control Box (BWS) <input type="checkbox"/> Emergency Stop Control Unit (BWS) <input type="checkbox"/> Lokomat Drives Cable <input type="checkbox"/> Lokomat Sensor Cable	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4.	Therapist Screen (Touch Screen)	<input type="checkbox"/> Touch screen function: Complete display surface gets recognized <input type="checkbox"/> Telestop warning sound: The warning tone sounds from the therapist screen	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
5.	Patient Screen (Augmented Feedback Screen)	<input type="checkbox"/> Monitor column: Can be adjusted from min. to max. height position <input type="checkbox"/> Augmented feedback sound: The AF tone/music sounds from the patient screen	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
6.	Orthosis	<input type="checkbox"/> Tigh length adjustment positions checked <input type="checkbox"/> AD: 35↔47 <input type="checkbox"/> PE: 21↔35 <input type="checkbox"/> Lower leg length adjustment positions checked <input type="checkbox"/> AD: A↔L <input type="checkbox"/> PE: A↔D	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
7.	Drives (Orthosis)	<input type="checkbox"/> Spindles can be moved the whole mechanical range <input type="checkbox"/> Force sensor / Motor cable are firmly connected	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
8.	Potentiometer Calibration	<input type="checkbox"/> "Manual calibration" performed <input type="checkbox"/> AD <input type="checkbox"/> PE <input checked="" type="checkbox"/> "Auto calibration" successfully performed <input type="checkbox"/> AD <input type="checkbox"/> PE	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
9.	Force-Sensor Calibration	<input type="checkbox"/> "Manual force sensor calibration" performed <input type="checkbox"/> AD <input type="checkbox"/> PE <input checked="" type="checkbox"/> "Auto calibration" successfully performed <input type="checkbox"/> AD <input type="checkbox"/> PE	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
10.	FreeD Module	<input type="checkbox"/> Linear Unit BWS FD: Can be moved the hole range <input type="checkbox"/> Hip Unit FD (Translation Drive): Can be moved the hole range <input type="checkbox"/> "Auto calibration" successfully performed <input type="checkbox"/> Force sensor "Manual calibration" performed <input type="checkbox"/> Harness can be attached to the "Hip Fixation FD"	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
11.	Hip Adjustment V5.0	<input type="checkbox"/> Back support can be adjusted to all positions <input type="checkbox"/> Hip adjustment (Width) can be adjusted to all positions <input type="checkbox"/> Pelvic support can be adjusted to all positions (Counter: Extended position = 0)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
12.	Parallelogram	<input type="checkbox"/> Spring Tension: Remains horizontal balanced with all cuffs and brackets attached	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
13.	Swivel Door	<input type="checkbox"/> Swivel door lock mechanism: 2x Star handles can be locked <input type="checkbox"/> Swivel door strap is attached on both sides and fixation screws are installed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
14.	Therapist Seats	<input type="checkbox"/> Can be moved to both end stops <input type="checkbox"/> Lock mechanism prevents the movement of the seat	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
15.	Treadmill	<input type="checkbox"/> Treadmill belt is centred <input type="checkbox"/> Treadmill belt tension adjusted <input type="checkbox"/> Treadmill motor drive belt tension adjusted <input type="checkbox"/> Treadmill break stops motor immediately after pressing the "Emergency stop" <input type="checkbox"/> Manual Training: The speed of max. 10km/h can be set	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
16.	Handrails	<input type="checkbox"/> Height adjustment: Can be adjusted from min. <b>65</b> to max. <b>107</b> position <input type="checkbox"/> Sideways adjustment: Can be adjusted from left to right position <input type="checkbox"/> Length adjustment: Can be adjusted from min. to max. length position	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
17.	Body Weight Support (BWS)	<input type="checkbox"/> Patient unloading rope is installed according to "L6-SA-01-Service Manual" <input type="checkbox"/> Lokomat unloading rope is installed according to "L6-SA-01-Service Manual" <input type="checkbox"/> BWS "Manual calibration" performed <input type="checkbox"/> BWS "Auto calibration" successfully performed <input type="checkbox"/> Set "Drive unloading" to maximum (> <b>85 kg</b> ). Move the "Drive patient" to the top, until the current limit shuts the drive off. The lifting force must be <b>≥ 135 kg</b> <input type="checkbox"/> Drive unloading can be moved from <b>0 kg to 85 kg</b> <input type="checkbox"/> Patient unloading force sensor: RAW SENSOR SIGNAL value: <b>500 (+/- 150)</b> <input type="checkbox"/> Lokomat unloading force sensor: RAW SENSOR SIGNAL value: <b>500 (+/- 150)</b>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
18.	Emergency Stop Control Unit (BWS)	<input type="checkbox"/> Patient- and unloading drive are deactivated when emergency stop button (Handrail) is pressed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
19.	Hand Control (BWS)	<input type="checkbox"/> All functions work corresponding to the layout of the hand control	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
20.	Backup (Lokocontrol Database)	Performed a backup (E.g., after a calibration of orthosis): <input type="checkbox"/> Performed a backup (Selected "BACKUP NOW" in the "Backup/Logs" screen)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
21.	Restore (Lokocontrol Database)	Performed a restore (E.g., after a software crash): <input type="checkbox"/> Performed a restore (Selected "RESTORE NOW" in the "Backup/Logs" screen)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		

No	Checkpoint	Instruction (select at least one for affected component check)	Pass	Fail	N/A
22.	Backup (Windows-System Drive)	Performed a backup (E.g., after Windows settings change, or Lokocontrol software change): <input type="checkbox"/> <b>Windows 7 / 10:</b> System drive backup performed (Used Windows 7 "Backup and Restore "Tool > Create a system image)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
23.	Restore (Windows-System Drive)	Restore performed of a previously saved backup: <input type="checkbox"/> <b>Windows 7 / 10:</b> Used the "Windows Recovery Environment"	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
24.	Cyber Security DIH personnel shall not access any customer/patient data without prior consent of the customer. DIH personnel shall not copy or move any data by using personal storage devices.	<input type="checkbox"/> No login or admin passwords visible <input type="checkbox"/> Only software for intended uses is installed <input type="checkbox"/> Windows defender up to date <input type="checkbox"/> No malware found on the HD <input type="checkbox"/> No cyber incident reported by the customer	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
25.	Orthopaedics	<input type="checkbox"/> Cuffs Carbon bracket condition (no cracks)  <input type="checkbox"/> Fleece Bands Wear / Seams condition Fleece Bands Rivets of fleece band fixation condition (4x) Fixation screws installed (2x)  <input type="checkbox"/> Clamp Blocks Fixation screws installed (3x) Bracket clamp mechanism (Sufficient clamping when release levers tight) Permaglide sleeves (Cuff brackets slide easily) <b>!Attention! Do not grease permaglide sleeve!</b>  <input type="checkbox"/> Release Levers Handle condition Thread condition  <input type="checkbox"/> Foot Lifters (AD/PE) Wear / Seams condition (Replace if worn or damaged) <b>!Attention! Springs must be exchanged!</b>  <input type="checkbox"/> Hip Pads (AD/PE) Condition (Replace if needed)  <input type="checkbox"/> Harness / Seat / Leg loops Condition: Seams Condition: Snap locks (Female) Condition: Quick release buckles (Male)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

## 5 Safety Features

No	Checkpoint	Instruction	Pass	Fail	N/A
1.	Emergency Stop Features	<b>System stops immediately and an error message on the screen appears triggered by:</b> <input type="checkbox"/> After 3min training (without pressing the acknowledge button and Telestop if available warning sound appears) <input type="checkbox"/> Press "Emergency stop button" (Treadmill handrail) <input type="checkbox"/> Remove magnet from "Magnet switch" (Treadmill handrail) <input type="checkbox"/> Press "Red emergency stop button" (Telestop sender if available) <input type="checkbox"/> Pull cord (Telestop sender if available) <input type="checkbox"/> Turn "Key switch" of the "Sensor Box" from "ON" to "OFF" <input type="checkbox"/> Blocking an orthosis at 100% guidance force	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	Emergency Patient Release (BWS)	<b>The "Harness support bracket" can be lowered by:</b> <input type="checkbox"/> Pulling the "Emergency release knob" (Column)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## 6 Electrical Safety Test

Electrical safety test must be performed according to IEC 62353:2014 following the instructions of the latest released "Service Manual LokomatPro V6" (L6-SA-01) and record the data below:

No	Checkpoint and instruction			
1.	<b>Visual inspection</b> (is ALWAYS required) <ul style="list-style-type: none"> <li>Specification (rated current, characteristics) and accessibility from the outside of fuses according to "Service Manual LokomatPro V6" (L6-SA-01)"</li> <li>Check main cables (230V/115V) Isolation and earth connections are intact</li> <li>Condition and completeness of cases covering (e.g. PC covers / Power electronics)</li> <li>Safety related marking, labels and labeling are legible and complete</li> </ul>		<input checked="" type="checkbox"/> Pass	<input type="checkbox"/> Fail
	<ul style="list-style-type: none"> <li>Device Type: B</li> <li>Isolation Class: I</li> <li><b>L6.2 or lower</b> - Supply voltage on Device Label: <input type="checkbox"/> 110-120 VAC <input checked="" type="checkbox"/> 220-240 VAC</li> <li><b>L6.3 or higher</b> - Supply voltage on Power Electronics Label: <input type="checkbox"/> 100 VAC <input type="checkbox"/> 110 VAC <input type="checkbox"/> 120 VAC <input type="checkbox"/> 200 VAC <input type="checkbox"/> 220-240 VAC</li> <li>Mains Frequency: <input checked="" type="checkbox"/> 50 Hz <input type="checkbox"/> 60 Hz</li> </ul>			
2.	<b>Prerequisite for the measurement</b> (for corrective maintenance only. Test is mandatory for Inspections) While visual inspection is always required, the electrical safety test with specific equipment according to IEC 62353, must be performed if certain conditions are met.  The following parts have been affected by the repair or replacement: <ul style="list-style-type: none"> <li>Parts powered by or leading mains voltage (e.g. 230V / 110V), including but not limited to, mains cables, Power electronic box, FreeD power supply, treadmill motor/power supply, PC's which could affect the electrical safety</li> <li>Parts which are equipped with a separate ground wire/strap, including but not limited to, main Lokomat components (Column, base frame etc.), Monitors or PC's which could affect the electrical safety</li> </ul> Was one or both questions answered yes? <input type="checkbox"/> Yes Test with special equipment required (Proceed to No. 3) <input checked="" type="checkbox"/> No No further test required (Proceed to No. 4)		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
3.	<b>Test with specific equipment</b>  Brand of Electrical Safety Tester: <u>ESA 612 FLUKE</u> Serial Number: <u>4481045</u> Last Calibration Date: <u>01/03/2024</u>  <b>Main Test – Lokomat Power Input</b> Supply voltage (measured range: Voltage configuration ±10%) <u>228</u> VAC <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail Protective earth resistance (Limit < 0.3 Ω) <u>0,280</u> Ω <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail Equipment leakage current ( <b>L6.2 or lower</b> : differential) (Limit < 500 µA) <u>175</u> µA <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail  <b>Treadmill Power Input (L6.2 or lower)</b> Supply voltage (measured range: Voltage configuration ±10%) <u>230</u> VAC <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail Protective earth resistance (Limit < 0.3 Ω) <u>0,270</u> Ω <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail Equipment leakage current (differential) (Limit < 500 µA) <u>280</u> µA <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail  <b>Comments:</b> <hr/>			<input type="checkbox"/> N/A  <input type="checkbox"/> N/A
4.	<b>Final test result</b> (Pass if none of the tests/visual inspections listed above have failed)		<input checked="" type="checkbox"/> Pass	<input type="checkbox"/> Fail <input type="checkbox"/> N/A
5.	If any of the above mentioned safety relevant features did not pass the test and cannot be fixed the device has to be locked and communicated (Liability exemption flyer) to the customer and the relevant DIH Service Manager		<input checked="" type="checkbox"/> Ok	<input type="checkbox"/> N/A
6.	Make sure the "Customer Service Order" is <b>fully completed and signed</b> by the customer		<input checked="" type="checkbox"/> Ok	

## 7 Follow-Up (Service Partner only)

No	Description	Check
1.	Forward any important information, all documents listed in part 9 and this document to DIH	<input checked="" type="checkbox"/> Ok
2.	If any urgent follow up is required (e.g., device had to be locked, another service visit is required) make sure the DIH-Service is informed	<input checked="" type="checkbox"/> Ok <input type="checkbox"/> N/A
3.	Filled in "Return Parts Form" QF3407 (if any parts being returned)	<input checked="" type="checkbox"/> Ok <input type="checkbox"/> N/A

### 8 Follow-Up (DIH only)

Do not write in these fields, DIH use only!	No	Description	Check	
	1.	Filled in used parts form QF3407 (if any parts being returned)	<input type="checkbox"/> Ok	<input type="checkbox"/> N/A
	2.	Follow up with customer request for spare parts, quotation, or information for other departments, etc.	<input type="checkbox"/> Ok	<input type="checkbox"/> N/A
	3.	Remote repair: All required tests according to report have been performed, passed, and confirmed by third party personnel before releasing device again for patient use	<input type="checkbox"/> Ok	<input type="checkbox"/> N/A
	4.	<b>Pending Points</b> (Oracle > Maintenance Management > Manage Asset > Pending Points) Update/Close pending point(s) (set Inactive, enter name and date)	<input type="checkbox"/> Ok	<input type="checkbox"/> N/A
	5.	<b>Pending Points (New)</b> (Oracle > Service > Pending Points And Issues) If necessary, create new pending point(s)	<input type="checkbox"/> Ok	<input type="checkbox"/> N/A
	6.	<b>Check Equipment File</b> (Oracle > Service > Equipment Track Form) Compare customer service order "Serial / Batch numbers" with existing "Equipment File", Change (if necessary)	<input type="checkbox"/> Ok	<input type="checkbox"/> N/A
	7.	<b>Service Request</b> (Oracle > Service > Service Request > Messages > Internal Note) 1. Update the "Service Request" by entering performed action during customer visit 2. Inform the responsible ticket owner about the status	<input type="checkbox"/> Ok	<input type="checkbox"/> N/A
	8.	<b>Operating Hours</b> (Oracle > Maintenance Management > Manage Asset > Operating Hours) Add "Operating hours" and "Date Recorded"	<input type="checkbox"/> Ok	<input type="checkbox"/> N/A
	9.	<b>Spare Parts (Follow Up)</b> (If necessary) (Oracle > Service > Service Request) Open a new "Service Request" to ship spare parts after a corrective maintenance visit	<input type="checkbox"/> Ok	<input type="checkbox"/> N/A
	10.	If any urgent follow up was required (e.g. device had to be locked, another service visit is required) make sure the follow up case (Service Request) has been created and the follow up process is initiated (offer, part shipment, service visit etc.)	<input type="checkbox"/> Ok	<input type="checkbox"/> N/A
	11.	Store important information such as pictures, additional documentation in the Logbook (electronic and hardcopy)	<input type="checkbox"/> Ok	<input type="checkbox"/> N/A
	12.	Scan and store this „Report“ and all other documents used for this corrective maintenance in the logbook	<input type="checkbox"/> Ok	

### 9 Documents Completed and Attached

No	Description	Check
1.	QF3401 Customer Service Order	<input checked="" type="checkbox"/> Ok

### 10 Further applicable documents

No	Description
1.	L6-SA-01-xxx <sup>1</sup> -Service Manual LokomatPro V6
2.	L6-IA-01-xxx <sup>2</sup> -Installation Instructions

All points on this report were checked, performed and completed.

Name of Hocoma certified technician:

Date: 18/06/2024

Name: Ivan Sacchetti

Signature: \_\_\_\_\_

a circle s.p.a.

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<sup>1</sup> xxx: latest release date

<sup>2</sup> xxx: latest release date