



INFORMATIONS
SÉCURITÉ PATIENTS

INFORMATION ISSUED UNDER THE AUTHORITY OF THE ANSM



Letter to healthcare professionals

Date: 06th August 2024

ANSM No.: R2421086

SAMSOFT 175 – MINI SAMSOFT 150

Preventive action of replacing hoist V1 spreader bars axis

Summary of preventive maintenance instructions for hoists

Information for healthcare service providers operating one or more hoists or responsible for their maintenance.

Dear Sir/Madam,

In 2019, following reports of abnormal wear to **SAMSOFT 175** and **Mini SAMSOFT 150** hoist spreader bars axis and, as well as extreme cases of breakage this part causing patients to fall while being hoisted, Drive Devilbiss Healthcare France issued **2 field safety notices**:

- Field Safety Notice No. **R1901643** in January 2019, regarding a reminder of **user and annual maintenance instructions for these devices**,
- Field Safety Notice No. **R1916625** in July 2019, concerning the request for **preventive replacement of spreader bars axis with reinforced versions** for **SAMSOFT 175 (SN < 90760371 and any serial No. starting with the letter D) and Mini SAMSOFT 150 (SN < 90760431)**. We should also be remind that spreader bar axis reinforcement does not cancel the essential realisation of maintenance and that these operations are main conditions to ensure completely safe use of these devices.

Unfortunately, we still receive reports of breakages of V1 spreader bars axis on these devices, in some case leading to the patient falling. In addition to failure to replace the part as required in Field Safety Notice No. R1916625, analyses have shown that annual hoist maintenance had never been performed or had been carried out without the required inspections having been performed.

In view of this situation and regarding of the potential severity that the patient's fall can represent, and incident reports including some from distributors who had answer at the previous filed safety notice, **Drive Devilbiss Healthcare France is issuing this new Field Safety Notice widely to all its customers who have bought these devices to date.**

The purpose of this field safety notice is to remind you that it is vital to rigorously conduct the maintenance tasks described in this instruction for use of these devices. **To mention the emergency to replace V1 spreader bars axis if they are still on your devices** and to remind of **our instruction for the preventive replacement of the spreader bar and axis every 5 years (whatever the version)**, instruction also found in the instruction for use. *This last instruction therefore applies from this year to all axis installed from 2019 and after.*

For safety, we also recommend that service providers of devices check that they have no V1 spreader bars axis in their stock of spare parts intended for repairs/maintenance.

Action plan:

1. Check that the 2019 preventive safety action No. R1916625 = preventive replacement of the V1 spreader bar axis has been completed for all relevant devices and still on the market, **SAMSOFT 175 (SN < 90760371) and any serial No. starting with the letter D and Mini SAMSOFT 150 (SN < 90760431)**.
2. If necessary, identify devices requiring the replacement of V1 spreader bar axis and record their serial numbers on the acknowledgement of receipt on the next page, so that you receive the corresponding quantity of kits.
3. Complete the acknowledgement of receipt below and return it to us **within a month**: your response is essential for the follow-up of this field safety notice.
4. When you receive the reinforced spreader bar axis kits (Reference SR2820900), please replace the V1 spreader bars axis: these must be replaced as soon as possible and, in any event, **within the 3-month** timeframe agreed with the ANSM.
5. Destroy V1 spreader bars axis.
6. Take acknowledgement of the reminder for service and maintenance mentioned in this FSN and ensure that they are properly applied in your activities.
7. Planned in your activities the replacement **spreader bars and its axis** all every five years for **SAMSOFT 175 and Mini SAMSOFT 150**.
8. Check in your stock of spare parts that you only have the spreader bars axis reinforced version.

Distribution of this field safety notice:

The ANSM has been notified. Drive DeVilbiss Healthcare France would be grateful if you would distribute this field safety notice to everyone concerned, and to your customers who have patient hoists, including anyone to whom these devices have been sold.

In accordance with ANSM decisions, we must send a report at the authority with a resume of the receipt returns within 3 months.

If you have any questions associated with this field safety notice, feel free to contact our vigilance department: materiovigilance@drivedevilbiss.fr

Amanda Lesire
Regulatory Affairs Manager

FSCA acknowledgement of receipt of DDHF-2024/02

Acknowledgement of receipt to be completed and returned to Drive Devilbiss Healthcare France, at the following address: materiovigilance@drivedevilbiss.fr

Company	
Address	
Contact (Name, Position and E-mail address)	

I hereby confirm that I have received information letter DDHF-2024/02 and agree to take all required measures and actions.

⇒ **Only for current operation of SAMSOFT 175 (SN < 90760371) and any serial No. starting with the letter D and Mini SAMSOFT 150 (SN < 90760431)**

I hereby confirm that preventive replacement of the V1 spreader bar axis with a reinforced spreader bar axis has been completed for all devices.

or

I have identified the following devices for which I request despatch of reinforced spreader bar axis kits.
(Please enter the serial numbers in the table below)

Signed in _____ on ____/____/____

Signature

Extract from the Samssoft 175 user manual:

USER MANUAL FOR SAMSOFT 175

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VIII-4) ROUTINE MAINTENANCE

(Monthly or as required; to be carried out by an authorised person). Routine maintenance consists of checking the patient lift functionality:

- With the patient lift on level ground, check the 4 castors are touching the floor.
- When the brakes are engaged, it must not be possible to move the patient lift (level and stable floor).
- Check the handles on the mast to ensure the boom and hoist legs move smoothly and without noise.
- Handle the handles on the mast and check there is no play between the boom and the mast and between the mast and the hoist legs.
- Check the plastic covers and protective housings are not broken and there are no cracks or missing parts.
- Check the condition of the connecting cables: power cable, handset, and actuator. If a cable shows the slightest trace of burning, wear, cut or if the wires are visible, quarantine the patient lift immediately and have the cables replaced by the technical service.
- The slings must be checked at least once a month, or more regularly if used intensively, to ensure the seams are not undone, the web of the upholstery and slings is not visible and there are no torn parts.

Never use a defective sling.

⚠ Only authorised service personnel or Drive DeVilbiss Sidhil Service Technicians should carry out repairs or service activities. Failure to do so may result in the manufacturer's warranty becoming void.

Worn or malfunctioning parts must be replaced with original parts manufactured by Drive DeVilbiss Healthcare France.

Complete a load test before putting patient lift back into service.

VIII-5) PREVENTIVE MAINTENANCE

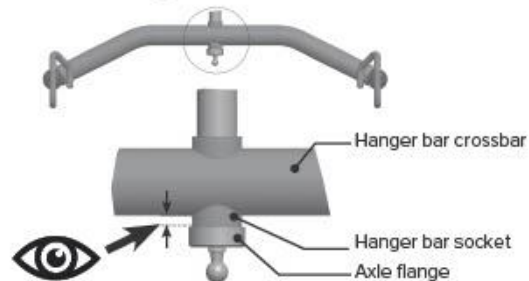
Annually or as required; to be carried out by an authorised person or Drive DeVilbiss Sidhil Service Technicians according with paragraphs 5.1, 5.2, and 5.3 below.

- It is a requirement to carry out preventative maintenance annually.
- Battery pack to be changed approximately every 18 months, depending on use.
- Annual maintenance must be carried out by technically qualified personnel trained in the maintenance of electromechanical equipment. Maintenance operations do not require any special tools; adequate tools must be used according to the best industry practices. Mechanical tightening, clearances, and adjustments must be carried out in accordance with the best industry practices.

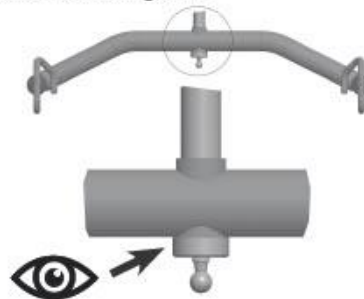
VIII-5.1) MECHANICAL CONTROL

- Remove the cover from the hanger bar and observe the axle and hanger bar assembly for wear:

Compliant assembly: the flange of the axle does not touch the crossbar of the hanger bar.



Non compliant assembly: the flange of the axle touches the crossbar of the hanger bar.



⚠ Caution: the axle and the hanger bar must be replaced immediately. The patient lift must not be used until all worn parts have been replaced and a verification has been carried out before putting it back into service.

- If the assembly is compliant, disassemble the axle from the hanger bar and clean any grease, debris or dust from the axle and hanger bar.
- Inspect the axle, flange, and cross hole for signs of damage, unacceptable wear or deformation.

A small amount of wear and tear may be seen on the inside of the flange in contact with the lifting beam socket. This small amount of wear is acceptable as long as the assembly is compliant (see above); if in doubt, replace the axle immediately.

- Repeat the inspection on the hanger bar **paying particular attention to the condition of the socket and welds.**
- Grease the axle and the socket of the hanger bar, taking care to grease the flange part and the socket.

Note: Use a suitable metal-to-metal grease or contact Drive DeVilbiss Healthcare France for any request.

- Carefully reassemble the assembly, ensuring everything is secure and the hanger bar rotates correctly around the axle.

Caution: The axle and hanger bar must be replaced every 5 years or when the above mentioned wear occurs, whichever comes first.

- Disassembly, cleaning and lubrication of front and rear castors.
- Disassembly, cleaning and lubrication of the mast hinge.
- Check the fastening, wheel play, and efficiency of the brakes.
- Check the welds. Visual inspection.
- Check the alignments. Visual inspection.
- Check and lubricate after dismantling the mast and hanger bar pivots.
- Check and grease the actuator fasteners.
- Re-tighten all parts.

Mechanical parts showing cracks, signs of wear or geometric defects must be replaced with original components supplied by Drive DeVilbiss Healthcare France.

VIII-5.2) ELECTRICAL INSPECTION

- Check the handset.
- Check the charger.
- Check the remote control box and the actuator.
- Check the lifting/lowering speed.
- Check the emergency stop and lowering.
- Condition of the electric cables (change the cables if in doubt).

Replace the electric cables, and/or the components to which they are connected, if they show signs of wear, sheathing cuts, plug degradation or blackening of the plastics and sheathing around the connection areas. Replace defective components with original ones. Never disassemble the protective covers of the actuator, battery pack, handset, control box and battery charger.

VIII-5.3) CHARGING TEST

- Charge the battery pack.
- Check the power and autonomy of the battery pack.
- Test of the patient when fully loaded at 175 Kg and check the cut threshold (230 Kg ± 10 Kg).

VIII-5.4) MAINTENANCE MANUAL

Every maintenance operation or intervention must be recorded in the maintenance manual attached to these instructions.

VIII-5.5) LIST OF SPARE PARTS

A list of spare parts is available on request.

IX - SHIPPING, STORAGE, AND DISPOSAL

- The patient lift must be returned or transported in its original packaging.
- Before storing the patient lift, clean it thoroughly and check its operation; store it in a dry room away from dust and moisture. The batteries must be fully charged every 3 months.
- When commissioning after storage, charge the battery pack, and check the operation before further use.
- Storage temperature: 0 to +50°C
..... Humidity between 10 and 80%
- Operating temperature: +10 to +40°C
..... Humidity between 30 and 80%

- Defective parts, packaging, and battery packs must be disposed of at authorised waste treatment centres.
- The device in question must not be disposed of with household waste, and must be handed in to an appropriate waste collection point or a distributor. The patient lift is subject to Directive 2002/96/EC on waste electrical and electronic equipment (WEEE) and marketed after 13 August 2015.
- By following these guidelines, you are doing your bit for the environment by helping to preserve natural resources and protect human health.

X - WARRANTY CONDITIONS AND LIABILITY

The SAMSOFT 175 is guaranteed for 5 years on structure, cylinder, and control box, in normal use according to the instructions given in this manual. Negligence, handling errors or accidents are excluded from the warranty. The remote control is guaranteed for 3 months, and the battery pack is guaranteed for 6 months.

- Any modification or addition of accessories without written consent from Drive DeVilbiss Healthcare France, will de facto exclude the patient lift from the warranty and from Drive DeVilbiss Healthcare France's liability. In particular, we cannot be held liable for the use of slings not marketed by Drive DeVilbiss Healthcare France for this patient lift.
- The periodic checks and inspections mentioned in the previous paragraph must be carried out by competent personnel and recorded in the maintenance book. Out of the warranty period, we cannot be held responsible if these checks and inspections are not carried out. Only spare parts and components supplied by Drive DeVilbiss Healthcare France can be used for repairs.
- Any serious incident occurring in connection with this patient lift must be notified to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

USER AND MAINTENANCE GUIDE FOR *Samssoft Mini* PATIENT LIFT

undone, the upholstery and sling weft is not visible, and there is no torn part.

Never use a defective sling.

⚠ The worn or malfunctioning parts should be replaced with original parts manufactured by Drive DeVilbiss Healthcare France. Have some tries with a load before commissioning the patient lift again.

9.5) Preventive maintenance

Every year or when necessary, and to be performed by a competent staff, according to paragraphs 9.5.1, 9.5.2, and 9.5.3 below.

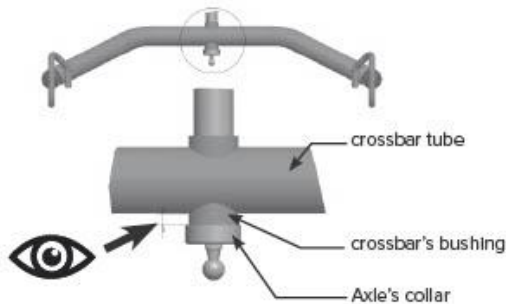
- It is necessary to control the device every year.
- The battery pack should be changed about every 18 months depending on how it is used.
- The crossbar suspension axle should be imperatively checked yearly on each maintenance task.

The yearly maintenance should be performed by skilled technical staff experienced with electromechanical device maintenance. The maintenance tasks do not require particular tools; adequate tools should be used according to the best industry practices. Mechanical fastening, plays, and adjustments should be realised according to the best industry practices.

9.5.1) Mechanical control :

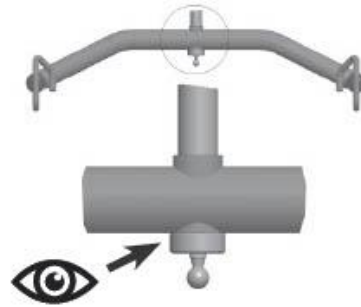
- Remove the crossbar's black padded cover (if fitted) and inspect the axle pin and crossbar interface to review any potential wear:

Compliant assembly: the collar of the axle does not touch the crossbar cross tube.



Non-compliant assembly: the collar of the axle touches the crossbar tube.

⚠ Warning: The axle and crossbar are to be replaced immediately. The hoist is to be taken out of service until the remedial work is completed and has been verified.



- If the assembly is deemed to be compliant, remove the axle from the crossbar and clean off all grease, debris and dust from the axle and the crossbar's bushing.
- Inspect the axle, its collar and the cross hole for any signs of damage, unacceptable wear, or deformation. A small amount of wear may be noticed to the face of the axle's collar where the crossbar's bushing end has rotated on it, a small amount of wear is acceptable but if in doubt replace it immediately.
- Repeat the inspection process for the crossbar, paying particular attention to the crossbar's bushing and all welds.
- Re-grease the axle/bushing ensuring that the contact face between the axle collar and the bushing end has grease applied. **Note:** use an appropriate metal to metal grease or contact Drive DeVilbiss Healthcare for product advice.
- Carefully reassemble all parts, ensuring that everything is secure and that the crossbar smoothly rotates about the axle.

⚠ Warning: the axle and crossbar are to be replaced every 5 years or when the wear identified above becomes apparent, whichever is sooner.

- Dismantling, cleaning, and lubrication of the front and rear casters.
- Control and lubrication after dismantling the mast and side rail pivots.
- Check the welding. Visual inspection.
- Check the alignments. Visual inspection.
- Control and lubrication of the cylinder fastenings.
- Check the tightening of all the parts.
- Dismantling, cleaning, and lubrication of the mast hinge. Check the fastening, caster play, and brake performance. The mechanical parts that have cracks, wear signs or geometrical defects should be replaced with original components delivered by Drive DeVilbiss Healthcare France.

9.5.2) Electrical inspection :

- Check the remote control. Reminder: the remote control does not enter the warranty field.
- Check the charger.
- Check the remote control box and the cylinder.
- Check the lifting/lowering speed.
- Check the emergency stop and lowering.
- Condition of the electric cables (change the cables in case of doubt).

Replace the electric cables and/or the components to which they

USER AND MAINTENANCE GUIDE FOR *Samssoft Mini* PATIENT LIFT

are connected if there are signs of wear, sheath cut, outlet damage or plastic and sheath darkening around the coupling area. Replace the electric cables and/or the components to which they are connected if there are signs of wear, sheath cut, outlet damage or plastic and sheath darkening around the coupling area.

Note : Never disassemble the protective housings of the cylinder, battery pack, remote control and control box, and battery charger.

9.5.3) Charging test:

- Charge the battery pack.
- Check the battery pack power and autonomy.
- Test the device when fully loaded (150 kg) and control the power cut threshold (230 kg +/- 10 kg).
- Tests.
- Battery pack should be changed every 18 months, depending on use.

9.5.5) Service book:

Every maintenance operation or intervention should be recorded in the service book attached to these instructions.

X - SHIPPING, STORAGE, AND DISPOSAL

- The patient lift should be returned or transported in its original packaging.
- Before storing the patient lift, clean it totally and check its performance. Store the patient lift in a dry place away from dust and humidity. The batteries should be totally charged every 3 months.
- When commissioning, after storing, charge the battery pack, and check its performance before using it again.
- Storage temperature: between 0 and + 50°C Humidity between 10 and 80%
- Service temperature: between +10 and + 40°C Humidity between 30 and 80%

- The disposal of defective parts, packaging and battery pack should be performed by approved waste treatment centres.



- The involved system should not be disposed of with household waste, but should be sent to an appropriate waste collection point or to a distributor.
- A financial contribution is given for collecting, dismantling, and recycling the system in question.
- By respecting these instructions, you respect the environment and participate in protecting the natural resources and the human health.

XI - WARRANTY CONDITIONS AND RESPONSIBILITIES

Samssoft Mini is warranted for 5 years as far as the structure, the cylinder and the control box are concerned, and in case of normal use according to the instructions given in this guide. Negligence, handling errors and accidents are excluded from the

warranty. The remote control is guaranteed for 3 months, and the battery pack is guaranteed for 6 months.

Any modification or addition of accessories without Drive DeVilbiss healthcare France's written consent will de facto exclude the product from the warranty and from Drive DeVilbiss healthcare France liability. In particular, using straps that are not marketed by Drive DeVilbiss healthcare France for this patient lift will not entail our liability.

The regular checks and inspections mentioned in the previous paragraph should be performed by a competent staff and recorded in the maintenance book. **Out of the warranty period, our liability will not be entailed if you do not respect these controls and inspections.**

Only spare parts and components provided by Drive DeVilbiss Healthcare France can be used to repair the device.

In case of unsolved technical problems, please contact the Customer Service:

Tél. : +33(0)3.83.495.451
Fax : +33(0)3.83.494.391
E-mail : sav@drivevilbiss.fr

SCHEDULE II: distinction between a V1 spreader bar axis (to be replaced) and a reinforced spreader bar axis

