REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

*NOTE: This form is to be used **after** an inquest.*

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. The Medicine Healthcare products Regulatory Agency (MHRA)** **2. London Borough of Southwark (Occupational Therapy Service and Asset Management Team).** **3. Prism Medical UK Ltd.** **4. Bureau Veritas UK Ltd.** **5. His Honour Judge Thomas Teague KC, The Chief Coroner for England, and Wales.**
1	**CORONER** I am Christopher Williams an Assistant Coroner, for the Coroner Area of Inner London South (Southwark Coroners Court).
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and Regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.
3	**INVESTIGATION and INQUEST** On the 27th July 2021 an investigation commenced into the death of **Shirley Frances Ashelford,** born 30th June 1961, and who died on 20th July 2021. The investigation concluded at the end of the inquest on 9th August 2023. The medical cause of death was: *1(a) Asphyxia* *1(b) Chest compression with suspension from Mobility Body Hoist Harness* *II Multiple Sclerosis.* I recorded the following factual findings in Box 3 of the Record of Inquest: *At the time of her death Shirley had secondary progressive multiple sclerosis, diagnosed in 2000, which severely restricted her mobility.* *Despite her condition, preventing her from standing up and walking, she was determined to live as independently as possible sharing a home with her husband.* *Her daily routine was to wake at 06:00 am, and call her husband between 07:00 and 07:30 am, to assist her getting dressed.* *On the morning of the 20/7/21 whilst she was transferring from her bed to a mobility scooter, using a mechanical ceiling hoist, the lowering mechanism failed leaving her suspended with her feet off the floor in the hoist chest harness.*

	The harness tightened causing compression of the chest which, in combination with respiratory weakness caused by multiple sclerosis, led to fatal asphyxia. *Her husband awoke at about 08:00 am, when he did not hear his usual alarm call, and discovered her unresponsive in the hoist harness.* *Despite attempts at resuscitation she was pronounced dead after the arrival of the ambulance service.* Based on those factual findings my Conclusion in Box 4 of the Record of Inquest was: *Misadventure*
4	**CIRCUMSTANCES OF THE DEATH** Shirley was aged 60 at the time of her death. Following a diagnosis of multiple sclerosis, in 2000, her mobility slowly declined, eventually losing the ability to stand and walk and becoming reliant on a mobility scooter. In February 2003 she referred herself to the London Borough of Southwark Occupational Therapy (OT) Services who over the years arranged adaptations to her home to assist with her declining mobility. She was provided with a powered transverse hoist to transfer her from her bed to a mobility scooter. The hoist was a Freeway Transactive Xtra, serial No. TXD23090, Manufactured by Prism Medical UK. It consisted of a motor which moved along an H-track frame, installed in the ceiling, above the bed. Attached to the motor was a harness consisting of 2 lines which attached to the front and back of a sling which fitted around the chest area. The sling was a Liko Mastervest MOD 64. The sling/harness was designed to tighten around the chest when put under weight to prevent a user sliding through it. When the hoist was working correctly Shirley would only be suspended for a matter of seconds before her feet encountered the floor when transferring to the scooter. She operated the hoist using a handheld control which had 6 buttons for movements in every direction, up/down, left/right, and forwards/backwards. The local authority employed an independent contractor, Higher Elevation Ltd to maintain the working of the hoist. The contractor's attendance was organised by the local authority Asset Management Team (AMT). Higher elevation produced visit report sheets which they sent to the AMT. The AMT in turn did not provide the visit reports to the OT department. In the months leading up to her death Shirley reported problems with the hoist getting stuck when trying to lower it and causing her to be suspended in mid-air. This was documented in emails to her Occupational Therapist (OT). On the 25/3/21 she described being trapped in the hoist for 5 minutes and stating *"… the pain all this is causing me is immense and the damage to my condition is noticeable…"* . On the 9/4/21 she emailed her OT describing the hoist lowering problem as being occasional and that it worked normally most of the time. On the same day Higher Elevation advised the AMT that the hoist should be replaced. This was not communicated to the OT team by the AMT. On the 30/6/21 Bureau Veritas UK Ltd, a private company, commissioned by the London Borough of Southwark, performed a 6 monthly inspection of the hoist, and reported no defects, which could become a danger to persons, were present. That report was made to the AMT but not to the OT department. The report does not

	indicate that Bureau Veritas was aware of the reports Shirley had made to the OT, and the Higher Elevation report of 9/4/23. On the morning of 20/7/21 Shirley's husband found her suspended in the hoist halfway between the bed and mobility scooter in an upright position with her feet about 2 inches off the floor. He manoeuvred her above the scooter using the hoist handheld control, which although unable to lower, was still operating in the horizontal plane. He then used a knife and scissors from the kitchen to cut the harness lines to lower her onto the scooter and called the ambulance. It is significant that he did not use a red emergency cord, located on the hoist unit underside, to lower her. He revealed at the inquest that he had not received training on its use. He then attempted to perform CPR whilst she was on the scooter because he could not move her onto the floor by himself. The ambulance service attended about 10 minutes later and pronounced life extinct. Rigor-mortis was noted. An initial Post-Mortem report, 3/11/21, considered that positional asphyxia was possible due to the presence of petechial haemorrhages of the sclera but the pathologist, [redacted], was only able to offer the cause of death as 1(a) Unascertained. A neuropathologist had also been unable to identify a cause of death. A second pathologist, [redacted], was provided with a diagram and description of the position in which Shirley was suspended in the hoist and concluded in a report 2/5/23 that the harness tightened causing compression of the chest which, in combination with respiratory weakness, from multiple sclerosis, led to the fatal asphyxia. When submitting his report [redacted] provided me with several medical publications of studies of deaths caused by straps and harnesses in different settings to illustrate his finding as to the cause of death. The Pathology Report and medical publications are attached. Based on the pathology findings I ruled out 'natural cause' on the basis that chest compression from a mobility hoist harness was not a natural event but the failure of a piece of manufactured equipment. I recorded a conclusion of Misadventure because death resulted from an unintended mechanical failure of the hoist to lower and the unforeseen increasing pressure on the chest area caused by the sling restricting Shirley's breathing movements.
5	**CORONER'S CONCERNS** From the evidence I received, at the inquest, there are matters giving rise to concern. In my opinion there is a risk that future deaths could occur unless action is taken. In the circumstances it is my statutory duty to report to you. During the inquest I heard evidence of the following matters: • Shirley was an unusual local authority OT service user because she operated her hoist and sling mainly without the assistance of a carer because she wanted to maintain her independence and dignity as much as possible. Because she had mental capacity the OT service respected her wishes. • Shirley's husband who was the main carer at the time of her death did not receive any training from the local authority in safe usage of the hoist and in particular use of the red emergency pull cord. It was not clear whether Shirley had received any training on the use of the red pull cord when she was

provided with the hoist because there was no paperwork confirming training had been delivered.

- I found that when Shirley was suspended in the hoist, she did not use the red pull cord, on the underside of the hoist unit, because it had not lowered and because her husband was able to use the hand control to manoeuvre her toward the scooter. He would not be able to do this if the red cord had been pulled because the electric power would switch off.

- Higher Elevation reported inspections of the hoist to the AMT but not to the OT department. The AMT, in turn, did not share those reports with the OT department.

- The Inspection by Bureau Veritas 30/6/23 only reported to AMT but not the OT dept. The AMT did not share the report with the OT department. I was informed that although the Lifting Operations and Lifting Equipment Regulations 1988 (LOLER) did not apply, nonetheless six-monthly inspections were performed on a voluntary basis.

- The last Bureau Veritas inspection was done without access to reports from Higher Elevation and email reports from Shirley to the OT department. Veritas reported there were no problems on its last inspection of 30/6/23 over 2 weeks before the death. That report was made without sight of the Shirley's report to the OT department, on 9/4/21, and the Higher Elevation report to the AMT on the same day.

- I was also told by Shirley's husband that the same model of hoist in the bathroom had also failed to lower on occasions.

- At present the bedroom hoist, and hoists in the bathroom and living room remain in situ at Shirley's home and are available for inspection. Shirley was a local authority tenant when she died and due to pressure on its housing stock the local authority is anxious to re-let the property to new tenants. Therefore, it is desirable that the hoists are inspected in situ as soon as possible. Otherwise, they will have to be inspected whilst in local authority storage.

- I was reassured that the London Borough of Southwark is seeking to introduce guidance to its OT service to ensure the risk of recurrence in future is reduced in relation to service users operating hoist equipment unassisted in their homes. However, given my concern that recurrence should be avoided elsewhere in England and Wales I am reporting this to the MHRA to investigate and if necessary, alert and give guidance to other local authorities regarding the evidence which emerged during my investigation.

The **MATTERS OF CONCERN** are as follows. –

<u>Awareness of Asphyxia Risk – Service Providers</u>

1) The risk of fatal positional asphyxia associated with the use of harnesses/slings when hoisting was not appreciated by the OT services and AMT concerned with the provision, use and maintenance of the hoist. This indicates that training may be required to raise awareness of the risk of positional asphyxia in order to reduce the risk of future deaths. I consider it important to highlight to service providers the dangers associated with unassisted use of ceiling hoists and sling harnesses.

	Awareness of Asphyxia Risk – Users and Carers 2) Users and carers did not appear to have been made aware of the asphyxia risk associated with hoisting. It was not clear whether Shirley was trained in the use of the red cord safety feature on the hoist as there was no documentation to confirm this. Her husband and carer had never received training in the use of the red cord for emergency lowering. He was also unaware of the risks of positional asphyxia when Shirley was operating the hoist on her own. My concern is that there may be a general a lack of training of users and carers in the operation of this type of hoist and the risk of positional asphyxia. Information Sharing – Service Providers 3) I am concerned that two departments in the local authority, the OT department and AMT, did not share information concerning the condition of the hoist, namely, Shirley's reports to OT were not shared with AMT and visit reports from contractors to AMT were not shared with the OT. Likewise, the Bureau Veritas inspection on 30/6/21 appears to have occurred in an information vacuum regarding recent problems with the hoist. Whilst the Veritas inspection report was shared with the AMT it was not shared with the OT department. Possible Hoist Design Problem 4) There was some evidence that another hoist of the same model in the bathroom had a problem with the lowering function and the possibility of a fault in the design of the lowering function. I raise this concern to alert the MHRA and Prism Medical UK Ltd in order to conduct appropriate safety investigations. The hoists are available in situ for a limited period or otherwise will be kept in storage by the Local Authority for inspection purposes. Inspection of Hoist without background information 5) I am concerned that the Bureau Veritas inspection report of 30/6/21 made no reference the report of Higher Elevation and Shirley's complaint on 9/4/21 indicating that the inspector was unaware of recent problems. Had they been aware they might have been able to detect the problem which caused the failure of the hoist to lower on the 20/7/21. Enclosures accompanying the Regulation 28 report: [redacted] Post-Mortem report 2/5/23, exhibiting 3 academic articles on positional asphyxia. Diagram prepared by [redacted] (Shirley's husband). Manufacturer's guidance on the use of Transactive-Xtra hoists.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe your organisations has the power to take such action.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by the day month **2023.** I, the coroner, may extend the period.

	Your responses must contain details of action taken, or proposed to be taken, setting out the timetable for action. Otherwise, you must explain why no action is proposed.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the Chief Coroner and to the following Interested Persons who may find it useful or of interest: 1. Solicitors representing the London Borough of Southwark. 2. Higher Elevation Ltd. 3. [redacted] next-of-kin. 4. [redacted] pathologist. 5. [redacted] pathologist. I am also under a duty to send the Chief Coroner a copy of your response. The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.
9	**Dated:** **Signed:** **17th August 2023** **Christopher Williams**