







Safety Communication

Instability in the baby scale cart

Device/ Product Description:	Baby Scale Carts: Wheels May Loosen		
Brand Name:	Seca 402 & 403		
Lot numbers/Serials:	Model	Serial No.	Material No.
	seca 402	6002142000002 to 6002142001101	4020000009
	seca 403	6002143000002 to 6002143001851	4030000009
Manufacturer:	Seca Ltd		
Problem:	<p>The wheels on the above carts may loosen and fall off, causing cart instability and potentially causing the scale to fall. The manufacturer also states that wheel loosening is difficult to see without specifically checking for the problem, which is unpredictable and may occur at any time.</p>		
Recommendation/Actions:	<ol style="list-style-type: none"> 1. Identify any affected carts in your inventory. 2. Using an Allen wrench (wrench size: 6 mm), re-tighten all screw connections as much as possible 3. Apply the brakes on both wheels. 4. Mark the baby scale with a warning label. 5. Quarantine the carts by placing them in one specific location. 6. Contact the Authorized Representative to provide your facility with an update kit to correct the problem <p>You can find more information and recommendations from (HERE).</p>		

Devices/Products photo:	seca 402	seca 403
		
	Wheel with brake (and loosened screw connection)	Screw connection
		
	Loosened screw connection	Tightening the screw connection with hex key (wrench size: 6 mm)
		
Authorized Representative Details	Company name:	AlgoSaibi Co.
	Contact Person:	Mouayad Al- Hamwi
	Phone:	+966 500618528
	Email:	malhamwi@aralgoSaibico.com



Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.

Medical Devices Sector

Saudi Food and Drug Authority

Postal Address: Saudi Arabia - Saudi Food and Drug Authority

4904 Northern Ring branch rd – Hitteen Dist.

Riyadh 13513 - 7148

Tel: +966 (11) 2038222 Ext: 2995, 2952

Fax: +966 (11) 2757245

Or

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Sincerely,
NCMDR Team

