

**Urgent Field Safety Notice**  
**Voluntary Field Safety Corrective Action**  
**seca 402 und seca 403 Cart for seca Baby Scale**

<b>Product:</b>	seca 402 und seca 403
<b>Possible Incidents</b>	Loosening of individual wheels (equipped with brake); potential risk of tipping of baby scale cart; potential risk of scale falling from cart
<b>Affected serial numbers</b>	seca 402: 6002142000002 - 6002142001101 seca 403: 6002143000002 - 6002143001851
<b>Material numbers</b>	seca 402: 4020000009 seca 403: 4030000009
<b>Immediate measures</b>	<ul style="list-style-type: none"><li>• <b>Re-tightening of screws</b></li><li>• <b>Apply the brakes</b></li><li>• <b>Stationary use only</b></li></ul>

During a recent quality control process, we identified an issue in the seca 402/403 (Carts for seca Baby Scales) which may pose a risk to the patient. We would like to inform you about this below.

**Reason for this notice: Instability in the baby scale cart**

Two wheels of the baby scale cart are equipped with a locking brake that prevents the cart from rolling away and the wheel mountings from rotating on their axes. The screw connections can loosen (see attachment 1) and, in worst case, the wheels can detach from the cart completely. The cart can become unstable and tip over, potentially leading to the scale falling from the cart.

The loosening and detachment of the wheels is difficult for the user to detect. The issue cannot be predicted and therefore can occur without warning at any time. We are issuing this notice and requesting your assistance to minimize any potential risk of injury. It is very important that you follow the below instructions carefully.

**DISTRIBUTORS: Immediate Measures to Take**

1. Please stop the delivery of the baby scale carts right away.
2. If you have any carts in stock, quarantine the carts by placing them in one specific location.
3. Complete your contact details in the section "our local contact person" of the Urgent Field Safety Notice and
4. IMMEDIATELY forward the Urgent Field Safety Notice to your customers.
5. Please confirm receipt of this Urgent Field Safety Notice by returning to us the response form in attachment 3 by e-mail to our local contact person within one week of receipt of this notice.

6. Wait for further information about Upgrade Kit to replace the affected wheels. (see section Upgrade Kits).

**End Users: Immediate Measures to Take (hospitals, medical practices etc.)**

1. With the appropriate hex key (wrench size: 6 mm), re-tighten all the screw connections as firmly as possible (see attachment 1).
2. Apply the brakes on both wheels.
3. Mark the baby scale cart with the warning label (see attachment 2).
4. Do not make mobile use of the cart, use it only at one fixed location.
5. Please confirm receipt of this Urgent Field Safety Notice by returning to us the response form in attachment 3 by e-mail to our local contact person within one week of receipt of this notice.
6. Wait for further information about Upgrade Kit to replace the affected wheels. (see section Upgrade Kits).

**Upgrade Kits**

seca is already working on a long-term solution in the form of an Upgrade Kit. The kit will consist of two wheels with optimized design and tools for the replacement.

Beginning in September 2019, seca will ship the Upgrade Kits. The issue can be corrected at the site where the carts are used or in stock. It is not necessary to return the carts to seca.

**Our local contact person**

For the return of the customer response or further support in connection with this corrective action, please contact our seca contact:

Company: (name and address)	
Contact person (name):	
E-mail address:	
Telephone number:	

Kind regards







seca gmbh & co. kg

**Attachments:**

1. Pictures to assist in implementing immediate measures
2. Warning labels
3. Customer Response

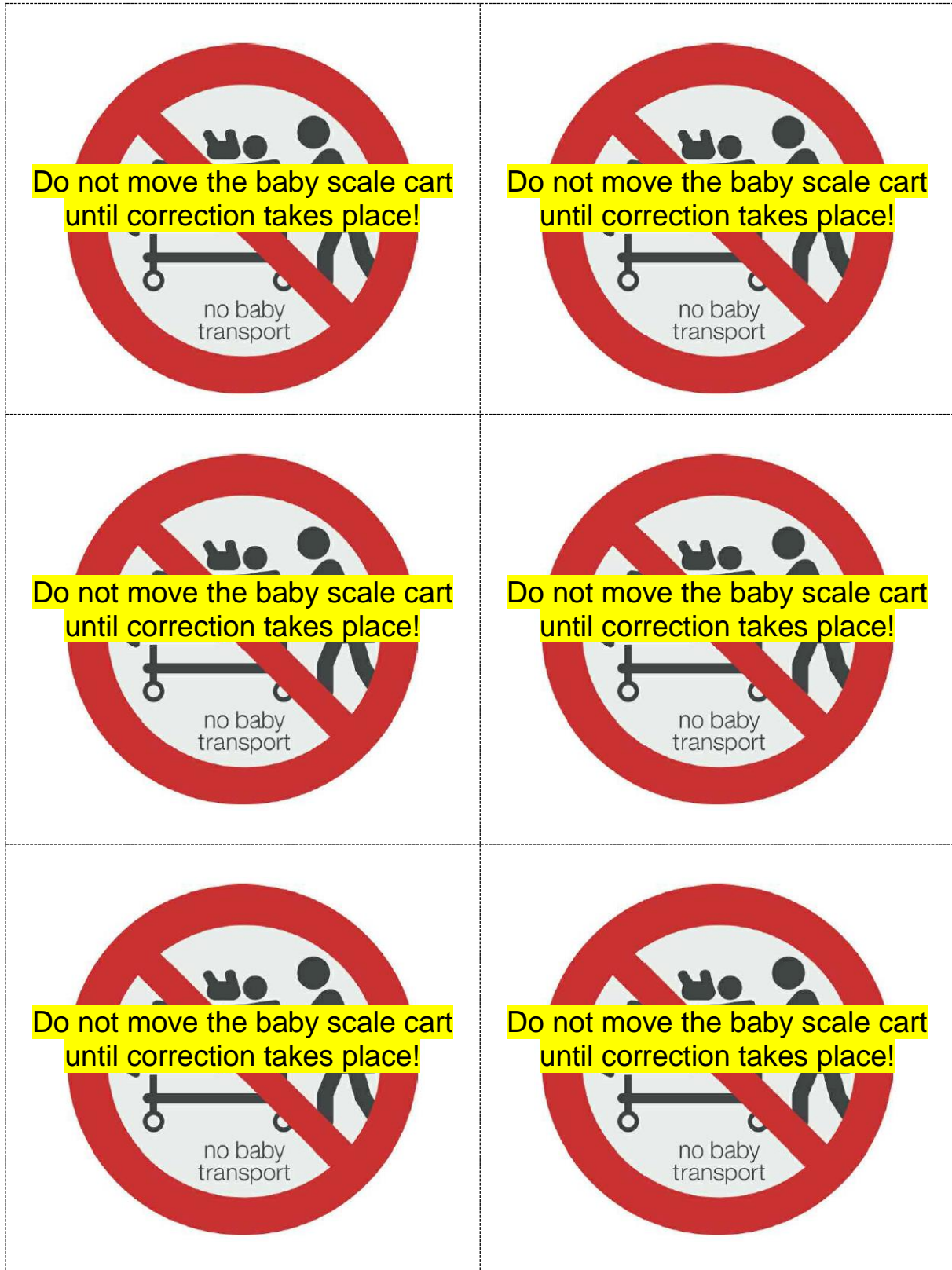
## Attachement 1

Pictures to assist in implementing immediate measures

<p><b>seca 402</b></p> 	<p><b>seca 403</b></p>  <p>Serial number and material number</p>
<p><b>Wheel with brake</b> (and loosened screw connection)</p> 	<p><b>Screw connection</b></p> 
<p><b>Loosened screw connection</b></p> 	<p><b>Tightening the screw connection with hex key</b> (wrench size: 6 mm)</p> 

## Attachement 2

**Warning labels** Print the template in colour, cut it out at the dashed edges and attach it clearly visible to the Baby Scale Cart



# Customer Response

**Urgent Field Safety Notice:** seca 402 and seca 403  
Cart for seca baby scale

<b>Product</b>	seca 402 und seca 403	
<b>Possible incidents</b>	Loosening of individual wheels (equipped with brake); potential risk of tipping of baby scale cart; potential risk of scale falling from cart	
<b>Affected serial numbers</b>	seca 402: 6002142000002 - 6002142001101 seca 403: 6002143000002 - 6002143001851	
<b>Material number</b>	seca 402: 4020000009 seca 403: 4030000009	
<b>Immediate measures</b>	<b>Distributors:</b> <ul style="list-style-type: none"> <li>• Stop the delivery of the baby scale carts right away</li> <li>• Quarantine the carts</li> <li>• Forward the Urgent Field Safety Notice to your customers</li> </ul>	<b>End User:</b> <ul style="list-style-type: none"> <li>• Re-tightening of screws</li> <li>• Apply the brakes</li> <li>• Stationary use only</li> </ul>

To be completed by the customer	
<b>Customer number</b>	
<b>Business Name and Business Type</b> (e.g., distributor, hospital)	
<b>Address</b>	
<b>Person in charge</b> (name, position)	
<b>Telephone number</b>	
<b>E-mail address</b>	

Please check the relevant boxes:

- I have received the Urgent Field Safety Notice from seca on a voluntary corrective action in the market for the seca 402 and seca 403. I have read and understand the instructions provided in this letter.
- I have implemented the immediate measures listed above.
- I have checked our inventory and the following products are in our possession.

→ Quantity:	seca 402:	seca 403:
→ Serial number: please attach your own list with serial numbers	seca 402:	seca 403:

**Please send this customer response to our local contact person**  
(see cover letter page 2)

Thank you very much for your support.  
seca gmbh & co. kg, Hammer Steindamm 3-25, 22089 Hamburg