



26 June 2008

Dear Sir/Madam,

Kaye Posture Control Walker™ Field Safety Notice / FSCA-identifier: 190508

Please find enclosed a copy of a Field Safety Notice concerning Kaye Posture Control Walkers™ issued in 2007.

Whilst the likelihood of any failure is extremely low, we would ask you to circulate this notice to the relevant person(s) who received a Kaye Walker of the sizes and types detailed in the attached notice, whether they are parents, therapists or end-users, during this period. Similarly to those involved in equipment provision, we would ask you to distribute copies to loan stores representatives and all personnel involved in the issue and re-issue of this piece of equipment.

Following dialogue with the MHRA, Quest 88 has raised this notice in order advise parents, guardians, users and therapists to check the equipment concerned. Should any remedial work be necessary as a result of inspecting the equipment, this can and will be carried out on-site or at home or clinic by a Quest 88 representative. With some 14,500 Kaye Walkers supplied by Quest 88 over the last 18 years, we are confident that this issue is extraordinarily rare, however, it is important that we do all we can to ensure that any risk of failure is eliminated relating to the use of the Kaye Walker.

Should you require further hard copies or electronic versions of this safety notice to assist you with distribution please contact us. Similarly, if you can assist us in our distribution by informing us of other key personnel in your organisation, or if you have passed your child's walker back to the supplying authority or to other parents – we would ask you to contact us in order that we can forward this information onto the relevant people. You may also download the Field Safety Notice from our website: www.quest88.com.

Finally we would ask you to complete the following slip and return it to us, via our freepost address, as a receipt of this letter. Thank you for your cooperation in this matter. If you have any questions concerning the contents of the Field Safety Notice or this letter please do not hesitate to contact us on 01952 463050.

Yours faithfully

Robert Henshaw (Joint Managing Director)

Quest 88 FSN - REPLY SLIP

Your name: _____

Your organisation and/or address: _____

Tel no. _____ Email address: _____

I confirm receipt of the above letter and of the enclosed field safety notice and (choose as applicable):

- I have distributed the notice to the relevant people in my organization.
- I have checked the equipment in question and I am satisfied that the walker is safe relevant to the conditions described in the field safety notice.
- I /We no longer have this equipment in our possession – please contact
Name: _____ Tel. No. _____
- Please supply me with a further ___ copies of the field safety notice.
- Please email me an electronic version of the field safety notice:
Email: _____

Return to: Quest 88 Limited, FREEPOST NWW16763, Shifnal, Shropshire. TF11 8ZZ



therapy through activity



Kaye Posture Control Walker - sizes W2, W3, W4L (excluding seated walkers)

FSCA-identifier: 190508

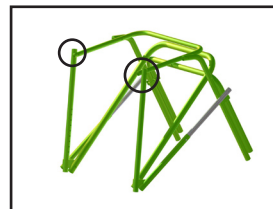
Type of action: Device Modification

Date: 19th May 2008

Attention: Physiotherapists, Occupational Therapists, Therapy Managers, Appliance Officers, Parents, Teachers, Stores Managers, Procurement Agents.

Details on affected devices:

Kaye Posture Control Walkers sizes W2, W3 & W4L
 Issued from 1st January 2007 to 17th December 2007



Description of the problem:

This Field Safety Notice has been raised to make people aware of a reported instance of a hand tube nut coming away during daily use of a Kaye Walker (please be advised that no injury was sustained). Following an extensive investigation, we believe that this failure was due to assembly operative error as it is feasible that an assembly operative failed to sufficiently tighten the nut on the hand U tube. Whilst this instance is extremely rare, we would ask you to be vigilant and respond to the advice that is detailed on page 2 of this notice.

Potential Risk: There is a perceived risk that the walker's hand tube could drop on one side should the affected nut and bolt come away simultaneously during use. Potentially this could temporarily disorientate the user of the walker and, if unsupervised, this could in extremely rare circumstances, result in a stumble or fall. Evidence following replicated tests would suggest that the nuts concerned would only loosen on a progressive basis and would not simply just drop off. In our own in-house tests, Quest 88 engineers have had to knock through the bolts with a nylon mallet in order to remove them, demonstrating that the bolt will not simply drop out should a nut unfasten, however it would be foolish for us to be complacent. The product user manual emphasises the importance of checking nuts and bolts regularly on Kaye Walkers, particularly if used by heavier users with erratic and awkward gait.

Advice on action to be taken by the user:

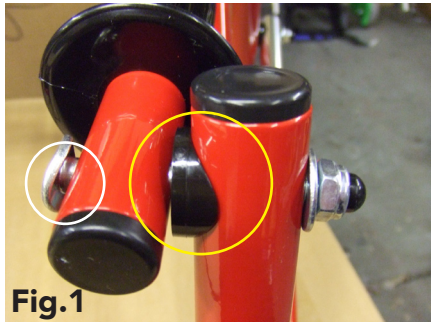
1. Identify all walkers with inspection stickers dated between the 1st January 2007 and 17th December 2007. If writing is unclear then contact the Quest 88 office on 01952 463050 and we will identify the date from the serial number.



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2. There was a design modification carried out on the Kaye Walker in mid August 2007. This will have a bearing on whether or not, you need to take further action!

If there is one saddle washer (spacer) between the hand tube and the upwrite (Fig.1) then you **DO NOT** need to take any further action. If there are two saddle washers (spacers) (Fig.2) then please do the following:



3. Ensure that the hand tube fixing bolts and nuts are secure and that the nuts (circled above) do not turn by hand. Also ensure that the contoured bolt head fits tightly against the hand tube and does not rotate when folding or unfolding the walker.
4. If you find that the nuts are loose, take the walker out of use immediately and contact Quest 88. If you have a servicing department or contact who has a torque wrench then the correct torque setting for the hand tube nut is: 4 N.m / 35.4 lbf.in. This is sufficient to penetrate the nyloc thread but not enough to restrict joint movement when folding the walker.
Alternatively, Quest 88 will arrange for a field representative to visit and secure the bolts using an appropriate torque wrench.
5. Label the walker and inform colleagues of your actions.
- 6.. **IMPORTANT:** If, after you have performed the checks above, you still have any doubts over the condition of the walker frame, please do not hesitate to contact Quest 88 for assistance.

Important: Transmission/Distribution of this Field Safety Notice:

Please complete the reply slip on the covering letter and return it to Quest 88 as receipt of this instruction as this will help us to ensure that this advice is reaching the correct recipient.

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact. If required, a PDF version of this notice can be obtained from Quest 88 for those who wish to redistribute this notice via email or intranet. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of any corrective action.

Contact reference person(s):

Robert Henshaw, Management Quality Representative	01952 468558
David Vernon-Henshaw, Operations Manager	01952 468557
Sandra Hall, Customer Services Representative	01952 468551

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Name: Robert Henshaw

Signature: 