

21 December 2005

FILE REF: 2005 Adult Circuit ROW Letter

Dear Sir/Madam,

Notice of Recall -

Fisher & Paykel Healthcare Adult Breathing Circuits - Dual Heated

Fisher & Paykel Healthcare has initiated a voluntary recall for adult breathing circuits that contain a spiral expiratory heater wire.

It has been identified that the manufacturing process of the Adult breathing circuits – dual heated, may have had the potential to damage the insulation of the heater wire in circuits within a specified lot range. This may lead to a potential risk of fire in some circumstances.

This recall affects ONLY adult breathing circuits with a spiral wound, expiratory heater wire manufactured by Fisher & Paykel Healthcare. The following circuits are NOT affected: EVAQUA™, single-limb heated circuits, and neonatal circuits.

The affected catalogue numbers are:

RT100, RT104, RT200, RT204, RT026, and 900MR914 (a starter kit which contains a RT200)

The affected lot codes are:

041101 to 050331 (inclusive).

Stock manufactured between 1 November 2004 and 31 March 2005.

Please check your stock of Fisher & Paykel Healthcare dual-heated, adult breathing circuits for any stock in the affected lot range, and destroy any stock you may have in that lot range. Please contact all your customers with this information and request they acknowledge this action and they destroy all stock.

In addition, Fisher & Paykel Healthcare wishes to take this opportunity to advise you that the labelling for the catalogue numbers listed in this recall letter will be modified in the future to introduce a recommendation of a maximum 7 day use.

We apologise for any inconvenience this recall will cause. Please contact us if further details or clarification is required.

Yours sincerely



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Urgent: Device Recall Response Form

Please return this form by fax or post to the fax number / address listed below.

NOTE: A response is required even if you have no stock in the affected lot range.

I, _____, PLEASE PRINT, have received and acknowledge the details outlined in this letter.

Please indicate the amount of stock in your distribution in the affected lot range (041101 to 050331, inclusive) and the amount destroyed in the table below:

Catalogue Number	Number in stock	Number destroyed
RT100		
RT104		
RT200		
RT204		
RT026		
900MR914		

Please note, 1 box = 10 circuits.

Signature: _____

Name: _____ PLEASE PRINT

Position: _____

Hospital: _____

Date: _____

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