Baxter

(SFDA Notification letter)

DEVICE CORRECTION

September 17th, 2015

At the kind attention of: **National Center for Medical Device reporting**
Medical Devices Sector - SFDA
Kingdom of Saudi Arabia
Tel.: (+966) (1) 2759222
Fax: (+966)(1)2757245
E-mail: ncmdr.md@sfda.gov.sa

Subject: Field Safety Notice - Type of FCA – EXACTAMIX - Change User Manuals

Product Name: EXACTAMIX compounder model numbers 2400-DY and 2400-DX.

Product Codes: 2400DY and 2400DX

Serial numbers: Refer to the Attached affected customers list.

Dear NCMDR team,

Baxter Healthcare Corporation is providing you with this important information regarding the application software for EXACTAMIX compounders' model numbers 2400-DY and 2400-DX. All EXACTAMIX Compounders updated to Version 1.10 Application Software or newer are affected.

Baxter Healthcare Corporation sent you a Device Correction letter on July 23rd 2014 (see Attachment 2). The letter provided important information concerning the use of the Configuration Editor and changes to Universal Ingredients.

As indicated in the July 23rd 2014 letter, Baxter is now providing their customers with a revised Operator's Manual incorporating this important information.

Baxter Healthcare Corporation is requesting their customers to retain the EXACTAMIX Operator's Manual and discard all previously provided EXACTAMIX Operator's Manuals.
Baxter Healthcare Corporation is requesting their dealer, wholesaler, or distributor/reseller that distributed any product to other facilities, to notify the end user customers in accordance with their customary procedures.

Baxter AG
Müllerenstrasse 3, Volketswil
Postfach CH-8604, Switzerland

Baxter AG Scientific Office
PO Box 64332, Dubai, UAE
Tel +971.4.4298100

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Our records indicate that 01 customer (our distributor Al-Olaya Medical Establishment) have purchased those machines in Saudi Arabia. For your information, please find attached the communication that is being sent to the customers (See Attachment 1).

Should you have any questions, please contact Ziad Awadallah at +966 11 4343714.

Yours Sincerely,

17th Sep. 2015

ZIAD AWADALLAH
CQA Officer KSA
Baxter AG.
P.O. Box 246968 Riyadh 11312 Saudi Arabia
Phone : +966 11 4343 714
Fax : +966 11 4343 777
E-mail : ziad_awadallah@baxter.com

Attachment 1: Customer Letter.
Attachment 2: Initial SFDA notification Letter

Attachment 1: Customer Letter

Baxter

DEVICE CORRECTION

Month DD, YYYY *(to be adapted locally)*

Dear Sir/Madam *(to be adapted locally)*,

Affected Product *(to be adapted locally)*	Baxter Healthcare Corporation is providing you with this important information regarding the application software for EXACTAMIX compounders' model numbers 2400-DY, 2400-DX, 2400-DYR, and 2400-DXR. All EXACTAMIX Compounders updated to Version 1.10 Application Software or newer are affected.
Problem Description	Baxter Healthcare Corporation sent you a Device Correction letter on *Date* (see enclosed). *(to be locally adapted)* The letter provided important information concerning the use of the Configuration Editor and changes to Universal Ingredients.
Actions taken by Baxter to avoid reoccurrence of the issue	As indicated in the *Date* letter *(to be locally adapted)*, Baxter is now providing you with a revised Operator's Manual incorporating this important information. The updated manual is enclosed.
Action to be taken by the user	1. Please retain the enclosed EXACTAMIX Operator's Manual and discard all previously provided EXACTAMIX Operator's Manuals. 2. If you are a dealer, wholesaler, or distributor/reseller that distributed any product to other facilities, please notify your end user customers in accordance with your customary procedures.
Further information and support	If you have questions regarding this communication, please call Baxter Technical Support at *XXXXXXX* between the hours of *XX and XX* Monday through Friday. *(to be locally adapted)*

We apologize for any inconvenience this may cause you and your staff and look forward to continuing to serve your total parenteral nutrition (TPN) needs.

Sincerely,

Name *(to be adapted locally)*
Title *(to be adapted locally)*
Medical Products *(to be adapted locally)*
Baxter Healthcare Corporation *(to be adapted locally)*

Attachment 2: Initial SFDA Notification Letter
Page 1 of 2

Baxter

MOH letter

July 23rd, 2014

At the kind attention of: **National Center for Medical Device reporting**
Medical Devices Sector - SFDA
Kingdom of Saudi Arabia
Tel.: (+966) (1) 2759222
Fax: (+966)(1)2757245
E-mail: ncmdr.md@sfda.gov.sa

Subject: EXACTAMIX Compounder all models

Product code: 2400DY
Serial numbers : 45227, 45228, 45290, 45291, 45292, 45293, 45327, 45341, 45342, 45343, 45346, 45386, 45484, 45490, 45491, 45499, 45598, 45599, 45600, 45601, 45602, 45603, 45620, 45668, 45669, 45729, 45730, 45731, 45732, 45733, 45734, 45917, 45918, 45919, 45920, and 45921.

Dear NCMDR team,

Baxter AG would like to inform you about a potential issue with the application software for EXACTAMIX Compounder models. Compounders which were sold or upgraded between March 2011 and June 2014 are affected by the issue.

The issue may occur if a non-standard Universal Ingredient (UI) swap is used on EXACTMIX compounders. This non-standard method of UI swap is not one of the prescribed methods of changing the UI during compounding. The EXACTAMIX compounder uses a UI to flush the common fluid pathway at the end of compounding activities. A condition has been identified where if the universal ingredient in an active configuration is changed using the Configuration Editor rather than following the normally prescribed and supported methods as outlined in the Operator Manual, a flush of the outlet pump tube will not be initiated by the software. As a result, the original universal ingredient may remain in the tube and could be delivered to into the next bag. This could lead to an over delivery of the first universal ingredient, an under delivery of the subsequent universal ingredient, or a delivery of an unintended universal ingredient.

Therefore Baxter has decided to update page 127 of the EM2400 and EM1200 Operator Manuals to provide this further clarification: **IMPORTANT! The Configuration Editor is to be used only to create and manage non-active configurations. All changes to the Universal Ingredient of an active configuration must be made through the "Change Universal Ingredient" functionality described on Page 105.**

Baxter AG
Müllerenstrasse 3, Volketswil
Postfach CH-8604, Switzerland

Baxter AG Scientific Office
PO Box 64332, Dubai, UAE
Tel +971.4.4298100

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No complaints or reports of adverse events regarding this issue have been received.

Our records indicate that 01 customer (our distributor Al-Olaya Medical Establishment) have purchased those machines in our country. You will find attached, for your information, the letter that is being sent to those customers.

Sincerely,

23rd July 2014

ZIAD AWADALLAH
CQA Officer KSA
Baxter AG.
P.O. Box 246968 Riyadh 11312 Saudi Arabia
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Fax : +966 11 4343 777
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Attachment 1: Customer Letter