Delivering Efficiency to Healthcare

FAX COVER

From: *National Distribution & Contracting, Inc.*
Djana Milliken – Compliance
URGENT
****This is being faxed/emailed to the "bill to" account for your company. Please distribute to any/all branches.****

To:	**Date:**
Purchasing or Regulations Department	*3/3/2017*

Pages: 7 *(Including cover page)*

Regarding:

Welch Allyn Medical Device Recall
ProBP 2400 Digital NIBP Device

Comments:

Dear Distributor,

Attached is a letter we received from Welch Allyn regarding the recall on item # 2400. Our records indicate that you purchased this product from us. Please read attached letter and check your inventory for any affected product with listed lot number. If you have any of this product in stock please fill out attached "Request for return" form, so that we can issue you a RGA for return. ***Also, please make note that no credit will be issued without an RGA. If you have any questions please feel free to contact me. It is very important that we receive a response, a record of receipt is very important in documentation of these types of notices.*** *Additionally, if you have distributed these products to your customers, please advise them of the recall, and have return any affected product to you.*

Thanks,

Djana Milliken

Djana Milliken

407 New Sanford Road, La Vergne, TN 37086
compliance@ndc-inc.com / Phone: 615-324-6375 / Fax: 615-229-6801

Welch Allyn

Corporate Headquarters
4341 State Street Road
Skaneateles Falls, NY 13153-0220 USA
www.welchallyn.com

URGENT: MEDICAL DEVICE RECALL

ProBP 2400 Digital NIBP Device

February 21, 2017

Dear Welch Allyn Customer:

Welch Allyn has been made aware of a product quality issue which could potentially affect the **ProBP 2400 Digital Blood Pressure** devices manufactured by Microlife and distributed by Welch Allyn.

As a result of a defective electrical component in the battery charging circuit, when the ProBP 2400 is connected to the external power supply/battery charger, a potential over-voltage battery charging condition may occur. This potential defect resides with the device, not the battery.

The over-voltage condition can result in high NiMH battery temperatures that, in some cases, can reach levels sufficient to cause melting of the plastic (ABS) battery door and other adjacent plastic and foam device components.

Please be aware the ProBP 2400 DOES NOT use Li-Ion batteries. There is no risk of the highly publicized battery fires currently associated with Li-Ion batteries in some popular consumer products.

Affected units were shipped from Welch Allyn warehouses between May 1, 2015 and July 31, 2016.

All customers who purchased one or more ProBP 2400 will receive this notification, however not all customers who purchased one or more ProBP 2400 will have devices in the affected lots.

Out of an abundance of caution and desire to provide the highest quality product to our customers, Welch Allyn is recalling two production lots of ProBP 2400 digital NIBP devices to the user level. The following devices are being recalled and will be replaced with new devices at no cost to our valued customers.

Affected devices will have a serial number in the following ranges:

(21)07150001 – (21)07150620 *(620 devices)*
(21)12150001 – (21)12150500 *(500 devices)*
Note: (21) is NOT part of the serial number. It is the Global Unique Device Identification (GUDI) Application Identifier that precedes the Serial Number on any GUDI compliant label.

How to Locate Serial Number

Serial Number of the device can be found on the bottom of the device (see Figure 1). The Serial Number of devices in unopened packages are printed on the package label (see Figure 2).

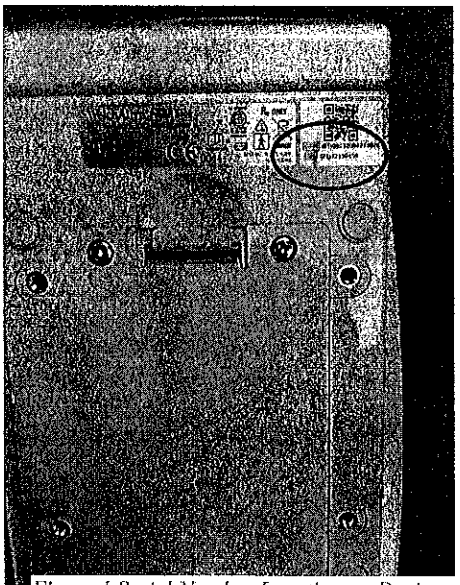

Figure 1 Serial Number Location on Device

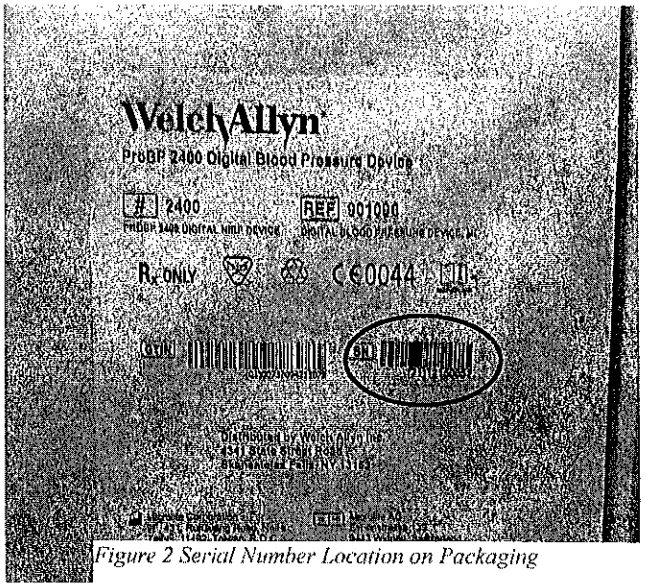

Figure 2 Serial Number Location on Packaging

Determine if you have any **Affected Devices** by comparing the serial number of each ProBP 2400 in your inventory against the serial number ranges described above.

Dealers: Inspect unsold inventory, quarantine any affected devices.

End users: Unplug the external power supply/battery charger from any device found to be in the affected lots. There is no risk of battery overheating when the device is operating on battery power.

See chart below for specific actions to take based on customer type.

CUSTOMER TYPE	ACTION TO TAKE	
US Sales Trace Reporting Distributors	Quarantine any remaining unsold inventory of devices displaying a serial number in the two affected lots as described above. Note the Serial Number of each Affected Device found in inventory. Welch Allyn will contact end user customers based on reported sales-trace data.	Obtain a Return Material Authorization (RMA) for return and replacement of Affected Devices. To obtain an RMA, you must provide the Serial Number of each Affected Device found in your inventory. Toll free contact number: 1-844 360 8220 (9:00am -- 4:00pm EDT) or Email: wa.recall@mdiconsultants.com

US Non-Sales Trace reporting resellers	Quarantine any remaining unsold inventory of devices displaying a serial number in the two affected lots as described above. Contact each of your customers who purchased one or more ProBP 2400. Provide them a complete copy of this notification and all accompanying documents. Provide Welch Allyn a complete list of your ProBP 2400 customers to whom you have forward this notice. Information for each customer should include: Facility name, complete mailing address, contact name and phone number. Email list to: wa.recall@mdiconsultants.com	Contact Ms. Maria Griffin, Recall coordinator mdi Consultants, Inc. at the below contact information to obtain a Return Material Authorization (RMA) for return and replacement of affected devices. To obtain an RMA, you must provide the Serial Number of each Affected Device found in your inventory. Toll free contact number: 1-844 360 8220 (9:00am – 4:00pm EDT) or Email: wa.recall@mdiconsultants.com
US End User Customers	Identify any ProBP 2400 in your facility that displays a Serial Number in the two affected lots as described above. Unplug the external power supply/battery charger from any device found to be in the affected lots. There is no risk of battery overheating when the device is operating on battery power.	Obtain an RMA for return and replacement of the recalled device. To obtain an RMA, you must provide the Serial Number of each Affected Device found in your inventory. Toll free contact number: 1-844 360 8220 (9:00am – 4:00pm EDT) or Email: wa.recall@mdiconsultants.com
Canada Dealers	Quarantine any remaining unsold inventory of devices displaying a serial number in the two affected lots as described above. Note the Serial Number of each Affected Device found in inventory. Contact each of your customers who purchased one or more ProBP 2400. Provide them a complete copy of this notification.	Obtain an RMA for return of the recalled device. New replacement devices will be shipped immediately To obtain an RMA, you must provide the Serial Number of each Affected Device found in your inventory. Toll free contact number: 1-844 360 8220 (9:00am – 4:00pm EDT) or Email: wa.recall@mdiconsultants.com

	Provide Welch Allyn a complete list of your ProBP 2400 customers to whom you have forward this notice. Information for each customer should include Facility name, complete mailing address, contact name and phone number with country code. Email list to: wa.recall@mdiconsultants.com	
Canada End User Customers	Identify any ProBP 2400 in your facility that displays a Serial Number in the two affected lots as described above. Unplug the external power supply/battery charger from any device found to be in the affected lots. There is no risk of battery overheating when the device is operating on battery power.	Obtain an RMA for return of the recalled device. New replacement devices will be shipped immediately To obtain an RMA, you must provide the Serial Number of each Affected Device found in your inventory. Toll free contact number: 1-844 360 8220 (9:00am – 4:00pm EDT) or Email: wa.recall@mdiconsultants.com
Dealers outside the US and Canada	Quarantine any remaining unsold inventory of devices displaying a serial number in the two affected lots as described above. Contact each of your customers who purchased one or more ProBP 2400. Provide them a complete copy of this notification. Provide Welch Allyn a complete list of your ProBP 2400 customers to whom you have forward this notice. Information for each customer should include Facility name, complete mailing address, contact name and phone number with country code. Email list to:wa.recall@mdiconsultants.com	Obtain an RMA for return of the recalled device. To obtain an RMA, you must provide the Serial Number of each Affected Device found in your inventory. For contact information, see list of country specific contact phone numbers.
End Users Outside the US and Canada	Identify and remove from service any ProBP 2400 in your facility that	Contact Welch Allyn to obtain an RMA for return of the recalled device.

	displays a Serial Number in the two affected lots as described above. Unplug the external power supply/battery charger from any device found to be in the affected lots. There is no risk of battery overheating when the device is operating on battery power	To obtain an RMA, Welch Allyn will need the Serial Numbers of each Affected Device found in your inventory. For contact information, see list of country specific contact phone numbers.

3/3/2017

Welch Allyn -ProBP 2400 Digital NIBP Device Recall

Please fill out and fax/email this distributor form within 10 business days, even if you do not have the recalled product.

Please complete and fax to: 615-229-6801 or email to: compliance@ndc-inc.com

REQUEST FOR RETURN FORM

Customer Information

Account No. _____

Account Name _____

Address _____

City/State/Zip _____

Contact Name _____

Phone No. _____

Fax No. _____

Email _____

Inventory Information

Item number	Lot number	Expiration date	Quantity to return

☐ I have read and understood the information within the accompanying notification. All relevant customers/ personnel have been informed of its contents, any necessary actions taken and records retained as part of our documentation.

☐ We have inspected our inventory and have no product related to this recall

_____

Completed by: (Print Name /Signature/Date)

Returned Completed form to:

Djana Milliken
Fax #: 615.229-6801
Email: compliance@ndc-inc.com