



لتقدم بثقة  
Moving Forward  
with Confidence



To:

**THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES**  
**Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)**  
**Director General of Engineering Affairs, MOH**  
**Director General of Royal Hospital**  
**Director General of Khoula Hospital**  
**Director General of Medical Supplies (MOH)**  
**Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)**  
**Hospital Director (Al Nahda Hospital)**  
**Hospital Director (Al Massara Hospital)**  
**The Head of Medical Services in SQU Hospital**  
**The Head of Medical Services in Royal Oman Police**  
**The Head of Medical Services in Ministry of Defence**  
**The Head of Medical Services in The Diwan**  
**The Head of Medical Services in The Sultan's Special Force**  
**The Head of Medical Services in Internal Security Services**  
**The Head of Medical Services in Petroleum Development of Oman**  
**The Head of Medical Services in LNG Oman**  
**ALL PRIVATE PHARMACIES & DRUG STORES**

After Compliments,

Please find attached our Circular No 68 dated 23/3/2025 Regarding SFDA Field Safety Corrective Action of Welch Allyn non-automated blood pressure gauges from (mfr: Welch Allyn, Inc).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information



**DSC**  
مركز سلامة الدواء  
Drug Safety Center





Circular No. 68 / 2025

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Moving Forward  
With Confidence



23 -09-1446 H

23 -03-2025

**Field Safety Corrective Action of Welch Allyn non-automated blood pressure gauges from Welch Allyn, Inc.**

Source	SFDA- Saudi Food & Drug Authority. <a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/315">https://ade.sfda.gov.sa/Fsca/PublishDetails/315</a>
Product	Welch Allyn non-automated blood pressure gauges.
Manufacturer	Welch Allyn, Inc.
Local agent	Ibn Sina Pharmacy LLC.
The affected products	Please refer to the attachment A.
Reason	Welch Allyn non-automated blood pressure gauges may not meet leak and accuracy specifications following exposure to high temperature storage. Baxter recommends storing the devices at a temperature not exceeding the operating temperature of 40°C/104°F.
Action	1. Customers may continue to use Welch Allyn non-automated blood pressure gauges if the device is calibrated. To check that the device is calibrated, please perform the following quick check of calibration as described in the product Instructions for Use. 2. At zero pressure, make certain the pointer is within the oval surrounding the zero-pressure gradation on the dial. If the pointer is fully outside of the tolerant zone (the darkly shaded area in the illustration) the device may need calibration. Although an unpressurized reading of zero does not guarantee accuracy at all scale points, failure of the pointer to indicate zero ( $\pm 3$ mm Hg) is an obvious sign of error. 3. For further information related to this product, visit the following link to the Instructions for Use: <a href="http://www.hillrom.com/content/dam/hillrom-aem/us/en/sap-documents/LIT/80025/80025959LITPDF.pdf4">www.hillrom.com/content/dam/hillrom-aem/us/en/sap-documents/LIT/80025/80025959LITPDF.pdf4</a> . 4. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: <a href="mailto:vigilance-md@moh.gov.om">vigilance-md@moh.gov.om</a>

Ph. Ibrahim Nasser Al Rashdi  
Director General



**DSC**  
مركز سلامة الدواء  
Drug Safety Center



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩  
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489  
☒ @DSCPHO Email: [dscpho@moh.gov.om](mailto:dscpho@moh.gov.om)



**Urgent Field Safety Notice**

**Welch Allyn non-automated blood pressure gauges.**

**FA-2024-071**

**Manufacturer: Welch Allyn, Inc (Single Registration Number: US-MF-000013394)**

**Important Product Information**

March 3, 2025

Dear Receiver:

Baxter Healthcare Corporation is issuing this Important Product Information letter to inform customers that **Welch Allyn** non-automated blood pressure gauges may not meet leak and accuracy specifications following exposure to high temperature storage. Baxter recommends storing the devices at a temperature not exceeding the operating temperature of 40°C/104°F.

**Affected Product**

Product Code	Product Description	UDI Number
See Attachment A	<b>Welch Allyn</b> non-automated blood pressure gauges. See Attachment A for detailed, individual product descriptions.	See Attachment A

**Hazard Involved**

There is a remote risk that blood pressure gauges exposed to high-temperature storage could lead to inaccurate measurement of blood pressure or the inability to inflate the blood pressure cuff.

**Actions to be Taken by Customers**

1. Customers may continue to use **Welch Allyn** non-automated blood pressure gauges if the device is calibrated. To check that the device is calibrated, please perform the following quick check of calibration as described in the product Instructions for Use.



At zero pressure, make certain the pointer is within the oval surrounding the zero-pressure gradation on the dial. If the pointer is fully outside of the tolerant zone (the darkly shaded area in the illustration) the device may need calibration. Although an unpressurized reading of zero does not guarantee accuracy at all scale points, failure of the pointer to indicate zero ( $\pm 3$  mm Hg) is an obvious sign of error.

2. For further information related to this product, visit the following link to the Instructions for Use: [www.hillrom.com/content/dam/hillrom-aem/us/en/sap-documents/LIT/80025/80025959LITPDF.pdf](http://www.hillrom.com/content/dam/hillrom-aem/us/en/sap-documents/LIT/80025/80025959LITPDF.pdf)
3. Complete the enclosed customer reply form and return it to Baxter by e-mailing it to [Bandar\\_Alosaimi@Baxter.com](mailto:Bandar_Alosaimi@Baxter.com) even if you don't have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

## Further Information and Support

For general questions regarding this communication or any product issue you are experiencing, contact Baxter at [Bandar\\_Alosaimi@Baxter.com](mailto:Bandar_Alosaimi@Baxter.com)

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Name Bandar Alosaimi  
Title CQA Lead  
Baxter A.G Saudi Arabia

Signature:

  
Bandar Alosaimi (Mar 3, 2025 14:45 GMT+3)

Email: [bandar\\_alosaimi@baxter.com](mailto:bandar_alosaimi@baxter.com)

Enclosures: Baxter Customer Reply Form  
Attachment A: Affected **Welch Allyn** Non-automated Blood Pressure Gauges

**Attachment A: Affected Welch Allyn Non-automated Blood Pressure Gauges**

PRODUCT CODE	PRODUCT DESCRIPTION	UNIQUE DEVICE IDENTIFIER
2254	PSS-45CB W/LARGE ADULT CUFF	20612479204120
105622	DS WALL UNIT GAGE	00732094236569
400270	HANDHELD GAUGE, SRC	00732094055184
400271	INTEGRATED POCKET GAUGE, SRC	00732094055177
400272	POCKET GAUGE, CLIP, SRC	00732094055160
402297	DS45 PSS LOGO	00732094052763
407450	ANEROID kPa GAGE COMPLETE	N/A
407637	MOBILE ANEROID W/ONE PIECE CUFF	00732094046755
407639	MOBILE ANEROID W/TWO PIECE CUFF	00732094046748
407671	MOBILE ANEROID W/NO CUFF	00732094046717
700875	GAUGE,DURASHOCK,WELCH ALLYN LOGO	00732094132335
704262	DS66 PURCHASED WITH MALE LUER	00732094128925
401183C	GAUGE, DURASHOCK, TYCOS LOGO INMETRO,CALIB	00732094006773
44S964	GAUGE,DS45,WELCH ALLYN	00732094004533
44S965-1C	GAUGE,DURASHOCK,PSS,LOGO,CALIBRATED	00732094004502
5090-02	POCKET GAGE W/ADULT CUFF	00732094110609
5090-02CB	POCKET GAGE W/ADULT CUFF	00732094110579
5090-03	PCKT MDL - GAUGE ONLY	00732094110548
5090-41	POCKET GAGE W/LARGE ADULT CUFF	00732094110494
5090-41CB	POCKET GAGE W/LARGE ADULT CUFF	00732094110463
5098-02	CLASSIC HAND GAGE, ADULT CUFF	00732094110128
5098-02CB	CLASSIC HAND GAGE, ADULT 2-PC CUFF	00732094110104
5098-03	CLASSIC HAND GAGE, W/O CUFF	00732094110081
5098-20	CLASSIC HAND, FAMILY PRACTICE KIT	00732094109955
5098-23	CLASSIC HAND, FAMILY PRACTICE KIT	00732094109900
5098-27	DS66 TRIGGER ANEROID, ADULT CUFF	00732094109856
5098-27CB	DS66 TRIGGER ANEROID, ADULT 2-PC CUFF	00732094109825
5098-28	DS66 TRIGGER ANEROID, LG ADULT CUFF	00732094109801
5098-28CB	DS66 TRIGGER ANEROID, LG ADULT 2-PC CUFF	00732094109788
5098-29	DS66 TRIGGER ANEROID, CHILD CUFF	00732094109764
5098-29CB	DS66 TRIGGER ANEROID, CHILD, 2-PC CUFF	00732094109740
5098-30	DS66 TRIGGER ANEROID, W/4-CUFF KIT	00732094109726
5098-30CB	DS66 TRIGGER ANEROID, 2-PC CUFF KIT	00732094109696
5098-31	DS66 TRIGGER ANEROID ONLY	00732094109672
5098-33	DS66 TRIGGER STUDENT BP CUFF SET	00732094109658
5098-42	DS66 TRIGGER STUDENT BP CUFF	00732094109603
5098-42CB	DS66 TRIGGER STUDENT BP 2-PC CUFF	00732094109580
51Y3000	MODUL WHITE	00732094108941
51Y40001	MODUL WITH POINTER WHITE	00732094108903
700875C	GAUGE,DURASHOCK,WELCH ALLYN LOGO, CALIBR	00732094079845



**Attachment A: Affected Welch Allyn Non-automated Blood Pressure Gauges**

PRODUCT CODE	PRODUCT DESCRIPTION	UNIQUE DEVICE IDENTIFIER
704262C	DS66 PURCHASED WITH MALE LUER,CALIBRATED	00732094079760
7670-01	767 WALL GAGE,ADULT CUFF	00732094072099
7670-01C	767 WALL GAGE,CHILD PRINT CUFF	00732094072075
7670-01CB	767 WALL GAGE,ADULT 2-PC CUFF	00732094072051
7670-01S	767 WALL GAUGE ONLY PLATFORM COLORS	00732094071986
7670-01W	767 INT WALL GAGE,ADULT CUFF	00732094071962
7670-02	767 WALL GAGE,WITH 8' TUBING	00732094071788
7670-03	767 MOBILE GAGE, ADULT, 4 LEG BASE	00732094071764
7670-03CB	767 MOBILE GAGE,ADULT, 2-PC 4 LEG BASE	00732094071740
7670-03K	767 MOBILE GAGE, W/O CUFF, 5 LEG BASE	00732094071719
7670-10	767 MOBILE GAGE,ADULT,5 LEG BASE	00732094071511
7670-10CB	767 MOBILE GAGE,ADULT,2-PC,5 LEG BASE	00732094071399
7670-16	767 DESK GAGE, ADULT CUFF	00732094071290
7670-33	DESK ANEROID W/ ADULT CUFF	00732094214079
DS44	DURASHOCK, GAGE ONLY	00732094085907
DS44-09	DURASHOCK, CHILD CUFF	00732094085884
DS44-09C	DURASHOCK,CHILD CUFF W/CASE	00732094085860
DS44-09CB	DURASHOCK, CHILD 2-PC CUFF	00732094085839
DS44-09P	DURASHOCK, CHILD PRINT CUFF	00732094085815
DS44-10	DURASHOCK, SMALL ADULT CUFF	00732094085662
<b>DS44-11</b>	<b>DURASHOCK, ADULT CUFF</b>	<b>00732094085631</b>
DS44-11BR	DURASHOCK, ADULT CUFF, BRAZIL	00732094215779
DS44-11C	DURASHOCK, ADULT CUFF & CASE	00732094085617
DS44-11CB	DURASHOCK, ADULT 2-PC CUFF	00732094085495
DS44-11CBT	DURASHOCK, ADULT 2-PC CUFF, TYCOS DIAL	00732094085488
DS44-11CV	DURASHOCK, ADULT & CASE, VARP	00732094085457
DS44-11V	DURASHOCK, ADULT CUFF, VARP	00732094085419
DS44-12	DURASHOCK, LARGE ADULT CUFF	00732094085389
DS44-12CB	DURASHOCK, LARGE ADULT 2-PC CUFF	00732094085365
DS44-13CB	DURASHOCK, THIGH 2-PC CUFF	00732094085341
DS44A	Durashock, Gauge Adapter	00732094084870
DS44A-001	DURASHOCK, FOR KENZ MEDICO	00732094084856
DS44-MC	DURASHOCK, DS44 MULTI CUFF KIT	00732094084924
DS45	DURASHOCK, GAGE ONLY	00732094084832
DS45-09	DURASHOCK, CHILD CUFF	00732094084818
DS45-10	DURASHOCK, SMALL ADULT CUFF	00732094084634
DS45-11	DURASHOCK, ADULT CUFF	00732094084610
DS45-11C	DURASHOCK, ADULT CUFF & CASE	00732094084498
DS45-11CB	DURASHOCK, ADULT 2-PC CUFF	00732094084474
DS45-12	DURASHOCK, LARGE ADULT CUFF	00732094084429



**Attachment A: Affected Welch Allyn Non-automated Blood Pressure Gauges**

<b>PRODUCT CODE</b>	<b>PRODUCT DESCRIPTION</b>	<b>UNIQUE DEVICE IDENTIFIER</b>
DS45-12CB	DURASHOCK, LARGE ADULT 2-PC CUFF	00732094084405
DS45-13CB	DURASHOCK, THIGH 2-PC CUFF	00732094084382
DS45A	DURASHOCK GAUGE ADAPTER	00732094083941
DS45-MC	DURASHOCK, DS45 MULTI CUFF KIT	00732094083965
DS48	DS48 GAUGE ONLY	00732094083927
DS48-11	DS48 W/ ADULT CUFF & CASE	00732094083903
DS48-11CB	DS48A W/ ADULT 2-PC CUFF & CASE	00732094083880
DS48A	DS48A GAUGE ONLY	00732094083866
DS-5401-189	DS-54 MANOMETER SINGLE TUBE	00732094087369
DS-5401-189CB	DS-54 MANOMETER WITH CUFF,	00732094087352
DS-5401-300	DS-54 MANOMETER ONLY WITH	00732094087338
DS-5402-189	DS-54 MANOMETER DOUBLE TUBE	00732094087307
DS-5402-189CB	DS-54 MANOMETER DBL TUBE	00732094087284
DS-5402-300	DS-54 MANOMETER ONLY WITH	00732094087277
DS-54L1-189	DS54 VERSION WITH SPOON	00732094087253
DS-54L1-189CB	DS54 VERSION WITH SPOON	00732094087239
DS-54L1-300	DS54 MANOMETER WITH SPOON W/O CUFF	00732094087215
DS-54L2-189	DS-54 MANOMETER DOUBLE TUBE WITH SPOON	00732094087093
DS-54L2-189CB	DS54 VERSION WITH SPOON Two Tube	00732094087079
DS-54L2-300	DS-54 MANOMETER ONLY WITH SPOON	00732094087048
<b>DS-5501-189</b>	<b>DS-55 MANOMETER CHROME HLIGHTS</b>	<b>00732094087024</b>
DS-5501-189CB	DS-55 MANOMETER CHROME HLIGHTS	00732094087000
DS-5501-300	DS-55 MANOMETER CHROME HLIGHTS	00732094086881
DS5502000	DS55, SCALE SW. RING CHROME 2 TUBE	00732094195675
DS-5502-189	DS-55 MANOMETER CHROME HLIGHTS	00732094086867
DS-5502-189CB	DS-55 MANOMETER CHROME HLIGHTS	00732094086843
DS-5502-300	DS-55 MANOMETER ONLY CHROME	00732094086829
DS-5511-189CBRMC	DS55, 1-TUBE,VELCRO CUFF, ROSER	00732094086805
DS-5511-189MH	DS55 SILVER LINE 1 TUBE MEDIKA HOF LOGO	00732094086775
DS-5511-189RMC	DS55, 1-TUBE, OPC, ROSER	00732094086737
DS-5511-300RMC	DS55, 1-TUBE,W/O CUFF, ROSER	00732094086713
DS-5512-189CBRMC	DS55, 2-TUBE,VELCRO CUFF, ROSER	00732094086706
DS-5512-189MH	DS55 SILVER LINE 2 TUBE MEDIKA HOF LOGO	00732094086683
DS-5512-189RMC	DS55,2-TUBE,OPC,ROSER	00732094086669
DS-5512-300RMC	DS55,2-TUBE,W/O CUFF, ROSER	00732094086652
DS-5521-129	DS-55 MANOMETER BLUE HLIGHTS	00732094086638
DS-5521-300	DS-55 MANOMETER BLUE HLIGHTS	00732094086614
DS-5521-400	PRACTITIONER SET, BLUE COLOUR	00732094086492
DS-5541-149	DS-55 MANOMETER RED HLIGHTS	00732094086478
DS-5541-300	DS-55 MANOMETER RED HLIGHTS	00732094086454

**Attachment A: Affected Welch Allyn Non-automated Blood Pressure Gauges**

<b>PRODUCT CODE</b>	<b>PRODUCT DESCRIPTION</b>	<b>UNIQUE DEVICE IDENTIFIER</b>
DS-5541-400	PRACTITIONER SET, RED COLOUR	00732094086430
DS-5561-169	DuraShock DS55 gelb, 1-SchIOPC MEt	00732094086416
DS-5561-300	DuraShock DS55 gelb, 1-SchIManalEt	00732094086287
DS-5561-400	SILVER LINE GELB PRAKT. SET FLEXI CUF	00732094208481
DS58	DS58 GAUGE ONLY	00732094083514
DS58-11	DS58 W/ ADULT CUFF & CASE	00732094083385
DS58-11CB	DS58 W/ ADULT 2-PC CUFF & CASE	00732094083361
DS58-MC	DS58 FAMILY PRACTICE KIT	00732094083347
DS58-MCCB	DS58 FAMILY PRACTICE KIT W/ 2-PC CUFFS	00732094083323
DS58-PD	DS58 PEDIATRIC KIT	00732094083309
DS58-PDCB	DS58 PEDIATRIC KIT W/ 2-PC CUFFS	00732094083194
DS58-ST	DS58 STUDENT KIT	00732094083170
DS58-STCB	DS58 STUDENT KIT W/ 2-PC CUFFS	00732094083149
DS-6501-189	DS-65 TRIGGER MODEL SILVER DUR	00732094086140
DS-6501-189CB	DS-65 TRIGGER MODEL SILVER WIT	00732094086126
DS-6501-300	DS-65 TRIGGER MODEL SILVER-MAN	00732094086102
DS-6601-000	DS-66 TRIGGER MODEL PREMIUM	00732094195736
DS-6601-189	DS-66 TRIGGER MODEL PREMIUM	00732094085983
DS-6601-189CB	DS-66 TRIGGER MODEL PREMIUM	00732094085952
DS-6601-300	DS-66 TRIGGER MODEL PREMIUM	00732094085938