



**PROSPERIDAD
PARA TODOS**

El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Informe de Seguridad asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Monitores de signos vitales WELCH ALLYN
NO. IDENTIFICACIÓN RISARH	I1402-60
REFERENCIAS DEL DISPOSITIVO MEDICO	ACUITY CENTRAL, MICROPAQ, MOBILE ACUITY LT, PROPAQ CS, COMMUNICATION SERVER (WACS), PROPAQ LT y 1500
REGISTRO SANITARIO	2009EBC-0003199
INDICACIONES Y USO ESTABLECIDOS	Aparato electrónico que capta y amplía la actividad eléctrica del corazón a través de electrodos colocados en las 4 extremidades y en 6 posiciones en el pecho, mide la presión arterial media, el pulso, la saturación de oxígeno y la temperatura.
NOMBRE DEL FABRICANTE	Welch Allyn Protocol Inc. Welch Allyn Inc
DESCRIPCION DEL PROBLEMA	Se afirma por parte del fabricante que la casa matriz WELCH ALLYN terminará con la fabricación y venta de las referencias antes mencionadas después de diciembre de 2014, en particular el PROPAQ CS con opción de CO ₂ fue suspendido desde el 24 de enero de 2014, sin embargo informa, que continuará proporcionando soporte y servicio técnico hasta por cinco (5) años mas o hasta que los repuestos y accesorios se agoten.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	10 de Febrero de 2014

RECOMENDACIÓN:

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con su proveedor quien determinara las acciones que se llevaran a cabo.

Es importante mantener un estado de alerta, realizando un seguimiento permanente a los productos que se fabrican y/o comercializan en el país, divulgando la información de seguridad respectiva entre los profesionales de la salud que realizan uso de estos recursos tecnológicos.

Para mayor información comuníquese al teléfono 2948700 extensión 3880 en Bogotá, ó al correo electrónico tecnovigilancia@invima.gov.co





ANEXO 1

A21633 - Normal Priority Medical Device Alert

Medical Device

Ongoing Action

Updated: February 7, 2014

UMDNS Terms:

- Monitoring Systems, Physiologic [12636]

Suggested Distribution:

- Cardiology/Cardiac Catheterization Laboratory
- Clinical/Biomedical Engineering
- Critical Care
- Nursing
- OR/Surgery

Geographic Regions:

- (Impact in specific regions has not been identified or ruled out at the time of this posting)
- Worldwide

Welch Allyn—Various Patient Monitoring Systems: Manufacturer Discontinues Sale

Product Identifier:

Patient Monitoring Systems: (1) Acuity Central, (2) Micropaq, (3) Moblie Acuity LT, (4) Propaq CS, (5) Welch Allyn Communication Server (WACS); Networked Patient Monitoring Systems (5) 1500, (6) Propaq LT [Capital Equipment]

Manufacturer:

- Welch Allyn Inc4341 State Street Rd, Skaneateles Falls, NY 13153-0220,

Problem: In a January 24, 2014, letter submitted by an ECRI Insitute member hospital, Welch Allyn states that it will discontinue the manufacture and sales of the above systems after December 2014 in non-CE marked countries, and after June 13, 2014, in CE marked countries. Welch Allyn also states that the manufacture and sales of the Propaq CS monitor configured with sidestream CO₂ option will be discontinued January 24, 2014. The manufacturer has not confirmed the information provided in the source material.

Action Needed:

Identify any affected product in your inventory. If you have affected product, verify that you have received the January 24, 2014, letter from Welch Allyn. Contact your Welch Allyn account manager or engineer to arrange for upgrades to the hardware and software before manufacturing ends. Welch Allyn states that it will continue to provide support and service to above product for up to 5 years or until parts and accessories are no longer available.

For Further Information:

Welch Allyn
Website: [Click here](#)

Comment:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our [HDA Format Guide](#).

Source(s):

- 2014 Feb 4. Member Hospital. Welch Allyn letter submitted by an ECRI Institute member hospital.