Medtronic

Hitna sigurnosna obavijest

Povlačenje ventilatora Newport™ HT70 i Newport™ HT70 Plus

21. svibanj 2025.

Medtronicova referencija: FA1479
jedinstveni registracijski broj proizvođača u EU-u (SRN): US-MF-000028763

Poštovani,

Svrha ovog pisma je obavijestiti vas da tvrtka Medtronic provodi povlačenje određenih serijskih brojeva Newport™ HT70 i HT70 Plus ventilatora te određenih povezanih Newport™ servisnih dijelova. Vezano uz ovo povlačenje, Medtronic preporučuje obustavu kliničke upotrebe zahvaćenih uređaja. Prema evidenciji tvrtke Medtronic, u vašu ustanovu poslan je jedan ili više ovih ventilatora ili servisnih dijelova.

Opis problema:
U našoj istrazi pritužbi korisnika identificirana su dva zasebna kondenzatora na jednoj od tiskanih pločica (PCBA) ventilatora, koji u slučaju kvara mogu dovesti do dva različita ishoda: ventilator se može isključiti tijekom upotrebe, što zahtijeva upotrebu alternativnog oblika ventilacije, ili se alarm za isključivanje uređaja ne oglašava učinkovito tijekom isključenja. Nije zabilježen nijedan slučaj kvara oba kondenzatora na istoj PCBA pločici, niti se takav scenarij očekuje jer su uzroci svakog od ishoda različiti i međusobno se ne preklapaju.

Rizik za zdravlje:
Zbog načina kvara povezanih s ovim povlačenjem može doći do ozbiljnih ozljeda i/ili smrtnog ishoda. Prekid rada i ventilacije ili gubitak zvučnog alarma za isključenje kod mehanički ventiliranog bolesnika može dovesti do respiratornog zatajenja, hipoventilacije, niske zasićenosti kisikom, hipoksije, kašnjenja u liječenju ili potencijalno teških posljedica kao što su oštećenje mozga i/ili smrt. Medtronic je zaprimio 63 pritužbe i izvješća o štetnim zdravstvenim događajima povezanima s ovim problemima, uključujući dvije teške ozljede i jedan smrtni slučaj.

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Liječenje bolesnika:

Zdravstveni djelatnici koji skrbe o bolesnicima koji se trenutno ventiliraju zahvaćenim ventilatorima Newport™ HT70 i HT70 Plus trebaju procijeniti ukupni rizik i odgovarajuće vrijeme za zamjenu uređaja. Pri određivanju alternativnog načina ventilacije nastavite slijediti pravilnike i procedure svoje ustanove te se pridržavajte Općih upozorenja navedenih u korisničkim priručnicima, uključujući sljedeće:

- Bolesnika koji je priključen na ventilator mora stalno nadzirati educirano osoblje koje prati njegovo stanje.
- Uvijek osigurajte alternativni izvor napajanja i način ventilacije dok je ventilator u upotrebi, u slučaju mehaničkog kvara ili kvara sustava.
- Uvijek upotrebljavajte odgovarajuće monitore kako biste osigurali dovoljnu oksigenaciju i ventilaciju (kao što su pulsni oksimetar i/ili kapnograf) kada se na bolesniku upotrebljava ventilator Newport™ HT70.
- Ako bolesnik u bilo kojem trenutku ne reagira odgovarajuće na ventilaciju, treba ga odmah odvojiti od ventilatora i priključiti na alternativni način ventilacije. Odmah kontaktirajte bolesnikovog liječnika ili pružatelja zdravstvene skrbi.

Medtronic također preporučuje da slijedite postupak pripreme bolesnika naveden u Korisničkom priručniku kako biste provjerili funkcionalnost alarma za isključenje prije upotrebe, iako ta provjera ne jamči sprječavanje budućih kvarova.

Radnje koje poduzima tvrtka Medtronic:

- Medtronic je identificirao serijske brojeve zahvaćenih ventilatora Newport™ HT70 i HT70 Plus. Pogledajte prilog A.
- Nadalje, Medtronic je identificirao zahvaćene PCBA servisne dijelove. Pogledajte prilog B.
- Medtronic neće popravljati ove probleme na zahvaćenim ventilatorima ili servisnim dijelovima. Medtronic više neće servisirati zahvaćene ventilatore identificirane u ovoj obavijesti.

Mjere koje trebate poduzeti:

- Pregledajte Priloge A i B kako biste utvrdili koji su od vaših ventilatora ili servisnih dijelova zahvaćeni.
- Ako je zahvaćeni ventilator ili servisni dio trenutno u kliničkoj upotrebi, uklonite uređaj iz upotrebe i zamijenite ga alternativnim oblikom ventilacije.
- Nakon dovršetka prijelaza na alternativne ventilatore, stavite sve zahvaćene ventilatore i servisne dijelove identificirane u Prilozima A i B u karantenu te slijedite interne procese i procedure svoje ustanove za uklanjanje i zbrinjavanje zahvaćenih uređaja. Ispunite Obrazac za potvrdu primitka i vratite ga tvrtki Medtronic.
- Ako imate dodatna pitanja ili nedoumice, obratite se lokalnom predstavniku tvrtke Medtronic.
- Proslijedite ovu obavijest svim relevantnim djelatnicima unutar svoje ustanove, kao i svim ustanovama kojima su ovi ventilatori ili servisni dijelovi možda preneseni ili distribuirani.

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- Priloženo pismo za bolesnika proslijedite svim svojim bolesnicima koji ovaj ventilator upotrebljavaju u okviru kućne njege kako biste ih informirali o ovom povlačenju.
- Ako znate za bilo kakve incidente povezane s ovim problemima, obratite se lokalnom predstavniku tvrtke Medtronic.

Dodatne informacije

Hrvatska Agencija za lijekove i medicinske proizvode (HALMED) je obaviještena o ovoj korektivnoj radnji.

Žao nam je zbog neugodnosti koje bi Vam ovo moglo prouzročiti. Posvećeni smo sigurnosti bolesnika i cijenimo Vašu hitnu pozornost na ovo pitanje. Ako imate bilo kakvih pitanja u vezi s ovom obavijesti, obratite se lokalnom predstavniku društva Medtronic Mirku Mindoljeviću na mirko.mindoljevic@medtronic.com odnosno na Medtronic Adriatic doo, Folnegovićeva 1c, 10000 Zagreb.

S poštovanjem,

Mirko Mindoljević

Voditelj OU Capital Equipment & Solutions

Prilozi:
Prilog A – zahvaćeni ventilatori Newport™ HT70 i HT70 Plus
Prilog B – zahvaćeni PCBA servisni dijelovi
Obavijest za primatelja proizvoda (bolesnika)
Obrazac potvrde kupca

Medtronic

Urgent Field Safety Notice

Removal of Newport™ HT70 and Newport™ HT70 Plus Ventilators

May 2025

Medtronic reference: FA1479
EU Manufacturer Single Registration Number (SRN): US-MF-000028763

Dear Directors of Inpatient and Home Respiratory Care, Critical Care Units, and Risk Management:

The purpose of this letter is to advise you that Medtronic is issuing a recall for specific serial numbers of Newport™ HT70 and HT70 Plus ventilators and certain related Newport™ service parts. In connection with this recall, Medtronic is advising discontinuation of clinical use of the affected devices. Medtronic's records indicate that one or more of these ventilators or service parts were shipped to your facility.

Issue Description:
Our investigation into customer complaints has identified two separate capacitors on one of the ventilator's Printed Circuit Board Assembly (PCBA), that, in case of failure, may result in one of two distinct outcomes: The ventilator either shuts down during use, thus necessitating the use of an alternate form of ventilation, or the shutdown alert alarm fails to alarm effectively during shut down. No instances of both capacitors failing on the same PCBA board have occurred, nor are they anticipated to occur, because the cause for each outcome is distinct and does not overlap.

Risk to Health:
Serious injuries and/or deaths could occur due to the failure modes associated with this recall. Cessation of operation and ventilation or loss of audible shutdown alarm in a mechanically ventilated patient may result in respiratory failure, hypoventilation, low oxygen saturation, hypoxia, delay to treatment, or potentially severe consequences like brain injury and/or death. Medtronic has received 63 complaints and adverse health events associated with these issues, including two serious injuries and one death.

Patient Management:
Healthcare providers with patients currently ventilated with the affected Newport ™ HT70 and HT70 Plus ventilators should assess the overall risk and appropriate timing for replacement of the device. As you

determine an alternate means of ventilation, continue to follow your facility's policies and procedures and adhere to the General Warnings outlined in the Operator's Manuals including:

- A patient connected to a ventilator requires the constant attention of trained caregivers to the patient's condition.
- Always have an alternate power source and means of ventilation available when the ventilator is in use in case of a mechanical or system problem.
- Always use appropriate monitors to ensure sufficient oxygenation and ventilation (such as a pulse oximeter and/or a capnograph) when the Newport™ HT70 ventilator is in use on a patient.
- If, at any time, the patient is not responding to ventilation appropriately, the patient should be taken off the ventilator immediately and connected to an alternate method of ventilation. Contact the patient's health care provider or physician immediately.

Medtronic also recommends you follow the Patient Set-up Procedure described in the Operator's Manuals to verify the shutdown alert alarm's functionality prior to use, however this verification will not necessarily prevent future failures.

Actions being taken by Medtronic:

- Medtronic has identified the serial numbers of affected Newport™ HT70 and HT70 Plus ventilators. Please see attachment A.
- Additionally, Medtronic has identified affected PCBA service parts. Please see attachment B.
- Medtronic is not correcting these issues on the affected ventilators or service parts. Medtronic will no longer service affected ventilators identified in this notification.

Actions you should take:

- Review attachments A and B to determine which of your ventilators or service parts may be affected.
- If an affected ventilator or service part is currently in clinical use, remove the device from service and replace it with an alternate means of ventilation.
- After completing the transition to the alternate ventilator(s), quarantine all affected ventilators and service parts identified in attachment A and B and follow your facility's processes and procedures for removal and disposal of the impacted devices. Complete the Customer Acknowledgement Form and return to Medtronic.
- Contact your local Medtronic representative for any additional questions or concerns.
- Distribute this notice to all relevant personnel within your organization and any organizations where these ventilators or service parts may have been transferred or distributed.
- Provide the enclosed patient letter to any of your patients using this ventilator in the home care setting to inform them of this recall.
- If you are aware of any incidents related to these issues, please contact your local Medtronic Representative.

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Additional Information

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact a local Medtronic Representative.

Enclosures:
Attachment A - Affected Newport™ HT70 and HT70 Plus ventilators
Attachment B - Affected PCBA service parts
Consignee Notification (Patient)
Customers Acknowledgement Form

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URGENT FIELD SAFETY NOTICE

Removal of Newport™ HT70 and Newport™ HT70 Plus Ventilators

May 2025

Medtronic reference: FA1479
EU Manufacturer Single Registration Number (SRN): US-MF-000028763>

Dear Patient and/or Caregiver:
The purpose of this letter is to advise you that Medtronic is recalling specific HT70 and HT70 Plus ventilators from use. Your healthcare provider is providing you this letter as their records show you have one of those ventilators.

Please review the following information. It is important for you, the patient, and your caregiver to understand the implications of this communication. Medtronic is not correcting the affected ventilators and will no longer service them.

Issue Description
Medtronic has identified the potential for failures which may result in either the ventilator shutting down during use, thus requiring the use of an alternate form of ventilation, or the shutdown alert alarm failing to alarm effectively during shut down. There have been 63 complaints and adverse health events reported associated with this issue, including two serious injuries and one death.

Risks to patient health
If a ventilator fails and does not provide adequate ventilation, the patient may not be able to breathe on their own, leading to low oxygen levels, high carbon dioxide levels, and potentially severe consequences like brain injury or death.

Recommended Actions you should take
As you and your healthcare provider determine an alternate means of ventilation, continue to follow the General Warnings outlined in the Operator's Manuals including:

- Ensure appropriate monitoring of the patient (e.g., use pulse oximetry, CO2 monitoring) and pay close attention to the alarms.
- Always have an alternate power source and means of ventilation available when the ventilator is in use in case of a mechanical or system problem.

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- If, at any time, the patient is not responding to ventilation appropriately, the patient should be taken off the ventilator immediately and connected to an alternate method of ventilation. Contact your health care provider or physician immediately.

Once you have transitioned to an alternate ventilator, return your affected ventilator to your healthcare provider.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your healthcare provider.