

Company

Flosonics Medical Inc.

Drug or Device Name

FloPatch (catalog #FP120)

Category

Medical Technology

Compound/Technical Name

FloPatch FP120

Trade Name

FloPatch FP120

Date of Approval

03/24/2020

Therapeutic Categories

Cardiovascular blood flowmeter

Indications

FloPatch FP120 is indicated for use for the noninvasive assessment of blood flow in the carotid artery. FloPatch FP120 operates in a single mode, the Continuous Wave (CW) mode, and is not capable of operating in any other mode. The device is intended to be used by medical professionals, such as physicians and nurses, in hospitals and professional environments. The device is intended for prescription use on adults only.

Background

When a patient arrives at the hospital in shock, the first line of treatment is intravenous (IV) fluids. Fluid resuscitation is beneficial because it helps restore blood volume, regain tissue perfusion, and reduce mortality in trauma patients. However, a substantial number of patients do not benefit from and may be harmed by excess IV fluids, even early in care. Excess IV fluids can lead to patient morbidity and mortality and increase the financial burden on the healthcare system. Historically, clinicians have relied on invasive catheters, expensive bedside ultrasound machines, or unreliable metrics like heart rate and blood pressure to monitor fluid responsiveness in critically ill patients, but these methods can be cumbersome, time-consuming and inaccurate. Clinicians lack a reliable method to monitor and assess blood flow during fluid resuscitation. FloPatch is the world's first wireless, wearable Doppler ultrasound system. The hands-free medical device provides a simple, fast and consistent method for predicting fluid responsiveness in critically ill patients earlier in the care pathway by enabling rapid and repeatable hemodynamic assessments. FloPatch adheres to a patient's neck over the carotid artery and wirelessly transmits blood flow data to a secure iOS mobile application within seconds. Simply activate, apply, and assess. The mobile application's advanced analytics engine quantifies and displays

changing carotid Doppler metrics over the course of an assessment, providing clinicians with actionable data at the bedside. The medical device, which has received regulatory clearance from the FDA and Health Canada, is capable of reducing Doppler workflow from 20 minutes to 20 seconds. Users have a 90% success rate in acquiring a signal and completing an assessment, even without advanced ultrasound knowledge or training. Using the FloPatch, Flosonics Medical is developing the world's largest Doppler database for machine learning and predictive monitoring with over 200,000 cardiac cycles recorded to date.

Development

FloPatch was developed and commercialized by Flosonics Medical, a Canadian startup founded on the mission to improve patient care. The initial concept for FloPatch was born out of a conversation between the company's CEO and his college roommate, an intensive care physician, who described the difficulties in using existing ultrasound technology to monitor fluid responsiveness in patients. Although the information is necessary and critical, the process is time-consuming and costly, often requiring two people to perform an assessment to ensure accurate readings. FloPatch was designed as a solution to this problem. The device features a single-button interface that turns on, indicates status, and connects to the monitor in one simple step. In a medical landscape full of information-dense displays and intrusive lights and sounds, FloPatch FP120 optimizes workflow by enabling immediate and informed dynamic assessments with unmatched simplicity. FloPatch's tablet-based mobile application leverages the digital innovation that is revolutionizing modern healthcare. The app features a user-friendly interface that displays trending data in real-time and promotes ease of use through seamless connectivity. A relentless drive for improvement was a core focus throughout the development of FloPatch. Additions like the hydrogel multilayer adhesive, algorithm and signal processing, and innovative transducer materials resulted in month over month improvement on the path to commercialization. Cutting-edge advancements in transducer manufacturing techniques resulted in a drastic reduction in typical ultrasound probe manufacturing costs. This was one of the biggest challenges overcome during the development phase. Although FloPatch is a single-use medical device, it was designed to be sustainable. Rather than disposal, customers have the option to return devices to the company. FloPatch's design permits the safe and effective reuse of both printed circuit boards and batteries. Our efforts to recycle and reuse these components reduces e-waste and eases pressure on the global supply chain.

Innovation

FloPatch is the world's first wireless, wearable Doppler ultrasound system designed to help clinicians predict fluid responsiveness in critically ill patients earlier in the care pathway. The medical device provides a simple, fast, and efficient method for detecting stroke volume change in response to IV fluid administration. FloPatch uses bi-quantitative continuous wave Doppler to assess blood flow in the carotid artery. The FloPatch app features a live Doppler spectrogram view that displays metrics like corrected flow time (FTc) and velocity time integral (VTI). Carotid Doppler metrics can be used for precision fluid management, which leads to a reduction in downstream complications associated with fluid overload. All elements of FloPatch's design were built to condense usability into its purest form. Using modern manufacturing techniques, innovative materials, and automated assembly, Flosonics Medical developed a low-cost transducer that adheres to a patient's neck at a fixed angle of insonation. In addition to shrinking the components of a bedside ultrasound machine into a push-button medical device that fits into the palm of your hand, Flosonics Medical simplified traditional monitor display into an intuitive tablet-based mobile application that supports ease of use. Other innovative features include the hydrogel adhesive strap, which absorbs moisture over time to promote adhesion and

comfort after applying ultrasound gel. This material also provides the user with the flexibility to reposition the device without compromising adhesion strength. The industrial design of FloPatch is innovative because of its simplicity. By combining various indicators and features into a single button for operation and connectivity, Flosionics Medical has drastically reduced Doppler workflow. Users do not require advanced ultrasound knowledge or training. The medical device is also hands-free, and requires only one clinician to operate. These innovations combined result in a disruptive new technology with the potential to change the care pathway.

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Kenny JS. Functional Hemodynamic Monitoring With a Wireless Ultrasound Patch. *J Cardiothorac Vasc Anesth*. 2021 May;35(5):1509-1515. doi: 10.1053/j.jvca.2021.01.040. Epub 2021 Jan 25. PMID: 33597088. <https://pubmed.ncbi.nlm.nih.gov/33597088/> Kenny JS, Munding CE, Eibl JK, Eibl AM, Long BF, Boyes A, Yin J, Verrecchia P, Parrotta M, Gatzke R, Magnin PA, Burns PN, Foster FS, Demore CEM. A novel, hands-free ultrasound patch for continuous monitoring of quantitative Doppler in the carotid artery. *Sci Rep*. 2021 Apr 8;11(1):7780. doi: 10.1038/s41598-021-87116-y. PMID: 33833288; PMCID: PMC8032670. <https://pubmed.ncbi.nlm.nih.gov/33833288/> Kenny JS, Barjaktarevic I, Mackenzie DC, Elfarnawany M, Math ZYB, Eibl AM, Eibl JK, Kim CH, Johnson BD. Carotid Doppler Measurement Variability in Functional Hemodynamic Monitoring: An Analysis of 17,822 Cardiac Cycles. *Crit Care Explor*. 2021 Jun 11;3(6):e0439. doi: 10.1097/CCE.0000000000000439. PMID: 34136821; PMCID: PMC8202589. <https://pubmed.ncbi.nlm.nih.gov/34136821/> Kenny JS, Barjaktarevic I, Mackenzie DC, Elfarnawany M, Yang Z, Eibl AM, Eibl JK, Kim CH, Johnson BD. Carotid Doppler ultrasonography correlates with stroke volume in a human model of hypovolaemia and resuscitation: analysis of 48 570 cardiac cycles. *Br J Anaesth*. 2021 Aug;127(2):e60-e63. doi: 10.1016/j.bja.2021.05.007. Epub 2021 Jun 9. PMID: 34116805. <https://pubmed.ncbi.nlm.nih.gov/34116805/> Kenny JS, Barjaktarevic I, Mackenzie DC, Rola P, Haycock K, Eibl AM, Eibl JK. Inferring the Frank-Starling Curve From Simultaneous Venous and Arterial Doppler: Measurements From a Wireless, Wearable Ultrasound Patch. *Front Med Technol*. 2021 May 14;3:676995. doi: 10.3389/fmedt.2021.676995. PMID: 35047930; PMCID: PMC8757733. <https://pubmed.ncbi.nlm.nih.gov/34940356/> Kenny JS, Eibl AM, Parrotta M, Long BF, Eibl JK. The Feasibility of a Novel Index From a Wireless Doppler Ultrasound Patch to Detect Decreasing Cardiac Output in Healthy Volunteers. *Mil Med*. 2021 Jan 25;186(Suppl 1):751-756. doi: 10.1093/milmed/usaa248. PMID: 33499507; PMCID: PMC7832258. <https://pubmed.ncbi.nlm.nih.gov/33499507/> Kenny JS, Elfarnawany M, Yang Z, Myers M, Eibl AM, Eibl JK, Taylor JL, Kim CH, Johnson BD. The Doppler shock index measured by a wearable ultrasound patch accurately detects moderate-to-severe central hypovolemia during lower body negative pressure. *J Am Coll Emerg Physicians Open*. 2021 Aug 7;2(4):e12533. doi: 10.1002/emp2.12533. PMID: 34401869; PMCID: PMC8349221. <https://pubmed.ncbi.nlm.nih.gov/34401869/>

Attachments

- 1656450179HERO-4k.jpg
- 1656450482Screenshot_2022-03-25_140243.jpg
- 1656450537background.jpg
- 1656449633FDA_Approval_FloPatch_FP120.pdf
- 1656450044FP120-MKT-EN003_v1.0.pdf
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