



Restoring Fluid Balance. Transforming Care.

## New Real-World Data Highlight the Clinical Benefits of Ultrafiltration Therapy with Hematocrit Monitoring for Pediatric Patients

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**The data demonstrate that the hematocrit sensor within the Nuwellis Aquadex® system offers unique advantages for fluid overloaded small patients**

MINNEAPOLIS, Nov. 28, 2023 (GLOBE NEWSWIRE) -- New real-world data demonstrate that pediatric patients with fluid overload respond well to Aquadex® ultrafiltration therapy with continuous hematocrit monitoring, announced [Nuwellis, Inc.](#) (Nasdaq: NUWE), a medical technology company focused on transforming the lives of people with fluid overload. The publication, "[Using Aquapheresis with Continuous Hematocrit Monitoring to Guide Ultrafiltration](#)," was featured in *Pediatric Nephrology*.<sup>1</sup>

The publication is a single-center case study review of pediatric patients with hypoalbuminemia and severe fluid overload. Patients were treated with Nuwellis' Aquadex® ultrafiltration therapy with continuous hematocrit monitoring to guide isotonic fluid removal. The study concluded that the therapy successfully treated small patients without hemodynamic instability or other complications, demonstrating that Aquadex is an effective treatment option for fluid overload.

"We're proud to share new evidence supporting the clinical need and applications for Aquadex among pediatric patients, and we're grateful to Dr. Michelle Starr and her colleagues for their trust and confidence in our therapy," said Nestor Jaramillo, Jr., President and Chief Executive Officer of Nuwellis. "Our proprietary hematocrit sensor which is incorporated into the Aquadex console was a result of physician feedback and observations from clinical studies that drove us to make our Aquadex therapy even smarter. Our team is committed to supporting diuretic-resistant patients broadly, and I'm encouraged to see data validating this strategy as Nuwellis works to expand access to ultrafiltration to even more patients and clinicians."

"Managing fluid overload for pediatric patients can be challenging, but these new data and our growing library of evidence support our view that Aquadex can provide a safe and effective method for restoring fluid balance," said John Jefferies, MD, Chief Medical Officer of Nuwellis. "The continuous hematocrit monitoring function within the Aquadex provides unique and proprietary therapeutic direction, as demonstrated in this important publication."

Effectively managing fluid overload for pediatric patients is critical. Fluid overload is associated with significant increases in mortality in pediatric patients. Research has shown that a 3% increase in mortality is observed for every 1% increase in fluid overload among these patients.<sup>2,3</sup>

Aquadex is proven to simply, safely, and precisely remove excess fluid from patients suffering from fluid overload who have not responded to conventional medical management, including diuretics. Providers can specify and adjust the rate of fluid removed for each individual patient, resulting in a gradual reduction of excess fluid. The device's built-in, customizable hematocrit monitoring technology provides real-time measurement of percent blood volume changes that can be tailored to individual patients' needs. A customizable fluid removal rate is particularly important for pediatric patients, who have a small amount of blood in their bodies. The Aquadex system is cleared by the FDA for use in adults and pediatric patients weighing 20 kg (44 lbs.) or more.

### About Nuwellis

Nuwellis, Inc. (Nasdaq: NUWE) is a medical technology company dedicated to transforming the lives of patients suffering from fluid overload through science, collaboration, and innovation. The company is focused on commercializing the Aquadex SmartFlow® system for ultrafiltration therapy. Nuwellis is headquartered in Minneapolis, with a wholly owned subsidiary in Ireland. For more information visit [www.nuwellis.com](http://www.nuwellis.com) or visit us on [LinkedIn](#) or [Twitter](#).

### About the Aquadex SmartFlow® System

The Aquadex SmartFlow system delivers clinically proven therapy using a simple, flexible and smart method of removing excess fluid from patients suffering from hypervolemia (fluid overload). The Aquadex SmartFlow system is indicated for temporary (up to 8 hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kg or more whose fluid overload is unresponsive to medical management, including diuretics. All treatments must be administered by a health care provider, within an outpatient or inpatient clinical setting, under physician prescription, both having received training in extracorporeal therapies.

### Forward-Looking Statements

Certain statements in this release may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including without limitation, statements regarding the new market opportunities and anticipated growth in 2023 and beyond. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this release, including, without limitation, those risks associated with our ability to execute on our commercialization strategy, the impact of the COVID-19 pandemic, the possibility that we may be unable to raise sufficient funds necessary for our anticipated operations, our post-market clinical data collection activities, benefits of our products to patients, our expectations with respect to product development and commercialization efforts, our ability to increase market and physician acceptance of our products, potentially competitive product offerings, intellectual property protection, our ability to integrate acquired businesses, our expectations regarding anticipated synergies with and benefits from acquired businesses, and other risks and uncertainties described in our filings with the SEC. Forward-looking statements speak only as of the date when made. Nuwellis does not assume any obligation to publicly update or revise any

forward-looking statements, whether due to new information, future events or otherwise.

<sup>1</sup> Starr MC, et al. Pediatric Nephrology, September 2023

<sup>2</sup> Sutherland SM, et al. American Journal of Kidney Diseases, vol. 55, no. 2, pp. 316-325, February 2010.

<sup>3</sup> Gillespie RS, et al. Pediatric Nephrology, vol. 19, no. 12, pp. 1394-1399, December 2004.

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