

The Quarterly

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“Sedation and restraints must be minimized and getting patients awake and alert must be maximized.”

- Theresa

Employee Spotlight

Meet Theresa McKenty

This April, Theresa joined HDmedical as our Clinical Excellence Liaison and Business Development Lead. Theresa brings with her over 15 years of experience in Neurorehabilitation and Early Mobility in Critical Care, and a passion for improving patient outcomes through innovative technology, medical devices, and education. When the opportunity to join HDmedical arose, Theresa was eager to join a company whose mission aligns so closely with her own values.



“I’m proud to be part of this innovative company with a mission to make transformational change in the care and outcomes of patients in ICU,” says Theresa. “We’re on a mission to end the practice of restraint and sedation and working hard as a team to provide the tools and education to help healthcare professionals do so and harness the empathy and caring they have for patients.” We are delighted she is here leading our efforts to partner with ICUs, Rehabilitation, Health Networks, VAs, Nurse Educators and Nursing and Medical Schools.

Theresa is particularly enthusiastic about HDmedical’s Exersides® Refraint®, the only all-in-one restraint alternative meeting CMS requirements of “least restrictive intervention”, and DelTrain™ VR, which educates staff and students on delirium and emphasizes minimizing sedation and restraints. She says “Sedation and restraints must be minimized and getting patients awake and alert must be maximized. It is exciting that HDmedical has designed such cutting-edge tools.”

Outside of work, Theresa enjoys spending her free time in the great outdoors. She loves hiking, biking, kayaking, golfing, and regularly participates in yoga classes. Summer is her favorite time of year thanks to long days and warm weather. We are very fortunate to have her!

Did You Know?

Restraint Usage: A Matter of Policy

What determines how hospitals and other healthcare institutions use restraints and monitor their usage? Let's take a look at how hospitals manage policies and compliance for the use of restraints.

The CMS and Restraints: The Centers for Medicare and Medicaid Services (CMS) has established guidelines for restraint usage, found in 42 CFR 483.13. This guidance document defines restraints as:

- 1) "A restraint is any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his/her arms, legs, or head freely"
- 2) "A drug or medication when it is used as a restriction to manage the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition."
- 3) "A restraint does NOT include devices. . . that involve the physical holding of a patient for the purpose of conducting routine physical exams or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities with the risk of physical harm... "

These definitions clearly identify both physical and chemical restraints, and also provide guidance for how a hospital may apply discretion for the benefit of the patient. **CMS does not set hospital policy on restraints, but rather provides the guidance for creating a policy.** The overriding mandate from CMS is that the institution must use "the least restrictive intervention" possible to protect patients and caregivers from harm. The **Exersides® Refrains®** is the only all-in-one device that meets this mandate in its intended use, and complies with item '3'), which allows hospitals to define the Refrain as a "non-restraint."

The Hospital and Restraints: How restraints are used in a hospital is defined by the hospital's restraint policy. Most hospitals have Patient Safety and Restraint committees that are tasked with reviewing guidance documents, expert consultation, and known best practices to create and deploy their restraint policy. **It is each hospital's responsibility to define and deploy a restraint policy specific to their needs that complies with the CMS guidelines and can be monitored.**

The Joint Commission and restraints: While its name brings to mind a congressional task force or a daunting government entity, the Joint Commission is actually an independent non-profit service organization adopted by the healthcare industry to provide third-party oversight to hospital policies. Their job is to engage with hospitals to ensure their policies comply with governmental guidance and that they are being followed consistently in day-to-day activities. **The Joint Commission does not set hospital policy of restraints, but merely confirms that a hospital's policy is appropriate and being followed.**

The broad definitions from CMS allow hospitals to apply their own discretion to their restraint policy, but often a hospital's own risk management interests and fear of Joint Commission audits can lead a policy to be unrealistically prescriptive and oversimplified to the point that compliance actually harms patients. It is HDmedical's position that updated guidance language from CMS would help to account for the latest best practices and the availability of new devices that meet the mandate for least restrictive intervention.



"...fear of Joint Commission audits can lead a policy to be unrealistically prescriptive and oversimplified to the point that compliance actually harms patients."

A Message from C4 (Chief Culture Change Catalyst)



A Letter to the HDmedical Team

In June, HDmedical took the stand to win our award as SBA Manufacturer of the Year for not only Vermont but also New England. This is quite an honor, and I would like to tell you how it happened.

The heart and soul of HDmedical are its people. Very fortunately, from our humble beginnings as winners of NIH awards that allowed us to gather a manufacturing team, we grew. And while our company was chosen for the manufacturer award, that was because it is the category of our company (i.e., we are not a service provider) rather than for purely our stellar manufacturing skills.

We have a clinical background that is second-to-none and engineers that rival the best tech and medical device companies; but since the award called out our manufacturing accomplishments, we must start the story back with our first Employee of the Quarter, Erica Caetano, Production and Operations Manager, who is also expecting her second child. Erica, a Vanderbilt-trained mechanical engineer, is obsessed with detail and driven to perfection. She learns and integrates like no other and is a stalwart defender of those in her charge.

Erica certainly has help:

Chief Operating Officer, Stephen Flint, a medical device expert of several decades, providing oversight and leadership;

Cortni Danyow, HDmedical's Quality and Regulatory Specialist who provides FDA and ISO13485 standards input;

Nathaniel Bohrs, biomedical engineer who provides Design for Manufacturing (DFM) input, and spends time in ICUs training medical staff while gathering post-market surveillance (PMS) data;

Julie Loyzelle, our soft-goods expert who provides invaluable input into design improvement and participates directly in the manufacturing process;

and the rest of the HDmedical team who both directly and indirectly support our manufacturing processes, a team that enjoys each other's company at regular potluck lunches, recognition celebrations, and spontaneous fun events.

Congratulations! You have earned and deserve the honor of being New England and Vermont's 2024 Manufacturer of the Year!

With my most heartfelt gratitude and admiration,

Marie Pavini, MD, FCCM, FCCP

"We have a clinical background that is second-to-none and engineers that rival the best tech and medical device companies."



Stomp Rockets at HDmedical's "Fun Day Out" in Burlington, VT

A Few Good Mentions

August 19 National Patient Advocacy Day

August 23 Health Unit Coordinator Day

August 28 World Day for Health and Safety at Work

In the News

June 13, 2024

Vermont Biz and U.S. Small Business Administration celebrated the winners of the 2024 Vermont SBA Awards at the Awards Ceremony. The lovely event was held at the Essex Resort and Spa, Essex, VT.

HDmedical is the 2024 Small Business Manufacturer of the Year, Vermont and New England Winner

CEO Marie Pavini, MD, receiving the award



The Proud HDmedical Team



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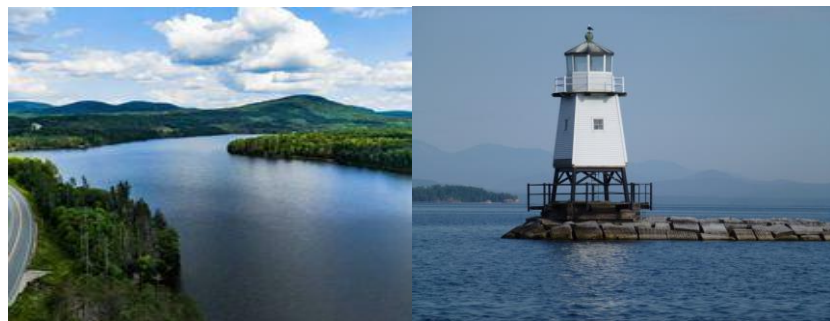
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meets healthcare..."*

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Home In Vermont



Vermont may be 6th smallest state in America, yet it boasts over 800 lakes and 7,000 miles of river. Stunning vistas can always be seen at Lake Champlain, nestled between the Green Mountains and the Adirondacks, and it is the joy of nature and outdoor enthusiasts who flock to enjoy its beauty, especially in the summer months.