

Adult and Pediatric

For Use In ICU • PICU • Medical/Surgical • Trauma Step-Down • PACU • Dementia Acute Rehab • EMS

Cost Savings Regulatory Compliance	2-3 4
Clinical Trials	5-6
Public Image	7
Differentiating Features	8
Company	9



13 Willow St., Rutland, VT 05701

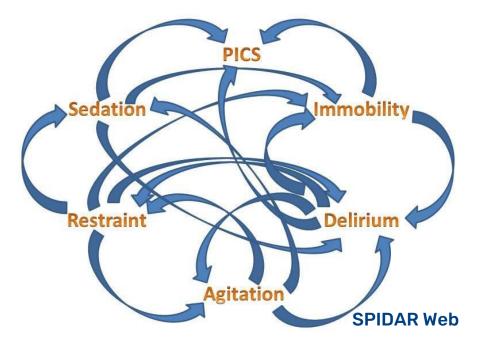
802.821.1002



Exersides®, Refraint® and TheraPete® are registered trademarks of Healthy Design Ltd. Co. 2023

Cost Savings

ICU Liberation/A-F bundle principles strive to reduce immobility and sedation, and encourage early mobilization and interaction with resultant fewer ventilator days and complication costs



Immobility and delirium costs

- ICU days by 4.77 days @ avg \$4k/day if intubated = \$19k/pt
- Hospital days ^ by 6.67 days @ avg \$1.5k-2k/day = \$12k/pt
- Sitter usage @ > \$160/shift
- Unplanned extubation \uparrow by >11x
- Doubled nursing hours
- IV/tube/catheter dislodgement
- Hospital-acquired pneumonia
- **Pressure injuries**
- Readmissions

Cost Savings \$56-\$110k/complicated extubation Confusion & Picking at IVs **Restraint & Sedation FXERSIDE** Complications 2X risk of up to \$43k/pressure ulcer **Immobility & Delirium** nosocomial infection \$17,800/delirium patient Length of Stay \$3,160 - \$4,119/patient Readmission \$11,200/patient **Post-Intensive Care** Syndrome (PICS) 51% increase cost of care 1

Validation Strategy: HD Medical can help you track above costs

Direct Costs

Sedation costs	\$50/day/intubated patient	
	Opiate costs	
	Anti-psychotic costs	

Staff

Length of Stay

Ventilator Days	\$1.5k/day
-----------------	------------

ICU Days \$4k/day if intubated

Hospital Days \$1.5k-2k/day

Regulatory Benefits

SCCM PADIS Guidelines on Restraints

RECOMMENDATIONS: ... studies...paradoxically report higher rates of the events that their use is intended to prevent. These events include more unplanned extubations and frequent reintubations; greater un-intentional device removal; longer ICU LOS; increased agitation; high-er benzodiazepine, opioid, and antipsychotic medication use; and in-creased risk for delirium or disorientation.

Patients' perceptions...provoke strong emotional responses that persist after the ICU stay. Given the prevalence, unintended consequences, and patients' perceptions of physical restraint use, critical care providers should closely weigh the risks...before initiating or maintaining phys-ical restraint use. Although certain countries report a "restraint-free" ICU environment, it may be possible that their use of bedside sitters and/or pharmacologic restraints is increased.

ACCM Clinical Practice Guidelines

RECOMMENDATION: The choice of restraining therapy should be the least invasive option capable of optimizing patient safety, comfort, and dignity.

Refraint & Guidelines

Exersides Refraint allows compliance with PADIS Guidelines & ACCM recommendations and the ONLY all-in-one device in compliance with CMS "Least Restrictive Restraint" The Exersides Refraint System prin-ciples are supported by Surgeons, Intensivists, Psychiatrists and Thera-pists. SCCM & CMS Guidelines recommend what only Exersides offers.

Clinical Trials

A Novel Physical Restraint Alternative for Early Mobilization, Delirium Prevention and Sedation Minimization in Intubated Patients.

Pavini, Marie MD; Washburn, Jolana RN. Department of Critical Care, Rutland Regional Med Ctr, Rutland, VT, US. 2017.

Less sedation; Better agitation scores; More movement; RESULTS Better interaction

Better Patient satisfaction, Better Family satisfaction, Better Staff satisfaction

n=10	Pre-study propofol (mcg/kg/hr)	During study propofol (mcg/kg/hr)	SAS*	Time spent moving (hrs)	Time spent interacting (min)
Wrist restraints	26±18.2	20±11.7	3.2±0.4	0±0	2.2±4.4
Exersides Refraint	28±8.4	11.2±10.0	4±0.7	2.6±1.6	66±73.8

*Sedation-Agitation Scale; 1=comatose, 4=calm and cooperative, 7=dangerously agitated

Phase I Pilot Safety And Feasibility Study Of A Novel Restraint Device In Critically III Patients With Acute Respiratory Failure.

Biren B. Kamdar, MD, MBA, MHS, Janelle Fine, BS, Dale Needham, MD PhD, Renee Stapleton, MD PhD, Marie T. Pavini, MD, et al.

No safety events were reported. Feedback from patients, RESULTS family and clinicians was positive and constructive.

	Day 1 (n=7)		Day 2 (n=4)	
	Exersides	Traditional Restraint	Exersides	Traditional Restraint
Time in restraint (mean hours ± SD)	4.0±0.6	2.1±1.9	1.8±2.1	3.8±1.2
Wrist activity level, median (IQR) ^a	59 (16–177)	92 (24-213)	92 (28–213)	77 (22–206)
RASS sedation score (mean hours ± SD) ^b	-1.5±1.8	-0.5±1.8	-0.6±1.5	-1.7±1.2
CAM-ICU delirium (n)°	1	1	1	1
Satisfaction with Exersides (mean hours \pm SD) ^d	3.3±0.7		3.8±0.4	

a) Represented as median (IQR) number of non-zero movements per 30-second epoch, as measured using bilateral wrist actigrpahy. Left and right wrist. b) Richmond Agitation-Sedation Scale (RASS). c) Confusion-Assessment Method (CAM-ICU). d) Quebec User Evaluation of Satisfaction with Assistive Technology (Quest 2.0) device subscale, higher score is better with a range from 1 (not satisfied at all) to 5 (very satisfied)

The Exersides Refraint System

802.821.1002

Ventilator Weaning and Restraints

Daily Sedation Interruption in Mechanically Ventilated Critically III Patients Cared for With a Sedation Protocol: A Randomized Controlled Trial. JAMA. 2012;308(19):1985–1992. Mehta S, Burry L, Cook D, et al.

RESULTS Daily sedation interruption is associated with more restraint use (OR 1.84, 95% CI 1.27, 2.67)

A-F Bundle Barriers and Restraints

Identifying barriers to delivering the ABCDE bundle to minimize adverse outcomes for mechanically ventilated patients: A systematic review. Chest. 2017 Aug;152(2). Costa DK, White MR, Ginier E.

RESULTS Perceived patient barriers to early mobilization in the intensive care unit: Patient and staff safety concerns

Unplanned Extubation and Restraints

Incidence, risk factors and outcomes of delirium in mechanically ventilated adults. Crit Care Med. 2015 Mar;43(3):557-66.

Mehta S, Cook D, Devlin JW, et al for the SLEAP Investigators and the Canadian Critical Care Trials Group.

RESULTS Restrained patients had: Lower APACHE ll mean scores; More delirium; More device removal; More reintubation; All statistically significant

Use of physical restraints in adult ICU patients to prevent patient-initiated device removal: a

Systematic review. Università di Bologna Facoltà di Medicina. 2011 Oct.

Bassi E, Ceresola M.

RESULTS One third or more of the self-extubation events occurred despite use of wrist restraints ... as it can heighten agitation and may have devastating physical and psychological effects on the patients.

Public Image

Look good for your close-up

NY Times Take a Vacation From Exercise? Your Body May Not Thank You: Two new studies look at what happens when we do not exercise or move around much for a period of time. *Aug 1 2018*

WSJ How to Minimize Permanent Mental Trauma from an ICU Stay *Mar 2, 2018*

PBS News Hour Why a stay in the ICU can leave patients worse off *Jun 16, 2017*

NY Times Nightmares After the I.C.U. July 22, 2013

PBS with Meg Ryan Pioneers in Healthcare

Magnet Status financial benefits

We can provide references and trial results for your proposal. Nurse-driven Quality Improvement will impress!

HCAPS/MIPS/Press-Ganey scores

In our Pilot Study, questionnaires revealed a greater satisfaction by patients and family (as well as staff).

Differentiating Features

Multiple levels of Refraint & restraint make the Exersides Refraint the only all-in-one device in compliance with CMS 'Least Restrictive Intervention'.



Unlike Wrist Restraints

No Head-to-Hand unplanned extubation

Allows safe arm movement

Wrist strap auto-regulates to prevent neurovascular injury and edema

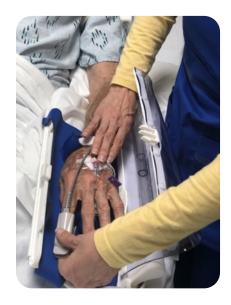
Does not obscure arterial lines

Unlike Mitts

Easy access to and visualization of hand/IVs No entanglement to dislodge catheters & IVs No entanglement or unplanned extubation

Unlike Anything

Tangle-free IV containment system for safety Titrate restraint from strict to liberal to none Built-in Occupational Therapy hand device Hand Shield prevents tube/catheter dislodgement



13 Willow St., Rutland, VT 05701

802.821.1002

8

$Exersides^{\$}, Refraint^{\$}$ and TheraPete $^{\$}$ are registered trademarks of Healthy Design Ltd. Co. 2023

Company

Healthy Design dba HD Medical

- FDA-Registered
- ISO13485-compliant manufacturing facility
- Woman-owned
- US manufacturing











Pioneering the way to better patient outcomes by empowering caregivers to safely improve cognition, mobility, and human spirit

Healthy Design

13 Willow St., Rutland, VT 05701

802.821.1002

HD*medical*.org