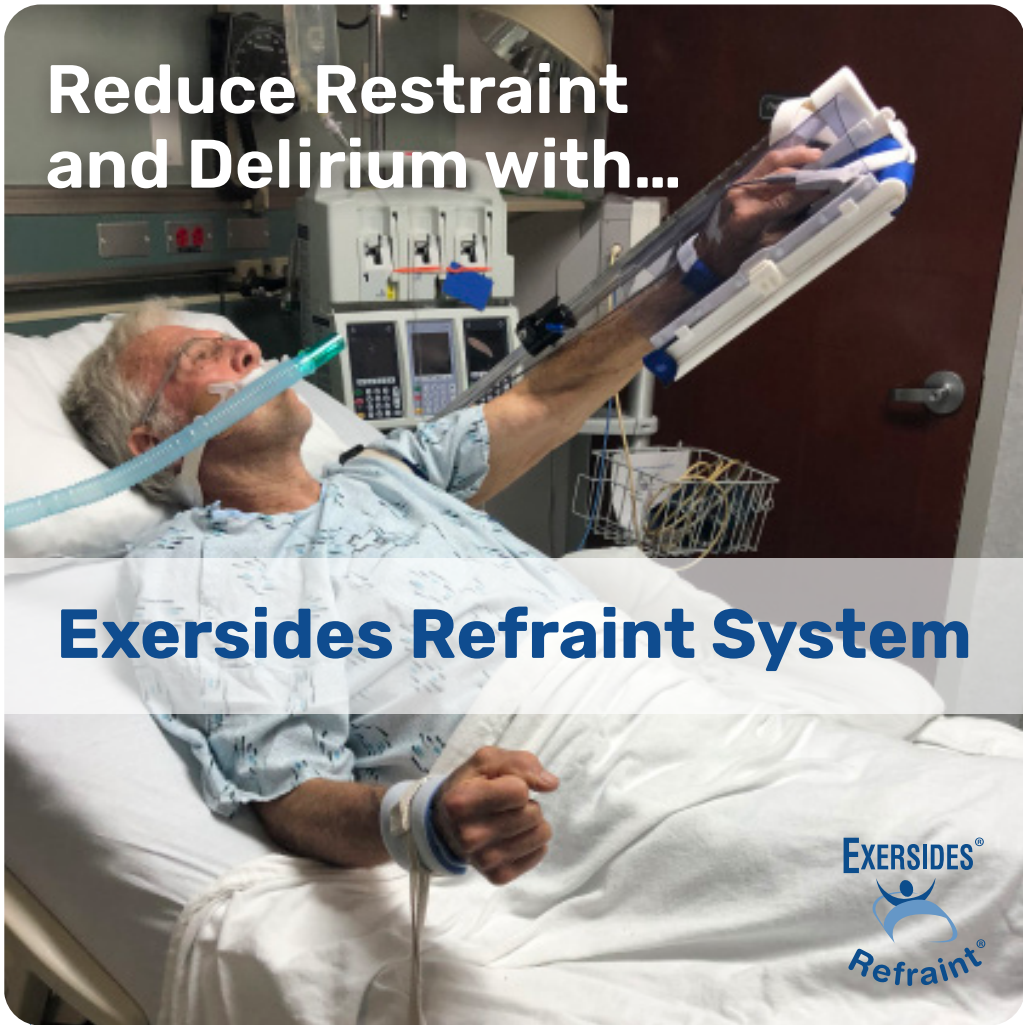


# Reduce Restraint and Delirium with...



## Exersides Refrstraint System



### Adult and Pediatric

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

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# Differentiating Features

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



## Unlike Wrist Restraints

No Head-to-Hand for self-extubation

Wrist strap auto-regulates to prevent neurovascular injury and edema

Space for arterial lines



## Unlike Mitts

Easy access to and visualization of hand/IVs

No squeezing mitts together to self-extubate

## Unlike Anything

Tangle-free IV containment system for mobility

Titrate restraint from strict to liberal

Built-in Occupational Therapy hand device

Hand Shield prevents tube/catheter dislodgement



## The Exersides Refrain System

# 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.

**RESULTS** Less sedation; Better agitation scores; More movement; 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)
<b>Wrist restraints</b>	26±18.2	20±11.7	3.2±0.4	0±0	2.2±4.4
<b>Exersides Refraint</b>	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 Ill Patients With Acute Respiratory Failure.

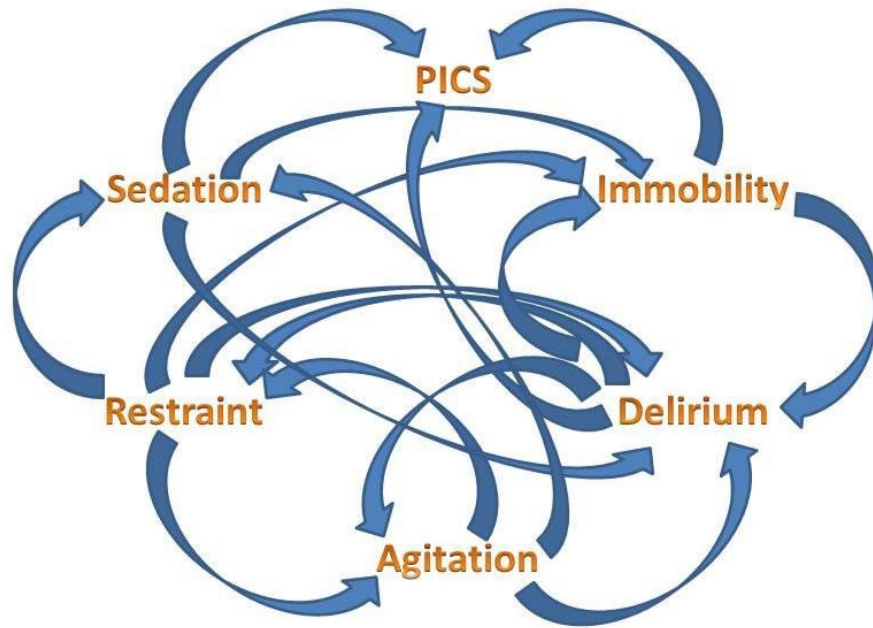
Biren B. Kamdar, MD, MBA, MHS, Janelle Fine, BS, Marie T. Pavini, MD, et al.

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

	Day 1 (n=7)		Day 2 (n=4)	
	Exersides	Traditional Restraint	Exersides	Traditional Restraint
<b>Time in restraint</b> (mean hours ± SD)	4.0±0.6	2.1±1.9	1.8±2.1	3.8±1.2
<b>Wrist activity level, median</b> (IQR) <sup>a</sup>	59 (16-177)	92 (24-213)	92 (28-213)	77 (22-206)
<b>RASS sedation score</b> (mean hours ± SD) <sup>b</sup>	-1.5±1.8	-0.5±1.8	-0.6±1.5	-1.7±1.2
<b>CAM-ICU delirium</b> (n) <sup>c</sup>	1	1	1	1
<b>Satisfaction with Exersides</b> (mean hours ± SD) <sup>d</sup>	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 actigraphy. 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



SPIDAR Web

# Research Linking Restraint to Costly Complications

## Delirium and Restraints

**Precipitating Factors for Delirium in Hospitalized Elderly Persons Predictive Model and Interrelationship With Baseline Vulnerability**

Inouye SK, Charpentier PA, JAMA. 1996;275(11):852-857.

**RESULTS** ...independent precipitating factors for delirium... : use of physical restraints (adjusted relative risk [RR], 4.4; 95% confidence interval [CI], 2.5 to 7.9)

## Sedation/Agitation and Restraints

**Predictors of physical restraint use in Canadian intensive care units. Crit Care. 2014;18(2).**

Luk E, Sneyers B, Rose L.

**RESULTS** Restrained and never-restrained patients had similar baseline characteristics... however, restrained patients were agitated and over-sedated...more...

## The Exersides Refraint System

**Daily Sedation Interruption in Mechanically Ventilated Critically Ill 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)

## Early Mobilization and Restraints

**Early mobilization of critically ill adults: a survey of knowledge, perceptions and practices of Canadian physicians and physiotherapists. CMAJ Open. 2016 Aug 18;4(3).**

Koo KK, Choong K, Cook DJ, et al.

**RESULTS**

Patient barrier to mobilization	All clinicians (n=311)	Physicians (n=194)	Physiotherapists (n=117)
Physical restraints	64 (20.6%)	50 (25.8%)	14 (12.0%)
Excessive sedation	187 (60.1%)	112 (57.7%)	75 (64.1%)

**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 II 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.

## The Exersides Refrains System

## Post-ICU Syndrome/PTSD and Restraints

**Patients' recollections of stressful experiences while receiving prolonged mechanical ventilation in an intensive care unit. Crit Care Med. 2002 Apr;30(4):746-52.**

Rotondi, A J.

**RESULTS** 44.8% remembered being restrained; 86% of those were moderately to severely bothered by it.

**Psychological sequelae following ICU admission at a level 1 academic South African hospital. South Afr J Crit Care. 2010 Nov;26:(2).**

Hatchett C, Langley G, Schmollgruber S.

**RESULTS** An unexpected finding of this study was that patients who had memory of physical restraints in the ICU were six times more likely to develop symptoms of PTS than those with no memory of physical restraints.

## Regulatory Benefits

### SCCM PADIS Guidelines

**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 unintentional device removal; longer ICU LOS; increased agitation; higher benzodiazepine, opioid, and antipsychotic medication use; and increased 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 physical 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.

## The Exersides Refrains System

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

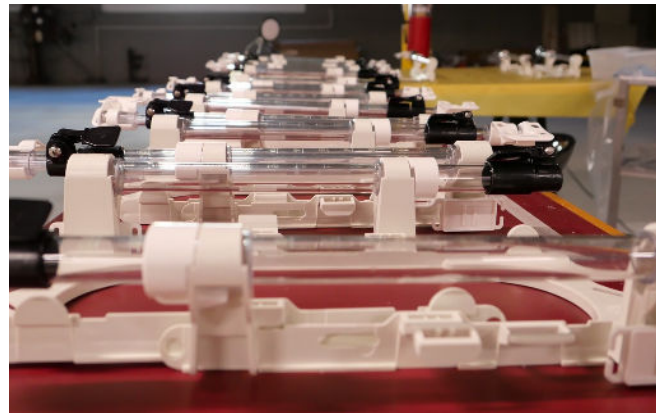
## Refract & Guidelines

Exersides Refract allows compliance with PADIS Guidelines & ACCM recommendations and the ONLY all-in-one device in compliance with CMS “Least Restrictive Restraint” The Exersides Refract System principles are supported by Surgeons, Intensivists, Psychiatrists and Therapists. SCCM & CMS Guidelines recommend what only Exersides offers.

# Company

## Healthy Design

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



## The Exersides Refract System

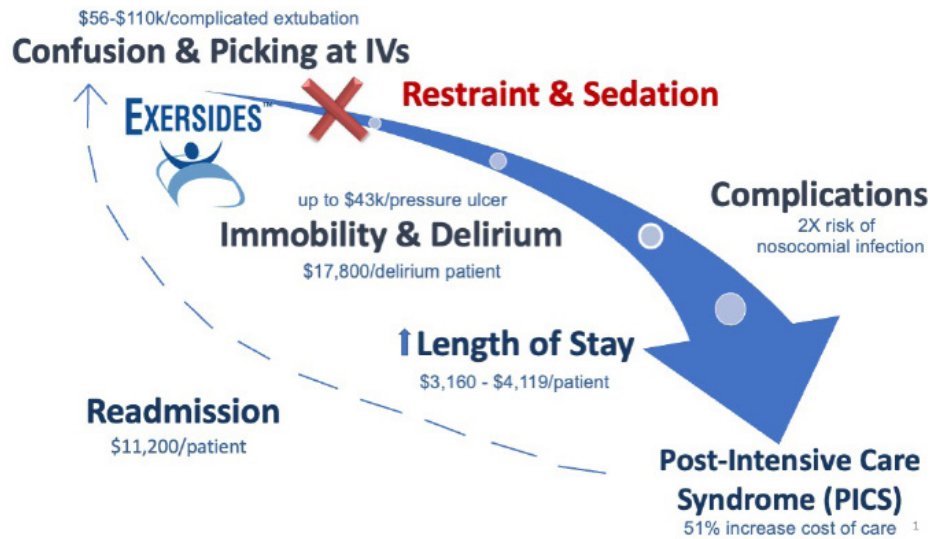
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**Validation Strategy** Healthy Design can help you track above costs

# Cost Savings

## Direct

**Sedation costs** \$50/day/intubated patient  
Save anti-psychotic/opiate restraint costs

## Staff

**Sitter Costs** \$160/shift Readmission

## Length of Stay

**Discharge to Nursing Home/Rehab days earlier by meeting 24-48hr restraint-free mandate**

**Ventilator Days** \$1.5k/day  
**ICU Days** \$4k/day if intubated  
**Hospital Days** \$1.5k-2k/day

## The Exersides Refraining System



## Complications

<b>Delirium</b>	\$4B-\$16B/year in US
<b>Pressure Injury</b>	\$17.5k/ulcer
<b>Pulmonary infectious complications</b>	\$17k/incident
<b>Encephalopathy</b>	\$11k/incident
<b>Unplanned extubations</b>	\$35k each Tracheostomy
<b>Hospital costs</b>	\$10k-150k
<b>Immobility complications</b>	Secretion retention, Gut dysmotility, Pressure injury, Muscle weakness

## Time Costs

RN/LNA cost to use assuming 5 days in restraints:

**Wrist Restraints** 1 minute to don pair/30 secs to doff; 2 minutes qshift to remove to check wrist IVs, a-lines and to deal with edema/skin integrity issues = 31.5 minutes

**Mitt Restraints** 1 minute to don pair/30 secs to doff; 2 minutes qshift to check back of hand IV, FSG, p.ox, hand edema, skin integrity, circulation, 1 minute to replace (if untied) when patient self-removes restraint or ETT/feeding tube= 36.5 minutes;

**Sleeve restraints** 1 minute to don pair/30 secs to doff; 1 min q hour to remove pair to check skin, IVs, clean arm and use BP cuff; 1 min to replace when patient self-removes = 126.5 minutes

**Exersides** 1 minute each to don each/ 30 secs to doff pair; no time to check IVs, a-lines, p.ox, FSG, circulation, skin integrity, edema, or to reposition patient = 2.5 minutes

## The Exersides Refraint System

## Readmission

**General complications** \$11.2k/readmission

**PICS readmission costs** \$26k/5yrs/patient

## Onboarding Costs

**RN Training** This should not require extra staff since we will train super-users. Training can be done remotely and can be scheduled to maintain appropriate patient care staffing ratios.

## Product change-over costs

You will likely maintain some of your current restraints. Therefore there should be no product change-over costs.

# Reimbursement

## Payor mix

Your payor mix for restraints will depend on whether you list Exersides as a line item or as part of the room charge, in which case it is the payor mix for your entire hospital.

## Reimbursement/Charge Code

In our Pilot Study, questionnaires revealed a greater satisfaction by patients and family (as well as staff). These satisfaction scores will boost reimbursement. A reduction in the complications of sedation reimbursement allowances and bed turn-over.

Service charge when using Exersides to deliver PT/OT

Orthotic charge possible

## The Exersides Refrains System

# Purchasing Options

Item	Catalog Price
<b>Single Patient Use</b> Exersides Refrains System (Frame + SoftKit)	\$390
<b>Reusable Option</b> (SoftKit only)	\$225

Sold as L/R pairs in packs of 10.

## Early Adopter

6-month contract  
Device/Training  
Coaching Support  
Single-patient Use

## Influencer

1+ year contract  
Early Adopter plus:  
Continuing Education  
DelTrain™ VR  
Certifications  
Single-use or Reusable

1. Choose Early Adopter or Influencer Package
2. Choose Single-patient Use or Reusable  
(note: Early Adopter package only available in Single-patient Use)
3. Choose number of units based on maximal number of patients restrained simultaneously

## The Exersides Refrain System

# 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*

## Magnet Status financial benefits

We can provide references and trial results for your proposal. QI will impress!

## MIPS/Press-Ganey scores

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

---

### The Exersides Refrains System

# Current Practice

The concept of Refrains is supported by:

- ERAS: Enhanced Recovery after Surgery
- ICU Rehab
- ABCDEF Bundle
- PICS Clinics
- Restraint, Delirium, and Sedation Reduction initiatives

**You do not need to remove your other restraining devices. They may come in handy for a minority of patients.**

## Device Details

### Refrain

While it may seem counter-intuitive, agitated patients often do better with less restraint. In many cases, their agitation stems from being restrained. Once the restraints are changed to Refrains, agitation can be safely reduced, leading to a calmer patient with better results. With easily changeable configurations, safety is designed into the Refrain.

### Documentation

CMS 42 CFR 482.13(e)(1)(i)(C): “A restraint does not include devices, ...to permit the patient to participate in activities without the risk of physical harm...”

This CMS language supports your decision to define the Exersides Refrain as a non-restraint when not attaching the restraint strap. Attaching the optional restraint bed strap is considered restraint and requires the same documentation as for traditional restraints. When using the intermediate exercise bed strap, if it is used for resistance exercise, it is not a restraint; however, if it is used to limit range of motion, it is a restraint (though the only device to meet CMS “least restrictive intervention”) and must be documented as such.

## The Exersides Refrain System

# Usage

## Refrain & Sedation Minimization

### How do I minimize sedation AND restraint?

First minimize sedation (chemical restraint) to a comfortable level for the patient that allows the most interaction or non-agitated movement. Then, select a level of restraint, or Refrain, to match the patient's predictability for safe arm movement. Repeat this process until both sedation and restraint are completely minimized and the patient can safely move.

### Do I need extra sedation for Exersides?

Definitely not. The purpose of Exersides is to promote non-agitated movement. You may find that if a patient is allowed to move, they will be less agitated and therefore require less sedation. Try it!

### Do I need a sitter for Exersides if the patient is not sedated?

No. As long as the nurse chooses an appropriate Exersides configuration based on the predictability of the patient, safe arm mobility is possible.

### "We don't use restraint – only versed, morphine and fentanyl"

Newsflash: Those are sedating and considered chemical restraint. That said, patients may need some amount of sedation to have non-agitated predictable safe arm movement. Challenge yourself and see how low you can go.

### Do I stop all sedatives to use Exersides?

No. Some patients do not require any sedation ever and some do. If patients are allowed to move, they may require less. Always minimize.

### What happens if the patient becomes agitated and moves too much in the Exersides Refraints?

Agitated movement is not good. It is better to find the least amount of sedation required by the patient than to select the next more restrictive level of Exersides. Minimize sedation first, then minimize restraint.

## Refrain & Early Mobilization

### How early is 'Early'?

Some hospitals wait 2 days before mobilizing patients! Exersides allows mobilization the MOMENT the patient is able.

## The Exersides Refrain System

**In general, how often should I mobilize my patient?**

Many patients only receive physical/occupational therapy sessions for 1/2 hour per day! Exersides allows movement 24 hours per day at the patient's own pace.

**Who is needed to mobilize a patient?**

Most hospitals require a Physical Therapist, Occupational Therapist, Respiratory Therapist, and a Nurse or LNA to mobilize patients. Exersides allows patients to move themselves and perform their own Active Range of Motion!

**Is Early In-Bed Mobilization safe?**

Certainly, but nursing judgment is required to assess a patient's readiness for safe movement. Fortunately, there are several levels of mobility to choose from and you will find one that is right for you and your patient.

**Can Family be involved?**

Most definitely! We believe it is healthy for family members to be involved in the healing process of their loved one. You may want to provide a general guideline for family to make the most of this precious asset.

## FAQ

**Is Exersides disposable or reusable?**

Exersides Refraints come in a single-patient use form and a re-usable form with disposable soft kits.

**How do you clean Exersides?**

Exersides Refraints can be cleaned for same patient use quickly and easily with traditional cleaning wipes and sprays. For use in between patients, Exersides Refraints can be cleaned with traditional cleaning wipes and sprays or in an automated cleaner. Disposable Soft Kits can be reapplied to the cleaned frame as required.

**How do you store Exersides?**

The reusable portion of Exersides can be stacked and stored neatly with other hospital supplies. It is recommended to maintain a small supply on the unit.

**Can Exersides go in an MRI?**

Yes.

**Is Exersides latex-free?**

Yes.

## The Exersides Refraint System

**Which patients benefit from Exersides?**

Exersides can be used with intubated as well as delirious or dementia patients. It can be used in: PACU, ICU, Surgical/Trauma, Step-Down, Floors: Dementia, Acute Rehab, EMS (ambulance and helicopter).

**Is Exersides for both arms?**

Yes. This is best for mobility and safety.

**Why is Exersides bigger?**

Sometimes bigger makes your job easier. Keep in mind, overhead lifts and stand assist devices replaced gait belts!

**How do you use Exersides?**

1. Choose a non-combative patient
2. Titrate Sedation
3. Titrate Restraint: No Bed Strap > Exercise Strap > Rigid Strap

**Can Exersides be removed emergently?**

Exersides removes in a few seconds although it does not need to be removed for CPR.

**Who can I contact with questions?**

Email us at [hello@exersides.com](mailto:hello@exersides.com) or call us at (802) 821-1002.



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

**The Exersides Refrains System**