MRidium® MRI Infusion Pumps

Infuse at the Bore*

IRadimed is the world's only provider of Non-Magnetic* IV infusion pumps. Infusing at the bore* can improve the MRI care cycle while reducing operating costs. The MRidium Non-Magnetic IV infusion pump allows clinicians to infuse patient medications and fluids at the MRI bore*, extending the same patient bedside practices to the MRI that are common throughout the rest of the hospital.

* Magnetic field line ≤ 10,000 Gauss

IRADIMED®

IRADIMED®

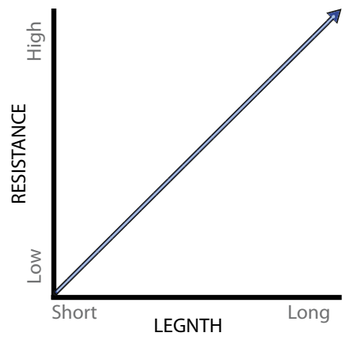
Infuse at the Bore*

MRI Safety is Patient Safety

The value of a Non-Magnetic infusion pump may not be readily apparent until an adverse event occurs. This can be a life changing situation for the patient, staff and the facility. **Joint Commission (JCAHO) mandates in 'Sentinel Event 38' that only equipment which "has been tested and approved for use during MRI scans"[1] should be used.** Infusion pumps containing ferrous material may become projectile hazards when used within the MRI scanner room. For example "the infusion pump "flew" into the scanner and struck the patient, causing a 2-cm laceration to the patients chin."[2,4]

In addition to the preventable magnetic attraction hazard, JCAHO warns that some "programmable infusion pumps may perform erratically"[1] when in the presence of a magnetic field. An evaluation of conventional infusion pumps within the MRI room found that the function was temporarily altered with three out of six infusion pumps during exposure to 3-Tesla MRI conditions.[3] IRadimed has been dedicated to advancing MRI safety with its Non-Magnetic[18] infusion pumps for nearly a decade. The MRidium system is the first and only infusion pump cleared to administer patient IV medications at the MRI bore*, directly contributing to JCAHO compliancy and safety when compared to using conventional magnetic infusion pumps.

Go With The Flow



The length of IV tubing directly impacts the resistance needed to push the medication through the tubing. Physics proves that tubing having twice the length will have twice the resistance, which reduces flow.[8,9] Each extension set addition, increases the fluid pathway requiring greater force and higher pressure (PSI) settings on the infusion pump. "It is dangerous if the pressure alarm limit is set too high"[10] as increasing the pressure limit (PSI) directly delays the time to activate the occlusion alarm[19]. "If a high alarm pressure has to be configured to sustain a high running pressure, there will be unavoidable consequences for patient safety, which should be understood."[19] **Clinical practice should create an environment where infusion pump "settings should be at the lowest appropriate pressure."**[10] IRadimed MRI infusion pumps allow you to infuse IV fluids at the bore* with the shortest possible IV line and lower pressure limit settings.

HAI: When 'Getting In On The Ground Floor' is Bad

87%
of BSI are associated with intravascular devices[6]

HAIs (Hospital-Acquired Infections) are among the major causes of death and increased morbidity among hospitalized patients.[5] HAIs add to the functional disability and emotional stress of the patient and in some cases, lead to disabling conditions that reduce the quality of life.[5] Approximately 87% of bloodstream infections (BSI) are associated with the presence of some type of intravascular device.[6] Airborne contaminates often settle on floors where IV tubing may be inadvertently contaminated when allowed to contact the floor[7] or through subsequent manipulation of multiple connections and access ports. **"Keep all IV tubing off the floor"[7] is one of the prevention measures that should be taken in the MRI.** IRadimed's MRidium infusion pumps operate at the bore* thereby reducing the chance IV tubing can contact the floor surfaces. Additionally, Non-Magnetic infusion pumps can minimize the number of IV connecting ports needed which can also decrease the potential for HAIs.

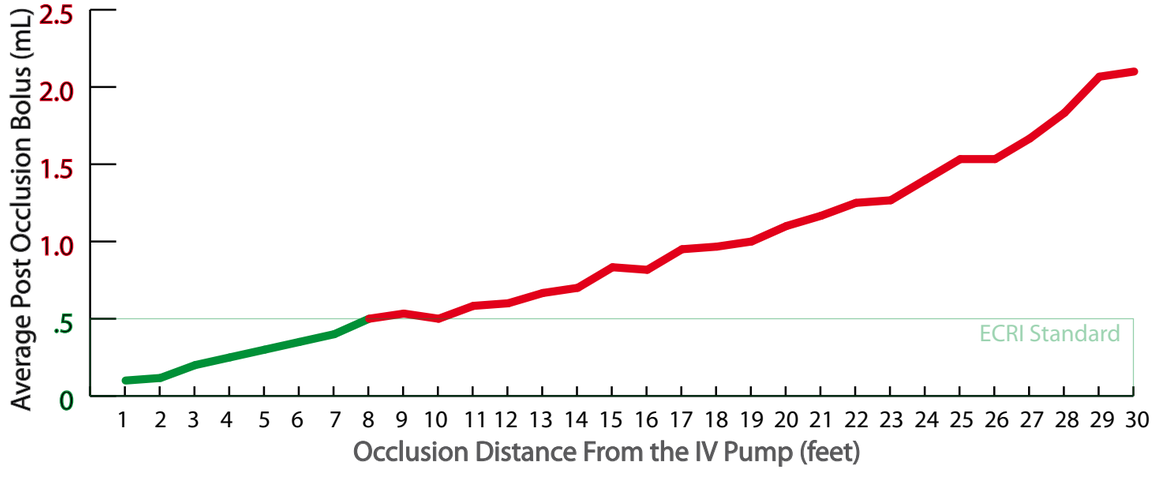
There's Safety in Numbers

IRadimed MRI infusion pumps deliver fluids at the bore* avoiding negative outcomes attributed to adding multiple IV extension sets. IV tubing "can easily be trapped in the closed [MRI] door"[4] increasing occlusion potential. The length of time it takes to detect an occlusion is directly related to the occlusion's distance from the infusion pump. **Increasing the IV tubing length has been demonstrated to prolong critical occlusion alarms by nearly 35 minutes[11] resulting in a delay of patient therapy.[10,19]**

35min
Possible time to detect occlusions with multiple extensions[11]

>0.5mL
Possible unintended bolus after occlusion release[13]

Once an occlusion happens, a patient will then inevitably suffer a significant period of time without the intended therapy.[19] Once the occlusion is released, an unintended bolus of medication occurs due to increased pressure generated in the IV tubing during the occlusion.[10,12,19] Post-occlusion boluses greater than 0.5 mL[13] have been demonstrated in a case study using standard bore extension IV tubing at ambient temperature. ECRI recommends that post-occlusion boluses should have a volume of 0.5 mL or less.[12] Depending on the situation, an unintended bolus greater than 0.5 mL could have a serious impact on a patient's condition. **A case study demonstrated that occlusions in the IV tubing greater than 8 feet (2.4 meters) away from the pump can exceed the 0.5 mL ECRI guideline.[13]** IRadimed's MRidium infusion pumps are designed to infuse at the bore* helping reduce the length of tubing needed for MRI infusions.



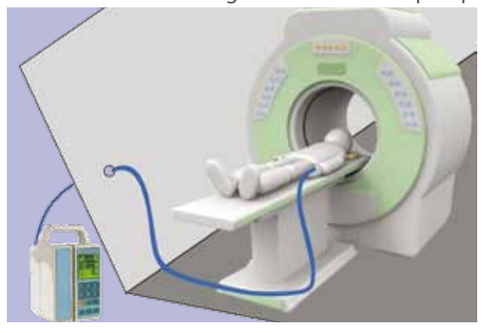
Don't Suffer From A (Re)Morse Code

When a patient codes in the MRI, clinical staff find themselves in a situation where every second matters. When infusion extension lines are used to connect a pump from within the control room to the patient inside the MRI room, emergency evacuation becomes much more cumbersome and time consuming due to line management. Extension lines routed through a MRI waveguide present additional patient complexities since critical medication must be stopped in order to disconnect the lines and evacuate the patient while performing CPR. Infusing at the bore* with the MRidium Non-Magnetic MRI infusion pump provides:

Faster Treatment: Infusing at the bore* utilizes shorter IV lines and allows emergency treatment to begin immediately.

Patient Safety: Critical infusions are maintained during the entire code event since IV tubing disconnection is not required to evacuate the patient.

Staff Efficiency: Clinicians have more time to focus on the patient instead of untangling IV tubing and manipulating access ports.



MRidium® MRI Infusion Pumps

Waste Not, Want Not

IRadimed Non-Magnetic MRI infusion pumps allow clinicians to infuse at the bore* using fewer line connections and tubing. Shortening the length of IV tubing used may contribute to improved financial scenarios with the reduction of waste and HAI's. Shorter IV lines reduce the amount of tubing and drug discarded after the MRI procedure. For example, 32.5 feet (9.9 meters / 390 inches) of common IV extension tubing will contain approximately 63.2 mL of medication per IV line. A comparison example utilizing Propofol at a cost of $40 per 100 mL illustrates a $28 savings** per patient IV medication. Infusing at the bore* means shorter lines, less waste and potential cost savings.

$28.89** Savings

Waste	MRidium	32.5' Line
Line	$15.64	$26.45
Drug	$7.20	$25.28
Total	**$22.84**	**$51.73**

**Contact your IRadimed representative for a comparison example based on your situation.

In addition to waste, HAIs can also negatively impact financial outcomes. According to CMS 2015 HAC List,[14] vascular HAIs are not eligible to receive additional payments to cover the incremental healthcare costs. **The CDC estimates that Blood Stream Infections (BSI) can cost between $5,734 and $22,939[15] for a single incidence.** A hospital-acquired IV infection increases a patient's hospital stay by approximately 20 days[17] which greatly contributes to the incremental costs. Hospital-acquired infections add to the imbalance between resource allocation by diverting scarce resources to the management of potentially preventable conditions.

	MRidium Non-Magnetic Pump[18]	Conventional Pump & Line Extensions
JCAHO Compliance	✓	JCAHO Sentinel Event 38 recommendation 7, mandates that only equipment approved for MRI should be used
HAI Reduction Potential	✓	Contamination increases with floor contact and each access port manipulation
Code Responsiveness	✓	IV Extension tubing can increase the code response time in critical situations
Flow Assurance	✓	Doubling the tubing length doubles the resistance which reduces the flow
Occlusion Relief Bolus	✓	Can exceed ECRI's 0.5 mL post-occlusion bolus guideline
Potential Cost Reduction	✓	32.5' of IV extension lines = $26.45 63.2mL drug waste in lines = $25.28 **Estimated Waste Cost Per Drug = $51.73**

References:
[1] The Joint Commission: Preventing accidents and injuries in the MRI suite. *Sentinel Event Alert #38*, February 14, 2008.
[2] Gosbee J, Gosbee L: Flying Object Hits MRI. *Agency for Healthcare Research & Quality WebM&M*, February 2003.
[3] Shellock FG, Crivelli R, Venugopalan R: Programmable infusion pump and catheter: evaluation using 3-tesla magnetic resonance imaging. *Neuromodulation*, 2008; 11(3):163-170.
[4] Wynnychenko T, Szokol J, Murphy G: Infusion Pump Use in the MRI. *Anesthesia & Analgesia*, July 2000; 91(1):249-250.
[5] World Health Organization: Prevention of hospital-acquired infections 2nd edition. WHO/CDS/CRS/EPH/2002.12.
[6] Richards MJ, Edwards JR, Culver DH, Gaynes RP: Nosocomial infections in medical intensive care units in the United States. *National Nosocomial Infections Surveillance System. Crit Care Med.* 1999; 27:887-892.
[7] Schmid MW: Preventing Intravenous Catheter-Associated Infections: An Update. *Infection Control Today*, June 1, 2001.
[8] Klabunde R: Determinants of Resistance to Flow (Poiseuille's Equation). *CV Physiology (www.cvphysiology.com)*, January 8, 2008.
[9] Naga J, Dabke H: The effect of IV cannula length on the rate of infusion. *Injury*, January 2006; 31(1): 41-45.
[10] Keay S: The safe use of infusion devices. *Continuing Education in Anesthesia Critical Care & Pain*, 2004; 4(3): 81-85.
[11] Deckert D, Buerkle C, Neurauter A, Hamm P, Linder K, Wenzel V: The Effects of Multiple Infusion Line Extensions on Occlusion Alarm Function of an Infusion Pump. *Anesthesia & Analgesia*, February 2009; 108(2):518-520
[12] ECRI: General-Purpose Infusion Pumps. *Health Devices*, April-May 1998, 27(4-5):151-159.
[13] Jirka K: Post Occlusion Bolus Case Study. *IRadimed internal investigation*, November 2014 (contact sales@iradimed.com for a copy of the case study)
[14] CMS: FY 2013, FY 2014, FY2015 Final HAC List. *www.cms.gov/medicare/medicare-fee-for-service-payment/HospitalAcqCond/Downloads/FY_2013_Final_HACsCodeList.PDF*, August 2014.
[15] Scott D: The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention. *Centers for Disease Control and Prevention*. March 2009
[16] Stone PW, Braccia D, Larson E: Systematic review of economic analyses of health care associated infections. *American Journal of Infection Control*, 2005; 33:501-509.
[17] Rello J, et al: Evaluation of Outcome of Intravenous Catheter-related Infections in Critically Ill Patients. American Journal of Respirator and Critical Care Medicine, 2000; 162:1027-1030
[18] MRidium uses a non-magnetic motor and contains less than 15 grams of ferrous material allowing it to operate at 10,000 Gauss
[19] Medicines and Healthcare Products Regulatory Agency (MHRA): *Infusion Systems v2.1*. December 2013

CE 0843

IRADIMED®

1025 Willa Springs Drive Winter Springs, FL 32708, U.S.A. Phone: (866) 677-8022 Email: Sales@Iradimed.com LB014-B