Deciphering **MR Conditional Labeling**

Tobias Gilk - Sept 27, 2022



GRC 2022 Dubai Advanced MRI Safety Seminar

Deciphering MR Conditional Labeling

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As a member of the the Board of the ABMRS, I am prohibited from speaking on specific examination question content, but permitted to provide education on MRI safety concepts and principles.

This presentation is not an exam preparation for any examination.

Rules of the Road

- Everything on the screen is for you (you can copy or take photos).
- If you have questions, ask!
- If you disagree, please speak up.

Outline

Deciphering MR Conditional Labeling

- Intro
- MR Conditional Labeling / Conditions
- How Devices Are Tested
- Violating MR Conditional Status
- Unlabeled Devices / Foreign Bodies
- "Off-Label" ≠ Unsafe ('It's All About Harm')
- Q & A

What Does "FDA Approved" Mean?

What exactly did the FDA approve?



What Does "FDA Approved" Mean?

What exactly did the FDA approve?

- Drug / device meets minimum criteria for efficacy?
- Drug / device meets minimum criteria for safety?

What Does "FDA Approved" Mean?

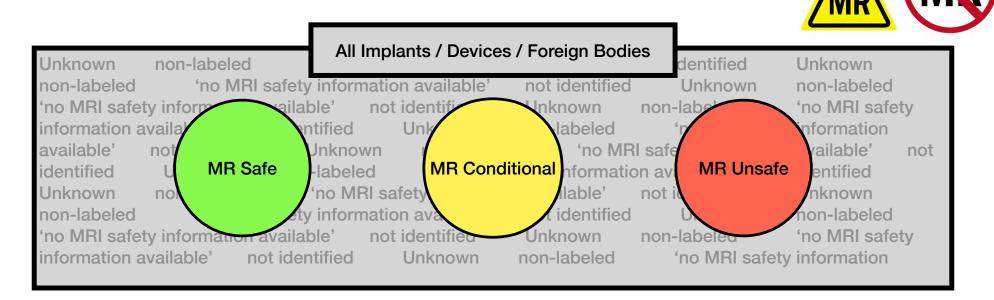
What exactly did the FDA approve?

The FDA's responsibility is to grant and oversee a company's interstate medical product marketing.

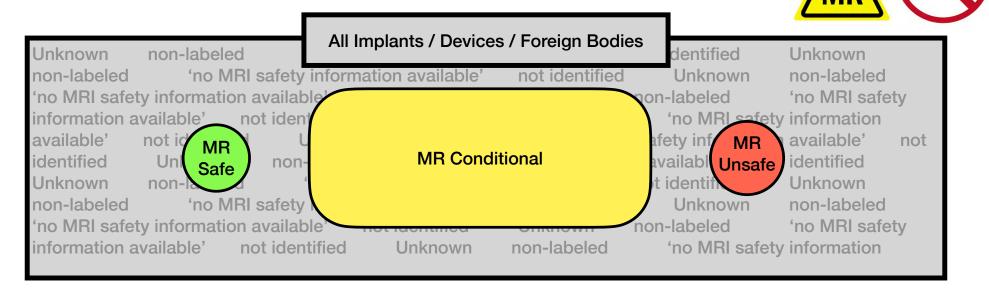
https://www.hudson.org/research/7264-fda-approval-does-not-mean-what-you-think-it-does-



MR safe	The device or implant is completely nonmagnetic, nonelectrically conductive, and nonradiofrequency reactive, therefore eliminating all the primary potential risks during MRI scanning
MR conditional	The device or implant may contain magnetic, electrically conductive, or radiofrequency-reactive components that are safe for operation in proximity to the MRI, provided the conditions for safe operation are defined and observed (both for the MR scanner and the device itself)
MR unsafe	Objects that are significantly ferromagnetic and pose a clear and direct threat to persons and equipment within the magnet room

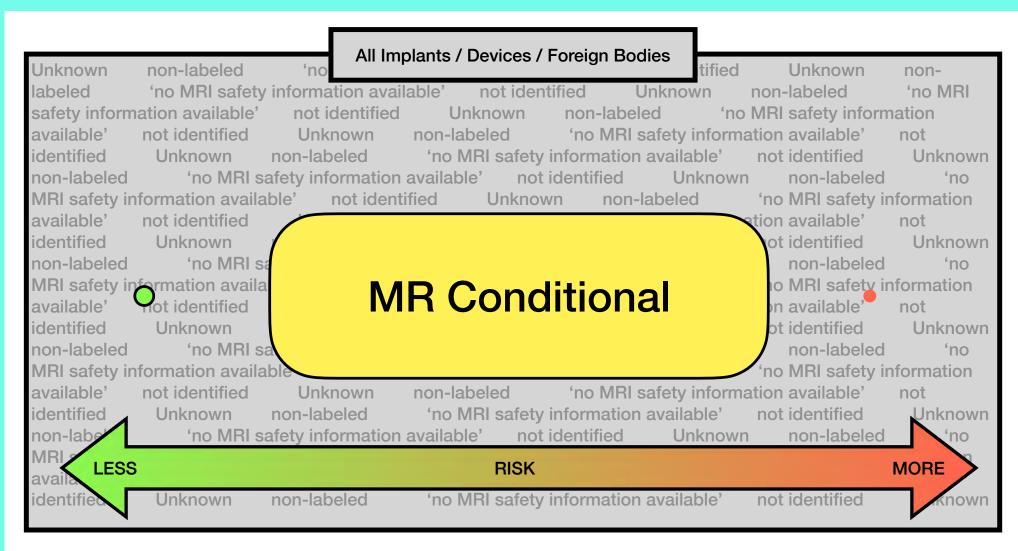








All Implants / Devices / Foreign Bodies tified Unknown non-labeled Unknown 'no nonlabeled 'no MRI safety information available' not identified Unknown non-labeled 'no MRI safety information available' not identified Unknown 'no MRI safety information non-labeled available' not identified Unknown non-labeled 'no MRI safety information available' not identified Unknown 'no MRI safety information available' not identified Unknown non-labeled non-labeled 'no MRI safety information available' not identified Unknown non-labeled 'no MRI safety information available' not identified Unknown non-labeled 'no MRI safety information available' not identified ation available' not Unknown Unknown identified ot identified non-labeled 'no MRI sa non-labeled 'no MRI safety information availa o MRI safety information MR Conditional available' not identified n available' not Unknown Unknown ot identified identified non-labeled 'no MRI sa non-labeled 'no MRI safety information available no MRI safety information not identified Unknown non-labeled 'no MRI safety information available' available' not Unknown identified Unknown non-labeled 'no MRI safety information available' not identified non-labeled 'no MRI safety information available' not identified non-labeled 'no Unknown MRI safety information available' not identified Unknown non-labeled 'no MRI safety information not identified available' Unknown non-labeled 'no MRI safety information available' not Unknown identified Unknown non-labeled 'no MRI safety information available' not identified

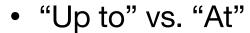




What is 'Conditionality'?



Manufacturer-Assured Safety When All Stated Conditions Are Met.



- Electromagnetic Fields
- Assemblies vs. Lone Objects
- Device Functionality



What is 'Conditionality'?

"Up to" vs. "At"

- All MR Conditional Conditions 'Up To' For All Risks **Except** Focal Heating (Burns)
- Field Strength In MR Conditional Labeling Two Separate Risks:
 - Torque ('Up To')
 - RF Frequency For Resonant Circuit Heating ('At')

What is 'Conditionality'?



Electromagnetic Fields

- Most of MR Conditional Labeling Parameters Are Based On Controlling Exposure To Electromagnetic Fields
 - By Position (e.g., 'Center Above / Below')
 - By Setting (e.g., 'no more than 2 W/kg or 150 T/m/s')
 - By Coil (e.g., 'T/R knee coil')

What is 'Conditionality'?



Assemblies vs. Lone Objects

- Many MR Conditional Implants Aren't Lone Objects, But Rather Assemblies:
 - Plates & Screws
 - Pulse Generator & Lead-Set
- If Assembly Hasn't Been Tested Together, Shouldn't Be Labeled.

What is 'Conditionality'?



Device Functionality

- MR May Affect Device Function:
 - Shunt Valve Position
 - Implanted Medication Pumps
 - 'MR Mode' For Pacemakers / Neurostimulators
 - ECG Readouts



What is 'Conditionality'?



e.g., Multichannel-2 (MC-2) or Circularly Polarized (CP) Note: Circularly polarized RF is also commonly referred to as e.g., Integrated Whole Body Transmit RF coil e.g., Detuchable Head Transmit/Receive RF coil e.e., Detachable Extremity Transmit/Receive RF coil E.R., Any Transmit RF Coil may be used. Note: All coils are either integrated or detachable. A detachable RF coil is one that must be plugged into the MR system. e.g., Any receive RF coil may be used. e.g., "Normal Operating Mode" e.g., "First Level Controlled Operating Mode or Normal Operating e.g., "RF Power Restricted" Note: For Normal Operating Mode and First Level Controlled Operating Mode, SAR information may be included Note: For RF Power Restricted, HI+xws and/or SAR information shall be included; BI+** is preferred. Landmark based restrictions may also e.g., By mas ≤ 2.8 uT e.g., Biasas $\leq 1.7~\mu T_{\rm c}$ for MR systems that do not report B1+asa, see Whole Body Averaged SAR Note: When both Brown and SAR limits are provided, include a note in the labeling to specify which single limit is preferred, if any. See Figure X.1.2 for examples For RF Power Restricted e.g., Whole Body Averaged 5AR 5 1.2 W/kg Note: It is not recommended to list a Whole Body Averaged SAR value Example for Head SAR labeling for less than the Normal Operating Mode: Hend SAR ≤ 1.2 W/kg

Item Configuration

Transmit Coil: Integrated Who Scan Regions: Superior. Place isocenter at or Inferior: Place isocemee at or are necessary, describe item po Include any restrictions on the system's isocenter. Consider is

e.g., Any anatomic location at i

Note: If the anatomic diagram different transmit enil, include

- e u. Scanning patients who has acceptable as long as the MR e.g., The safety of this item dur
- c.g. The patient has no implanted e.p. Patient height greater than I
- Note: Include any constraints patient and potential patient co well as the patient's physical a in this implant should be place
- e.g., Supine, patient's arms mu e.g., Patient must be wiented is e.g., The item may not be scan

Required programming settings

and/or after the MRI exam

Instructions to be followed before, during

- e.g., Any patient position is acc e.g., The item shall not be scan
- e.g., Lead wires shall exit strain without loops, positioned away the patient with appropriate pac

e.g., Catheter shall be oriented parallel to patient's lega-
e.g., This item shall be used only with the following specified MR Conditional components (Implantable Pulse Generator (IPG) Model A with Leads Model B-or Model C),
e.g., The injection port for this item shall be secured to prevent movement in the magnetic field.
e.g., The external pulse generator for this item shall be kept omside the 200 Gauss line.
e.g., The external components for this item shall remain outside the MR environment.
e.g., The item shall stay outside the RF Transmit/Receive coil
e.g., The item shall stay putyide the hors of the MR system at all times
e.g., The drug reservoir shall be emplied prior to scanning.
Note: Include any constraints or special instructions on positioning the item or component with respect to the patient or the MR system. Include any constraints/instructions about components that can be used lugether. Consider including figures or diagrams to show what is acceptable.
e.g., Scan for 15 minutes of continuous RF exposure with one or more MR imaging pulse sequences (scans or series) followed by a wait time of 5 minutes before resuming scanning.
e.g., There is no limit on MR scan duration for the labeled RF conditions.
e.g., Scan for 60 minutes with one or more MR imaging pulse sequences (scans or series) followed by a wait time of 15 minutes before resuming scanning.
Note: Autoscanning / Autoscan Mode is considered continuous scanning.
Note: Short pauses between scan sequences are considered part of the scan time.
e.g., Image distortion and artifacts mass he considered when planning an MR exam and when interpreting MR scan images in proximity to the implanted item. Distortion and artifacts may occur beyond the boundaries of the item.
e.g., In non-clinical testing, the MR image artifact caused by the item extended approximately 14 mm from the item when imaged with a gradient echo pulse acquence using a TE of 20 mL and a 3 T MR system.
e.g., The presence of this tiem may produce an MR image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.
e.g., Detailed image artifact information is available upon request.
e.g., The presence of the item may produce an MR image utiliact. Imaging protocol medifications may be necessary to compensate for the MR image artifact.
e.g., Pulse generator is in MRI made during the MR exam.

e.g., Turn off item during the MR exam.

e.g., Patient required to have item programmed and checked before and, after the MR exam by an appropriate expert.

e.g., Radiographic setting confirmation might be required following the

e.g.. Proper patient monitoring shall be provided during the MR exam.

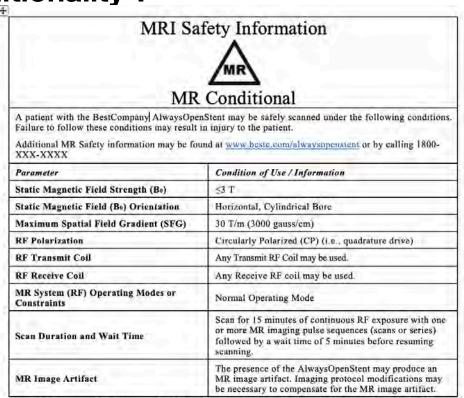
R exam to verify item settings and/or functional

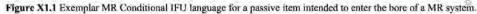
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Head SAR [W/kg]

Whole Body Averaged SAR |W/kg|

Deciphering MR Conditional Labeling







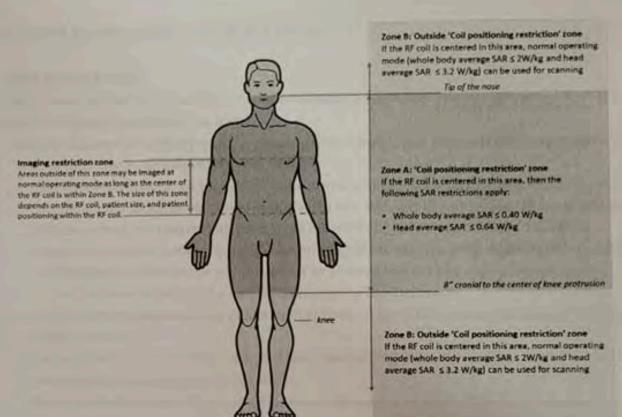
What is 'Conditionality'?



MRI Statement

The MULTI-LINK VISION Coronary Stent has been shown in non-clinical testing to be MRI safe immediately following implantation. MRI test conditions used to evaluate this stent were: for magnetic field interactions, a static magnetic field strength of 3 tesla with a maximum spatial gradient magnetic field of 3.3 tesla/meter; for MRI-related heating, a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MR imaging. While a single stent produced a temperature rise of less than 0.6°C and should not migrate under these conditions, the response of overlapping stents or stents with fractured struts is unknown. Non-clinical testing has not been performed to rule out the possibility of stent migration at field strengths higher than 3 tesla. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

What is 'Conditionality'?





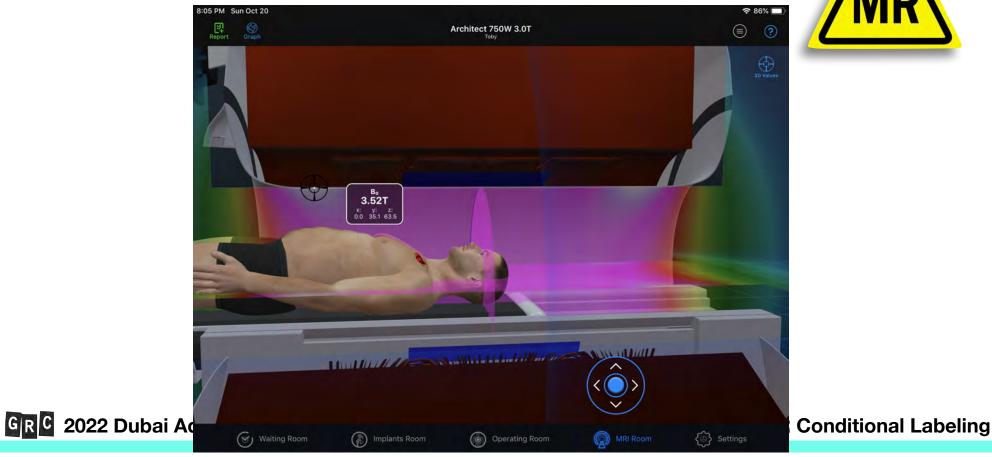
Conditional Labeling

What is 'Conditionality'?



Static Magnetic Field (1 of 2) - Torque / Rotation

- 'Up To' System Rating (For Torque)
- What The System Is Sold As (e.g., 1.5T, 3.0T)
- Not The Specific Exposure Of The Device (Even If The Exposure Is Greater Than The Listed Value)



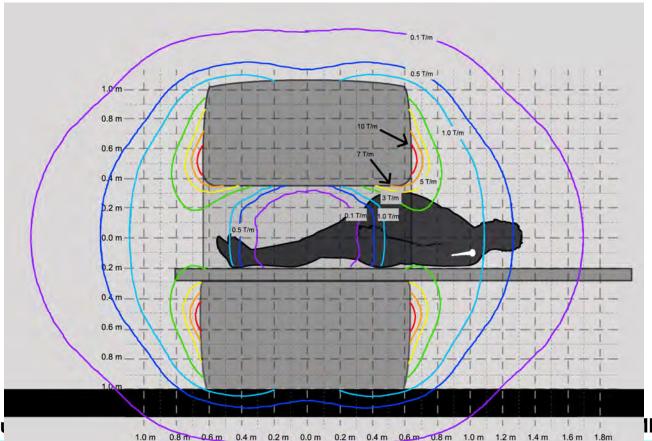
What is 'Conditionality'?

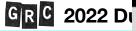


Spatial Field Gradient - Translation / Attraction

- 'Up To' Exposure Value (T/m, G/cm)
- Not System Max. What Device Will Be Exposed To.

What is 'Conditionality'?





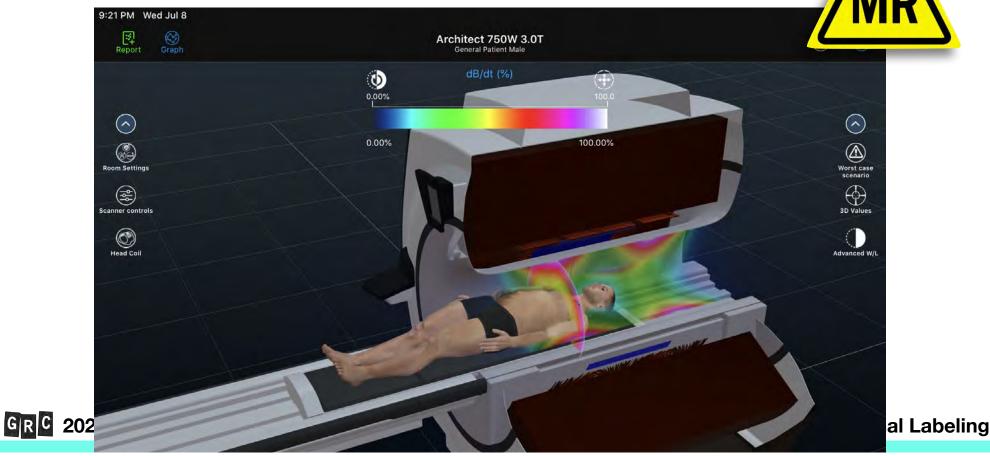
IR Conditional Labeling

What is 'Conditionality'?



Time-Varying Gradient - Neuromuscular Stim / Device Interference

- 'Up To' Exposure Value (T/m/s)
- Not System Max (If Your System Allows TVG Controls). What Device Will Be Exposed To.
 - May Be Managed By Setting (e.g., 'Slew Rate ≤ 150 T/m/s')
 - May Be Managed By Position (e.g., 'Landmark Above / Below x')
- If System Doesn't Allow TVG Controls...

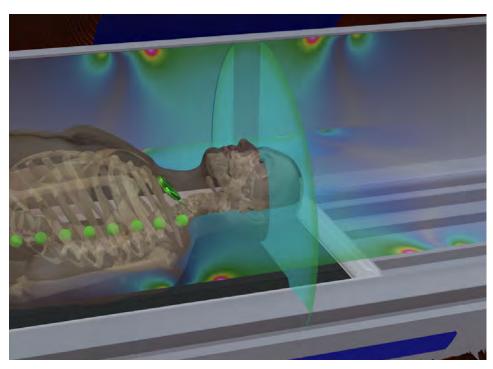


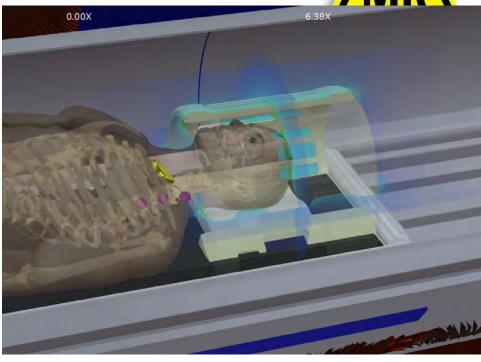
What is 'Conditionality'?



RF Magnetic Fields (1 of 2) - Diffuse Thermal Loading

- 'Up To' Pulse Sequence Setting (Whole Body Averaged SAR)
- May Be Managed By:
 - Pulse Sequence Setting
 - Smaller Transmit Volume (Local T/R Coils)





What is 'Conditionality'?



"What's the center frequency of your MR system?"

What is 'Conditionality'?



RF Magnetic Fields & Static Magnetic Field (2 of 2)

- Focal Heating (Burns) Specifically From Resonant Circuit Effects

- Field Strength (Really Frequency)
- May Be Managed By:
 - Position Within Bore (e.g., 'Route Cable Along Central Z-Axis')
 - Position Outside Volume of Deposition (e.g., 'Above / Below x')
 - Pulse Sequence (e.g., 'SAR ≤ 0.5 W/kg')



Acme Buzz-O-Matic Neurostimulator		
Static Magnetic Field	1.5 or 3.0 Tesla	
Spatial Field Gradient	9 T/m (900 G/cm)	
SAR	Normal Operating Mode (up to 15 minutes)	
B1+ _{RMS}	2 μT at 1.5 T	
Time-Varying Gradient	150 T/m/s (150 mT/m/ms)	



What is 'Conditionality'?



Acme Buzz-O-Matic Neurostimulator	
Static Magnetic Field	1.5 or 3.0 Tesla
Spatial Field Gradient	9 T/m (900 G/cm)
SAR	Normal Operating Mode (up to 15 minutes)
B1+ _{RMS}	2 μT at 1.5 T
Time-Varying Gradient	150 T/m/s (150 mT/m/ms)



- 'Up To' Highest System **Rating For Torque**
- But 'At' 1.5 or 3.0 T For Resonant Circuit Heating

What is 'Conditionality'?



Acme Buzz-O-Matic Neurostimulator		
Static Magnetic Field	1.5 or 3.0 Tesla	
Spatial Field Gradient	9 T/m (900 G/cm)	
SAR	Normal Operating Mode (up to 15 minutes)	
B1+ _{RMS}	2 μT at 1.5 T	
Time-Varying Gradient	150 T/m/s (150 mT/m/ms)	



• 'Up To' 9 T/m Device Exposure For Attraction

What is 'Conditionality'?



Acme Buzz-O-Matic Neurostimulator		
Static Magnetic Field	1.5 or 3.0 Tesla	
Spatial Field Gradient	9 T/m (900 G/cm)	
SAR	Normal Operating Mode 👍 (up to 15 minutes)	
B1+ _{RMS}	2 μT at 1.5 T	
Time-Varying Gradient	150 T/m/s (150 mT/m/ms)	



- 'Up To' Normal Mode Console Readout **RF** Heating
- 'Up To' 15 Minutes Per Pulse Sequence (default)

What is 'Conditionality'?



Acme Buzz-O-Matic Neurostimulator		
Static Magnetic Field	1.5 or 3.0 Tesla	
Spatial Field Gradient	9 T/m (900 G/cm)	
SAR	Normal Operating Mode (up to 15 minutes)	
B1+ _{RMS}	2 μT at 1.5 T	
Time-Varying Gradient	150 T/m/s (150 mT/m/ms)	



• 'Up To' 2 μT Console Readout RF Heating

What is 'Conditionality'?



Acme Buzz-O-Matic Neurostimulator		
Static Magnetic Field	1.5 or 3.0 Tesla	
Spatial Field Gradient	9 T/m (900 G/cm)	
SAR ("AND" / "OD"	Normal Operating Mode (up to 15 minutes)	
SAR "AND" / "OR" B1+RMS	and the second s	

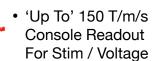


• But Which To Use When Both Are Listed?

What is 'Conditionality'?



Acme Buzz-O-Matic Neurostimulator		
Static Magnetic Field	1.5 or 3.0 Tesla	
Spatial Field Gradient	9 T/m (900 G/cm)	
SAR	Normal Operating Mode (up to 15 minutes)	
B1+ _{RMS}	2 μT at 1.5 T	
Time-Varying Gradient	150 T/m/s (150 mT/m/ms)	





What is 'Conditionality'?



"Just Follow The Label, Right?"

What is 'Conditionality'?



Acme Buzz-O-Matic Neurostimulator		
Static Magnetic Field	1.5 or 3.0 Tesla	
Spatial Field Gradient	9 T/m (900 G/cm)	
SAR	Normal Operating Mode (up to 15 minutes)	
B1+ _{RMS}	2 μT at 1.5 T	
Time-Varying Gradient	150 T/m/s (150 mT/m/ms)	

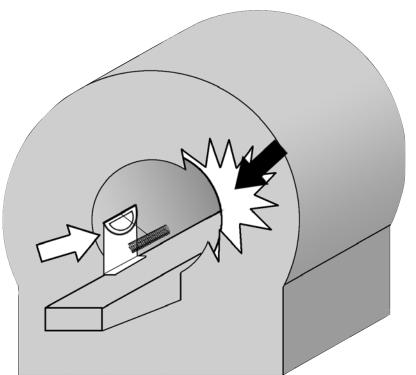


- 'Up To' <u>Highest System</u> <u>Rating</u> For Torque
- But 'At' 1.5 or 3.0 T For Resonant Circuit Heating
- 'Up To' 9 T/m <u>Device</u> <u>Exposure</u> For Attraction
 - 'Up To' Normal Mode <u>Console Readout</u> RF Heating
 - 'Up To' 15 Minutes
 <u>Per Pulse Sequence</u>
 (default)
 - 'Up To' 2 μT Console Readout RF Heating
 - 'Up To' 150 T/m/s
 <u>Console Readout</u>
 For Stim / Voltage

Deciphering MR Conditional Labeling



- Manufacturer Defines Test Parameters
- They Then Test (or contract-out testing)
- Manufacturer Reviews Test Data (& Decides On Whatever Parameters They Wish For FDA Submittal)
- **FDA Reviews**
 - Approves, or
 - Requests Supporting Data For Claims, or
 - Rejects



- Testing / Labeling Is Not Required To Indicate Safe Limits / **Thresholds**
- Manufacturer's Can Build-In Whatever Safety Margins They Choose To

- I Worked With A Manufacturer On Relabeling Their Device With A Greater Spatial Field Gradient Value (extrapolated).
- When the Manufacturer Sent Me A Courtesy Copy Of Their Draft FDA Application, I Discovered A Math Error. They Were Applying For Labeling ~65% Of What The Calculation Said They Could.
- Attorneys / Risk-Management Said It Wasn't Worth Correcting For The FDA.

What If We Go Beyond / Outside MR Conditional Terms?



What If We Go Beyond / Outside MR Conditional Terms?

If You Violate Even 1 Of 20 MR Conditional Conditions, That Scan Is 'Off-Label'

But...

 If You Know How To Identify MRI Risks & How To Break-Down MR Conditional Labeling, You Can Make Many Safety Deductions Even If You Go Outside MR Conditional Conditions

What About Devices (FBs) With No Labels?

"This Device Not Tested For MR Safety"



What About Devices (FBs) With No Labels?

"This Device Not Tested For MR Safety"

- Just Because It Hasn't Been Manufacturer Tested Doesn't Mean You Can't Make Safety Assessments
 - Published Studies
 - Exposure Analysis (i.e., 'to what will it be exposed?')
 - Applying Standards (e.g., 'FDA 2 cm standard')
 - Materials Analysis (e.g., 'are the materials ferromagnetic?')

"Off-Label" ≠ Unsafe

It Means No Manufacturer Guidance

"Off-Label" ≠ Unsafe

It Means No Manufacturer Guidance

- When Manufacturer MRI Safety Is Not Provided, A Site May Operate Under The *Presumption* That Unlabeled / Off-Label Imaging Is Unsafe, But *MR Unsafe* Is A Known Condition... Not An Unknown One.
- Yes, Some Off-Label Conditions Are Dangerous, But Just Because It's Unlabeled / Off-Label Does Not Automatically Mean That All MR Imaging Is Dangerous.

It's All About The Harm

MRI Hippocratic Oath: First Find The Harm, Then Avoid It

It's All About The Harm

MRI Hippocratic Oath: First *Find* The Harm, Then Avoid It

- Risk vs. Benefit Requires That You Identify & Characterize The Risks
- In Identifying The Specific Risks, You Also Define What Is In Your Control / Outside Of Your Control To Manage
- If You Can Not Identify Specific Risks / Harms, You're Making Decisions Out Of Ignorance, Not Information

Q&A

Thank You

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