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Evaluation of the proposed MR Fixed Parameter Option for scanning AIMDs

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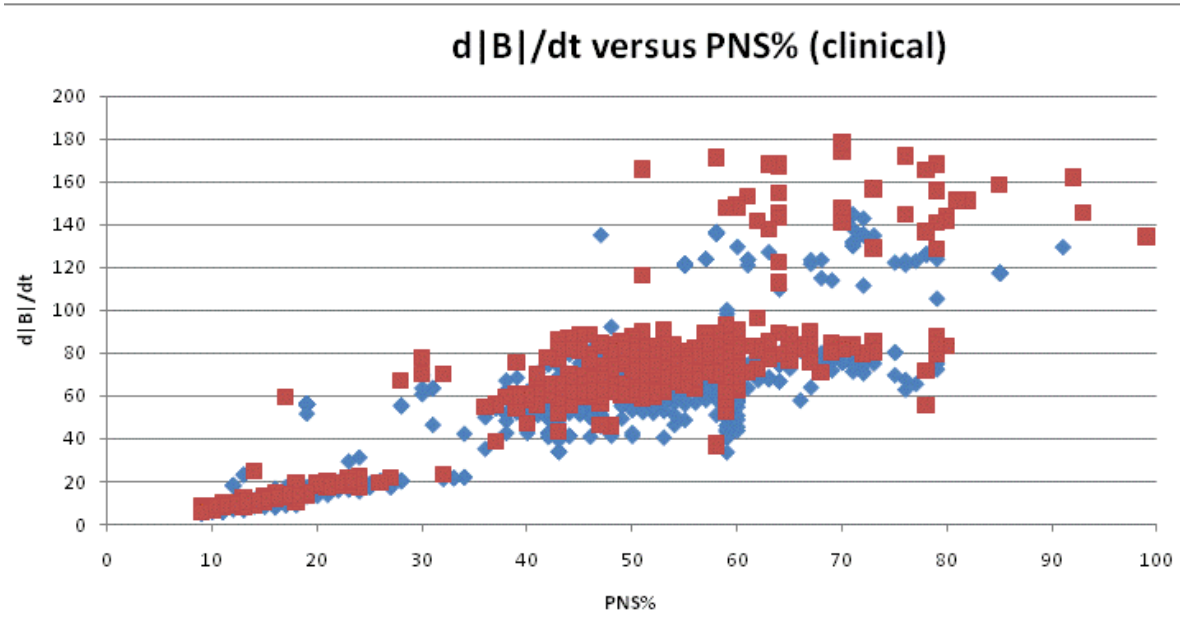
FPO:B, what is it?

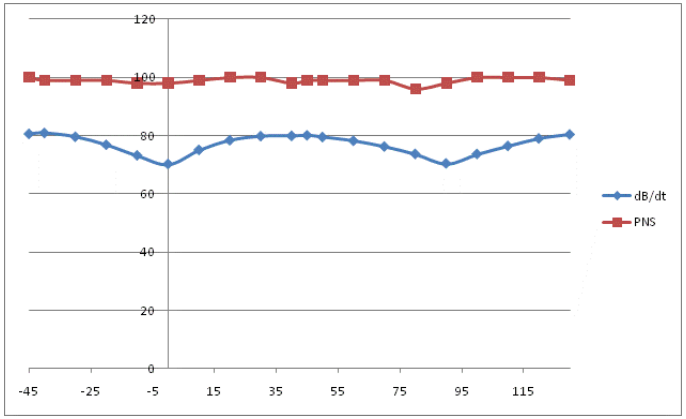
- FPO:B is a proposed option at (1.5T) MR systems
  - to facilitate development of MR Conditional implants
    by controlling and limiting the physical parameters for RF (B1) and gradients (dB/dt)
    at values (significantly) lower than typical system capabilities
  - to simplify workflow decisions in the hospital
    by condensing technical information into a ‘symbol’
- FPO:B intends to
  - replace (unintended) references to First Level Controlled Mode, SAR values, or dB/dt values in current labeling of MR Conditional implants
  - provide performance close to that provided in Normal Mode
- Selected FPO:B parameter values

RF Parameter	FPO-Basic: Value shall be less than		Gradient Parameter	FPO-Basic: Value shall be less than
B1+(peak)	30 µT		(d|B|/dt peak)FPO	100 T/s
B1+RMS	3.2 µT		(d|B|/dt RMS)FPO	56 T/s

Normal Mode is inadequate & insufficient

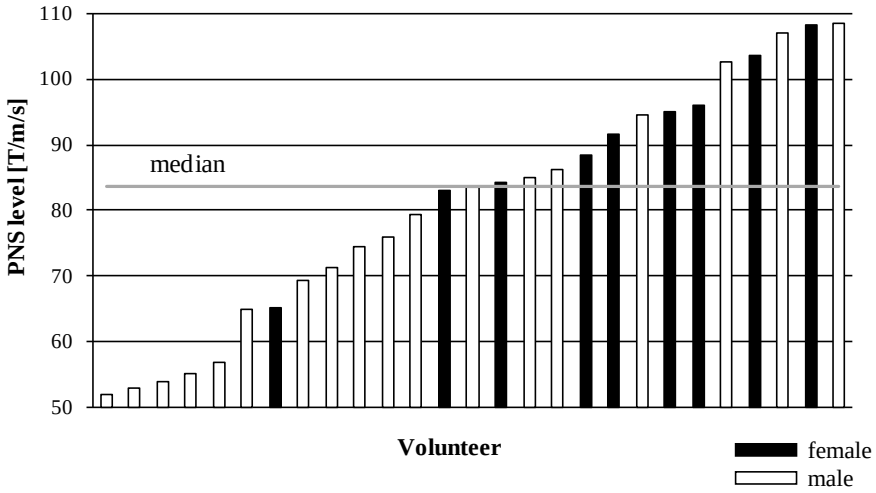
- IEC 60601-2-33 uses Normal / First Level Controlled Mode to control *physiological* effects in patients, by limiting
  - RF heating using SAR levels; MR vendors implement different conversion **margins**
  - Peripheral Nerve Stimulation, which is a function of the **orientation** of the switching gradient field relative to the patient, and its **frequency** content
- Technical effects in MR Conditional implants only depend on *physical* parameters: avoid variability and margins

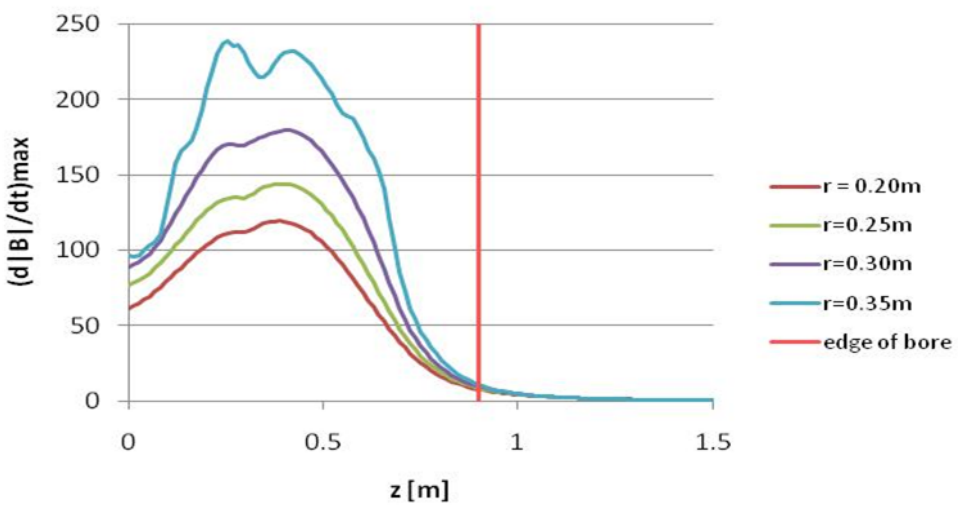




Some further comments on PNS & dB/dt

- PNS is the result of neuronal electrical depolarization by the induced E-field from the switching gradients
  - apart from **orientation** and **frequency** dependence,
  - the patient **perception threshold** varies over subjects

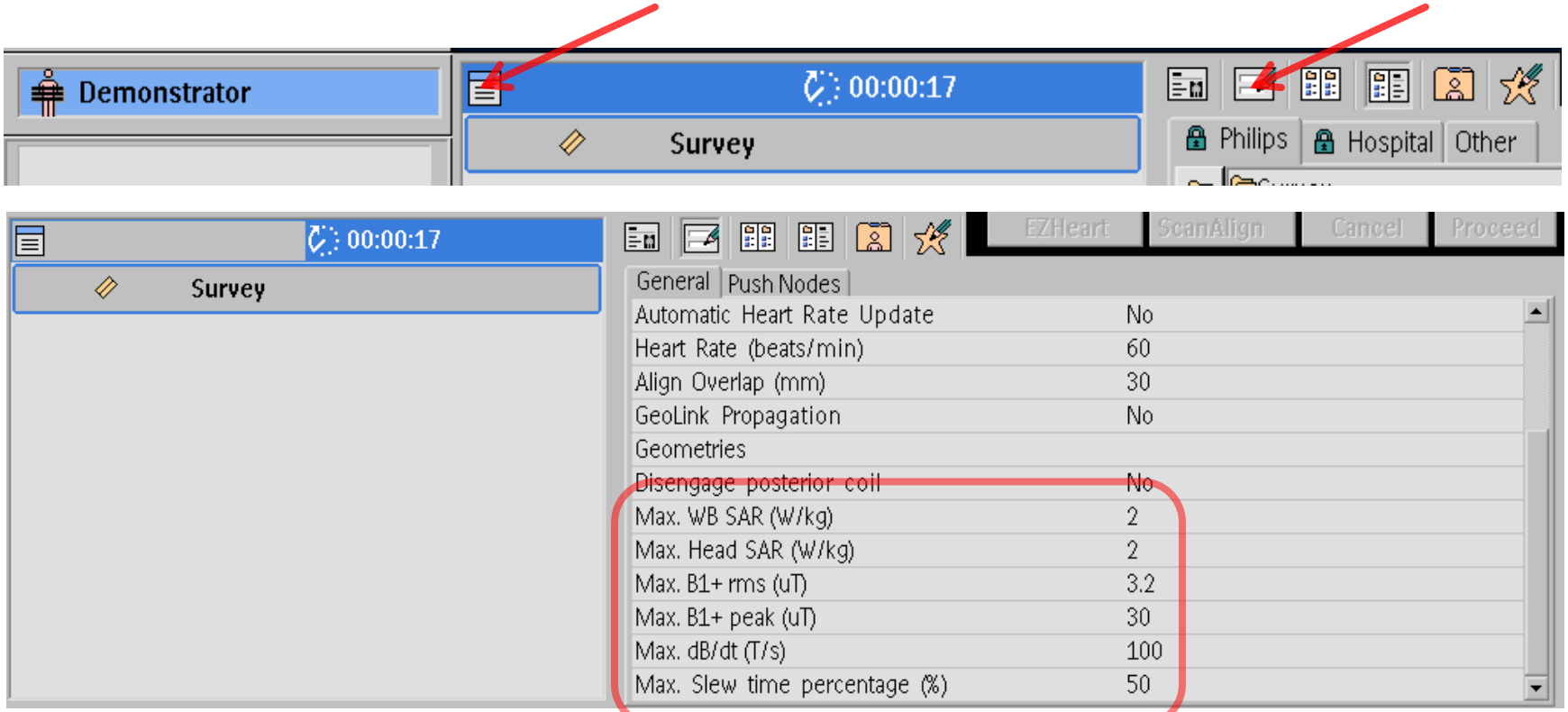


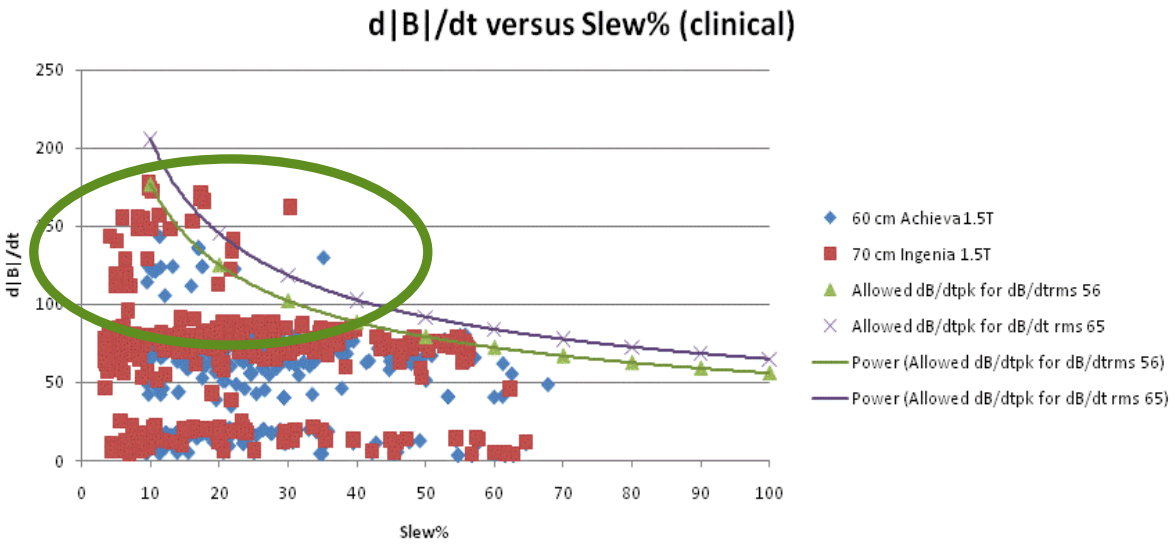


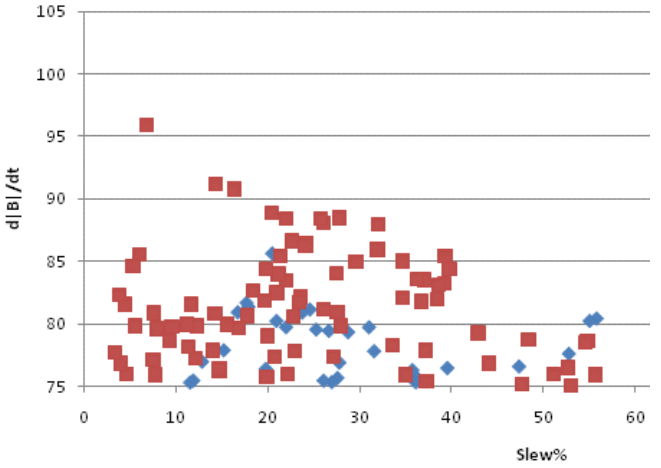
- d|B|/dt must be evaluated as full vector, whose magnitude depends strongly on the location inside the gradient tube

FPO:B prototype implementation 1.5T

- Extension of the sequence definition software to apply proposed limits
  - Model-based run-time evaluation of d|B|/dt
  - Run-time evaluation of B1+rms and dB/dtrms (or slew percentage)
  - Freedom to vary the limit values for further studies
- Applied to factory sequences for both 60 cm (Achieva) and 70 cm (Ingenia) systems







Affected protocol classes

80 < dB/dt < 100

- CE angio, dynamic perfusion
- 2D TSE (body, MSK, brain)
- non-CE angio & flow (cardiac, brain, extr.)
- perfusion, diffusion

Affected protocols mainly at 70 cm system

It will be very difficult to match clinical performance at 80 T/s pk

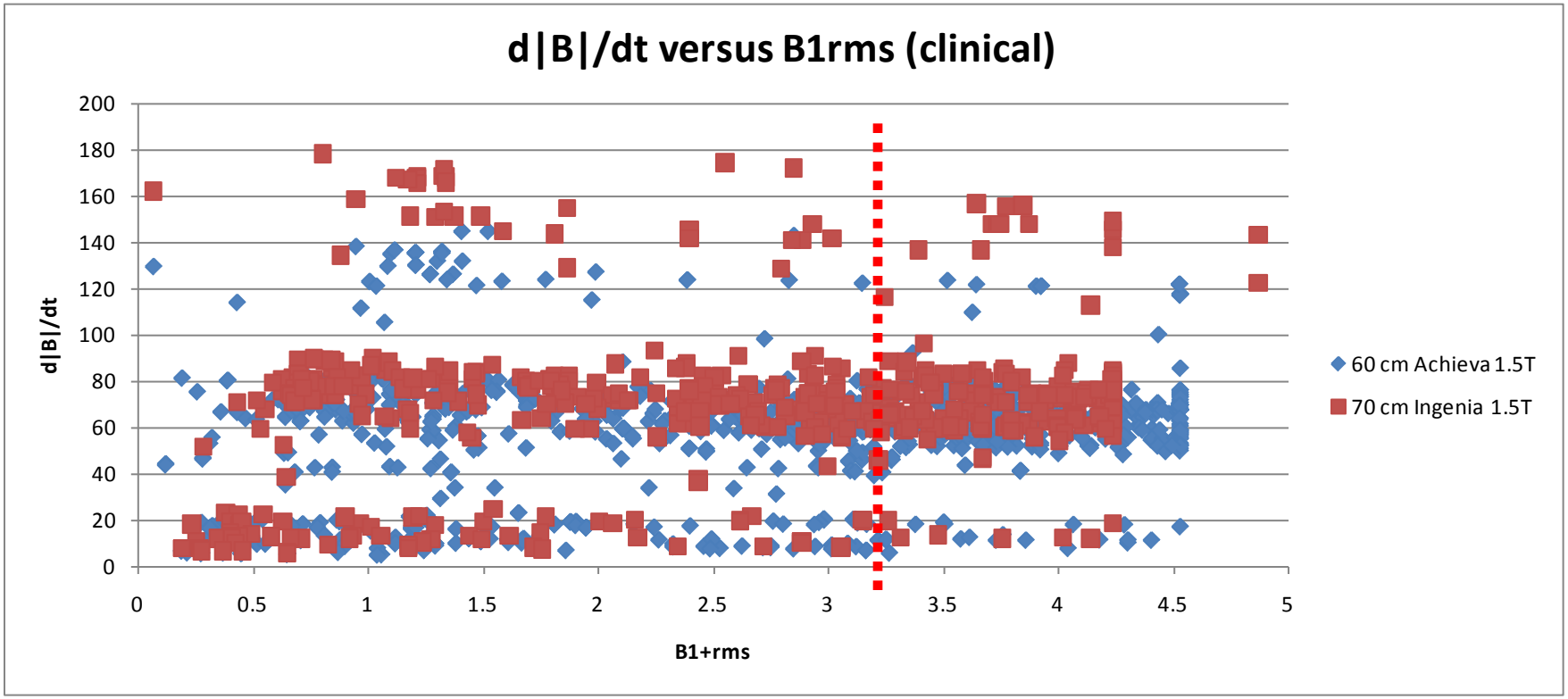
dB/dt > 100

- bFFE / true FISP (cardiac / abdomen)
- high-res (3D) TSE (brain, MSK)
- fMRI, perfusion, diffusion (brain)
- multi-echo FFE (spine)
- dyn. FFE, DIXON FFE (CE abdomen)

These “modern” sequences are painful to miss in advanced neuro and oncology diagnosis

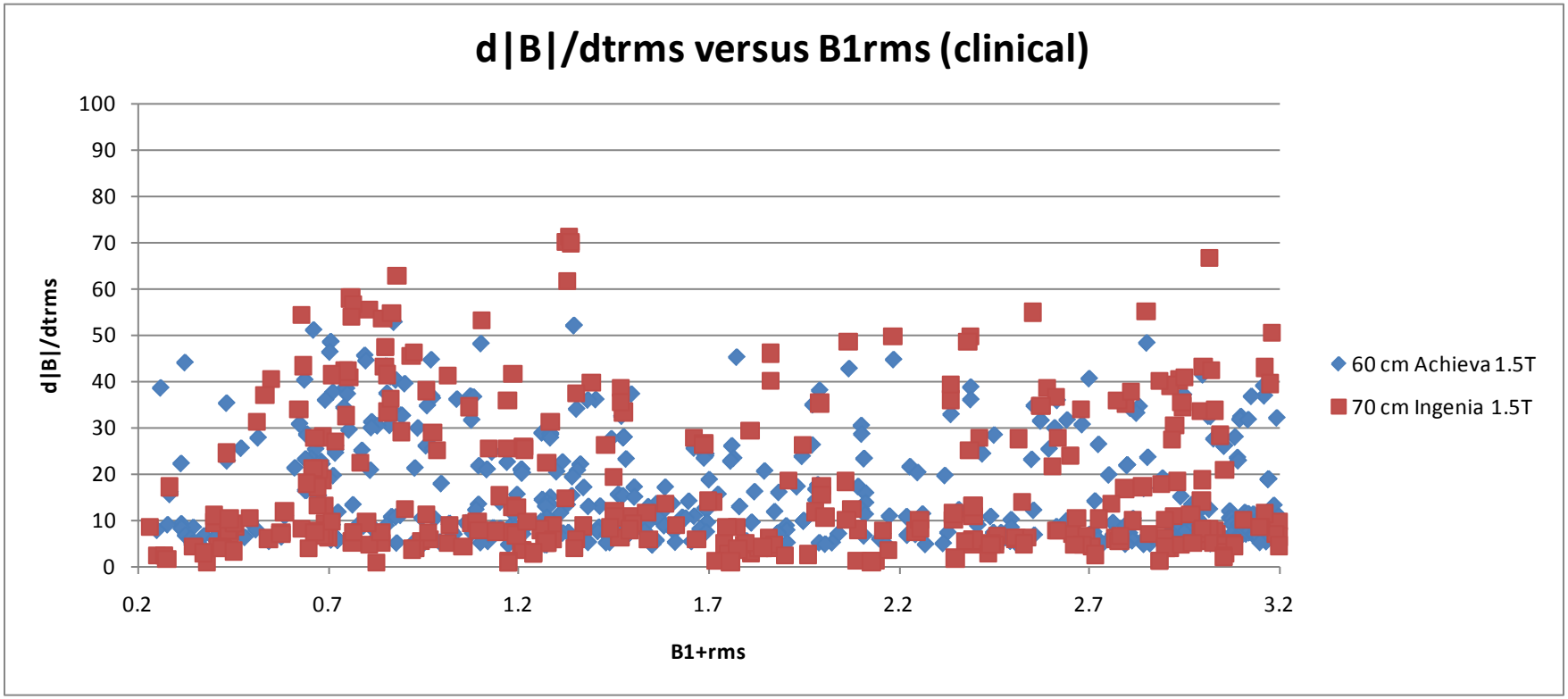
It will be difficult to provide alternatives, and may cause difficulties in 510(k) for FPO

Evaluation of factory sequences (subset)



Consequence of B1+rms limit (close to Normal Mode):
nearly all TSE and bFFE protocols must be re-evaluated

Evaluation of factory sequences (subset)



Conservative estimate of d|B|/dt(rms) shows that
no relevant factory clinical protocols will exceed 56 T/s
Given B1rms-dominated dutycycle constraints
except for DIXON at Ingenia

Summary

- A SW implementation of FPO:B was created to evaluate the impact of limiting physical outputs of the MR system to facilitate AIMD design

- The intent of FPO:B is to provide performance comparable to Normal Mode. The implications of such a performance envelope is that modern sequences cannot be run, or come with a performance penalty

- The clinical impact of reduced performance for diagnosis of patients with AIMDs is to be balanced against (a) the design costs of AIMDs against full MR system performance characteristics, and/or (b) potential full exclusion of patients from MR examination.
  Normal Mode alike performance can likely be considered sufficient for most routine MR examinations.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