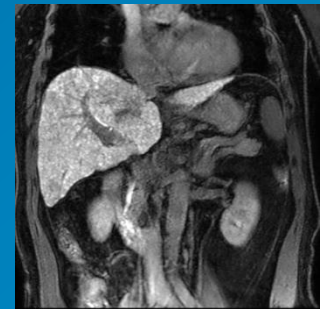


# Evaluation of estimated CEM43 values attained for realistic use cases under (local) SAR constraints imposed by IEC60601-2-33

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# Outline

- Overview of IEC60601-2-33 ( $\Delta$ )T and SAR limits for patients
- Retrospective CEM43 analysis using the Neufeld–Murbach model
- Discussion

## Acknowledgements:

dr Geran Peeren implemented the fast model for data evaluation

dr Cecilia Possanzini for helpful discussions

# IEC60601-2-33 and SAR safety management

- IEC60601-2-33 is a voluntary consensus standard to ensure safe operation of MRI
- MRI intentionally applies high power RF to generate images
- Three operating modes are defined with different safety profiles
  - Normal operating mode
    - mode of operation in which none of the outputs have a value that may cause physiological stress to patients
  - First level controlled operating mode
    - one or more outputs reach a value that may cause physiological stress which needs to be controlled by medical supervision

**Table 201.104 – Temperature limits**

Operating mode ↓	Maximum CORE TEMPERATURE	Maximum Local tissue temperature	Rise of CORE TEMPERATURE °C
NORMAL	39	39	0,5
FIRST LEVEL CONTROLLED	40	40	1
SECOND LEVEL CONTROLLED	>40	>40	>1

Compliance to the limits to temperature rise may be reached by limiting the SPECIFIC ABSORPTION RATE (SAR) as specified in 201.12.4.103.2. These SAR values limits are derived such that the spatially localized temperatures are expected not to result in tissue damage.

# SAR has been used as surrogate for Temperature

- Whole Body (WB) SAR limits have been successful in preventing thermal damage
- Advanced RF modeling revealed higher than expected values for **local SAR (psSAR10g), energy dose and local temperatures**
- Vendors evaluate local SAR as voluntary control on RF exposures
- Is there a need for more advanced measures like deposited energy or CEM43?  
In other words: is the concept of exposure duration critical to patient safety?



IEC 60601-2-33 limit values (edition 3)

	Normal operating mode	1 <sup>st</sup> level controlled operating mode	2 <sup>nd</sup> level controlled operating mode
RF: SAR limits			
- whole body SAR	$\leq 2 \text{ W/kg}$	$\leq 4 \text{ W/kg}$	$> 4 \text{ W/kg}$
- head SAR	$\leq 3.2 \text{ W/kg}$	$\leq 3.2 \text{ W/kg}$	$> 3.2 \text{ W/kg}$
- local SAR head/trunk	$\leq 10 \text{ W/kg}$	$\leq 20 \text{ W/kg}$	$> 20 \text{ W/kg}$
- local SAR extremities	$\leq 20 \text{ W/kg}$	$\leq 40 \text{ W/kg}$	$> 40 \text{ W/kg}$
energy dose	$240 \text{ W min / kg}$		

# Exposure duration to reach $\Delta T_{\text{core}} < 0.5^\circ\text{C}$ & $< 1.0^\circ\text{C}$

- Core temperature increase estimated from *Adair & Berglund, 1989*

- $T_a = 25^\circ\text{C}$

healthy patient

$\Delta T_{\text{core}}$	uncovered		covered	
	WB SAR	tmax (min.)	WB SAR	tmax (min.)
0.5°C	1.2	71.0	1.2	59.2
	1.4	53.6	1.4	41.2
	1.6	43.0	1.6	31.6
	1.8	35.9	1.8	25.6
	2	30.9	2	21.6
	2.2	27.1	2.2	18.7
	2.4	24.1	2.4	16.9
	2.6	21.6	2.6	15.1
	2.8	19.7	2.8	13.8
	3	18.1	3	12.7
	3.2	16.9	3.2	11.9
	3.4	16.1	3.4	11.3
	3.6	15.6	3.6	10.8
	3.8	15.2	3.8	10.4
	4	14.9	4	10.1

thermoregulatory  
compromised patient

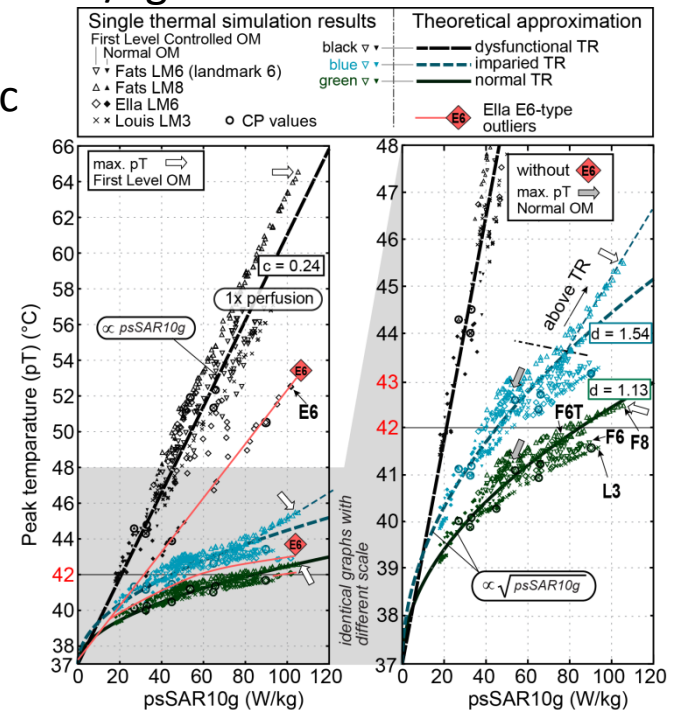
uncovered		covered	
WB SAR	tmax (min.)	WB SAR	tmax (min.)
1.2	31.8	1.2	29.2
1.4	27.1	1.4	23.5
1.6	23.6	1.6	19.7
1.8	20.9	1.8	16.9
2	18.7	2	14.8

- True 2 W/kg WB SAR can be considered stress-free for most historical MRI exam durations
- MR manufacturers apply a margin to reported WB SAR – so that longer durations are also safe
- SAR comes with a ‘scan/exposure profile’
- A critical assumption is that users never expose vulnerable patients to high SAR

# Peak Temperature evaluation

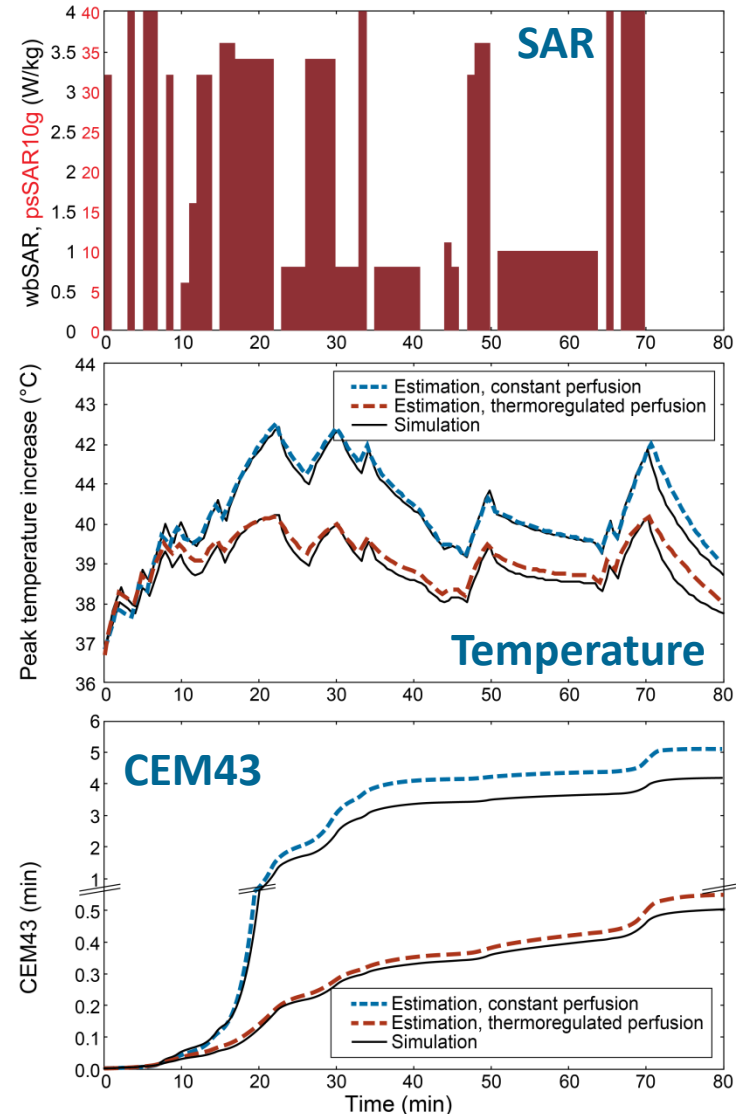
## Neufeld-Murbach model and real examination exposures

- Data extraction for **17010** exams at 1.5T from **100** randomly selected hospitals, scanned in April 2014
- Scans are effectively limited by Head SAR, Local Torso (LT), or Local Extremity (LE) SAR in the Philips implementation
  - LT: NM: 10 W/kg FL: 20 W/kg
  - LE: NM: 20 W/kg FL: 40 W/kg
- Use model parameters for hotspot temperature inc DOI: 10.1002/bem.21919
- Note: starting temperature 36.7 °C
- CEM43 sensitivity to initial temperatures evaluated for 38 °C and 39 °C



# Peak Temperature Evaluation – Example

Scan Name	Anatomy	lim SAR Type	lim SAR [W/kg]	Scan Time [sec]	Wait Time [sec]
CoilSurveyScan	KNEE	LT	1.55	5	20
SURVEY_LEFT	KNEE	LE	2.06	15	45
SenseRefScan	KNEE	LE	0.13	8	23
PDW_aTSE	KNEE	LE	11.52	102	6
STIR_longTE	KNEE	LE	15.56	127	5
COR_T1_1min_	KNEE	LE	35.68	42	15
T2W_FFE	KNEE	LE	0.23	78	3
PDW_SPAIR	KNEE	LE	19.75	107	19
T2W_TSE_HR_SENSE	KNEE	LE	20.67	78	6
T2_TSE_VKB_2mm	KNEE	LE	13.88	40	7
STIR_longTE	KNEE	LE	15.57	127	6
PDW_SPAIR_HR	KNEE	LE	14.92	130	20
T2W_TSE_korr_te	KNEE	LE	15.17	72	7
COR_T1_1min_	KNEE	LE	35.94	31	36
PDW_SPAIR_HR	KNEE	LE	14.92	90	1800

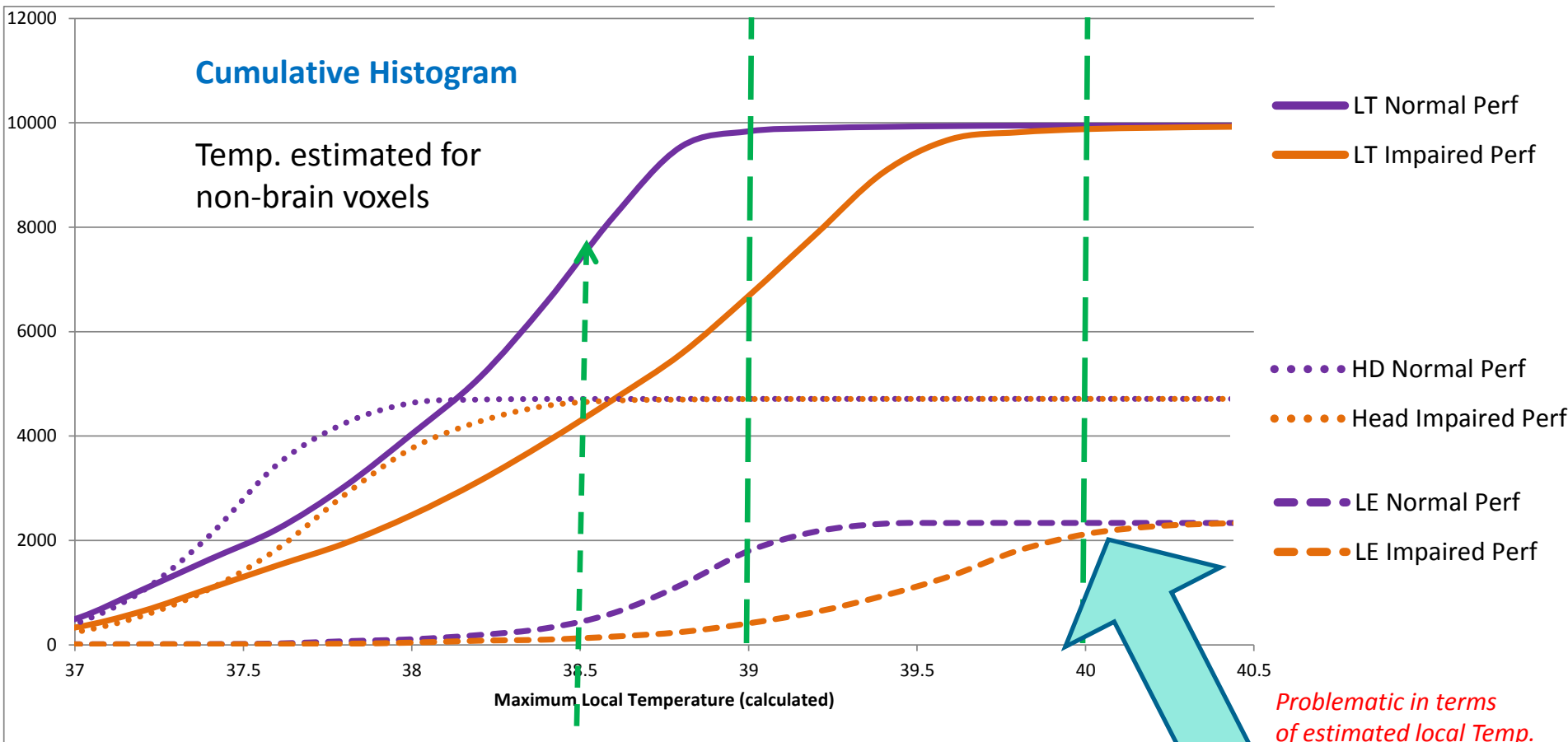


Courtesy Manuel Murbach

# Temperature estimates (Neufeld – Murbach model)

Final T from psSAR10g – all exams;  $T_b = 36.7\text{ }^\circ\text{C}$

# patients



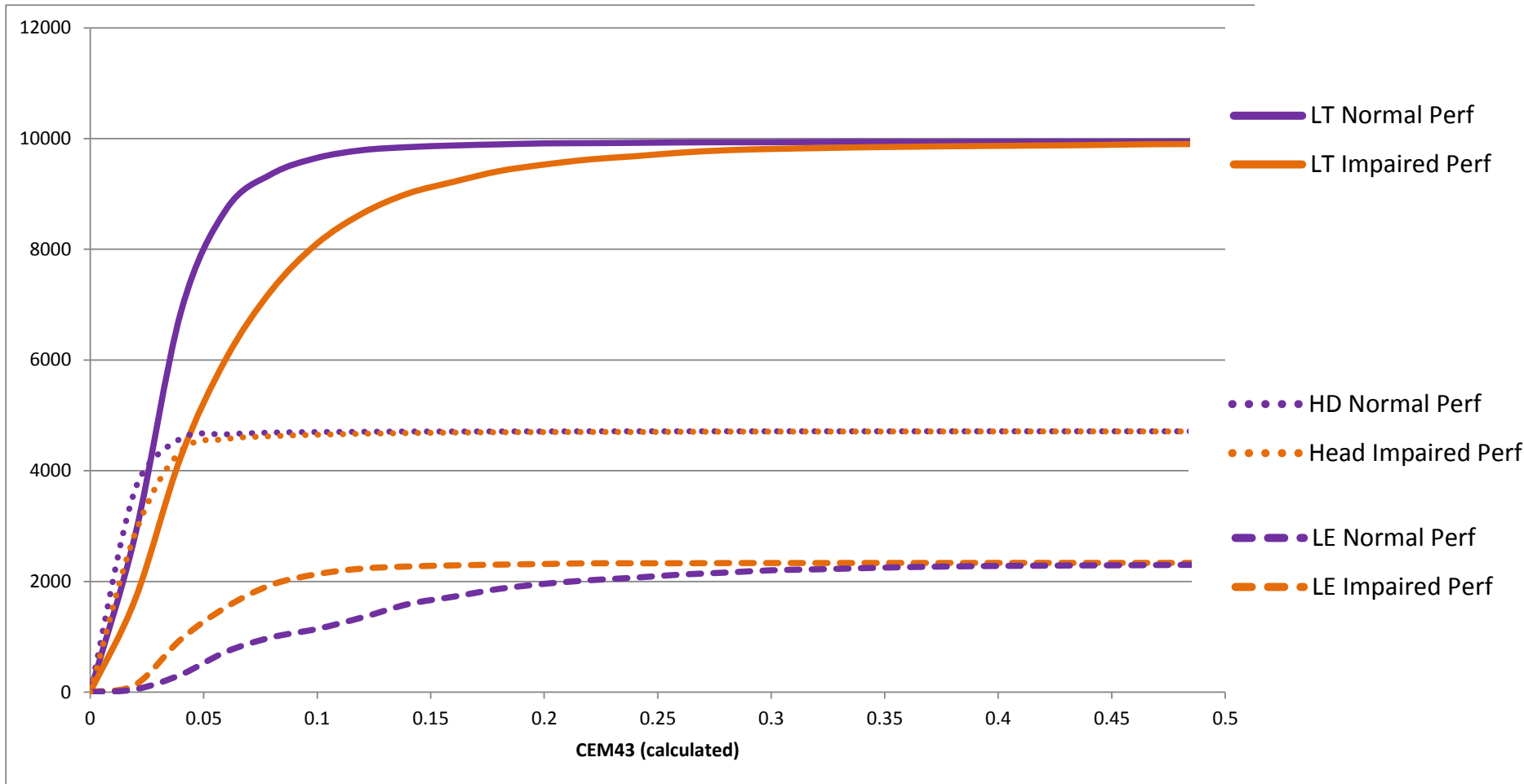
# patients with local temp less than  $38.5\text{ }^\circ\text{C}$

*Problematic in terms of estimated local Temp. exceeding limit in 2-33*



# CEM43 from psSAR10g (Neufeld – Murbach model)

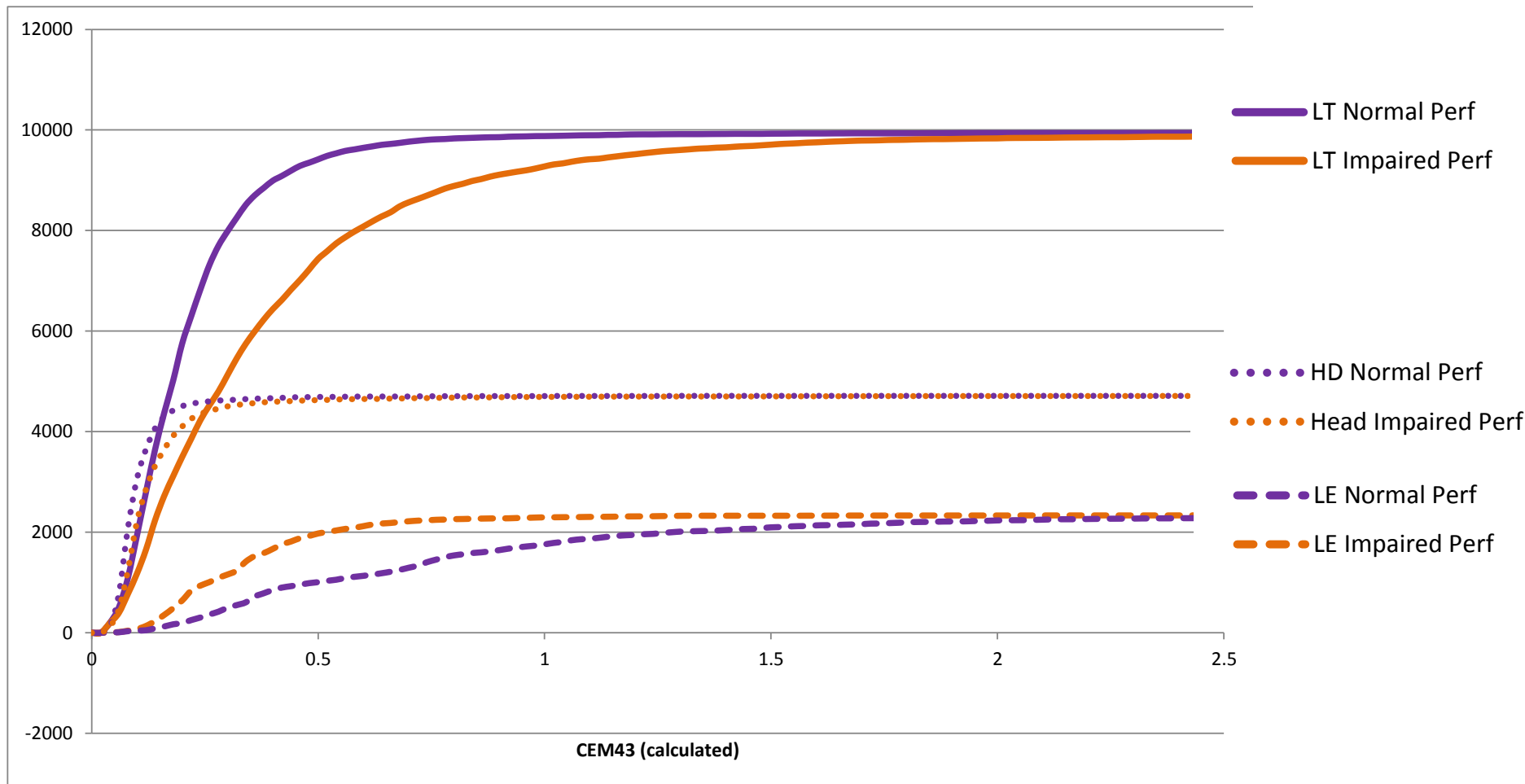
Tb = 36.7 °C, all exams



Note the very low CEM43 under non-fever conditions (Tb = 36.7 °C)  
Note that patients will still report unpleasant sensations (sweating)

# CEM43 from psSAR10g (Neufeld – Murbach model)

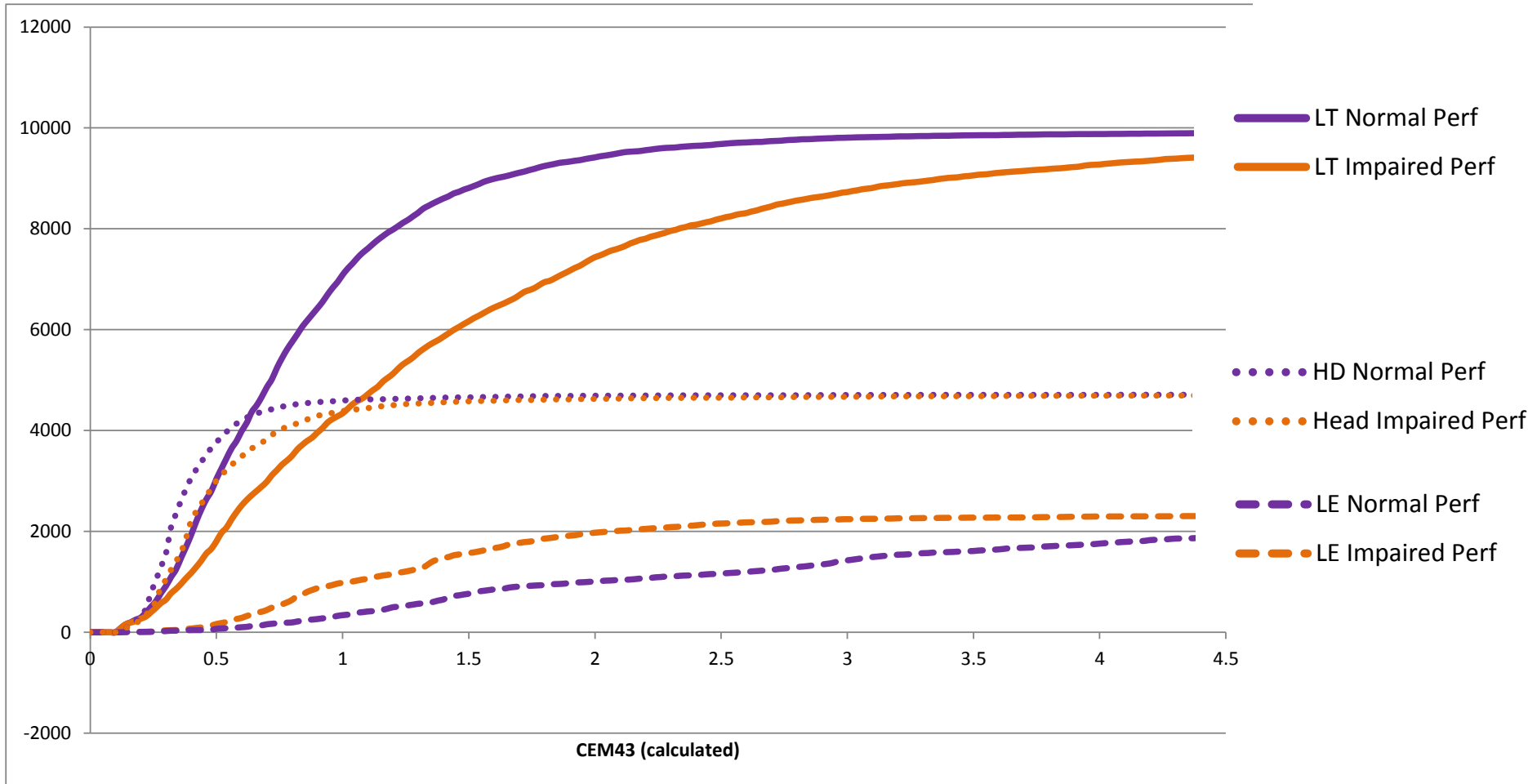
Tb = 38 °C, all exams



If CEM43 = 2 min is 'unconditionally' safe, IEC First Level Mode is safe in most compromised patients, even with slight fever

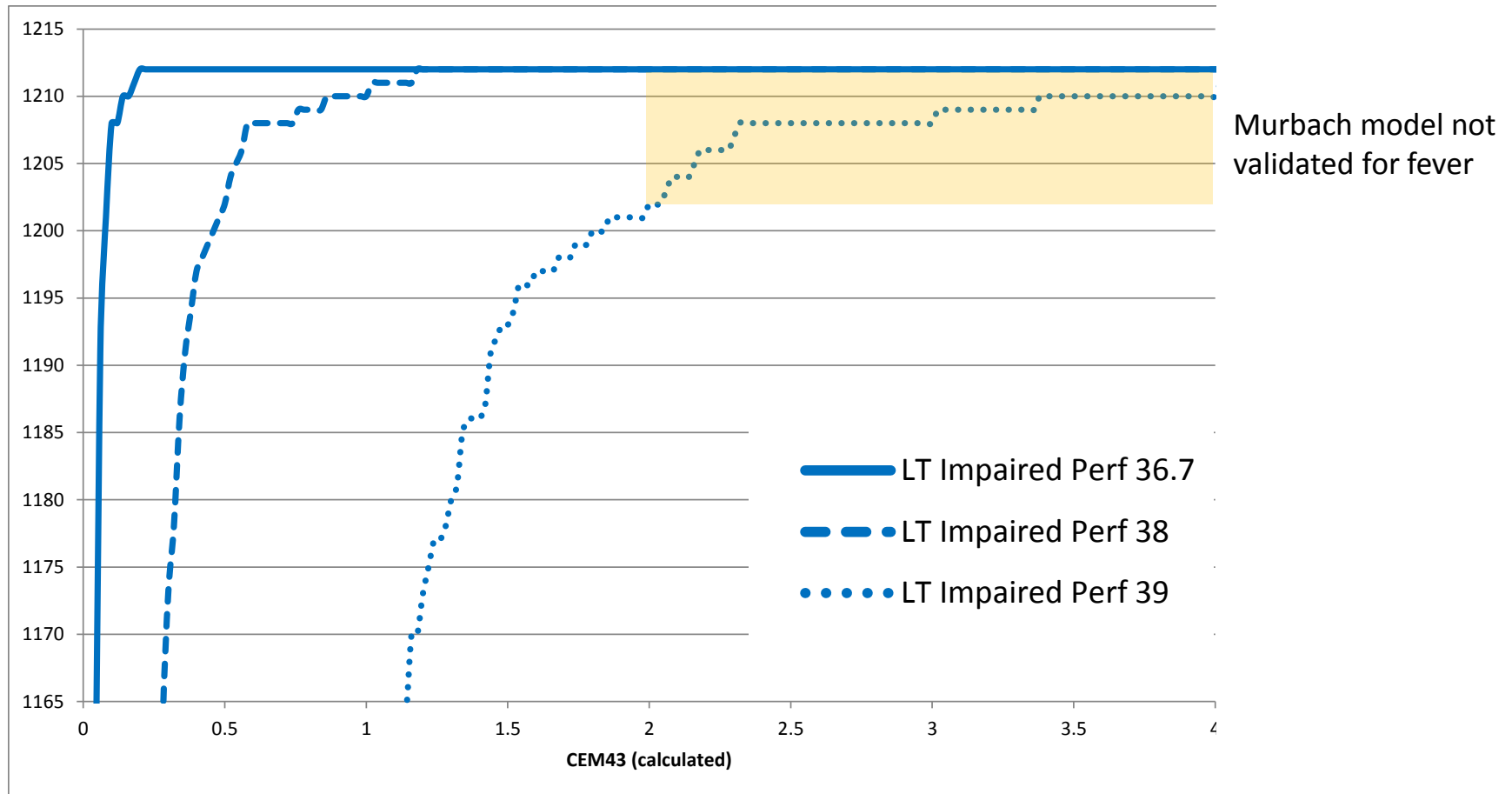
# CEM43 from psSAR10g (Neufeld – Murbach model)

Tb = 39 °C, all scans



In case of a real fever, RF exposure should better be limited to NM

# CEM43 from psSAR10g – LT NM scans



Approx. 10% of NM (body) exams shows >2 CEM43 if patient presented with fever and under compromised conditions

# Discussion

- **The low calculated temperatures and insignificant CEM43 corroborates the historical RF safety experience with MRI (100s millions patient examined)**
- Calculated local temperatures from Murbach's model exceed 40 °C in a few cases
  - only for
    - extremities of
    - patient with compromised thermoregulation
    - scanned in First Level controlled IEC mode – *which is forbidden*
  - note: critical assumptions are low starting temperature – and constant  $T_{\text{core}}$
- Limiting exposure by local SAR effectively implies that WB SAR is well below 4 W/kg
  - Philips has no experience how psSAR10g > 20 or 40 W/kg affects RF safety
- The proposed level of CEM43 = 9 min cannot be justified based on Philips field data
- Existing RF safety control measures are generally sufficient
- Awareness for Normal Mode should be improved
- Philips invests in ALAP by providing more protocols tuned to NM exposure, and provides a feedback to monitor the total deposited RF energy for comfort reasons

