The British Medical Ultrasound Society.

Guidelines for the safe use of diagnostic ultrasound equipment

Prepared by the Safety Group of the British Medical Ultrasound Society.

Part II: Detailed guidelines

1. Scope and Purpose

These Detailed Guidelines are intended to assist all those who use diagnostic ultrasound equipment for any purpose in order that they may be able to make informed judgements about ultrasound safety, and in order to protect patients from excessive exposure. These BMUS Detailed Guidelines are based on the best scientific information available at the time of writing, using advice and evidence from international experts. They must be read and understood in conjunction with the BMUS Safety Statement (http://www.bmus.org) and the BMUS Basic Guidelines. Further background information on the safe use of ultrasound may be found in more extensive texts, including ter Haar and Duck (2000).

2. Guidelines for probe and system use

Initial power setting. Scanners should be set up so that the default (switch-on) setting of the acoustic output power control is low. If a low default setting cannot be achieved, a low setting should be selected after switching on. A low setting should be selected for each new patient. The output should only be increased during the investigation if this is necessary to produce a satisfactory result.

Exposure time. The overall examination times should be kept as short as is necessary to produce a useful diagnostic result.

Stationary probe. The probe should not be held in a fixed position for any longer than is necessary, and should be removed from the patient whenever there is no need for a real-time image or spectral Doppler acquisition. For example, using the freeze frame or cine loop facilities allows images to be reviewed and discussed without continuing the exposure.

Probe self-heating. Endo-cavitary probes (e.g. vaginal, rectal or oesophageal probes) should not be used if there is noticeable self heating of the probe when operating in air. This applies to any probe, but particular care should be taken if trans-vaginal probes are to be used to investigate a pregnancy during the first 10 weeks after LMP.

The raised tissue temperature due to probe self-heating is likely to be greater for endo-probes than for surface probes. This is because the adjacent tissue is at an initial temperature of 37^{O}C, or higher in the case of a febrile patient, rather than closer to room temperature as in the case of surface-applied probes. Also, there is no opportunity for heat removal by air-convection or radiation, as is the case for probes applied to the patient's skin. International Standards (IEC 2007) are intended to limit the maximum temperature of the probe in contact with the patient to 43^{o}C, either internally or externally, or to 50^{o}C when running in air.

Doppler modes. The use of spectral pulsed Doppler, or colour Doppler mode with a narrow write-zoom box selected, is not recommended for the investigation of any of the sensitive tissues identified in section 3, unless the user monitors the TI (if available), and performs a risk-benefit analysis (see section 4). If the TI is not available, the user should find an alternative method of estimating the maximum likely temperature rise.

Pulsed Doppler techniques generally involve greater temporal average intensities and powers than B- or M-mode, and hence greater heating potential, due to the high pulse repetition frequencies and consequent high duty factors that are often used. In the case of spectral pulsed Doppler, the fact that the beam is held in a fixed position during an observation leads to a further increase in temporal average intensity. Colour flow mapping and Doppler power mapping involve some beam scanning, and so generally have a heating potential that is intermediate between that of B- or M-mode and that of spectral pulsed Doppler.

3. Hazard and risk factors

Awareness of scanner factors influencing hazard. Operators should understand the likely influence of the scanner controls, the operating mode (e.g. B-mode, colour Doppler imaging or spectral Doppler) and probe frequency on the thermal and cavitation hazards.

There are no universal rules for predicting the effect of scanner controls (other than the output power control) on output, since, in an effort to limit outputs, manufacturers often arrange for more than one parameter to change when a particular control is adjusted. However, the following may be helpful as general guide. In scanning modes, greater heating potential is often associated with multiple or deep transmission focus settings, and the use of write zoom (particularly with a long, narrow or deep zoom box). In spectral pulsed Doppler mode, greater heating potential is usually associated with a high pulse repetition frequency (e.g. a high limit on the frequency scale), and a shallow range gate. The likelihood of cavitation is greater for large output settings and lower frequencies. In Doppler modes, the likelihood is increased by selecting short range gates or by selecting a high Doppler frequency scale.

Sensitive tissues. Particular care should be taken to reduce the risk of thermal hazard when exposing the following to diagnostic ultrasound:

- an embryo less than eight weeks after conception;
- the head, brain or spine of any fetus or neonate;
- an eye (in a subject of any age).

Up to eight weeks after conception, organogenesis is taking place in the embryo. This is a period when cell damage might lead to fetal anomalies or subtle developmental changes. The brain and spinal chord continue to develop through to the neonatal period.
The presence of bone within the beam greatly increases the likely temperature rise, due to both direct absorption in the bone itself and conduction of heat from bone to adjacent tissues. The following table identifies the important relevant landmarks in early pregnancy.

Gestation From LMP	***Gestation from Conception/ fertilisation***	***Title of Conceptus***	***Major relevant events***
0-14 days	*Nil*	*-*	*-*
14-28 days	*0-14 days*	*Zygote*	*Rapid cell multiplication*
29-70 days 4.1-10 weeks	*15-56 days 2.1-8 weeks*	*Embryo*	*Organogenesis*
10-11 weeks	*8-9 weeks*	*Fetus*	*Ossification of spine starts*
13-14 weeks	*11-12 weeks*	*Fetus*	*Ossification of skull and long bone starts*

The eye is particularly vulnerable to thermal hazard since the lens and the aqueous and vitreous humours have no cooling blood supply. This applies to an eye of a subject of any age (e.g. child or adult) as well as a fetus, although a fetal eye is better cooled, due to its liquid environment.

Pre-existing temperature elevation. Particular care should be taken to reduce output and minimise exposure time of an embryo or fetus when the temperature of the mother is already elevated.

Thermal and Mechanical Indices. For scanners which display on-screen thermal index (TI) and mechanical index (MI) values, operators should continually monitor their values and use control settings that keep them as small as is consistent with achieving diagnostically useful results. There should be independent checks that the displayed TI and MI values are accurate. These should be made soon after installation and after hardware or software changes.

- The MI is an on-screen indicator of the relative potential for ultrasound to induce an adverse bio effect by a non-thermal mechanism including cavitation.

The mechanical index (MI) is intended to offer a rough guide to the likelihood of the occurrence of cavitation. Its value is constantly updated by the scanner, according to the control settings, using the formula $MI = p\text{-}_{0.3}/\sqrt{f}$, *where f is the pulse centre frequency and* $p\text{-}_{0.3}$ *is the maximum value of peak negative pressure anywhere in the ultrasound field, measured in water but reduced by an attenuation factor equal to that which would be produced by a medium having an attenuation coefficient of 0.3 dB* cm^{-1} MHz^{-1}.

- The TI is an on-screen indicator of the relative potential for a tissue temperature rise.

The thermal index (TI) is intended to give a rough guide to the likely maximum temperature rise that might be produced after long exposure. Three forms of TI may be displayed, according to the application. TIS assumes that only soft tissue is insonated. TIB assumes bone is present at the depth where temporal intensity is greatest. TIC assumes bone is very close to the front face of the probe. However, note that errors in calculating TI values, and the limitations of the simple models on which they are based, means that TI values can underestimate the temperature elevation by a factor of up to two.

4. Application-specific guidelines

For scanners which display thermal index (TI) and mechanical index (MI) values on-screen, operators should continually monitor their values and use control settings that keep them as small as is consistent with achieving diagnostically useful results.

Where on-screen mechanical or thermal index can be displayed, the recommended exposure times and upper levels for the indices depend on the clinical application. These recommended levels are given in Table 1 for obstetric (including gynaecological examinations when pregnancy is possible) and neonatal ultrasound, and in Table 2 for other applications. Many scanners allow MI and one of the TI values to be displayed simultaneously: the appropriate TI value depends on the clinical application and the recommended indices to monitor are also given in Tables 1 and 2.

Where an on-screen thermal index (TI) or mechanical index (MI) is not displayed, try to obtain **worst case** estimates (considering all possible combinations of control settings) of temperature elevation (ΔT_{max}) and mechanical index (MI_{max}) for the particular probe and mode in use. If these can be obtained, assume that the MI value is equal to MI_{max} and the TI value is equal to 0.5 ΔT_{max} and refer to Table 1 or 2 as appropriate.

A Medical Physics department may be able to make these estimates, using either a thermal test object or measurements of acoustic power and intensity. For abdominal and obstetric applications, the worst case estimate of temperature elevation should use a model similar to TIB in which soft tissue overlies bone, with the interface lying at the depth where the derated temporal average intensity is a maximum. For other applications (e.g. the eye or superficial bone), the model used should be appropriate to the particular tissues involved.

The operator should aim to stay within BMUS recommended scan times. If there is a clinical need to exceed these recommended times, the ALARA principle should still be followed. When overall times longer than those recommended here are essential, the probe should be removed from the patient whenever possible, to minimise exposure.

Table 1. Recommended exposure time and index values for obstetric and neonatal ultrasound.

Application	Values to monitor (A)	Thermal Index value			Mechanical Index value		
		0 - 0.7	0.7 - 3.0	>3.0	0 - 0.3	>0.3	>0.7
Obstetrics up 10 weeks after LMP (and gynaecology when pregnancy is possible)	TIS and MI	✓	(B) restrict time to 0.7<TIS≤1.0 : 60 min 1.0<TIS≤1.5 : 30 min 1.5<TIS≤2.0 : 15 min 2.0<TIS≤2.5 : 4 min 2.5<TIS≤3.0 : 1 min	**Scanning of an embryo or fetus is not recommended, however briefly**	✓	✓	(E) risk of cavitation with contrast agents
Obstetrics more than 10 weeks after LMP	TIB and MI	✓	(B) restrict time to 0.7<TIB≤1.0 : 60 min 1.0<TIB≤1.5 : 30 min 1.5<TIB≤2.0 : 15 min 2.0<TIB≤2.5 : 4 min 2.5<TIB≤3.0 : 1 min	**Scanning of an embryo or fetus is not recommended, however briefly**	✓	✓	(E) risk of cavitation with contrast agents
Neonatal – transcranial and spinal	TIC and MI	✓	(B) restrict time to 0.7<TIC≤1.0 : 60 min 1.0<TIC≤1.5 : 30 min 1.5<TIC≤2.0 : 15 min 2.0<TIC≤2.5 : 4 min 2.5<TIC≤3.0 : 1 min	**Scanning of the central nervous system is not recommended, however briefly**	✓	✓	(E) risk of cavitation with contrast agents
Neonatal - general and cardiac imaging	TIB and MI recommended	✓	(C) restrict time to 1.0<TIB≤1.5 : 120 min 1.5<TIB≤2.0 : 60 min 2.0<TIB≤2.5 : 15 min 2.5<TIB≤3.0 : 4 min 3.0<TIB≤4.0 : 1 min 4.0<TIB≤5.0 : 15 sec 5.0<TIB≤6.0 : 5 sec TIB>6: **not recommended.**		✓	(D) Possibility of minor damage to lung or intestine. Minimise exposure time.	(E) risk of cavitation with contrast agents
Fetal Doppler heart monitoring	TI or MI are not usually available for dedicated fetal heart monitors.	The power levels used by dedicated fetal heart monitors are sufficiently low that the use of this modality is not contra-indicated, on safety grounds, even when it is to be used for extended periods.					

✓: There is no known reason to restrict scanning times in this region.
A: Many scanners allow MI and one of the TI values to be displayed simultaneously: the most appropriate TI value depends on the clinical application.
B: TI > 0.7 - the overall exposure time (including pauses) of an embryo or fetus or of the neonatal central nervous system should be restricted.
C: TI > 1.0 - the overall exposure time (including pauses) of other parts of the neonate should be restricted.
D: MI > 0.3 - there is a possibility of minor damage to neonatal lung or intestine. If such exposure is necessary, try to reduce the exposure time as much as possible.
E: MI > 0.7 - there is a risk of cavitation if an ultrasound contrast agent containing gas micro-spheres is being used. There is a theoretical risk of cavitation without the presence of ultrasound contrast agents. The risk increases with MI values above this threshold.

Table 2. Recommended exposure time and index values for non-obstetric and non-neonatal ultrasound.

Application	Values to monitor (A)	Thermal Index value		Mechanical Index value	
		0 – 1.0	> 1.0	0 - 0.3	> 0.7
General abdominal Peripheral vascular Unlisted applications	Usually TIB and MI. [use TIC and MI if bone closer than 1 cm; TIS and MI only if bone does not come into the image]	✓	(B) restrict time to 1.0<TIB≤1.5 : 120 min 1.5<TIB≤2.0 : 60 min 2.0<TIB≤2.5 : 15 min 2.5<TIB≤3.0 : 4 min 3.0<TIB≤4.0 : 1 min 4.0<TIB≤5.0 : 15 sec 5.0<TIB≤6.0 : 5 sec TIB>6: **not recommended**	✓	(C) risk of cavitation with contrast agents
Eye	TIS and MI recommended	✓	**Scanning of the eye is not recommended**	✓	(C) risk of cavitation with contrast agents
Adult transcranial (imaging and stand-alone) (D)	TIC and MI	✓	(B) restrict time to 0.7<TIC≤1.0 : 60 min 1.0<TIC≤1.5 : 30 min 1.5<TIC≤2.0 : 15 min 2.0<TIC≤2.5 : 4 min 2.5<TIC≤3.0 : 1 min TIC>3: **not recommended**	✓	(C) risk of cavitation with contrast agents
Peripheral pulse monitoring	TI or MI are not usually available for dedicated peripheral pulse monitors.	The output from CW Doppler devices intended for monitoring peripheral pulses is sufficiently low that their use is not contra-indicated, on safety grounds			

✓: There is no known reason to restrict scanning times in this region.
A: Many scanners allow MI and one of the TI values to be displayed simultaneously: the most appropriate TI value depends on the clinical application.
B: TI > 1.0 - the overall exposure time (including pauses) should be restricted.
C: MI > 0.7 - there is a risk of cavitation if an ultrasound contrast agent containing gas micro-spheres is being used. There is a theoretical risk of cavitation without the presence of ultrasound contrast agents. The risk increases with MI values above this threshold.
D: Transcranial ultrasound investigations may require higher acoustic output or longer monitoring times than other applications. When times longer than those recommended here are required, it is recommended that monitoring is paused regularly to minimise exposure.

Thermal index values and maximum exposure time recommendations for fetal and neonatal tissues.

TI values are intended to give a rough indication of the likely equilibrium temperature rise that might be produced. However, theoretical (Jago et al 1999) and experimental (Shaw et al 1998) studies have shown that, in some circumstances, TI can underestimate the temperature elevation by a factor of up to two. As a safety precaution, the TI values given in Table 1 are assumed to be half the actual worst case temperature elevations. Thus a TI value of 1 is considered to correspond to a worst case temperature elevation of 2 ^{o}C.

Following their review of the literature on the effects of temperature elevation on animal fetuses, the WFUMB (1998) concluded that an ultrasound exposure that elevates human embryonic or fetal temperature by 4^{o}C above normal for 5 minutes should be considered potentially hazardous. Miller and Ziskin (1989) showed that there is a logarithmic relationship between temperature elevation and the exposure time needed to produce adverse biological effects in animal fetuses. They showed that, for temperatures below 43^{o}C, the necessary exposure time reduced by a factor of four for every 1^{o}C increase in temperature elevation. Adopting a maximum safe exposure time of 4 minutes for a temperature elevation of 4^{o}C, and applying the above logarithmic rule, results in the following exposure times:

Temperature elevation (^{o}C)	Maximum exposure time (minutes)
5	1
4	4
3	16
2	64
1	256

In Table 1, rounded values of the above exposure times have been used for obstetric exposures up to 15 minutes. The 64 and 256 minute maximum exposure times have been reduced to 30 and 60 minutes respectively as a safety precaution to reflect the present lack of knowledge about possible subtle bioeffects associated with prolonged moderate temperature elevation. No time limit is specified for TI values of less than 0.7, in accordance with the statement in the WFUMB (1998) recommendations on thermal effects that a diagnostic exposure that produces a maximum temperature rise of no more than 1.5^{o}C above normal physiological levels (37^{o}C) may be used clinically without reservation on thermal grounds.

In examinations of the embryo or fetus in the first eight weeks post conception, when there is no ossified bone, only soft tissue is exposed and so TIS should be monitored. In all other obstetric applications, TIB is recommended as the particular thermal index value to monitor. This avoids the complication of constantly switching attention between TIS and TIB according to whether or not bone is being insonated, and introduces a safety factor since TIB values are always greater than or equal to TIS values.

To protect the still rapidly developing neonatal central nervous system, the time limits recommended for fetal examinations are also applied to imaging of the brain or spine of a neonate. When imaging other parts of the neonate, the recommended time limits match those for adult tissues.

Thermal index values and maximum exposure time recommendations for non-fetal tissues.

In eye scanning applications, it is recommended that TIS is monitored as this is the thermal index used in the study by Herman and Harris (1999), which concluded that, in eye scanning, TIS values should be limited to a maximum of 1.0.

In other applications TIS, TIB or TIC may be monitored depending on the tissue being scanned: in most applications TIB is recommended. AIUM (2008) concluded that there was a maximum safe exposure time for thermal damage to non-fetal tissue which depended on temperature.

Temperature elevation (°C)	Maximum exposure time (minutes)
10	0.07
8	0.25
6	1
5	4
4	16
3	64
2	256

Harm at a particular temperature increase had not been observed for shorter times. In formulating Table 2, we have assumed that TI may underestimate temperature rise by a factor of 2, and we have rounded the maximum exposure times. The 256 minute maximum exposure time has been reduced to 120 minutes as a safety precaution to reflect the present lack of knowledge about possible subtle bioeffects associated with prolonged moderate temperature elevation. As a precaution for transcranial ultrasound, the recommended time limits are the same as those for neonatal brain, except that there is no specific restriction when TIC is less than or equal to 1.0.

Mechanical Index threshold values.

The MI value of 0.3, representing the threshold for the possibility of capillary bleeding in gas-containing organs, such as the lungs and intestines, is taken from the 1992 Statement on Non-human Mammalian in vivo Biological Effects of the American Institute of Ultrasound in Medicine (AIUM 1993).

The MI value of 0.7 is chosen as the threshold for cavitation, following the theoretical study by Apfel and Holland (1991), from which the formula for MI is derived. The model used for this study assumes the availability of micro-bubble nuclei of all sizes. These are believed to be produced when the shells of the micro-bubbles of some ultrasound contrast agents are destroyed by pulses with higher acoustic pressures. There is experimental evidence that cavitation damage occurs in animals when contrast agents are present (Miller and Gies 1998, Skyba et al. 1998). In tissues not containing such artificially introduced nuclei, cavitation due to diagnostic ultrasound remains a theoretical possibility only, although it is produced in tissue during lithotripsy treatment (ECURS 1994) and bubble formation has been demonstrated in agar gel exposed to diagnostic levels of ultrasound (ter Haar et al 1989).

5. References

AIUM 1993. *Bioeffects and Safety of Diagnostic Ultrasound*. AIUM, 11200 Rockville Pike, Suite 205, Rockville, Maryland 20852-3139, USA.

AIUM 2008. American Institute of Ultrasound in Medicine Consensus Report on Potential Bioeffects of Diagnostic Ultrasound*. J Ultrasound Med*; **27**:503–515.

Apfel R.E., Holland K.H. 1991. Gauging the likelihood of cavitation from short pulse low duty cycle diagnostic ultrasound. *Ultrasound Med & Biol*; **17**:179-185.

ECURS, 1994. Guidelines for the safe use of extracorporeal shock-wave lithotripsy (ESWL) devices. *European J. Ultrasound*; **3**: 315-6.

Herman B.A., Harris G.R. 1999. Theoretical study of steady-state temperature rise within the eye due to ultrasound insonation. *IEEE Transactions on Ultrasonics, Ferroelectrics and Frequency Control*: **46:** 1566-1574.

IEC 2007. IEC 60601-2-37 Ed. 2.0: Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment. *International Electrotechnical Commission, Geneva, ISBN 2-8318-9266-X*.

Jago J.R, Henderson J, Whittingham TA , Mitchell G. 1999, A comparison of AIUM/NEMA Thermal Indices with calculated temperature rises for a simple third trimester pregnancy tissue model. *Ultrasound in Med. & Biol*.: **25**: 623-628.

Miller D.L., Gies R.A. 1998. Gas-body-based contrast agent enhances vascular bioeffects of 1.09 MHz ultrasound on mouse intestine. *Ultrasound in Med. & Biol*; **24**: 1201-1208.

Miller M.W., Ziskin M.C. 1989. Biological consequences of hyperthermia. *Ultrasound Med & Biol*; **15**:707-722.

Shaw A, Pay N. M. ,Preston R.C. 1998 Assessment of the likely thermal index values for pulsed Doppler ultrasonic equipment - Stages II and III: experimental assessment of scanner/transducer combinations. *NPL Report CMAM 12*, *April 1998.* National Physical Laboratory, Teddington. UK

Skyba D.M., Price R.J., Linka A.Z., et al. 1998. Microbubble destruction by ultrasound results in capillary rupture: adverse bioeffects or a possible mechanism for in vivo drug delivery? *J Am. Soc. Echocardiology*; **11**: 497.

ter Haar G, Duck F, Starritt H, Daniels S. 1989. Biophysical characterisation of diagnostic ultrasound equipment - preliminary results. *Phys Med Biol*; **34**:1533-1542

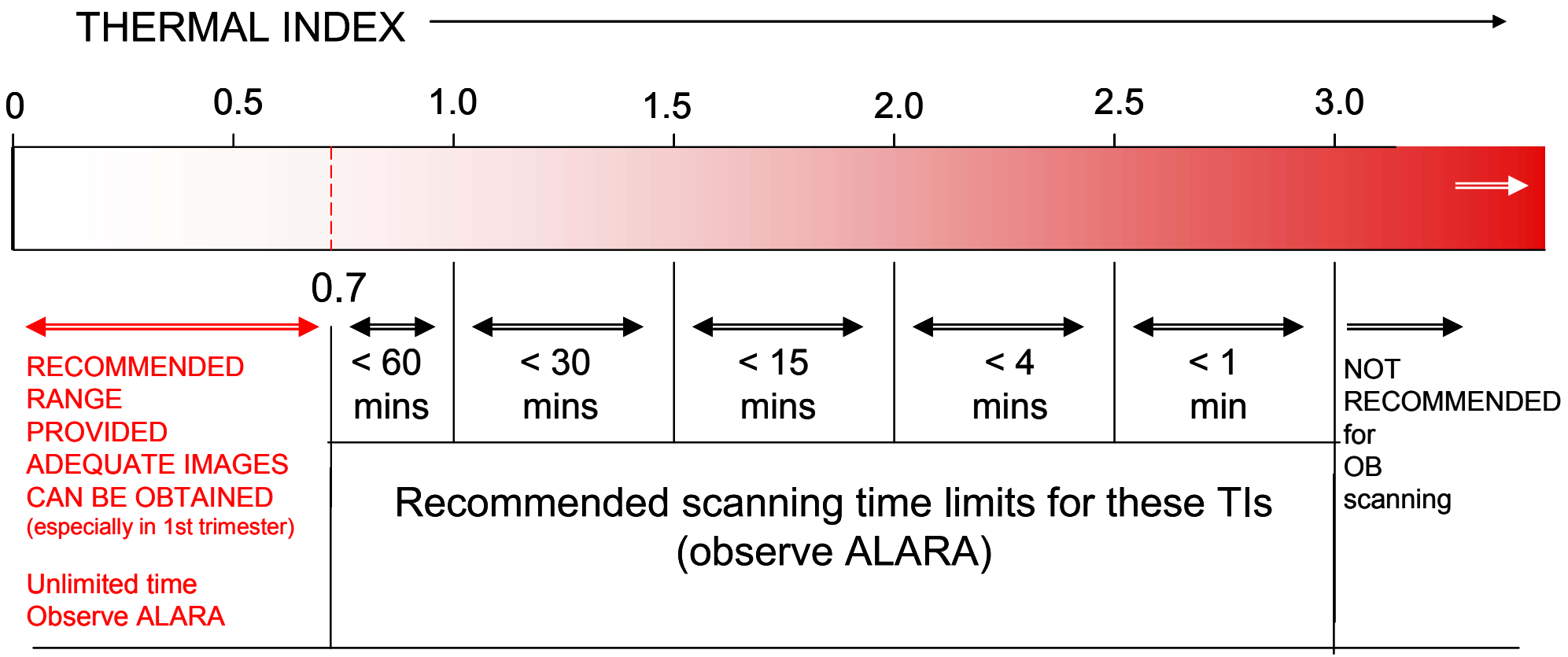
ter Haar G, Duck FA (eds). 2000. *The Safe Use of Ultrasound in Medical Diagnosis*, BMUS/BIR, London.

WFUMB 1998. Conclusions and Recommendations on Thermal and Non-thermal Mechanisms for Biological Effects. *Ultrasound in Med. & Biol*; **24**: Supplement 1, xv-xvi.

Appendix I

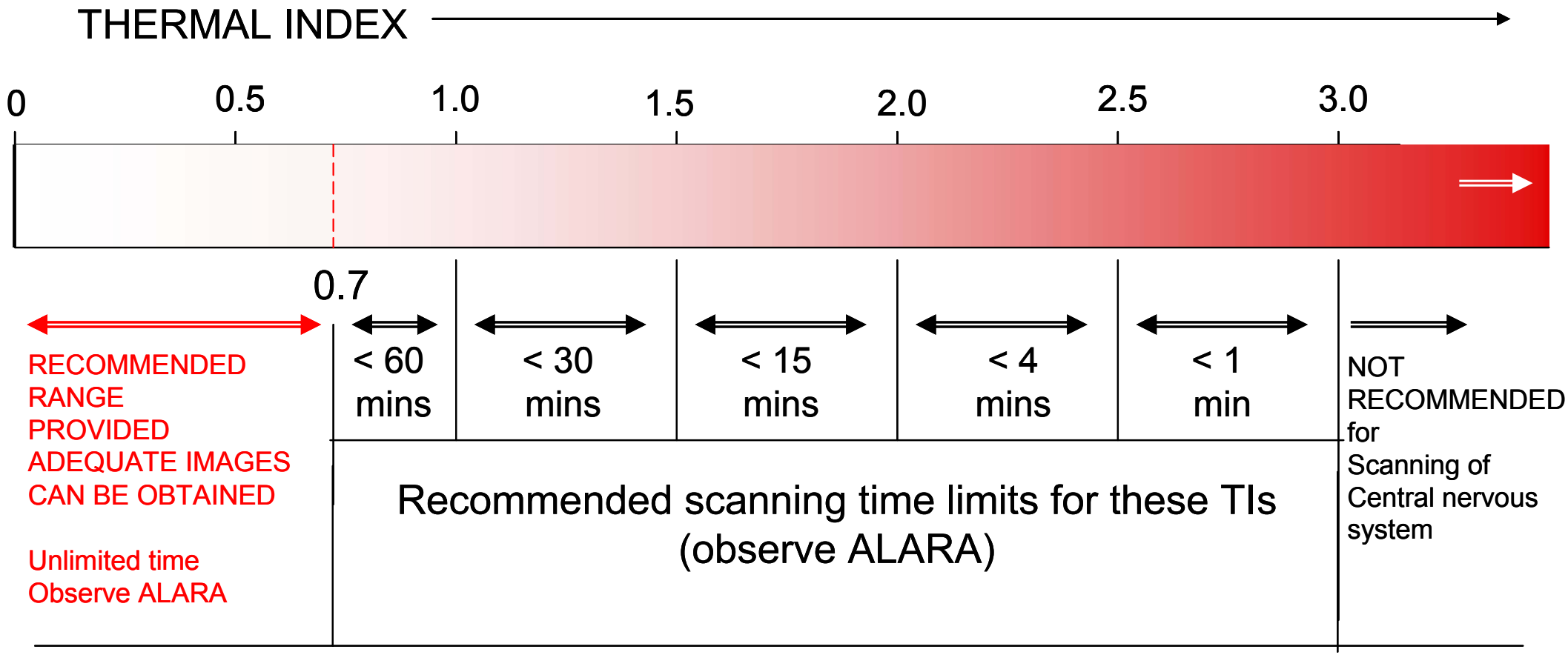
Graphical representation of the recommended exposure times at different index values for different applications, as listed in Tables 1 & 2, is presented below. It is hoped these figures may serve as useful easy reference during scanning sessions:

OBSTETRIC SCANNING



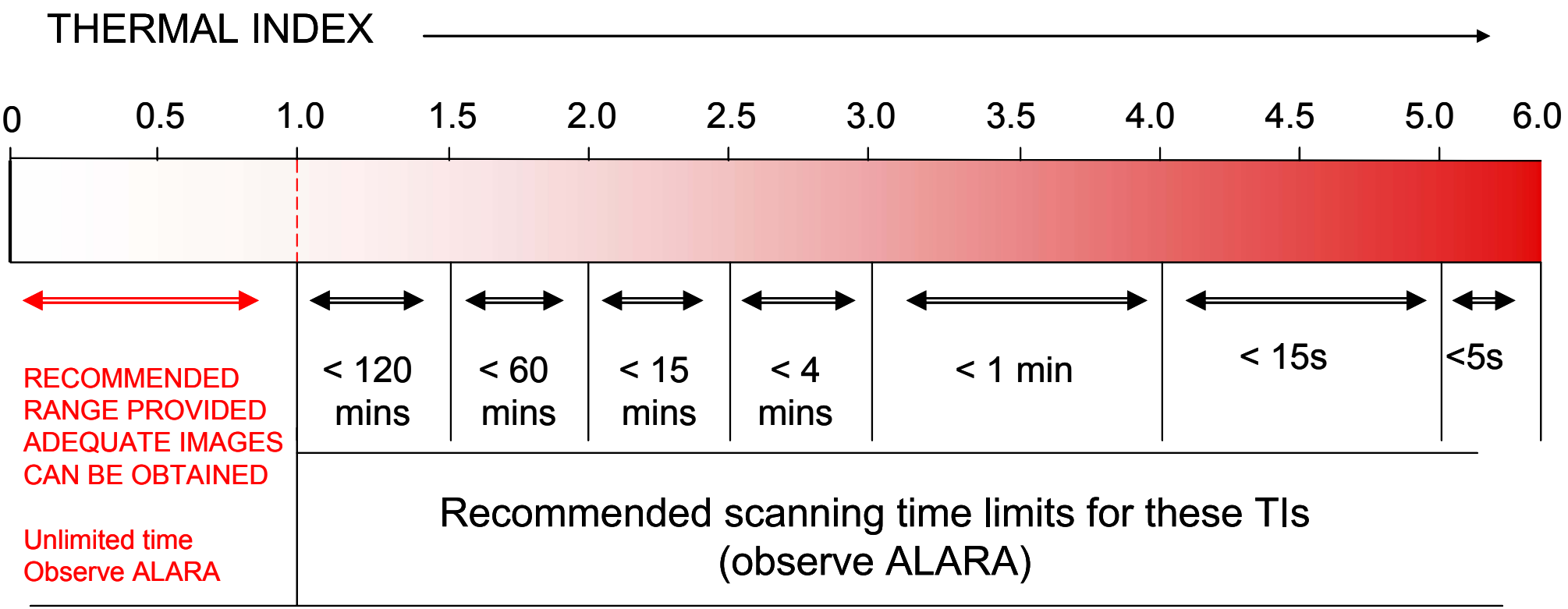
Monitor TIS up to 10 weeks post-LMP, TIB thereafter.

NEONATAL trans-cranial & spinal SCANNING



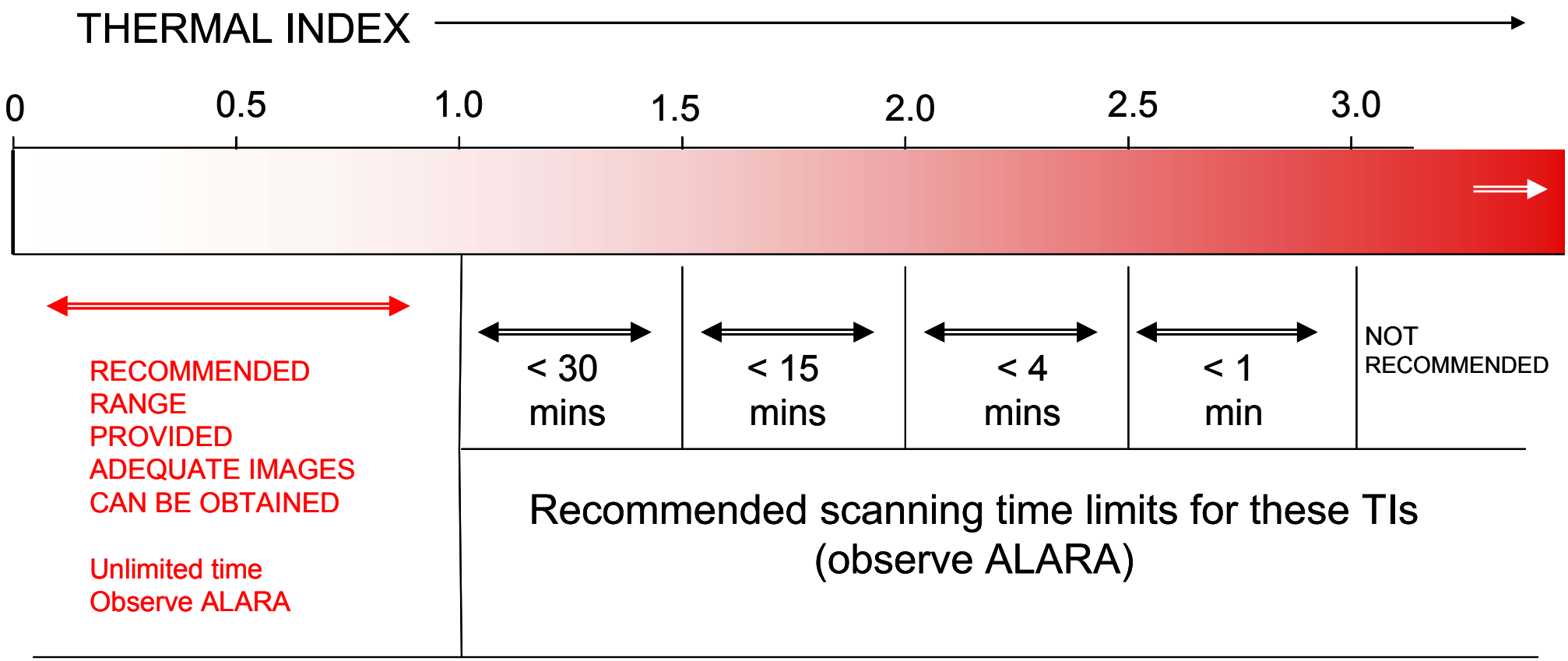
Monitor TIC. MI>0.7 should be used with caution in the presence of contrast agents

NEONATAL general & cardiac SCANNING



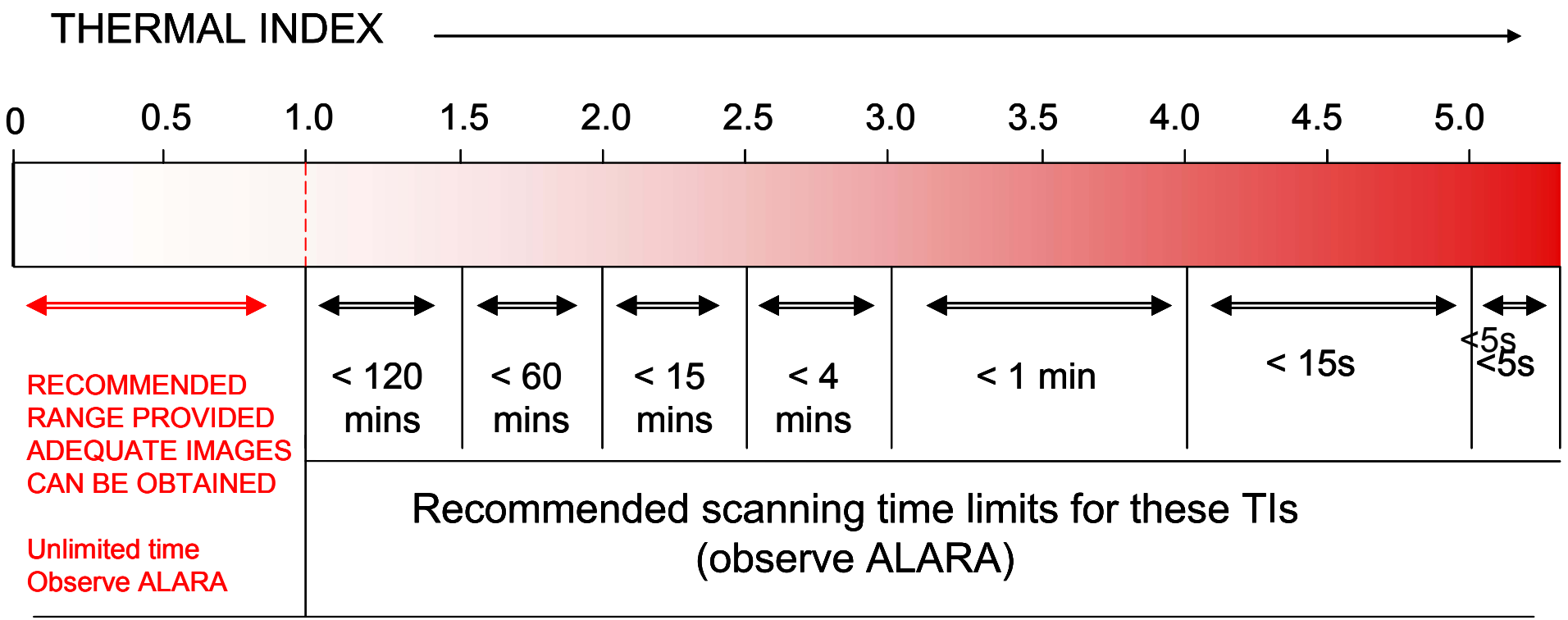
Monitor TIB. Use of TIB>6 is not recommended.
MI>0.7 should be used with caution in the presence of contrast agents

ADULT trans-cranial SCANNING



Monitor TIC. Use of TIC>3 is not recommended.
MI>0.7 should be used with caution in the presence of contrast agents

GENERAL ABDOMINAL, PERIPHERAL VASCULAR and other SCANNING (excluding the eye)



Monitor TIB, or TIC if bone closer than 1 cm; TIS if no bone is in image.
Use of TI>6 is not recommended
MI>0.7 should be used with caution in the presence of contrast agents