National Institute for Health and Care Excellence

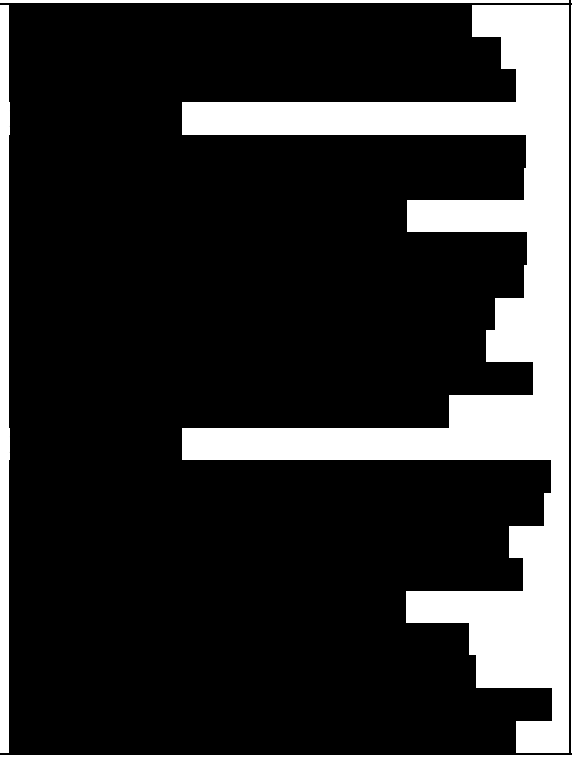
External Assessment Centre correspondence

ENDURALIFE Technical Report

The purpose of this table is to show where the External Assessment Centre relied in their assessment of the topic on information or evidence not included in the sponsors' original submission. This is normally where the External Assessment Centre:

a) become aware of additional relevant evidence not submitted by the sponsor
b) need to check "real world" assumptions with NICE's expert advisers, or
c) need to ask the sponsor for additional information or data not included in the original submission, or
d) need to correspond with an organisation or individual outside of NICE

These events are recorded in the table to ensure that all information relevant to the assessment of the topic is made available to MTAC. The table is presented to MTAC in the Assessment Report Overview, and is made available at public consultation.

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	Cedar requested a telephone conference and documents from Boston Scientific.	[redacted]	These documents form the basis of Section 7 of the Technical Report.
	When in the manual it states that: "*Based on simulated studies, it is anticipated that these pulse generators have average longevity to explants as shown below."* Followed by a table showing (for Autogen, Dynagen, Inogen and Origen) a range of settings resulting in years life from 5.7 to 8.6 years, a) What does "average" mean in this context? b) How does it relate to the estimated longevity line in the PPR graphs (in this case 50% device survival at a range of 5.7 (ish) years to 7.5 (ish) years) c) When interpreting BS ISO 5841-2:2014 definition of normal battery depletion, using the clause: *"for pulse generators, the condition when (a) a device is returned with no associated complaint and the device*		Background information for understanding PPR reports and product manuals. Indirectly used in informing Section 6 of the Technical Report

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	has reached its elective replacement indicator(s) with implant time that meets or exceeds the nominal (50 percentile) predicted longevity at default (labeled) settings" is the lifetime stated in the manual the nominal predicted longevity?	[redacted]	
	Do you have a reference for the French Health Authorities guidance on CRT-D settings for longevity projections please?	Please see page 48 of the attached document. The reference is as follows: Haute Autorité de Santé. Evaluation des défibrillateurs cardiaques automatiques implantables avec sonde(s) endocavitaire(s). Saint-Denis La Plaine: HAS; 2015 (page 48). (document attached)	Referred to in Section 4 of the Technical Report. Background information to available standards.
	Information volunteered by Boston Scientific	In addition, perhaps you would be interested in the attached poster which some of our US colleagues presented at HRS 2016 in May. It demonstrates the impact of various device programming parameters on longevity. (poster attached, Chelu 2016))	Background information for understanding the subject, not used directly.
	"The energy consumption in the longevity table is based upon theoretical electrical principles and verified via	As agreed, we will follow up with you on the below points which we discussed during the call:	No impact, discussion on information to provide.

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	bench testing only" Please could you describe the bench testing that is involved, and what it is able to verify [redacted] Are you able to share any protocols and results of the bench testing with Cedar and NICE? (This can be commercial in confidence if necessary, in which case it would be seen by the MTEP committee, but would not be published). It would also be very helpful to go over the different pacing parameters use to establish longevity, how and why they are chosen, and the implications for battery life.	[redacted]	

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		[redacted]	
	[redacted]	[redacted]	Clarification of information provided for use in Section 7 of the Technical Report. Used in interpreting the supplied documents and summarising them in the report.

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	[redacted]	[redacted]	
	[redacted]	[redacted]	No direct impact, this is a description of the documents that were provided, and guidance on their use and interpretation. The documents themselves form the basis for Section 7 of the Technical Report.

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	Information was requested for the assessment report from competitors	Full details of responses are provided with the assessment report correspondence log.	Responses were used for information on warranty length for Appendix A of the

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			Technical Report