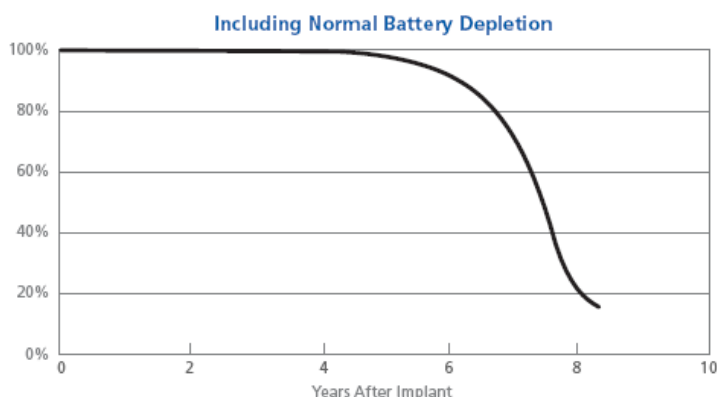


So sánh thời gian hoạt động các máy tạo nhịp
Trần Thống
18/5/2008 – cập nhật 2/2/2010

Nhân dịp dự hội nghị về nhịp tim, Heart Rhythm Society 2008 ở San Francisco, có một số bạn hỏi tôi tìm hiểu xem vì sao máy tạo nhịp của St Jude có thời gian hoạt động 17-20 năm (theo lời các đại lý máy St Jude tại VN), trong lúc các máy tạo nhịp của Biotronik, Medtronic chỉ khoảng 10 năm. Tôi có lại gian hàng của StJude, hỏi nhân viên StJude về thời gian hoạt động của máy tạo nhịp dòng (family) Zephyr, máy vừa mới được giấy phép lưu hành của cơ quan FDA Hoa Kỳ. Cô nhân viên nói là có 2 loại máy Zephyr: loại với pin nhỏ (0,55¹ Ah) và loại với pin lớn (0,95 Ah). Máy loại nhỏ có thời gian hoạt động khoảng 6 năm. Máy với pin lớn (máy XL) thì có thời gian hoạt động 10 -12 năm khi dùng Automatic Capture, nhưng cô nói 10 năm thì có thể thực tế hơn. Đây là loại máy tối tân nhất của StJude. Máy đang được bán ở VN, dòng Affinity² (1999), Verity (2003), Integrity (2003) là 2 thế hệ cũ hơn (trước Zephyr (2008) còn có Victory (2006)) nên không thể nào tốt hơn loại máy Zephyr khi cùng một kích cỡ và nói chung không có sự khác biệt nhiều về chức năng!

Dưới đây là tỉ lệ tồn tại (survival probability) máy Affinity DR 5330, Affinity DC 5230, hai máy được bán ở VN, được đăng trong báo cáo Performance Report của công ty St Jude. Tất cả các máy trong dòng Affinity đều dùng pin 0,95Ah.

Affinity [®] DR (Models 5330 & 5331)		Affinity [®] DC (Model 5230)	
US Market Release	(5330) Jan. 1999 (5230 & 5331) June 1999	Normal Battery Depletion	18,160
Registered US Implants	65,474	Malfunctions	199
Estimated Active US Implants	10,333	Malfunctions w/ Compromised Therapy (0 related to Advisory)	15
Estimated Longevity	6.3 Years	Malfunctions w/o Compromised Therapy (64 related to Advisory)	184
		Number of Advisories (see pages 134-139)	One



Year	2	4	6	8	at 100 months
Survival Probability	99.81%	99.60%	92.04%	21.57%	15.59%
± 1 standard error	0.02%	0.03%	0.07%	0.18%	0.22%
Sample Size	57900	46700	31500	144000	500

Các máy 1 buồng của St Jude bán ở VN, như Microny II SR+ 2525T (2001)³ (máy này sản xuất ở Thụy Điển, chứ không phải Hoa Kỳ), Verity ADx XL SC 5056 (2003)⁴ còn mới quá nên chưa có thời gian hoạt động dài.

¹ Điện lượng dựa theo các máy đời trước của St Jude, chỉ dùng pin 0,55 Ah với các máy nhỏ và 0,95 Ah với các máy XL lớn. Về phương diện này, máy StJude có vẻ dùng ít điện hơn là các máy Medtronic và Biotronik, khi không tạo nhịp. Tuy nhiên, cũng vì vậy mà StJude dùng pin nhỏ hơn là hai công ty kia. Nếu nhận xét này đúng, thì nếu không cần tạo nhịp các máy StJude có thể có thời gian hoạt động bằng các máy M & B, mặc dầu nhỏ hơn. Nhưng nếu tạo nhịp nhiều thì thời gian hoạt động các máy StJude sẽ bị rút ngắn rất nhiều.

² Năm 2009, không còn được bán ở VN. Verity và Integrity là cùng loại máy. Integrity có thêm chức năng AF Suppression. AF Suppression theo nghiên cứu Burden II (Puglisi, PACE 2008) đã tỏ ra không công hiệu bằng tạo nhịp DDDR!

³ Máy Microny dùng pin 0.35 Ah, thường chỉ dùng với BN nhì nhờ kích thước nhỏ.

⁴ Máy Verity XL dùng pin 0.95 Ah.

Microny® (Models 2425T, 2525T & 2535K)	
US Market Release	April 2001
Registered US Implants	5,090
Estimated Longevity	7.5 Years
Number of Advisories	None

Thời gian hoạt động dự đoán của Microny 2525T là 7,5 năm, nhưng chưa chứng thực được.

Verity® ADx XL SR (Model 5156); Verity® ADx XL SR M/S (Model 5157M/S); Verity® ADx XL SC (Model 5056)			
US Market Release	May 2003	Normal Battery Depletion	0
Registered US Implants	9,908	Malfunctions	4
Estimated Active US Implants	7,846	Malfunctions w/ Compromised Therapy	1
Estimated Longevity	10.2 Years	Malfunctions w/o Compromised Therapy	3
		Number of Advisories	None

Thời gian hoạt động dự đoán của Verity ADx XL SC là 10,2 năm, nhưng chưa chứng thực được.

**Verity® ADx XL DR (Model 5356)
Verity® ADx XL DR M/S (Model 5357M/S)
Verity® ADx XL DC (Model 5256)**

US Market Release	May 2003	Normal Battery Depletion	0
Registered US Implants	13,497	Malfunctions	6
Estimated Active US Implants	11,192	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	6.9 Years	Malfunctions w/o Compromised Therapy	6
		Number of Advisories	None

Tìm trên internet, chúng tôi khám phá một số mâu thuẫn giữa các trang quảng cáo và các báo cáo chính thức công ty

St Jude đã đăng về máy Identity ADx DR XL 5386 (pin 0,95 Ah) và máy Identity ADx DR 5380 (pin 0,55 Ah).

Bài quảng cáo trên mạng về máy 5386 ghi là thời gian hoạt động là 12,3 năm (ở trang 2 quảng cáo). Trong lúc trong báo cáo về thành tích (performance)⁵ tháng 10, 2007, thì lại dùng thời gian hoạt động dự đoán là 6,9 năm! Quảng cáo lạc quan gấp 1.78x!

Identity® ADx XL DR (Model 5386)		Identity® ADx XL DC (Model 5286)	
US Market Release	March 2003	Normal Battery Depletion	2
Registered US Implants	53,151	Malfunctions	17
Estimated Active US Implants	46,524	Malfunctions w/ Compromised Therapy (0 related to Advisory)	1
Estimated Longevity	6.9 Years	Malfunctions w/o Compromised Therapy (0 related to Advisory)	16
		Number of Advisories (see pages 134-139)	One

Trong hồ sơ thầu cho chính phủ Pháp, St Jude có ghi là thời gian hoạt động của máy Identity ADx DR 5380 là 6,7-7,2 năm (trang 8

Identity® ADx DR (Model 5380)			
US Market Release	March 2003	Normal Battery Depletion	907
Registered US Implants	48,790	Malfunctions	32
Estimated Active US Implants	39,503	Malfunctions w/ Compromised Therapy (0 related to Advisory)	1
Estimated Longevity	3.8 Years	Malfunctions w/o Compromised Therapy (0 related to Advisory)	31
		Number of Advisories (see pages 134-139)	One

trong hồ sơ thầu). Trong báo cáo về thành tích tháng 10, 2007 thì lại dùng 3,8 năm! Lại lạc quan 1.76x!

Vậy là thời gian hoạt động trong các quảng cáo của St Jude hầu như là 180% thời gian trong báo cáo thành tích cho FDA!

Chúng tôi nghi là sự khác biệt giữa thời gian quảng cáo và thời gian thực tế do truyền thống kỹ thuật (engineering practice) của nhóm Marketing. Marketing dùng những số liệu quá lạc quan (optimistic). Thí dụ khi thử 10 pin, thì sẽ có pin có thời gian hoạt động dài, có pin có thời gian ngắn. Như vậy là St Jude dựa quảng cáo trên pin tốt nhất ??? Trong Performance Report với FDA thì chắc dùng thời gian trung bình, vì không thể dùng thời gian dài khi có biểu đồ tỉ lệ tồn tại các máy !

Công ty Biotronik có bảng so sánh giữa các máy Talos, Philos II (cùng loại máy, chỉ khác nhau ở chương trình) và các máy Medtronic và St Jude. Kèm đây là bảng so sánh giữa Talos (Biotronik) và Kappa (Medtronic), Affinity (St Jude).

Máy Kappa có pin 1,2 Ah trong lúc máy Sensia đang được bán ở VN có pin 0.86 Ah (máy 1 buồng), 1.2 Ah (máy 2 buồng), 1,4 Ah (máy 2 buồng Sensia L DR ... không có bán ở VN). Máy Talos với tạo nhịp 100% 1V (khi ngưỡng 0,5 V) ở thất với tất cả các chức năng chẩn đoán (kể cả điện tim) được bật lên có thời gian hoạt động 11,4 (1 buồng)/9,7 năm (2 buồng) nhờ pin 1,3 Ah Máy Sensia ngay cả với **tạo nhịp 0%** và với chức năng chẩn đoán tối thiểu (không có điện tim⁶) chỉ có thời gian hoạt động 9/9,8 năm! Máy 2 buồng Sensia có thời gian hoạt động dài hơn nhờ pin

⁵ Theo quy định của cơ quan FDA, các công ty bán máy tạo nhịp ở Hoa Kỳ phải có báo cáo thành tích (Performance Report) hàng năm.

⁶ Khi lưu lại điện tim, máy Kappa sẽ mất 1 ngày hoạt động cho mỗi 2 ngày ghi lại điện tim, Như vậy là thời gian hoạt động giảm xuống còn 66%.

lớn hơn! Như vậy là máy Sensia không có thời gian hoạt động dài bằng Talos, mặc dù đã tắt một chức năng chẩn đoán quan trọng là điện tim!

Các dự đoán thời gian hoạt động các máy có chính xác không? Theo kinh nghiệm bản thân của tôi, công ty Biotronik rất dè dặt khi tính thời gian hoạt động. Các kỹ sư bên Đức phụ trách pin, cho tôi biết là họ lấy 10 pin, thử. Họ dùng số liệu từ pin với thời gian ngắn nhất nên thời gian hoạt động của máy sẽ dài hơn thời gian dự đoán.

Tôi có tìm được bài so sánh các máy thường gặp ở Canada: Senaratne, *PACE* 2006. Vì bài này dùng số liệu thực tế, nên chỉ có thể bàn về các máy đời cũ đã hết pin. Bài được tóm tắt ở Bảng II, trang 1050. Thời gian hoạt động dự đoán máy Medtronic trung thực. Thời gian dự đoán các máy St Jude quá lạc quan (optimistic) với mức sai trung bình là 27%!

Kết luận

Chúng ta hãy trở lại nguyên do bài này, là thông tin từ các đại lý StJude ở VN là máy tạo nhịp của công ty StJude có thời gian hoạt động “17-20 năm”. Dựa theo lời nói của cô nhân viên StJude tại HRS và dựa theo báo cáo của StJude với cơ quan FDA, tôi chỉ có thể nói là các đại lý ở VN quá lạc quan về thời gian hoạt động các máy tạo nhịp ... khoảng 2x thời gian thực tế (10,2 năm -> 20 năm)!

Và các máy Medtronic và StJude, vì dùng pin nhỏ, nên thời gian hoạt động đều thua tất cả các máy tạo nhịp dòng Talos của Biotronik!

Tài liệu tham khảo

1. Quảng cáo Identity ADx ghi thời gian hoạt động là 12,3 năm – StJude 4 trang
2. Báo cáo St Jude về máy Identity ADx XL DR ghi rõ là thời gian hoạt động dự đoán là 6,9 năm - St Jude tháng 10, 2007, 1 trang
3. Hồ sơ thầu máy Identity DR 5380 với chính phủ Pháp – 4/2/2004, 13 trang. Có ghi là thời gian hoạt động là từ 6,7- 7,2 năm.
4. Báo cáo St Jude về máy Identity ADx DR 5380 ghi rõ là thời gian hoạt động dự đoán là 3,8 năm. St Jude tháng 10, 2007, 1 trang.
5. So sánh thời gian hoạt động – Biotronik: 3 trang
6. Thời gian hoạt động Kappa DR 901 – Medtronic 1 trang
7. Pin Kappa DR 901 – Medtronic 1 trang
8. Thời gian hoạt động Sensia – Medtronic 2 trang
9. Pin Sensia – Medtronic 1 trang
10. Senaratne et al.. Pacemaker Longevity: Are we getting what we are promised? *PACE* 2006; 29: 1044-1054

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**Identity® ADx
Pacemaker**

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Identity® ADx Pacemaker

Approved for Use: United States & International

This device is approved for use in the United States and internationally.

The Identity ADx pacemaker family, which includes the world's smallest dual-chamber pacemaker, provides clinicians with the most advanced pacemaker technology available, including the revolutionary [AF Suppression™ algorithm](#), the first and only U.S. commercially approved algorithm designed to suppress atrial fibrillation (AF). The AF Suppression algorithm in the Identity ADx pacemaker family is combined with the most advanced diagnostic systems and bradycardia feature set available today, establishing the Identity ADx pacemaker as the premier product offering in advanced arrhythmia care.



Identity ADx Pacemaker

Models: Identity ADx DR (5380), Identity ADx XL DR (5386), Identity ADx SR (5180), Identity ADx XL DC (5286), & Identity ADx VDR (5480)

The premium line of Identity ADx devices collects and interprets critical diagnostic data for advanced patient management.

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The Identity ADx pacemakers feature AF management, a suite of therapeutic and diagnostic capabilities designed to help manage pacemaker patients suffering from AF. This tool kit includes:

- **AT/AF Diagnostic Suite** - AT/AF Burden Trend, AT/AF Stored EGM trigger, AT/AF Histogram, and AT/AF Episode Log
- **AF Suppression Algorithm** - Clinically proven and designed to suppress AF before it happens
- **AF Suppression Histogram** - Allows you to evaluate the success of the AF suppression algorithm
- **Stored Electrograms (EGMs)** - Provides a comprehensive overview of patient-device interactions, especially high atrial rate activity
- **Auto Mode Switch (AMS) Log** - Stores rate and duration information for mode switch episodes
- **Ventricular Rate Control** - Separately programmable AMS base rate for improved patient comfort
- **Physician Commanded Atrial Therapy (NIPS - Non-Invasive Programmed Stimulation)** - Provides the clinician with another option for the treatment of atrial arrhythmias

Tachyar (Fast He

Arrhythmia term that is rate that is normal ran 60 to 100 t minute.) At that is too l tachyarrrhy

[View All C](#)

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The Identity ADx pacemaker family also encompasses the most advanced bradycardia feature set, including the exclusive ventricular AutoCapture™ Pacing Systems, assuring Beat-by-Beat™ capture verification and a projected longevity of 12.3 years.¹

Other features available in the Identity ADx pacemaker family include:

- **Advanced Hysteresis Response** - Manages special rate situations including abrupt rate drop
- **Automatic P & R Wave Measurements** - Provides accuracy and speed in follow-up
- **Omnisense® Accelerometer Sensor** - Provides appropriate and prompt rate response for your patient's activity level
- **Auto Rest Rate** - Provides patient comfort during periods of inactivity and rest
- **Cross Sensor AMS** - Offers cross sensor mode switching (such as DDDR to DDI) when sensor is programmed on
- **FastPath™ Programmer Software** - The FastPath summary screen provides one-step access to and from all diagnostics and tests. FastPath programmer software also includes several programmer speed enhancements.
- **Onscreen Help** - Offers the option of viewing the software reference manuals on the programmer by selecting the Help button on the programmer console
- **Previous Test Results** - Records the results from the last sense or capture test in the pacemaker's memory
- **Remaining Longevity Estimate** - Gives an estimate of the remaining life of the device

¹Identity ADx XL 5386 DDDR, AutoCapture Pacing Systems on, 100% DDD pacing, 60 bpm, 0.4 ms, 2.5 V atrium, 1.0 V ventricle, 500 ohms

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Models

Select a link below to jump down the page:

- [Identity ADx DR 5380](#)
- [Identity ADx XL DR 5386](#)
- [Identity ADx SR 5180](#)
- [Identity ADx XL DC 5286](#)
- [Identity ADx VDR 5480](#)

Identity ADx DR 5380

World's smallest dual-chamber, rate-responsive pacemaker

43 x 44 x 6 mm, 18 g, and 8 cc

[AF Suppression algorithm](#)

AF Suppression histogram & event counter

AT/AF burden trend

AT/AF histogram & episode log

Stored electrograms (EGMs)

Automatic mode switch (AMS) with AMS log

Programmable AMS base rate

Physician commanded atrial therapy (NIPS - Non-Invasive Programmed Stimulation)

Beat-by-Beat [AutoCapture Pacing Systems](#)

[Omnisense accelerometer sensor](#)

Auto rest rate

FastPath programmer software enhancements

Automatic P& R wave measurements

Advanced hysteresis response for sudden drops in rate

AutoIntrinsic Conduction Search (AICS)

Rate responsive PVARP & rate responsive AV/PV delay

Connector that accepts all unipolar and bipolar IS-1 3.2 mm short terminal pin leads

Cellular Tested™

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Identity ADx XL DR 5386

Dual-chamber, rate-responsive, extended longevity pacemaker

44 x 52 x 6 mm, 23.5 g, and 11 cc

[AF Suppression algorithm](#)

AF Suppression histogram & event counter

AT/AF burden trend

AT/AF histogram & episode log

Stored electrograms (EGMs)

Automatic mode switch (AMS) with AMS log

Programmable AMS base rate

Physician commanded atrial therapy (NIPS - Non-Invasive Programmed Stimulation)

Beat-by-Beat [AutoCapture Pacing Systems](#)

[Omnisense accelerometer sensor](#)

Auto rest rate

FastPath programmer software enhancements

Automatic P& R wave measurements

Advanced hysteresis response for sudden drops in rate

AutoIntrinsic Conduction Search (AICS)

Rate responsive PVARP & rate responsive AV/PV delay

Connector that accepts all unipolar and bipolar VS-1 or IS-1 leads

Cellular Tested

Identity ADx SR 5180

Single-chamber, rate-responsive pacemaker

41 x 44 x 6 mm, 17 g, and 8 cc

Stored electrograms (EGMs)

Beat-by-Beat [AutoCapture Pacing Systems](#)

[Omnisense accelerometer sensor](#)

Auto rest rate

FastPath programmer software enhancements

Automatic P& R wave measurements

Advanced hysteresis response for sudden drops in rate

Connector that accepts all unipolar and bipolar IS-1 3.2 mm short terminal pin leads

Cellular Tested

Identity ADx XL DC 5286

Dual-chamber, extended longevity pacemaker

52 x 44 x 6 mm, 23.5 g, and 11 cc
[AF Suppression algorithm](#)
AF Suppression histogram & event counter
AT/AF burden trend
AT/AF histogram & episode log
Stored electrograms (EGMs)
Automatic mode switch (AMS) with AMS log
Programmable AMS base rate
Physician commanded atrial therapy (NIPS - Non-Invasive Programmed Stimulation)
Beat-by-Beat [AutoCapture Pacing Systems](#)
Auto rest rate
FastPath programmer software enhancements
Automatic P & R wave measurements
Advanced hysteresis response for sudden drops in rate
AutoIntrinsic Conduction Search (AICS)
Connector that accepts all unipolar and bipolar VS-1 or IS-1 leads
Cellular Tested

Identity ADx VDR 5480

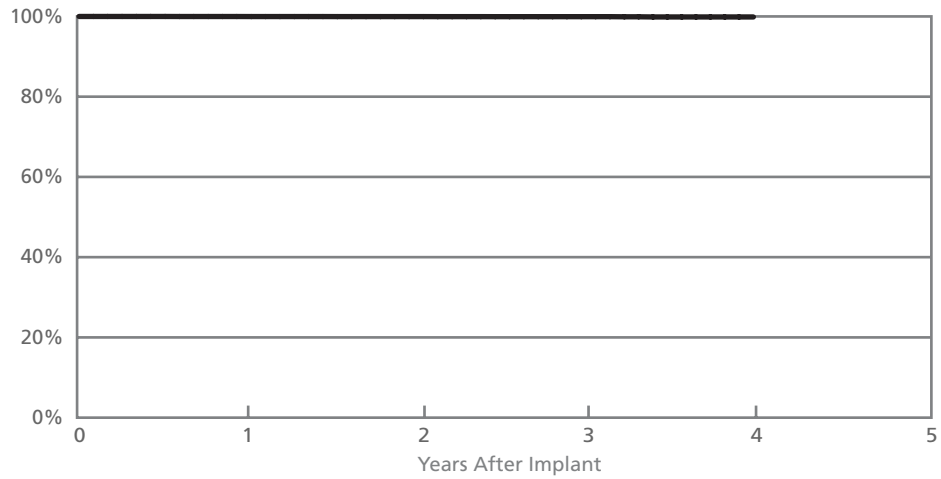
Dual-chamber sensing, single-chamber pacing, rate-responsive pacemaker
43 x 44 x 6 mm, 18 g, and 8 cc
AT/AF burden trend
AT/AF histogram & episode log
Stored electrograms (EGMs)
Automatic mode switch (AMS) with AMS log
Programmable AMS base rate
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AutoIntrinsic Conduction Search (AICS)
Connector that accepts all unipolar and bipolar IS-1 3.2 mm short terminal pin leads
Cellular Tested

View [Indications, Contraindications, Warnings, Precautions & Potential Adverse Events](#).

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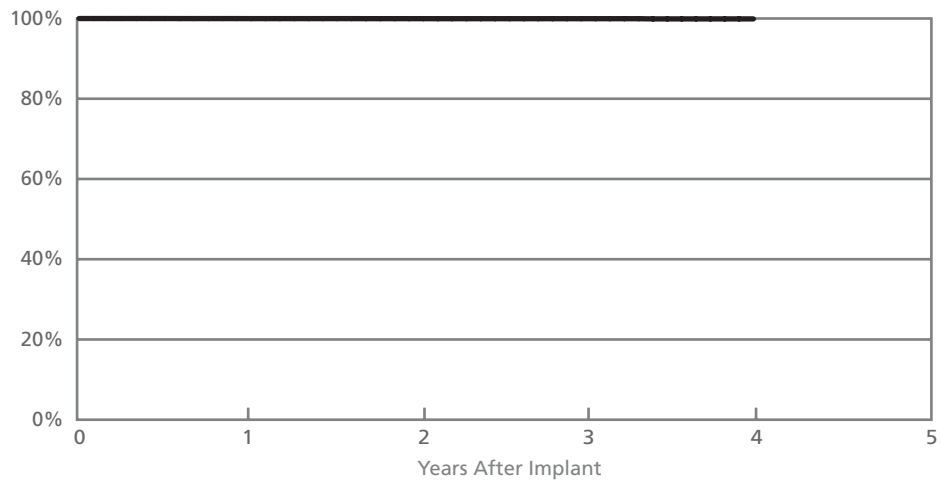
Identity® ADx XL DR (Model 5386) Identity® ADx XL DC (Model 5286)			
US Market Release	March 2003	Normal Battery Depletion	2
Registered US Implants	53,151	Malfunctions	17
Estimated Active US Implants	46,524	Malfunctions w/ Compromised Therapy (0 related to Advisory)	1
Estimated Longevity	6.9 Years	Malfunctions w/o Compromised Therapy (0 related to Advisory)	16
		Number of Advisories (see pages 134-139)	One

Including Normal Battery Depletion



Year	1	2	3	4	
Survival Probability	99.98%	99.96%	99.94%	99.87%	
± 1 standard error	0.01%	0.01%	0.02%	0.05%	
Sample Size	47900	29500	12500	2900	

Excluding Normal Battery Depletion



Year	1	2	3	4	
Survival Probability	99.98%	99.96%	99.95%	99.90%	
± 1 standard error	0.01%	0.01%	0.01%	0.04%	

Avis de la Commission

4 février 2004

Dispositif : **IDENTITY ADX DR**, stimulateur cardiaque implantable double chambre à fréquence asservie (DDDR)

Modèle : **5380**

Conditionnement : le conditionnement interne comporte :
- le stimulateur à implanter
- un kit de connexion
- une clé dynamométrique n°2
- trois clés allen supplémentaires (2, 4, 6) pour la déconnexion des anciens stimulateurs.

Fabricant : **St Jude Medical INC. (Etats-Unis)**

Demandeur : **St Jude Medical France SAS**

Nature de la demande

Demande d'inscription sur la liste des produits et prestations mentionnés à l'article L 165-1 du code de la Sécurité Sociale
--

Secrétariat de la Commission : **afssaps**

I - Caractéristiques du produit ou de la prestation

Marquage CE

Dispositif médical implantable actif (DMIA), notification par TÜV Product Service GMBH (0123).

Fonctions assurées

Le fonctionnement d'un stimulateur est décrit de manière globale par un code international.

La première lettre correspond au site de stimulation, la seconde au site de détection :

- S : simple chambre
- A : atrial
- V : ventriculaire
- D : les deux chambres
- Ø : aucun

La troisième lettre correspond à la réponse à la détection :

- I : inhibé
- T : déclenché
- D : les deux simultanément
- Ø : aucun

La lettre R en quatrième position désigne la possibilité de programmer un asservissement de la fréquence.

IDENTITY ADX DR est un stimulateur multiprogrammable de type DDDR.

Le mode DDD correspond à une stimulation atriale et ventriculaire, une détection atriale et ventriculaire, une inhibition par les événements atriaux et ventriculaires.

Applications

Dans le cadre des indications générales reconnues par les sociétés savantes, les stimulateurs cardiaques implantables double chambre de type DDDR sont pris en charge dans les situations suivantes :

- Bloc auriculo-ventriculaire du 2nd ou du 3^{ème} degré nécessitant une stimulation ventriculaire permanente ou intermittente (si la conduction auriculo-ventriculaire est préservée) :
 - chez le patient ayant une insuffisance chronotrope, lorsque le maintien d'une activité physique est possible,

- et si l'oreillette est stimuable de façon prédominante,
- Dysfonction du nœud sinusal avec insuffisance chronotrope associée soit à des anomalies de la conduction auriculo-ventriculaire, soit à une maladie rythmique atriale.

La fibrillation auriculaire chronique et permanente n'est pas une indication de la stimulation double chambre DDD(R).

Modalités d'utilisation

Les stimulateurs sont implantés sous anesthésie locale dans la région pectorale abordée par une simple incision ; ils sont reliés à une ou deux sondes endocavitaires dont les extrémités sont placées au niveau des cavités cardiaques.

Le stimulateur IDENTITY ADX DR doit être utilisé avec un programmeur modèle 3510/3500 pourvu du logiciel modèle 3307/version 4.4 ou plus récent.

Le stimulateur IDENTITY ADX DR est compatible avec les sondes uni/bipolaires IS1.

Durée de vie du dispositif

La longévité du stimulateur IDENTITY ADX DR est estimée à 6,7 ans dans les conditions suivantes : 2,5 V – 0,5 ms – 70 min⁻¹ – 100% stimulation DDDR – 500 Ω ± 1% (jusqu'à l'indication de remplacement).

II – Service rendu

1 Caractère de gravité

Il faut distinguer les dysfonctions sinusales et les blocs auriculo-ventriculaires (BAV).

La dysfonction sinusale peut voir apparaître au cours du temps une fibrillation auriculaire, avec les complications thrombo-emboliques associées et évoluer vers une insuffisance cardiaque.

Dans les blocs auriculo-ventriculaires, les symptômes sont fréquents. Ils sont en relation avec la bradycardie ou l'arythmie ventriculaire (étourdissements, syncopes, absences). Le pronostic vital peut être compromis.

La dysfonction sinusale est à l'origine d'une dégradation marquée de la qualité de vie.

Certains blocs auriculo-ventriculaires peuvent engager le pronostic vital.

2 Rapport performances/risques

Performances

Selon un rapport de l'ANAES¹, «les indications de pose de stimulateur cardiaque ne reposent pas sur des études à fort niveau de preuve. Des études randomisées sont en cours. Cependant, l'historique de la stimulation cardiaque et l'observation clinique rendent la réalisation de telles études non éthiques dans les blocs auriculo-ventriculaires».

«Les patients doivent être pris en charge sur le plan clinique, malgré les incertitudes issues de cette analyse de la littérature, selon l'expérience clinique accumulée au cours des décennies précédentes».

La subdivision en trois classes et trois niveaux de preuves selon les définitions américaines a été adoptée². Selon les cas, les indications sont de classe I, IIa ou IIb ; et les niveaux de preuves B ou C.

Niveaux de preuves
<i>A : fondé sur des données provenant de plusieurs études randomisées comprenant un grand nombre de patients</i>
<i>B : fondé sur des données provenant d'un nombre limité d'études randomisées comprenant un faible nombre de patients ou de bons travaux non randomisés ou de registres d'observations</i>
<i>C : fondé sur un consensus des experts consultés</i>
Classes (grades de recommandations)
<i>Classe I : situations dans lesquelles il y a une preuve et/ou un accord général pour dire que le traitement est bénéfique, utile et efficace</i>
<i>Classe II : situations dans lesquelles il y a des éléments contradictoires et/ou des divergences d'opinion sur l'utilité et l'efficacité du traitement :</i>
<i>- II a : le poids des preuves est plutôt en faveur de la technique</i>
<i>- II b : le poids des preuves est insuffisant pour avoir une opinion.</i>
<i>Classe III : situations dans lesquelles il y a une preuve et/ou un accord général pour dire que le traitement n'est ni utile ni efficace ou éventuellement nuisible</i>

¹ ANAES, évaluation clinique et économique des stimulateurs cardiaques, mai 1999

² Gregoratos G et al. J Am Coll Cardiol 1998 ; 31 : 1175-1209

Risques

Les risques présentés ci-après sont communs à l'ensemble des stimulateurs cardiaques. Aucun n'est spécifique au stimulateur IDENTITY ADX DR.

Ainsi, l'implantation d'un stimulateur cardiaque peut entraîner des complications¹ :

liées à l'acte médico-chirurgical (implantation)

- déplacement des sondes : 1,1 à 6 %, souvent précoce, nécessite une réintervention
- hémorragies et hématomes : 0,5 à 1,5 %
- perforation du cœur, de la plèvre, des poumons, hémothorax : 0,35 à 1,7 %
- infections : 0,23 à 4 %
 - locales
 - générales, parfois tardives, de pronostic sévère (mortalité > 30 %)
- thromboses veineuses symptomatiques ou non

électrophysiologiques précoces ou tardives

- syndrome du pacemaker : 0,2 à 26 %
- reconversion des stimulateurs cardiaques (en dehors du syndrome du pacemaker)
- fibrillation auriculaire et thromboembolie

liées à la fiabilité et à la sécurité des stimulateurs cardiaques

- interférences électromagnétiques
- autres : sur/sous-détection, batterie hors service prématurément, ...

L'analyse des données¹ montre que:

- les risques liés à l'utilisation des stimulateurs cardiaques dépendent de nombreux facteurs dont l'expérience du centre qui semble être le facteur le plus lié au taux de réintervention
- la détection d'une complication relève à la fois des méthodes de diagnostic et du rythme de suivi.

Ces données sont en faveur d'un encadrement de l'utilisation des stimulateurs cardiaques.

- les interférences électromagnétiques créées par certains appareils contre-indiquent leur utilisation chez les patients porteurs de stimulateur cardiaque ou nécessitent des précautions particulières. Il s'agit des IRM, de la cobaltothérapie, du bistouri électrique, de la lithotritie extracorporelle, de la défibrillation transthoracique. En milieu industriel, chaque cas doit être étudié. En revanche, les risques dans la vie courante sont négligeables.

Les interférences électromagnétiques potentielles avec de nombreux appareils dans l'environnement domestique et hospitalier ainsi que la conduite à tenir doivent être connues des médecins et des patients.

Au total, le rapport performances/risques des stimulateurs en général est favorable à leur utilisation.

3 Exposé des alternatives thérapeutiques

Le rapport ANAES¹ et l'analyse de la littérature montrent qu'il n'y a pas d'autre alternative thérapeutique dans les blocs auriculo-ventriculaires, et dans la dysfonction du nœud sinusal.

Il n'y a pas d'alternative à l'implantation d'un stimulateur cardiaque.

4 Intérêt pour la santé publique

Dans les conditions d'indication, compte tenu de l'absence d'alternative et de la gravité de l'affection, les stimulateurs cardiaques présentent un intérêt en terme de santé publique.

En conclusion, la Commission d'Evaluation des Produits et Prestations estime que le service rendu par les stimulateurs cardiaques implantables est suffisant pour l'inscription sur la liste des Produits et Prestations prévue à l'article L. 165-1 du code de la sécurité sociale.

Néanmoins, la Commission conditionne leur service rendu à des spécifications techniques minimales et à des conditions de prescription et d'utilisation.

III – Éléments conditionnant le service rendu

Indications

Celles retenues pour la ligne générique des stimulateurs cardiaques implantables double chambre de type DDDR (ligne 3489875).

Spécifications techniques minimales

Celles retenues pour la ligne générique des stimulateurs cardiaques implantables double chambre de type DDDR (ligne 3489875).

Le stimulateur IDENTITY ADX DR répond à toutes ces spécifications techniques minimales.

Modalités d'inscription et d'utilisation

Celles retenues pour la ligne générique des stimulateurs cardiaques implantables double chambre de type DDDR (ligne 3489875).

La Commission d'Evaluation des Produits et Prestations s'est prononcée pour un service rendu suffisant du stimulateur cardiaque implantable IDENTITY ADX DR.

IV – Amélioration du Service Rendu

Comparaison aux spécifications techniques minimales décrites par la ligne générique des stimulateurs double chambre de type DDDR (ligne 3489875)

IDENTITY ADX DR est un stimulateur correspondant en tous points aux spécifications techniques minimales requises pour cette gamme de produit. Néanmoins, il présente en plus des fonctions thérapeutiques et diagnostiques supplémentaires :

- 120 secondes d'électrogrammes endocavitaires mémorisés (EGMs) enregistrables sur 2 canaux : il s'agit d'une fonction holter embarquée qui permet le diagnostic automatique et rétrospectif des arythmies. Ces EGMs remplacent des marqueurs dont on connaissait les limites. L'application d'un aimant permet en outre de corrélérer les symptômes du patient à la réalité électrocardiographique. Ces véritables mémoires implantées permettent une meilleure connaissance de l'histoire naturelle des pathologies présentées par le patient, un diagnostic rapide de dysfonctionnement d'entraînement ou d'écoute, et une adaptation au mieux du traitement au patient. En particulier, cette fonction permet de détecter, et de traiter, des arythmies auriculaires souvent asymptomatiques, bien que graves (1 essai non comparatif sur 56 patients avec des appareils de génération antérieure d'une autre firme³), ce qui rend particulièrement indiqué chez des patients susceptibles d'avoir des troubles atriaux ou ventriculaires.

D'autres dispositifs possèdent une telle fonction avec des enregistrements de résolution et de durée variables.

- Une mesure continue de l'impédance des sondes

- Une mesure automatique du seuil ventriculaire (AUTOCAPTURE) : cette fonction teste en permanence le seuil de stimulation du patient, et adapte automatiquement l'amplitude des impulsions. Elle permet d'augmenter la longévité de la pile par rapport au même appareil programmé à amplitude fixe en délivrant l'énergie juste nécessaire^{4,5}.

La longévité calculée du stimulateur IDENTITY ADX DR est ainsi égale à **6,7 ans dans les conditions fixées pour les spécifications techniques minimales, et peut atteindre 7,2 ans avec cette fonction activée.**

Cet allongement de la durée de vie de l'appareil réduit de fait les complications liées au changement du boîtier, et le rend particulièrement indiqué chez les sujets jeunes ou dépendants de la stimulation.

De plus, cet algorithme améliore la sécurité du patient car il permet de vérifier l'efficacité de la stimulation (signal de réponse évoqué). A chaque cycle, si la stimulation ventriculaire n'est pas confirmée par la détection d'une réponse évoquée, l'appareil délivre une impulsion de secours afin de garantir une contraction

³ Pollak W. et al. Pace 2001 ; 24 (Pt II) : 424-429

⁴ Simeon L. et al. Pace 2000 ; 23 (Pt II) : 1788-1791

⁵ Boriani G. et al. Pace 2000 ; 23 (Pt II) : 1783-1787

ventriculaire. La sécurité et les performances de cet algorithme ont fait l'objet de 2 essais non comparatifs publiés^{6,7}.

- Une fonction NIPS (Non Invasive Programmed Stimulation) qui permet de réaliser des études électrophysiologiques répétées de façon non invasive.

- Une fréquence automatique de repos: cette fonction permet de stimuler à une fréquence inférieure à la fréquence de base pendant les phases de sommeil ou de repos, et donc de mieux respecter le rythme circadien.

Cette fonction est disponible sur la plupart des appareils de dernière génération.

- Une possibilité de stimuler à 7,5 V, intéressante en cas d'élévation du seuil chez un patient.

- Un hystérésis de fréquence dont le but est de préserver un rythme spontané. Cette fonction est disponible sur la plupart des appareils de dernière génération.

- Un hystérésis du délai auriculo-ventriculaire permet une meilleure expression de l'activité ventriculaire spontanée et économiser une stimulation ventriculaire droite inutile. Une désynchronisation des deux ventricules qui aurait un effet délétère sur le plan hémodynamique⁸, et augmenterait le risque de fibrillation atriale⁹ peut ainsi être évitée.

- Un algorithme anti-TRE (tachycardies par ré-entrée électronique)

- Une période réfractaire auriculaire post-ventriculaire (PRAPV) automatique. Cette fonction a pour objectif d'empêcher le canal atrial de détecter une dépolarisation atriale rétrograde et d'initier une tachycardie potentielle par réentrée électronique.

- Une commutation automatique de mode: cette fonction permet de préserver la stimulation synchronisée auriculo-ventriculaire.

Les avantages de la commutation de mode sont les suivants¹⁰: les patients présentant des tachycardies atriales paroxystiques peuvent devenir très symptomatiques à cause de la détection de l'arythmie, qui est responsable de stimulations ventriculaires rapides. Si un mode de non détection atriale permanent est programmé, ces patients ne ressentiront pas de rythme rapide, mais il n'y aura pas de synchronisme auriculo-ventriculaire pendant les périodes de rythme sinusal. La commutation de mode permet à ces patients de bénéficier d'une stimulation physiologique pendant les périodes d'activité atriale normale, et d'être asymptomatiques lors des tachycardies atriales (commutation du stimulateur).

En revanche, la sensibilité doit être assez haute pour assurer la détection des arythmies atriales. Les tachycardies sinusales peuvent entraîner des commutations inappropriées. Les critères doivent donc être assez rigoureux pour éviter cela. Ils doivent également éviter qu'il y ait trop de commutations, ce qui peut être désagréable pour le patient. Cependant si les critères sont trop sévères, le patient

⁶ Clarke M. et al. Pace 1998 ; 21 : 1567 - 959

⁷ Lau C. et al. Pace 2000 ; 23 : 953-959

⁸ Tse HF et al. JACC 1997 ; 29(4) : 744-749

⁹ Sweeney M et al. Circulation 2003 ; 107 : 2932-2937

¹⁰ Sutton R. et al.. Am J Cardiol 1999 ; 83 : 202D-210D.

pourra éprouver des rythmes ventriculaires rapides prolongés avant que la commutation ne se produise. Il faut donc faire un compromis dans la programmation.

L'étude de Kamalvand¹¹ sur des appareils de différentes firmes, et de génération antérieure à l'IDENTITY ADX DR a confirmé l'efficacité clinique de la commutation automatique de mode, et la préférence de ce mode par les patients interrogés. L'étude comparait 3 modes de stimulation : DDDR avec commutation, DDDR sans commutation, et VVIR, chez les patients ayant des antécédents de tachyarythmie atriale. Cependant, dans cette étude, la moyenne de la durée d'exercice et la fréquence maximale lors d'un test d'effort ne sont pas significativement différentes entre les modes DDDR avec ou sans commutation.

- Un algorithme de prévention de la fibrillation auriculaire (FA) : il s'agit d'un algorithme d'overdrive auriculaire.

Parmi les patients candidats à la stimulation cardiaque permanente, certains présentent en plus des troubles du rythme auriculaire. En particulier, la maladie de l'oreillette se caractérise par une alternance d'épisodes de bradycardie et d'épisodes de FA. La FA est un trouble évolutif apparaissant de manière paroxystique pour devenir permanente en quelques années. Il n'existe pas de facteur prédictif identifiés. Or ses complications sont graves, allant jusqu'à l'accident vasculaire cérébral.

Une étude (ADOPT-A) multicentrique randomisée sur 288 patients utilisant des stimulateurs antérieurs, a mis en évidence une réduction relative de 25% de la charge de FA paroxystique ou persistante¹². Cette réduction est significative et se maintient au cours de temps. Deux études (OASES et INOVA) dont les résultats ont fait l'objet de communications fin 2003 semblent confirmer l'intérêt de cet algorithme.

Cet algorithme est particulièrement indiqué pour les sujets présentant une cardiopathie ou des troubles du rythme atrial.

De plus, le stimulateur IDENTITY ADX DR possède une taille particulièrement réduite, cependant cette miniaturisation du boîtier est au détriment de la longévité de l'appareil.

Comparaison aux stimulateurs double chambre de type DDDR inscrits sous nom de marque :

Le comparateur retenu par la Commission est le stimulateur IDENTITY DR.

Toutes les fonctions du stimulateur IDENTITY ADX DR sont disponibles sur le stimulateur IDENTITY DR.

Les différences entre les deux versions du stimulateur DR sont les suivantes :

- amélioration des fonctions mémoires, notamment avec la possibilité de suivre la charge en fibrillation auriculaire,
- nouveau logiciel de programmation.

Il n'est présenté aucune donnée concernant ces modifications.

¹¹ Kamalvand K. et al. JACC 1997 ; 30 (2) : 496-504.

¹² Carlson M. et al. JACC 2003 ; 42(4) : 627-633

Pour cet ensemble de fonctions, IDENTITY ADX DR est intéressant dans les situations suivantes :

- sujets dépendants de la stimulation,
- ou présentant une cardiopathie associée,
- ou présentant des troubles du rythme atrial.

Au total, dans les indications retenues, la Commission d'Evaluation des Produits et Prestations s'est prononcée pour une absence d'amélioration du service rendu (ASR V) du stimulateur IDENTITY ADX DR par rapport au stimulateur IDENTITY DR.

V – Conditions du renouvellement

Le renouvellement sera subordonné à la présentation d'études confirmant la portée clinique des caractéristiques techniques du stimulateur IDENTITY ADX DR, ainsi que des données actualisées du suivi des dispositifs implantés confirmant le rapport performances/risques favorable.

VI – Population cible

D'après les données 2001 du Programme de Médicalisation des Systèmes d'Implantation (PMSI), le nombre total d'implantations de stimulateurs cardiaques est de 54 526 par an, dont la moitié dans le secteur privé (chiffres obtenus à partir des actes classants stimulation cardiaque définitive et changement de stimulateur).

Acte	Ensemble des établissements	Part du secteur privé
Stimulation cardiaque définitive	41 826	48 %
Changement de stimulateur	12 700	58 %
TOTAL	54 526	49 %

D'après les statistiques communiquées par les fabricants proposant des stimulateurs en France, les ventes de stimulateurs atteignaient un total de 54 508 en 2002¹³, si l'on exclut les boîtiers spécifiques pour stimulation biventriculaire. L'utilisation de boîtiers DDDR utilisés avec un adaptateur en Y porte à environ 1 850 le nombre d'implantations pour stimulation biventriculaire.

¹³ Dodinot B. Stimucoeur 2003 ; 31(2) : 126-140

Type de stimulateur	2002
SSI	6,8 % soit 3 685
SSIR	21,7 % soit 11 841
VDD(R)	5,6 % soit 3 081
DDD	8,9 % soit 4 884
DDDR	56,9 % soit 31 017
TOTAL	100 % soit 54 508

Enfin, d'après les données du fichier français 2002 du Collège Français de Stimulation Cardiaque¹⁴, le nombre d'implantations définitives réalisées par an en primo-implantation est de 26 065, représentant 77 % des dossiers enregistrés.

Les proportions des différents types de stimulateurs implantés en primo- et ré-implantation sont les suivantes :

Type de stimulateur	Primo-implantations	Ré-implantations	Ensemble
SSI	7 %	7 %	6,9 % soit 2 369
SSIR	18 %	28 %	20,3 % soit 6 872
VDD(R)	6 %	4 %	5,6 % soit 1 875
DDD	11 %	10 %	10,8 % soit 3 646
DDDR	58 %	51 %	56,4 % soit 19 088
TOTAL	26 065	7 785	33 850

Les données du PMSI et les statistiques des fabricants sont cohérentes.

Les chiffres rapportés par le fichier français, en nombre d'implantations, sont certainement inférieurs à la réalité puisque basés sur une participation volontaire des centres.

En revanche, les proportions relatives des différents types de stimulateurs sont cohérentes avec celles des fabricants.

Au total, la population cible retenue pour le stimulateur IDENTITY ADX DR est comprise entre 19 088 et 31 017 implantations par an.

Il est à noter une augmentation prévisible dans les années à venir, liée au vieillissement normal de la population et au pic démographique d'après guerre.

¹⁴ Salvador-Mazenq M. Stimucoeur 2003 ; 31 (3) : 200-204

**RECOMMANDATIONS DE LA COMMISSION D'ÉVALUATION
DES PRODUITS ET PRESTATIONS**

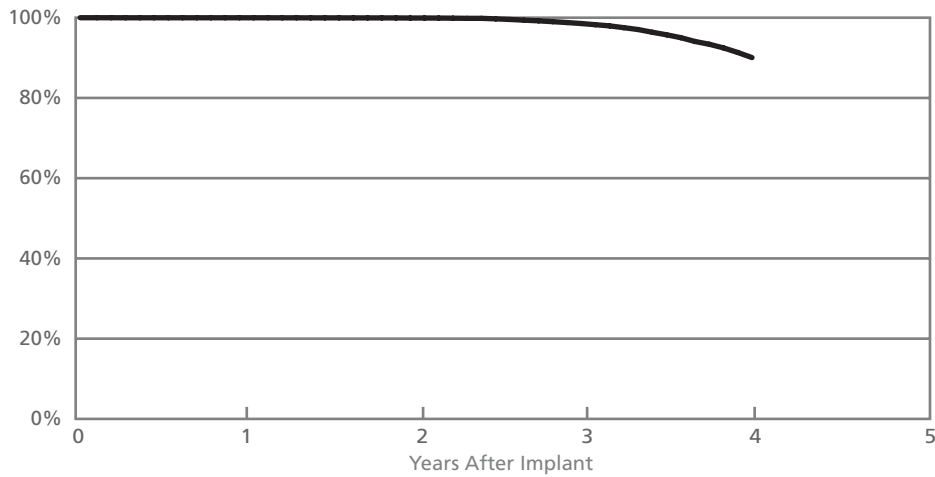
NOM :	IDENTITY ADX DR stimulateur cardiaque implantable double chambre à fréquence asservie de type DDDR
SR :	Suffisant
Éléments conditionnant le SR	
Indications	Celles de la ligne générique 3489875
Conditions de prescription et d'utilisation	Celles de la ligne générique 3489875
Spécifications techniques	Celles de la ligne générique 3489875
ASR :	V (pas d'amélioration du service rendu) par rapport au stimulateur IDENTITY DR.
Type d'inscription :	Nom de marque
Durée d'inscription :	5 ans
Conditions du renouvellement :	Le renouvellement sera subordonné à la présentation d'études confirmant la portée clinique des caractéristiques techniques du stimulateur IDENTITY ADX DR, ainsi que des données actualisées du suivi des dispositifs implantés confirmant le rapport performances/risques favorable.
Population cible :	La population cible est comprise entre 19 088 et 31 017 implantations de stimulateurs DDDR par an (dont la moitié dans le secteur privé).

Pulse Generators

Identity® ADx DR (Model 5380)

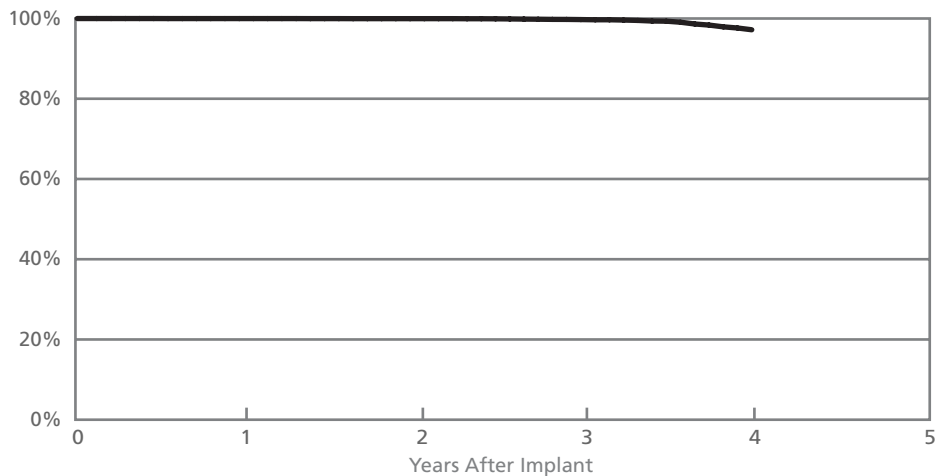
US Market Release	March 2003	Normal Battery Depletion	907
Registered US Implants	48,790	Malfunctions	32
Estimated Active US Implants	39,503	Malfunctions w/ Compromised Therapy (0 related to Advisory)	1
Estimated Longevity	3.8 Years	Malfunctions w/o Compromised Therapy (0 related to Advisory)	31
		Number of Advisories (see pages 134-139)	One

Including Normal Battery Depletion



Year	1	2	3	4
Survival Probability	99.98%	99.92%	98.55%	90.06%
± 1 standard error	0.01%	0.01%	0.06%	0.63%
Sample Size	45200	29600	14000	4100

Excluding Normal Battery Depletion



Year	1	2	3	4
Survival Probability	99.98%	99.96%	99.73%	97.19%
± 1 standard error	0.01%	0.01%	0.04%	0.53%

Longevity projections

Longevity projections (normal operating life)

Longevity projections (normal operating life)

Table C-1 through Table C-5 show the estimated time from implant to the Elective Replacement Indicator (ERI) being set at nominal and low output amplitudes. The estimated time varies based on the lead impedance (either 500, 600, or 1000 Ohms) and the percent of time spent pacing (either 50% or 100%).

Note: These longevity projections are based on calculations using deliverable battery capacity. These values are estimates of projections from implant to ERI and can help the clinician in understanding the effects of various pacing conditions on battery longevity. These values should not be interpreted as precise numbers.



Caution: When ERI is set, the pacemaker must be replaced within three months. The time and date when ERI was set is shown on the Significant Events window.

Models KDR901/903/906, KDR801/803/806, and Kd901/903/906 longevity projections

Table C-1. Implant to ERI projections for Models KDR901/903/906, KDR801/803/806, and Kd901/903/906

Programmed settings	Percent paced	Projected longevity (years) at listed lead impedance		
		500 Ohms	600 Ohms	1000 Ohms
Mode: DDDR ^a Lower Rate: 60 min ⁻¹				
Nominal outputs	100%	6.3	6.6	7.7
Amplitudes: 3.5 V	50%	7.8	8.0	8.8
Pulse Widths: 0.4 ms				
Low outputs	100%	7.7	8.0	8.6
Amplitudes: 2.5 V	50%	8.6	8.8	9.2
Pulse Widths: 0.4 ms				
Lower ventricular output	100%	8.1	8.3	8.8
A. Amplitude: 2.5 V	50%	8.9	9.0	9.4
V. Amplitude: 1.5 V				
Pulse Widths: 0.4 ms				

^a For models Kd901/903/906, the programmed mode is DDD.

Battery specifications

The three type of batteries used in Kappa 900/800 Series pacemakers are listed in the tables below. Note that the projected deliverable capacity is the estimated average capacity of the battery.

Table C-12. Battery specifications for models **KDR901/903/906**, KDR801/803/806, and KD901/903/906

Type	Sigma 263 Lithium-Iodine
Voltage	2.8 Volts
Projected Deliverable Capacity	1.2 ampere-hour

Table C-13. Battery specifications for models KDR921, KVDD901, and KSR901/903/906

Type	Sigma 213 Lithium-Iodine
Voltage	2.8 Volts
Projected Deliverable Capacity	0.83 ampere-hour

Table C-14. Battery specifications for models KDR931/933

Type	Sigma 303 Lithium-Iodine
Voltage	2.8 Volts
Projected Deliverable Capacity	1.4 ampere-hour

**Projected service life: ADR01/03/06,
 SESR01, SES01**

Table C-4. ADR01/03/06, SESR01, SES01 Projected service life from implant to RRT/ERI in years

Pacing	Amplitude	Rate, Pulse Width	Lead impedance	
			500 Ω	1000 Ω
			Longevity (years)	
SSIR or SSI, 0%	2.0 V	60 ppm, 0.4 ms	9.0	9.0
	2.5 V		8.5	8.5
	3.5 V		8.8	8.8
SSIR or SSI, 50%	2.0 V	60 ppm, 0.4 ms	8.4	8.7
	2.5 V		7.8	8.1
	3.5 V		7.4	8.0
SSIR or SSI, 100%	2.0 V	60 ppm, 0.4 ms	7.9	8.4
	2.5 V		7.3	7.8
	3.5 V		6.4	7.4
SSIR or SSI, 0%	2.5 V	70 ppm, 0.5 ms	8.3	----
	5.0 V		8.2	----
	SSIR or SSI, 100%		2.5 V	70 ppm, 0.5 ms
5.0 V	4.1	----		
SSIR or SSI, 100%	5.0 V	70 ppm, 1.0 ms	2.9	----
SSIR or SSI, 100%	5.0 V	100 ppm, 1.0 ms	2.2	----

**Projected service life: VEDR01,
 SEDR01, SED01**

Table C-6. VEDR01, SEDR01, SED01 Projected service life from implant to RRT/ERI in years

Pacing	A Amplitude, V Amplitude	Rate, Pulse Width	Lead impedance	
			500 Ω	1000 Ω
			Longevity (years)	
DDDR or DDD, 0%	1.5 V, 2.0 V ^a	60 ppm, 0.4 ms	9.8	9.8
	2.5 V, 2.5 V		9.3	9.3
	3.5 V, 3.5 V		9.6	9.6
DDDR or DDD, 50%	1.5 V, 2.0 V ^a	60 ppm, 0.4 ms	9.0	9.4
	2.5 V, 2.5 V		8.2	8.7
	3.5 V, 3.5 V		7.4	8.3
DDDR or DDD, 100%	1.5 V, 2.0 V ^a	60 ppm, 0.4 ms	8.2	8.9
	2.5 V, 2.5 V		7.4	8.2
	3.5 V, 3.5 V		6.0	7.3
DDDR or DDD, 0%	2.5 V, 2.5 V	70 ppm, 0.5 ms	9.0	----
	5.0 V, 5.0 V		8.9	----
	DDDR or DDD, 100%		2.5 V, 2.5 V	70 ppm, 0.5 ms
5.0 V, 5.0 V	3.5	----		
DDDR or DDD, 100%	5.0 V, 5.0 V	70 ppm, 1.0 ms	2.4	----
DDDR or DDD, 100%	5.0 V, 5.0 V	100 ppm, 1.0 ms	1.7	----

^a For ACM the Minimum Adapted Amplitude is 1.5 V (nominal). For VCM the Minimum Adapted Amplitude is 2.0 V (nominal).

Longevity projections
Battery specifications

Table C-12. Battery specifications for Models ADSR01, ADSR03, ADSR06, SESR01, SES01

Type	Sigma 213 Lithium-Iodine
Voltage	2.8 Volts
Projected deliverable capacity	0.86 ampere-hour

Table C-13. Battery specifications for Model ADVDD01

Type	Sigma 213 Lithium-Iodine
Voltage	2.8 Volts
Projected deliverable capacity	0.86 ampere-hour

Table C-14. Battery specifications for Models VEDR01, SEDR01, SED01

Type	Sigma 263 Lithium-Iodine
Voltage	2.8 Volts
Projected deliverable capacity	1.2 ampere-hour

Table C-15. Battery specifications for Model SEDRL1

Type	Sigma 303 Lithium-Iodine
Voltage	2.8 Volts
Projected deliverable capacity	1.4 ampere-hour

Pacemaker Longevity: Are We Getting What We Are Promised?

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Background: Although pacemaker manufacturers provide projections on longevity, these projections cannot be relied upon due to the assumptions of output parameters being far in excess of those programmed in clinical practice.

Objective: The purpose of this review was to compare the actual longevity to the calculated longevity of pacemakers based on battery cell characteristics taking into account individual programmed parameters, mode, degree of usage, and percent pacing. This was also compared to the manufacturers' own projected longevities.

Methods: Patients who had a pacemaker replaced between 1998 and 2003 were included ($n = 124$). Cell characteristics were obtained from manufacturers and programmed parameters were obtained at each visit. Stepwise calculations were done for each visit to find current drain during each interval, and then were used in a weighted average to find the total average lifetime current drain. This was subsequently used to find a calculated longevity for each pacemaker to be compared to the actual longevity observed.

Results: The pacemakers lasted 491 ± 92 days (mean \pm SEM) less than calculated. There was also a difference between dual- and single-chamber devices (though not statistically significant). Moreover, it was found that there were significant differences between manufacturers.

Conclusions: There appears to be a significant discrepancy between calculated and actual longevities, confirming that battery depletion occurs earlier than expected. This suggests that current drain expended for ancillary functions may be considerable. Another factor may be pre-implantation drain. Vigilance with programming of outputs, modes, sensors, heart rates, and ancillary functions could potentially extend longevity and postpone/obviate the need for costly repeat surgery with its attended risk of complications. Furthermore, the differences between manufacturers seem to parallel the clinical impressions. (*PACE* 2006; 29:1044–1054)

pacemaker longevity, battery life, current drain, pacemaker ancillary functions, pacemaker replacement

Introduction

Pacemakers have undergone many significant changes since the first battery-powered pacemaker was implanted in 1958. Since that time, advances in technology have given clinicians a host of programming capabilities ranging from arrhythmia review to remote transmission of information via satellite communication technology.¹ Unfortunately, these added capabilities place an added drain on the battery. Pacemaker manufacturers have traditionally provided estimates on pulse generator longevity (herein referred to as "projected longevity"). However, these projected

longevities are based on voltages, pulse durations, pacing rates, pacing percentages, and impedances that are almost always different from that observed in clinical practice. As a result, the projected longevities cannot be relied upon, especially considering that the voltages and pulse durations used in their calculation are significantly higher than that required to effectively and safely capture the patient. For example, several manufacturers report projected longevities based on voltages as high as 3.5–4.0 volts. Thus, the projections may give a good picture in terms of the manufacturers keeping to their projected longevity when in reality it is quite feasible that these pacemakers are not lasting as long as they should given that they are programmed at lower settings, which should extend the lives of these pacemakers. The intention of this project was to account for the effect of lead impedance, programmed output parameters, and the degree of usage of the pacemakers by finding a calculated longevity to be compared with the actual longevity observed clinically based on the time to pulse generator replacement due to battery depletion. We therefore did not use the pre-defined

Disclosure: None of the authors or their immediate families have any ties with any pulse generator manufacturers or any other companies mentioned hereafter.

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projected longevities provided in the device manuals in finding the calculated longevity for each patient.

Methods

Patient Selection and Data Collection

A group consisting of 124 consecutive patients who had a pulse generator replaced due to battery depletion between 1998 and 2003 were included in the study. Patients who had a pulse generator replaced due to reasons other than battery depletion (e.g., lead malfunction, infection, component failure, etc.) were excluded from the study. The study included both single- and dual-chamber devices. All clinical, investigational, and demographic data were collected in a prospective manner and entered into a database within the Statistical Package for the Social Sciences (SPSS) data management system. The information collected in the pacemaker clinic was also entered into a pacemaker data management system (Medtronic Paceart, Arden Hills, MN, USA).

For each type of pulse generator found within this patient sample, information regarding inhibited current drain (in milliamperes) and cell capacity (in ampere-hours) was obtained directly from the manufacturers. The inhibited or static current drain is the drain on the battery when it is in an inhibited mode (i.e., only sensing with no pacing).

For each patient within this sample, the output parameters were programmed and recorded at each clinic visit (including the initial implant visit). These programmed parameters included the cell voltage, lead impedance, and output of the pacemaker, which itself consisted of output voltage (in volts) and pulse duration (in milliseconds). The programmed parameters are essentially the direct result of clinical manipulation of each individual pacing system and the patient specific output energy requirements for optimal stimulation.

Also recorded at each visit was information regarding the degree of usage of each pacemaker. This involved percent pacing and the mean rate of pacing in beats per minute. These were obtained for either one chamber or both depending on the mode of pacing. Whenever the percent pacing parameter was not available, 100% pacing was assumed avoiding overestimation of the calculated longevity thus favoring the comparison toward the pacemaker/manufacturer. This occurred in instances where the percent pacing parameter was not available in a particular device and rarely where it was not documented at a clinic visit.

Calculation of Actual and Calculated Longevities

Actual longevity was defined as the time between pacing system implantation and pulse gen-

erator replacement. The clinical sequence adapted for pulse generator replacement (for battery depletion) was as follows. After a pulse generator was noted to have reached elective replacement indicator, an increased surveillance was adapted with quarterly clinic visits. All patients deemed to have a pacing dependency status of 1+ or 2+ (defined as nondependent with prevailing intrinsic rhythm) were then followed to the point of end of (pacemaker cell) life indicator with generator replacement arranged at that point. In the case of 4+ dependency patients (defined as full ventricular pacing during a 60-second period of pacing at a programmed rate of 30 beats/min), programmed parameters were adjusted as required to extend battery life. Follow-up was done at 1–2 month intervals with careful evaluation of battery cell characteristics and the rate of cell depletion. In the 4+ dependent group of patients, pulse generator replacement was done following a period of time after the elective replacement indicator and extending up to the end-of-life indicator. The timing of surgery was based on the evaluations as well as the patient's ability to comply with the more frequent follow-up. In general, the practice of the pacemaker program at the Grey Nuns Hospital has been to delay pulse generator replacement as far as practically feasible. Pulse generator replacements done for reasons other than battery depletion were excluded. All explanted devices were returned to the respective manufacturers for analysis and feedback.

Estimation of the calculated longevity (done for all 124 patients individually) required three separate sets of information: battery cell characteristics (manufacturer-set), programmed parameters (clinic-set), and degree of usage of pacemaker (patient/lifestyle dependent). The initial step involved the determination of the total current drain (in microamperes, μA) for the pulse generator. This was the sum of the inhibited/static current drain and the pacing current drain.

The value for inhibited current drain was obtained directly from the manufacturer. The pacing current was further split into (patient specific) mean atrial and ventricular pacing currents, each of which was calculated independently and then summed.

Neither mean atrial nor mean ventricular pacing currents could be calculated directly, since during the lifetime of a pulse generator, programmed parameters and thus pacing currents change. First, the atrial and ventricular pacing currents between two visits for each patient were found (given that during the time interval between visits, programmed parameters did not change). Once the pacing currents were known for each visit, a mean value over the lifetime of that pulse

generator was calculated. The physics formulae used for these calculations were²:

$$\begin{array}{ll} (1) & (2) \\ V = IR & E = VI t \\ \text{(volt)} = \text{(ampere)}\text{(ohm)} & \text{(joule)} = \\ & \text{(volt)}\text{(ampere)}\text{(second)} \end{array}$$

Calculation of atrial and ventricular pacing currents (for a single visit) involved finding an energy per beat using the programmed parameters (output voltage, pulse duration, and lead impedance). This represents the amount of energy expended for each current emitted to stimulate and capture the heart. The delivered energy is independent of the type of pacemaker but affected only by the output voltage, pulse duration, and lead resistance. The calculation requires both formulae noted above. To find energy, Formula 2 was used; but, since current was unknown, Formula 1 was solved for current and substituted into Formula 2 such that the final equation involved only resistance, voltage, and time (pulse duration):

$$\begin{array}{l} E = VI t \quad (1) \\ V = IR \quad (2) \\ \text{Rearrange(2): } I = V/R \\ \text{Substitute in(1): } E = VVt/R \\ E = V^2t/R \end{array}$$

$$\begin{array}{l} \text{(Energy per beat } - \mu\text{J)} \\ = \frac{\left[\begin{array}{l} \text{(Output voltage } - V)^2 \\ \text{(Pulse duration } - \text{ms)} \times 1,000 \end{array} \right]}{\text{(Resistance } - \Omega)} \end{array}$$

The energy per beat was in microjoules since both output voltage and pulse duration were found in volts and milliseconds, respectively, and then multiplied by 1,000. The second step in calculating the atrial and ventricular pacing currents involved taking into account the remaining cell voltage in the pulse generator as obtained at each visit along with the degree of usage of the pacemaker. This calculation involved equation (1), though rearranged to solve for current I as was required. In this case, E was the energy per beat calculated from equation (1), V was the cell voltage, and the inverse of time was beats per second. Beats per second was a product of mean pacing rate (in beats/min)

and percent pacing (the percentage of time during which pulse generator was pacing), divided by 60, in order to convert to beats/sec:

$$\begin{array}{l} E = VI t \quad (1) \\ \text{Rearrange(1): } I = E/(Vt) \\ I = (E)(1/t)/(V) \end{array}$$

$$\begin{array}{l} \text{(A/V Pacing Current } - \mu\text{A)} \\ = \frac{\left[\begin{array}{l} \text{(Energy per beat } - \mu\text{J)} \\ \text{(beats per second } - 1/\text{s)} \end{array} \right]}{\text{(cell voltage } - V)} \end{array}$$

Note:

$$\begin{array}{l} \text{(Beats per second } - 1/\text{s)} \\ = \frac{\left[\begin{array}{l} \text{(mean pacing rate } - 1/\text{min)} \\ \text{(Percent pacing } - \%) \end{array} \right]}{(60 - \text{s}/\text{min})} \end{array}$$

The atrial and ventricular pacing currents were determined for each inter-visit period (i.e., the time between two clinic visits). Thereafter, the mean atrial and ventricular pacing currents were found by multiplying the value for each inter-visit period with the number of days between that visit and the next. This was then summed with calculations for all such visits. The total was then divided by the total number of days between pulse generator implant and replacement to give final mean atrial and ventricular pacing currents for the entire life of the pacemaker. Note that mathematically, this was the equivalent of a weighted average:

Mean A/V current

$$= \frac{\left[\begin{array}{l} \text{(A/V current}_{\text{visit 1}})(\text{date}_{\text{visit 1}} - \text{date}_{\text{visit 2}}) \\ + \text{(A/V current}_{\text{visit 2}})(\text{date}_{\text{visit 2}} - \text{date}_{\text{visit 3}}) + \dots \end{array} \right]}{\left[\begin{array}{l} \text{Total number of days between} \\ \text{pulse generator implant and replacement} \end{array} \right]}$$

The mean atrial and ventricular pacing currents (in μA) were combined with the inhibited current drains to derive the total current drains. This value was then used along with the cell capacity (in ampere-hours) from the manufacturers to find the calculated longevity in years for each pulse generator, thus taking into account different

sized batteries. A unit conversion factor was used to convert hours and μA into years:³

$$\begin{aligned} & (\text{Longevity} - \text{yrs}) \\ &= \frac{\left[\frac{(\text{Ampere} - \text{hours} - \text{A} \cdot \text{h})}{(1 \times 10^6 - \mu\text{A per A})} \right]}{\left[\frac{(\text{total current} - \mu\text{A})}{(24 \times 365 - \text{hours per year})} \right]} \end{aligned}$$

It should be emphasized that the projected pulse generator longevities provided by the manufacturers were not used in the estimation of the calculated longevity. The manufacturers' projected longevities are reported separately, having been acquired directly from the manufacturers themselves.

The energy drain from the pacemaker during the pre-implantation period (i.e., from the date of manufacture to the date of implant) was not utilized in calculating longevity. This was due to the lack of accurate data regarding the energy drain during this period for all pacemaker models—manufacturers were contacted regarding this, but two of the four declined giving out this information. However, the available data regarding the time to implant was pooled to find a mean pre-implantation period so as to make sure that the shortfall in longevity could not be explained by this pre-implantation drain.

Statistical Analysis

The clinical, investigational, and demographic characteristics, as well as the calculated and actual longevities, were entered into the database formulated within the SPSS data management system. Continuous variables were entered as such and all discrete variables were broken down into mutually exclusive categories. The results for continuous variables are given as mean \pm standard error of the mean (SEM). Comparisons between continuous variables were made using a student's *t*-test for unpaired data. A multiple logistic regression analysis was done to determine the variables that had significant independent influence on the differences between calculated and actual longevities (i.e., shortfall in longevity). The following variables which could be expected to have an influence on the calculated longevity were entered in a stepwise manner: age of patient (at time of implantation), gender, pulse generator cell capacity, pacing mode (DDD, VVI, AAIR, etc.), pacemaker manufacturer, and total current.

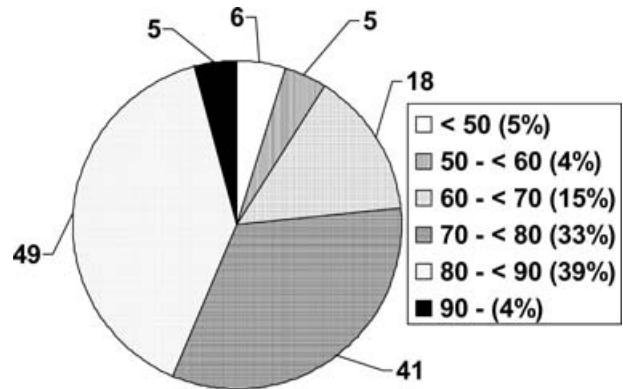


Figure 1. Frequency-distribution of the explanted pacemakers according to age (at time of implantation) of patients (n = 124).

Results

Clinical Features

During the period of the study (1998–2003), there were 124 patients who had pulse generators replaced for battery depletion. The age of the patients was 75.7 ± 1.1 years (mean \pm standard error of the mean). There were 73 males (58.9%; age 76.3 ± 1.3 years) and 51 females (41.1%; age 74.7 ± 2.1 years). Figure 1 shows the frequency distribution of the patient sample according to age at the time of implant. No patients died and/or had syncope during the increased surveillance period beyond Elective Replacement Indicator.

The characteristics of pacemakers selected are outlined in Table I. The mean cell capacity was 1.20 ± 0.24 A-h. Seventy-nine devices (63.7%) were dual chamber whereas 46 (36.3%) were

	Frequency	Percent
Chamber type		
Dual chamber	79	63.7
Single chamber	45	36.3
Pacing model		
AAIR	8	6.5
VVI	11	8.9
VVIR	26	21.0
VDD	9	7.3
DDD	29	24.3
DDDR	41	33.1

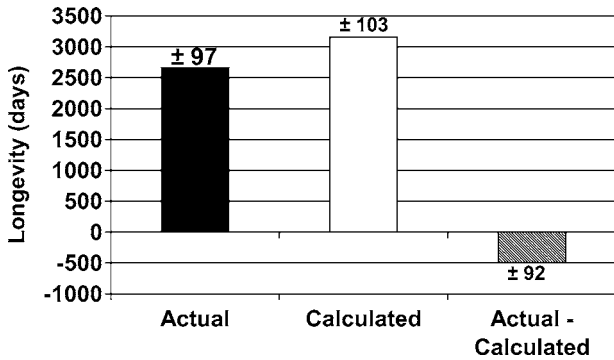


Figure 2. Actual, calculated, and difference between actual and calculated longevity of the explanted pulse generators (n = 124). Mean ± standard errors of the mean are given.

single chamber. The breakdown according to implanted pacing mode was as follows: AAIR = 8 (6.5%), VVI = 11 (8.9%), VVIR = 26 (21.0%), VDD = 9 (7.3%), DDD = 29 (23.4%), and DDDR = 41 (33.1%).

Overall Longevity of Pacemakers

The results for the actual and calculated longevity for the entire sample of 124 patients are summarized in Figure 2. The differences between actual and calculated longevity are also given. The negative value for this difference represents that the pacemaker lasted less than it should have. The mean actual longevity for the group of pacemakers was 2,664 ± 103 days whereas the mean calculated longevity was 3,155 ± 103 days. The mean shortfall in longevity (actual minus calculated longevity) was 491 ± 92 days. There were no significant differences in actual and calculated longevity between males and females (P > 0.05).

Dual- Versus Single-Chamber Devices

Figure 3 shows calculated and actual longevity for dual- and single-chamber devices. The dual-chamber devices lasted a mean of 573 ± 109 days less than expected, whereas the single-chamber devices lasted a mean of 347 ± 165 days less than expected (P > 0.05).

Comparison Between Manufacturers

A review of the differences between manufacturers was also undertaken. Figure 4 demonstrates the frequency distribution (by manufacturer) of pulse generator implants and the frequency distribution of pulse generator replacements due to battery depletion from 1998 to 2003. Guidant (St. Paul, MN, USA) accounted for 56.5% (70) of replacements and 38.6% (581) of the implants; Medtronic accounted for 19.4% (24) of the replacements and 32.7% (493) of the implants; St.

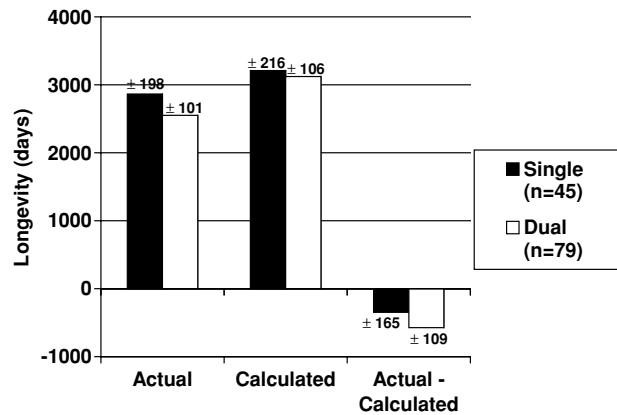


Figure 3. Actual, calculated, and difference between actual and calculated longevity for the explanted pulse generators (n = 124) by single- versus dual-chamber mode. Mean ± standard errors of the mean are given.

Jude (St. Jude Medical Ir) accounted for 18.5% (23) of the replacements and 27.1% (408) of the implants; and Vitatron (St. Paul, MN, USA) accounted for 5.6% (7) of the replacements and 1.7% (25) of the implants.

Figure 5 shows a comparison between manufacturers of actual, calculated, and actual minus calculated longevity. Medtronic pulse generators (n = 24) lasted a mean of 434 ± 268 days more than expected. The mean actual longevity for the other manufacturers were less than the calculated longevity. Guidant pulse generators (n = 70) lasted a mean of 548 ± 61 days less than expected. St. Jude pulse generators (n = 23) lasted 947 ± 246 days less than expected while Vitatron pulse generators (n = 7) lasted 1,595 ± 367 days less than expected. The actual minus calculated longevity for the Medtronic pacemakers was significantly different from all other manufacturers (P < 0.001).

Table II shows the breakdown of pulse generators into families within the four companies studied with corresponding actual, calculated, and shortfalls in longevity (actual minus calculated). As shown, the shortfall in longevity with Guidant and St. Jude pacemakers did not appear to be limited to a single family of units.

“Older” Versus “Newer” Models

Although this distinction is somewhat arbitrary, it was felt that a comparison would be useful. For the purpose of this comparison, the following models were classified as Older models: Spectrax, Legend, Synergyst, Solus, and Cosmos. The rest of the models shown on Table II were classified as Newer models. The cell capacities in Older (n = 17) and Newer (n = 107) models were

PACEMAKER LONGEVITY

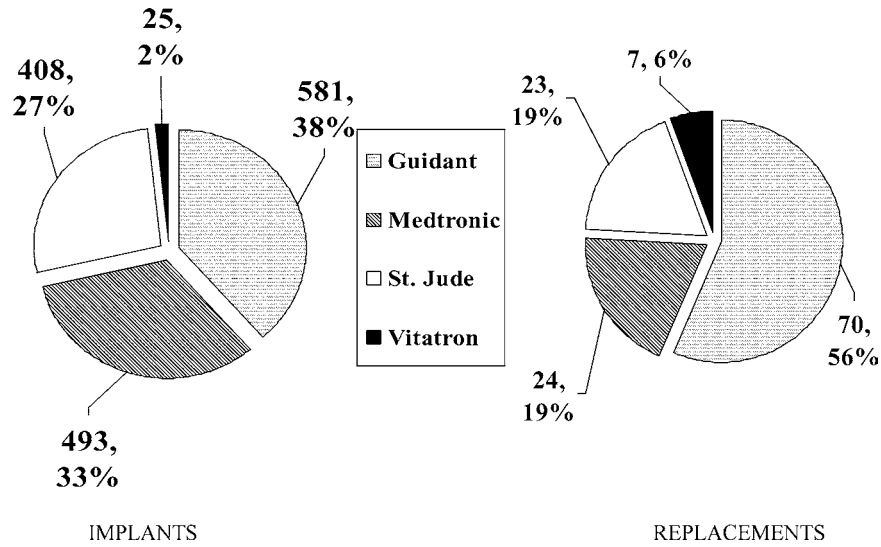


Figure 4. Frequency-distributions of the new pacemaker implants (n = 1,507) and pacemaker replacements (n = 124) between 1998 and 2003 by the different manufacturers.

1.15 ± 0.09 A-h and 1.20 ± 0.02 A-h, respectively (P > 0.05). The mean actual longevity for the Older and Newer models were 3,767 ± 390 days and 2,489 ± 82 days, respectively (P < 0.001). The corresponding calculated longevity were 3,580 ± 390 days and 3,084 ± 102 days, respectively (P > 0.05). The Older models lasted a mean of 184 ± 30 days more than expected while the Newer models lasted 598 ± 91 days less than expected (P = 0.003).

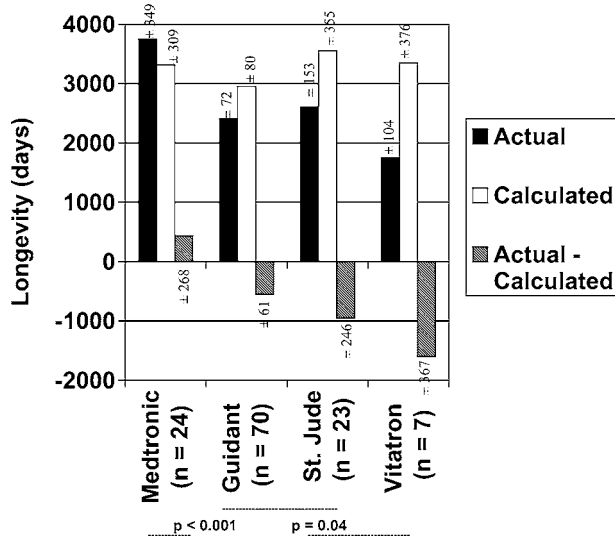


Figure 5. Actual, calculated, and difference between actual and calculated longevity for replaced pacemakers (n = 124) for the different manufacturers. Mean ± standard errors of the mean are given.

A multiple logistic regression analysis was done to determine the variables having an influence on the shortfall in longevity. This demonstrated that the pacemaker manufacturer was the only significant variable to have a significant independent influence (P = 0.003). The standardized coefficient for the regression analysis for the pulse generator manufacturer variable was 0.266. The age, gender, cell capacity, and the mode of pacing did not have any significant influence on the shortfall in longevity. The presence of rate modulation did not have any significant influence on the shortfall.

The duration of time that elapsed between the date of manufacture of the pacemaker and the date of implantation was available for 71 (57.2%) of the implanted units. The mean pre-implant duration was 4.9 ± 0.1 months with no significant differences noted between the manufacturers.

Projected Longevity

The projected longevity provided by the manufacturers are outlined in Table II, citing only the value based on the lower current drain parameters where two projected longevity were provided. This is because the programmed output parameters in clinical practice are usually closer to the lower values although often below this as well. The projected longevity for Guidant and St. Jude Medical are on average lower than that for Medtronic, thus making them appear better in comparison to the actual longevity observed. However, this is solely due to the fact that the projected longevity cited by St. Jude and Guidant are based on higher output parameters compared

Table II.

The Actual, Calculated, and Actual Minus Calculated Longevities of Replaced Pulse Generators According to Pulse Generator Families as Well as Manufacturers' Projected Longevities

	Frequency	Actual	Calculated	Actual – Calc.	Projected	Parameters*
Medtronic	24	3747 ± 349	3313 ± 309	434 ± 268	3883 ± 192	
Elite	8	2805 ± 261	2579 ± 192	227 ± 206	2555–4161	2.5/0.5/500/60/100%
Spectrax	2	6315 ± 296	7267 ± 277	–953 ± 573	5001	2.5/0.5/500/60/100%
Legend	7	4263 ± 604	3533 ± 420	730 ± 644	4088–4782	2.5/0.5/500/60//100%
Minix	1	3407 ± 0	4092 ± 0	–685 ± 0	4453	2.5/0.5/500/60/100%
Symbios	1	5727 ± 0	3168 ± 0	2559 ± 0	2774	2.5/0.5/500/60/100%
Synergyst	1	3083 ± 0	2190 ± 0	893 ± 0	2227	2.5/0.5/500/60/100%
Thera	3	1959 ± 488	2083 ± 291	–124 ± 364	2701–3541	2.5/0.5/500/60/100%
Prodigy	1	6925 ± 0	3913 ± 0	3012 ± 0	3541	2.5/0.5/500/60/100%
Guidant	70	2403 ± 72	2951 ± 80	–548 ± 61	2150 ± 34	
Vigor	15	2097 ± 62	2615 ± 67	–518 ± 44	1643–2190	3.5/0.4/500/60/100%
Vista	2	2845 ± 219	3900 ± 35	–1055 ± 184	1424	3.75/0.5/750/65/100%
Unity	3	2646 ± 262	3818 ± 195	–1172 ± 456	2409	3.5/0.45/500/60/100%
Dash	4	2372 ± 356	2734 ± 544	–362 ± 416	2446	3.5/0.45/500/70/100%
Dart	6	2643 ± 96	3323 ± 73	–680 ± 59	2446	3.5/0.45/500/70/100%
Relay	19	2599 ± 148	3191 ± 159	–592 ± 116	2263	3.5/0.45/500/60/100%
Marathon	7	2081 ± 138	2861 ± 271	–780 ± 180	2300	3.5/0.45/500/60/100%
Discovery	4	1226 ± 136	2027 ± 382	–801 ± 253	1643–2446	3.5/0.4/750/60/100%
Stride	5	2581 ± 103	2678 ± 193	–98 ± 159	2263	3.5/0.45/500/60/100%
Cosmos	3	3192 ± 149	3057 ± 189	134 ± 257	2190	3.5/0.45/500/60/100%
Quantum	2	3237 ± 357	2966 ± 283	270 ± 74	1825	3.5/0.45/500/60/100%
St. Jude	23	2608 ± 153	3556 ± 355	–947 ± 246	2465 ± 96	
Paragon	8	3366 ± 143	5112 ± 455	–1746 ± 445	2811	4.0/0.4/500/70/100%
Trilogy	7	1930 ± 161	2146 ± 264	–216 ± 191	1825–2811	4.0/0.4/500/60/100%
Synchrony	4	2663 ± 290	3898 ± 977	–1236 ± 781	2920	4.0/0.4/500/60/100%
Solus	4	2228 ± 101	2568 ± 125	–340 ± 97	2190	4.0/0.4/500/70/100%
Vitatron	7	1747 ± 104	3342 ± 376	–1595 ± 367	3238 ± 177	
Saphir	7	1747 ± 104	3342 ± 376	–1595 ± 367	2738–3614	2.5–4.0/0.5/500/60/100%

Mean ± standard errors of the mean are given in days.

*Projected longevities were obtained directly from manufacturers and based on the parameters shown as output voltage (in Volts) / pulse duration (in milliseconds) / lead impedance (in ohms)/beats per minute / percent pacing. For a few pacemakers, more than one set of projected longevities were available at different programmed parameters. In such cases, the projected longevity at lower output parameters was reported given that it is closer to clinical practice. A few families have a range in longevities because different pacemakers within the family have different projected longevities. Guidant, Medtronic, and St. Jude Medical stated that their projected longevities are reported at elective replacement indicator whereas Vitatron reports at cell depletion (an interval in between elective replacement indicator and end-of-life).

to Medtronic as evident in Table II. It should also be noted that several of the pacemaker reference guides from some of the manufacturers do not list projected longevities citing that it would result in non-equivalent comparisons between pacemakers due to the variability in parameters used in their calculation.

The mean total current drain for all pacemakers (used in calculated longevity) was $17.9 \pm 0.8 \mu\text{A}$. The mean inhibited current drain was $11.8 \pm 0.4 \mu\text{A}$. As for the manufacturers' projections, a mean projected current drain was also found using the equation for longevity in reverse (i.e., using

the projected longevity and ampere-hour rating of each pacemaker to find a mean projected current drain). This amounted to $20.6 \pm 0.5 \mu\text{A}$.

Discussion

The present study evaluated the clinical impression that current pacemakers seem to have a shorter longevity than ought to be expected given that pacemakers are programmed at levels lower than those used to calculate projected longevities (provided by the manufacturer). As such, rather than relying on projected longevity, which is an estimate on the part of the manufacturer based

on assumed and constant stimulation thresholds, output parameters, and degree of usage by the patient, the expected longevity was calculated. This allowed for a clinically relevant comparison between actual and calculated longevities.

Thus, the design of this study was specifically made with the following goals in mind: (1) to correct for the effects of clinically programmed output parameters (based on stimulation thresholds, pacing dependency, and lead impedance) by including them into the calculation of longevity; (2) to correct for the effects of a patient's physiology and lifestyle by taking into account the effects of mean pacing rates (with rate modulated devices) as well as percent pacing. The results confirmed the clinical impression of a shortfall of 491 ± 92 days in the actual longevity when compared to the calculated longevity. Given the study design outlined above, the difference between actual and calculated longevities was not caused by the individual programmed output characteristics or lead impedance and/or the degree of usage of the pacemaker by the patient as these were specifically accounted for in the calculation (unlike the manufacturers' projected longevities, which have no corrections for these elements); nor was it due to the sensing function of the pacemakers (included in the static or inhibited current drain). Thus, explanations for the shortfall must come from aspects outside of those variables accounted for in the calculation.

The explanations for the shortfall in longevity remain speculative. As one does not, for obvious reasons, wait for complete battery exhaustion prior to replacement, a shortfall in longevity is inevitable.⁴ However, this would not be expected to amount to 491 days (the mean shortfall in longevity observed) based on the information provided by manufacturers for expected battery life longevity at signs of battery depletion in the clinic. Furthermore, the delay of pulse generator replacement (as outlined in the "Methods" section) based on pacemaker dependency of the patient would have resulted in minimizing the influence of this factor although not negating it completely. Though this is a practice that may not be well accepted in North America, delaying pulse generator replacement as is done here appears to be a safe and effective means of extending pulse generator longevity, thereby getting the most out of the devices.

One of the major influences with respect to circuit design is the inclusion of many new ancillary functions (mode switching, storage of electrograms, etc.). It has been suggested that only half of the energy expended by a pacemaker is actually used for pacing while the other half is expended on sensing as well as these other functions.¹ The energy expended to enable these an-

cillary functions was not taken into account in the design of this study as no reliable data could be obtained from the manufacturers (personal communications). Two manufacturers estimated the excess drain for ancillary functions as "minimal" with no comments on an actual value. Another manufacturer's response was that functions such as storage of electrograms should be used only on the short term (presumably implying a not so insignificant drain) but with lack of provision of a numerical value. One manufacturer was able to provide an estimate of the magnitude of the energy drain in the following manner: "if pacing without ancillary features with average thresholds provides a longevity of 119 months, activating all ancillary functions (including electrograms ON) with 100% pacing would result in a longevity of 85 months." Thus, the current drain by these ancillary functions may well be much more significant than generally thought and may be a significant factor in shortening device longevity. However, these ancillary functions may assist in improving patient symptoms as well as in the evaluation and diagnosis of arrhythmias thus contributing positively to overall patient care. Nevertheless, given the results of the present study, it is important to consider each patient on an individual basis to judge the benefits of having the ancillary functions activated in relation to the expected shortfall in longevity. Activating these ancillary functions appears to be often based on "how much more information" the current pulse generators can provide as opposed to the clinical usefulness of the additional functions. This type of approach may be ill advised on many patients. Further, given a situation of clinical need, it may often be possible to turn these functions off after a sufficient interval of diagnostic review and programming management.

Another aspect of the circuit function that was not included in the experimental design was the effect of the pre-implantation current drain. During this period, some energy drain can be expected even though the pulse generator is not attached to leads.⁵ This could be considered similar to the drain observed in an automobile battery even when the terminals are disconnected (battery self-discharge). This energy drain may be part of the reason for the manufacturers' request that pulse generators be returned if not implanted by a pre-specified date although the inability to guarantee sterility may also be a factor. Information was sought from the four manufacturers (associated with the study patients) with regards to the magnitude of the energy loss during this period. The maximum recommended "shelf life" (time from date of manufacture to date of implant) was 12 months for one manufacturer and 18 months for the rest. Two of the manufacturers declined to

provide energy drain values citing the information as being of proprietary nature with one stating that the projected longevity will be reduced by approximately 2 months if implantation occurred at the 18 month "Use before" date. The other two manufacturers estimated the loss of cell capacity at 4 and 18 months of "shelf life" at 25 $\mu\text{A-h}$ and 100 $\mu\text{A-h}$, respectively. Considering an average shelf life of approximately 4.9 months at this institution, the influence on the shortfall in longevity would be expected to be minimal as 27 $\mu\text{A-h}$ (the approximate expected loss based on the above estimate of a 100 $\mu\text{A-h}$ loss at 18 months) would represent only 2.3% of the mean cell capacity of 1.2 A-h for all the pacemakers in the study. Nevertheless, it would be prudent to keep the in-hospital inventories low, thus reducing the pre-implant duration. Thus, this mean pre-implant duration would not be enough to explain for the overall shortfall in longevity of 491 ± 92 days.

Dual- Versus Single-Chamber Devices

Although there was a trend toward a higher shortfall in longevity of dual-chamber units as compared to single-chamber units, the difference did not reach statistical significance. This may have simply been due to a small sample size. This may point toward the possibility that dual-chamber devices are somehow less efficient than single-chamber devices. Another factor may be that dual-chamber devices tend to be significantly more complex both in terms of engineering as well as in terms of the programmable ancillary functions within the device. The difference is not explained by the presence of two leads as this was accounted for in the calculated longevity.

Older Versus Newer Devices

The study suggests that Older devices fared better than Newer devices with regards to longevity although the authors accept the limitation that the division is somewhat arbitrary and done *post hoc*. Furthermore, the assumption of 100% pacing whenever the percent pacing parameter was not available (more likely in Older devices) could have led to a bias favoring Older devices. Nevertheless, lower than anticipated longevity with Newer devices is the clinical impression in many pacemaker clinics and this was an impetus to consider the study. The availability of many more ancillary functions in newer devices could account for this difference.

Differences Between Manufacturers

Medtronic pacemakers lasted longer than expected whereas all the others demonstrated a shortfall in longevity: Guidant was the next best, then St. Jude, and finally Vitatron. Although last-

ing beyond a calculated value could be considered as not possible from a pure physics point of view, there are possible explanations. The cell capacity provided by the manufacturers (and used for the calculations) was the estimated available cell capacity as opposed to the total cell capacity. The estimated available cell capacity may be conservative and the battery may function beyond the calculated longevity. In addition, as noted in the Methods, whenever the percent pacing parameter was not available in the chart, 100% pacing was assumed for the calculation. This could also lead to a pacemaker lasting longer than the calculated longevity. The better results observed with Medtronic pacemakers paralleled the clinical impression of increased longevity observed with this manufacturer. Further support for this is provided by the discrepancy in the frequency distribution of the implanted versus replaced pacemakers during the same time period (Fig. 4). Although Medtronic pacemakers accounted for 32.7% of the implants, they accounted for only 19.4% of the replacements. The shortfall in longevity with St. Jude Medical and Guidant devices was not limited to one family of pacemakers (Table II). In particular, families that had given the impression of early battery depletion in practice (e.g., Vigor family from Guidant, Trilogy family from St. Jude) were not the primary causes for the shortfalls in longevity. These two families of pacemakers had a shorter calculated longevity with the shortfall in longevity being less than that observed with other families from the same manufacturer. With regards to the Vitatron devices, there were only seven pacemakers belonging to one "family" (Saphir) in the present study. Given the low number, less reliance could be placed on the large shortfall in longevity. Other factors could also have contributed. The company has subsequently disseminated information that the replacement indicators for their devices are in three phases (as opposed to the customary two phases): intensified follow-up indicator, elective replacement indicator, and end-of-life indicator. However, this information was not made available to us at the time of replacement of these devices. This additional phase coupled with the fact that all seven patients who had the Saphir VDD(R) device implanted had third-degree heart block with Class 4 dependency could have possibly led to a somewhat pre-mature replacement. Nevertheless, the relatively large shortfall in longevity would not be totally accounted for by these factors alone. In addition, there were no comments made by the manufacturer following the factory analysis of the returned explanted devices with regards to pre-mature replacement. This was the case with all the manufacturers where no feedback was received commenting on

pre-mature explantation during the entire period of the study.

Although the results parallel the clinical impression, one cannot exclude that the differences between manufacturers could have been due to differences in the reporting of available versus total cell capacity. In addition, a particularly "good" or "bad" period with regards to one or more manufacturers could also have played a role. A larger sample size would be beneficial in confirming these differences between manufacturers.

Projected Longevity

The clinical relevance of manufacturers' projected longevity is questionable given the assumed output voltages, pulse durations, and percent pacing, which are in the majority of instances higher than programmed in clinical practice while the impedances are lower. Thus, actual clinical circumstances should result in the longevity being greater than that projected by the manufacturers based on their own calculations. The present study confirmed the significantly lower mean calculated current drain (based on the programmed values at clinic visits) compared to the mean projected current drains. Another flaw in the projected longevity is the assumption that the pacing parameters are constant over the lifetime of a pacemaker, which is never the case. In addition, as there does not seem to be an industry standard for reporting, it is even difficult to compare between pacemakers. Regarding a comparison between manufacturers, Guidant and St. Jude Medical performed best in comparison to their projected longevity. However, this is simply due to the assumption of higher programmed parameters in their calculations (see Table II) resulting in a shorter projected longevity that could mask a shortfall in longevity when the pacemakers are programmed at lower levels. In summary, the clinical relevance of these projections must be questioned, and little importance paid to them as no relevant information can be gained from them. In this regard, many current generation pacemakers are an advancement providing a better projection of longevity based on the ongoing-programmed parameters as well as the battery loss to date. This current system of "projections" is very much equivalent to what was done in finding the calculated longevity in the present study.

Suggestions for Increasing Longevity

Though the programmed parameters were taken into account by the design of this study, it is clear that high-programmed outputs would result in an overall decrease in longevity (both calculated and actual). Thus, it is possible to increase device longevity by setting the programmed parameters at

levels closer to threshold based on the pacing dependency of each patient.⁶ New features such as automated stimulation threshold evaluation with adjustments of outputs would also be helpful.^{7,8} Moreover, since current is inversely proportional to resistance according to Ohm's Law ($I = V/R$), it has been suggested that the use of high impedance leads would produce a clinically relevant increase in longevity.⁹

The industry may also need to resist pressure to continue to decrease pulse generator size for cosmetic reasons whenever a concomitant decrease in cell capacity would be expected. Although a substantial decrease in size compared to the first generation of devices was clearly desirable, the pendulum might have swung a little too far for a perceived cosmetic need.

Other suggestions for increasing longevity include reducing on-shelf time, thereby lessening the impact of any pre-implant drain. Moreover, it is possible to safely extend the life beyond Elective Replacement Indicator with increased surveillance of a substantial proportion of patients. Of course, the other factor that will help to increase longevity would be the careful evaluation of the need for long-term activation of the ancillary functions of pacemakers.

The present study is limited by the retrospective nature of the study design and data collection which can introduce bias as well a slightly higher likelihood of imprecision in the data. However, the data itself had been collected from the time of pulse generator implantation through the clinic visits to the time of explantation in a prospective manner and entered into the Paceart and SPSS data bases. In spite of these limitations, it is believed that the present study investigates an important issue that has been hitherto neglected. A prospective study to confirm the findings would be desirable.

Conclusions

Overall, pulse generators appear to have a shorter than expected longevity. It is necessary that the industry attempt to explain the discrepancies and correct them. This is especially important given that there is a direct effect to patients as well as the Health Care System.¹⁰ Repeat surgery has a small but definite risk to the patient including a slightly higher risk of infection with dire consequences. Furthermore, there is an additional cost to Health Care Systems. The results of the study show that the most probable origins of the shortfall are the energy drain from ancillary functions as well as pre-implant drain. It is of interest that since the completion of the study several advisories have surfaced from more than one manufacturer with regards to premature unexpected, excessive battery

depletion with selected families of devices. The results of the present study in essence highlight the same, i.e., sooner than expected battery depletion. However, the present study suggests that it

is a more widespread issue which is not necessarily restricted to a few families of devices. Preliminary reports of this study have been presented previously.^{11,12}

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