



1st Invitational Workshop on
Body Area Network Technology and Applications
Future Directions, Technologies, Standards and Applications
June 19-20, 2011
Worcester Polytechnic Institute

An Overview of the Medical Device Radiocommunications Service (MedRadio) and Future Telemetry Considerations

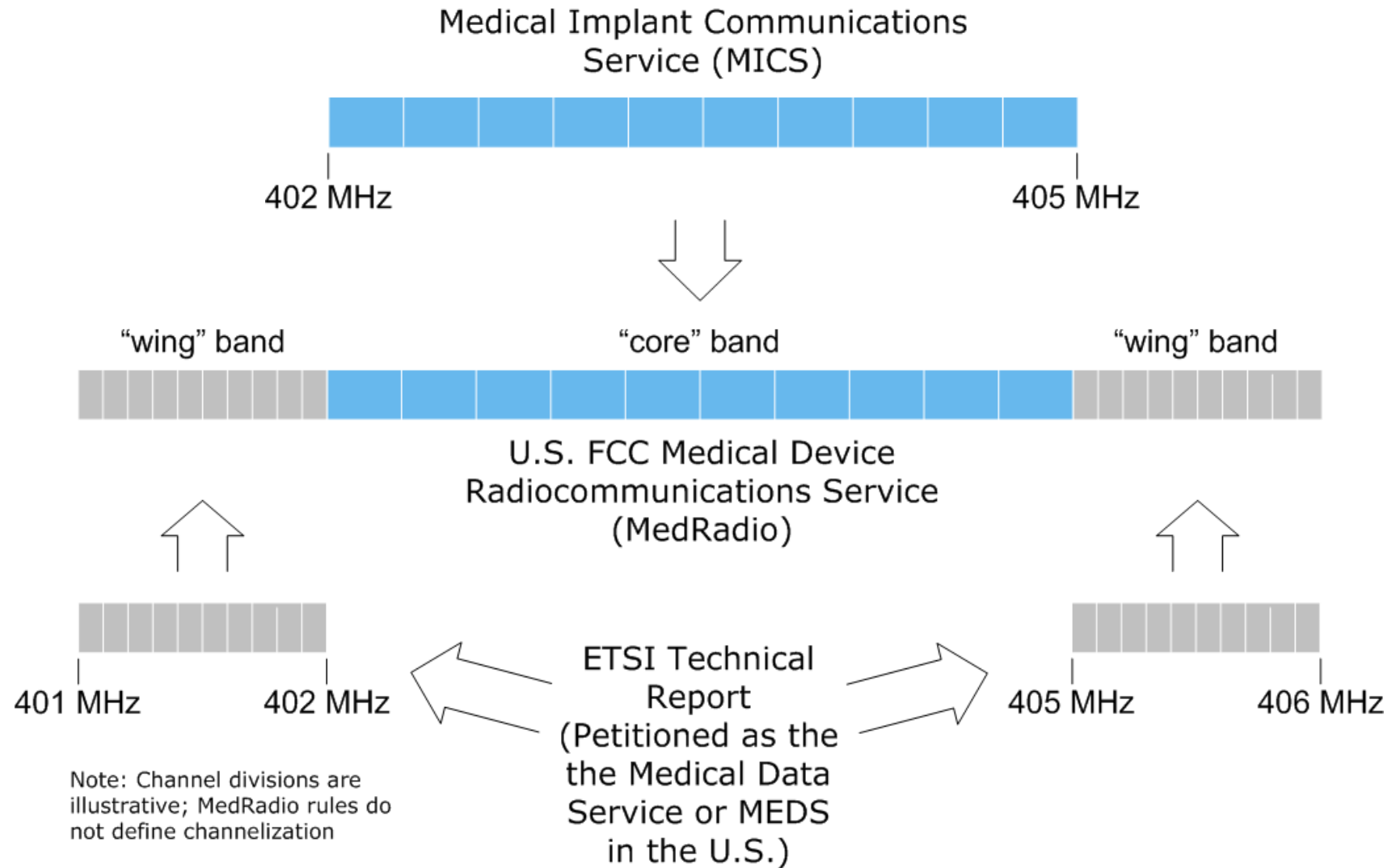
Prepared for:
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Agenda

- Overview of FCC MedRadio rules
 - Historical context
 - Unique attributes
- Future telemetry considerations

MedRadio (401-406 MHz) introduction



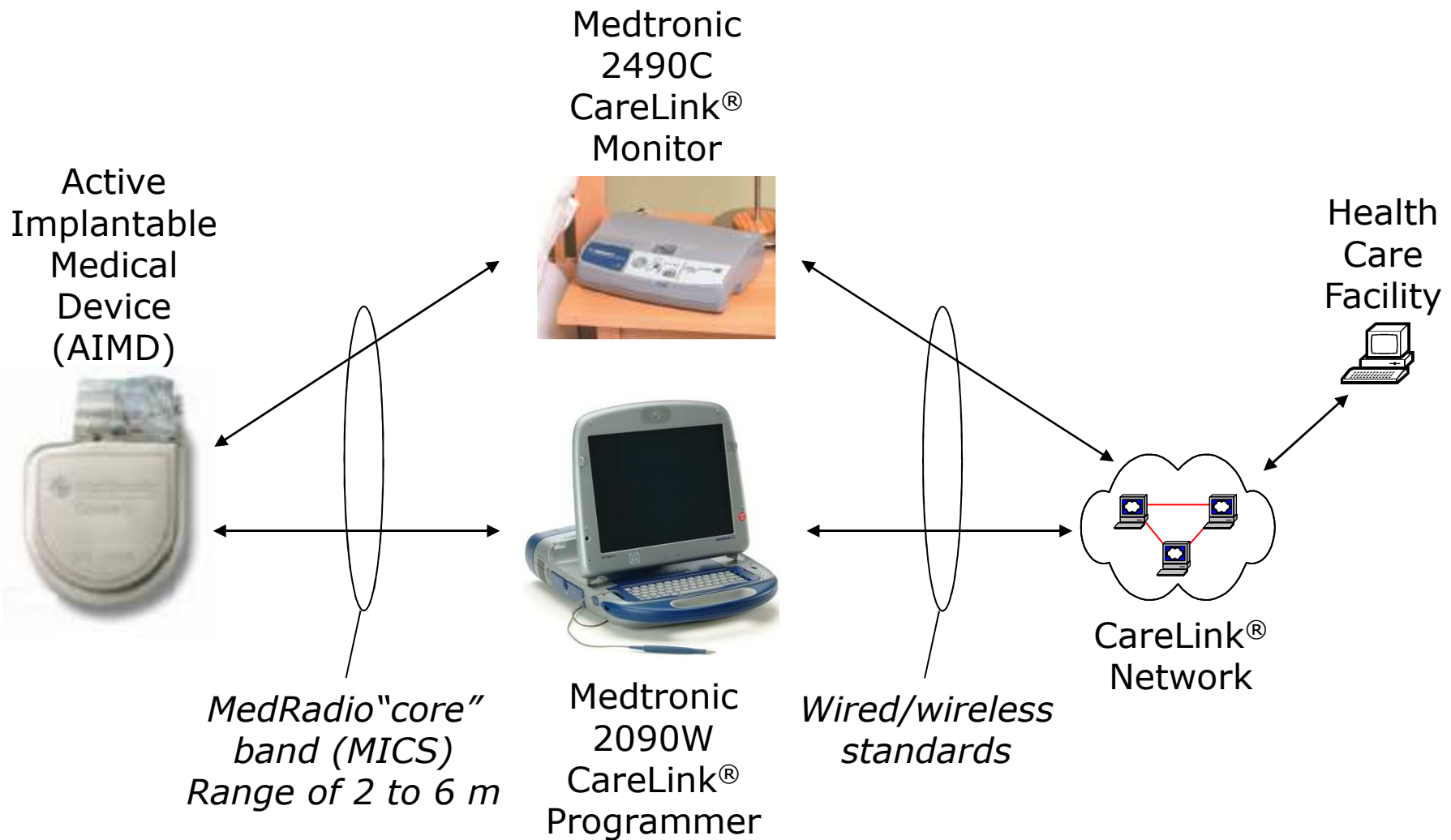
What happened to MICS in the U.S.?

- MedRadio “core” band (402-405 MHz) rules are essentially unchanged from prior MICS rules
- “MedRadio” is an FCC term
 - All other countries refer to the “core” band as MICS, “wing” bands as MEDS
 - Medtronic will continue to advocate MICS and MEDS as separate bands worldwide

MedRadio vs. prior MICS rules

MedRadio Part 95 paragraph	Description	Same as MICS?
95.1201 Eligibility	Licensed by rule operation: "Operation in the MedRadio service is permitted by rule and without an individual license issued by the FCC ..."	Yes
95.1201 Eligibility	Supervisory requirements: "... at the direction of a duly authorized health care professional ..."	Yes
95.631(h) Emission types	"... Voice communications, however, are prohibited."	Yes
1.1307(b)(2) Actions that may have a significant environmental ...	RF exposure compliance showing: "... prior to equipment authorization, ... by finite difference time domain computational modeling or laboratory measurement techniques ..."	Yes

Medtronic Conexus[®] Wireless Telemetry System – “core” band



MedRadio “wing” band evolution

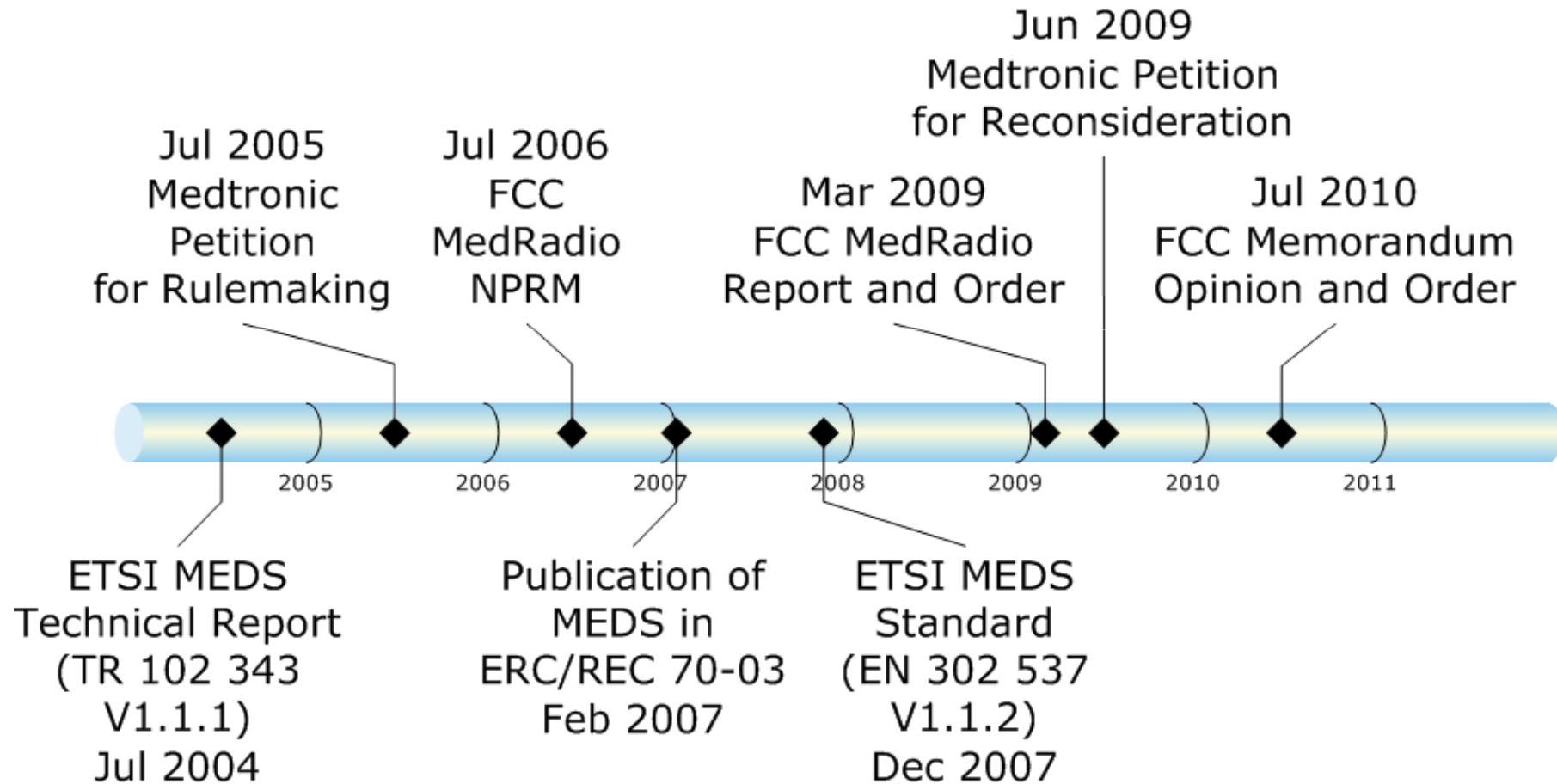
- In 2004, two new medical communication needs were identified for the 401-402/405-406 MHz band
 - External-to-external communication
 - Miniaturized transmit-only devices
- Effort began in Europe

ETSI TR 102 343 V1.1.1 (2004-07)

Technical Report

**Electromagnetic compatibility
and Radio spectrum Matters (ERM);
Ultra Low Power Active Medical Implants (ULP-AMI)
operating in the 401 MHz to 402 MHz
and 405 MHz to 406 MHz bands;
System Reference Document**

MedRadio "wing" band evolution



Significant new MedRadio definitions¹

- *MedRadio programmer/control transmitter.* A MedRadio transmitter that operates or is designed to operate outside of a human body for the purpose of communicating with ... medical implant device or to a medical body-worn device ...
- *Medical body-worn device.* Apparatus that is placed on or in close proximity to the human body (e.g., within a few centimeters) for the purpose of performing diagnostic or therapeutic functions.

¹Appendix 1 to Subpart E of Part 95 – Glossary of Terms

MedRadio regulations summary – fundamental RF parameters

Parameter/use	MedRadio "core" band	MedRadio "wing" bands
Frequency	402-405 MHz	401-402/405-406 MHz
Maximum emission bandwidth	300 kHz	401-401.85/405-406 MHz: 100 kHz 401.85-402 MHz: 150 kHz
Maximum freq. tolerance	+/-100 ppm	+/-100 ppm
Communication with medical implant devices?	Yes	Yes
Communication with medical body-worn devices?	No (except under rules for temporary operation)	Yes

MedRadio regulations summary – spectrum access/radiated power

Access technique	MedRadio "core" band	MedRadio "wing" bands
Listen Before Talk/Least Interfered Channel (LBT/LIC)	$\leq 25 \text{ uW EIRP}$	$\leq 25 \text{ uW EIRP}$
Medical Implant Event	$\leq 25 \text{ uW EIRP}$	$\leq 25 \text{ uW EIRP}$
Low Power Low Duty Cycle (LPLDC)	403.5-403.8 MHz only: $\leq 100 \text{ nW EIRP}$ $\leq .01\% \text{ duty cycle/hour}$ $\leq 10 \text{ transmissions/hour}$	401-401.85/405-406 MHz: $\leq 250 \text{ nW EIRP}$ 401.85-402 MHz: $\leq 25 \text{ uW EIRP}$ $\leq .1\% \text{ duty cycle/hour}$ $\leq 100 \text{ transmissions/hour}$

MedRadio summary

- The MedRadio “core” band (402-405 MHz) will continue to support implantable medical device use conditions
 - Implant procedure
 - Wireless follow-up
 - Remote monitoring



MedRadio summary

- MedRadio “wing” bands address emerging medical device communication needs
 - Permits communication with medical body-worn devices
 - LPLDC provisions accommodate miniaturized devices and sensors





Future telemetry considerations

Innovation

1 MRI Safe ICD/CRT

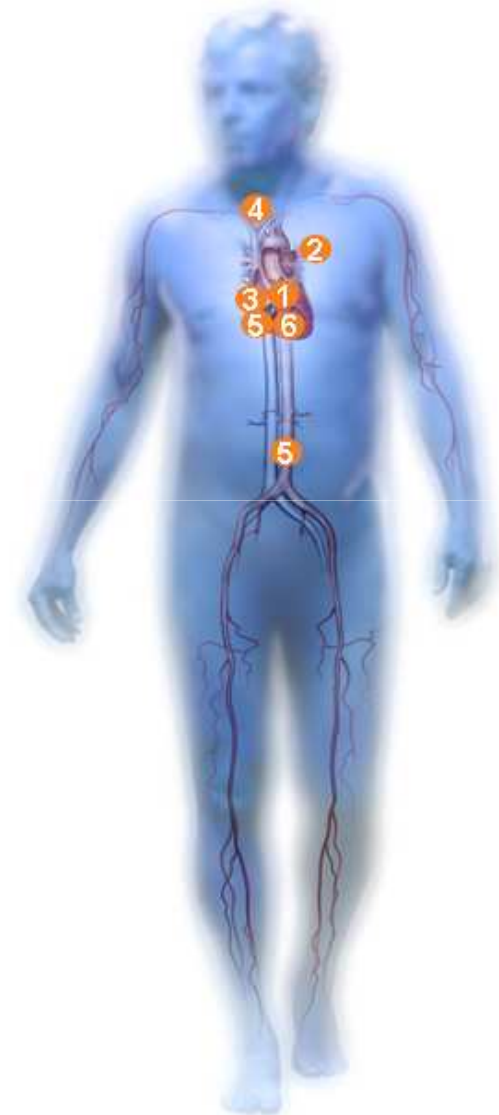
2 Injectable Reveal

3 Reduced Size CRT/ICD w/ Remote Programming

4 ALPS

5 Autonomic Modulation

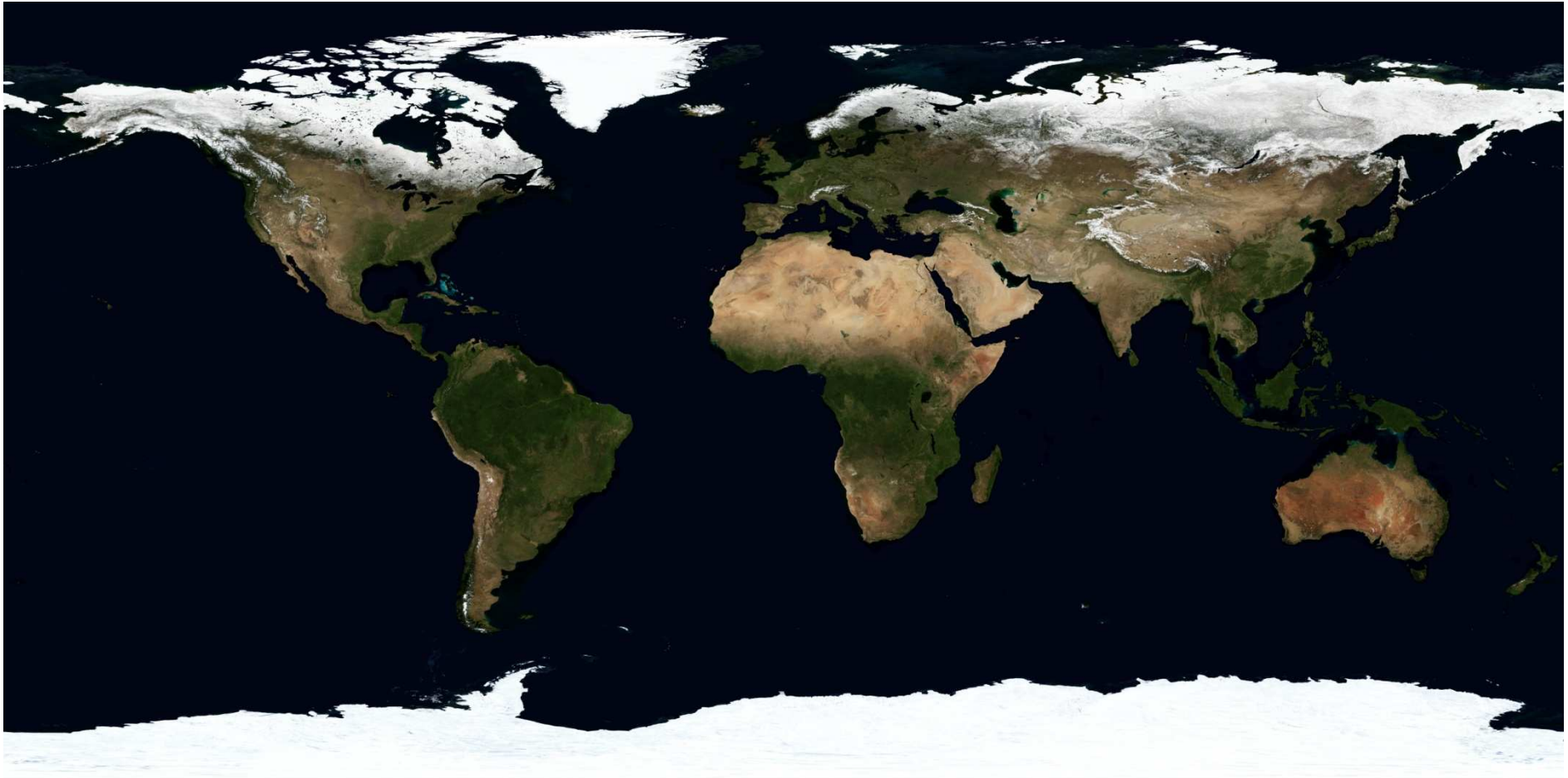
6 Leadless Pacemaker



Trends and needs

- Device miniaturization
- Remote monitoring and programming
- Conventional batteries → in-body thermal, chemical, and kinetic sources
- Ultra low leakage current semiconductor technologies
- Data analytics
 - Physicians want actionable information

A global view





Thank you