

**Neurizon Database  
Examples of data analysis**

**2019**



## Background

Registries of medical implants are lacking and presently in public demand due to shortage of implant performance monitoring.

Accordingly, the documentation for implant treatment effect, implant longevity, electrode durability, implant-related complications etc. is lagging behind, despite the fact that neuromodulation implants have been marketed for decades.

The Neurizon Neuromodulation Database is a user-friendly, generic, international neuromodulation database system that tracks the patients from the pre-implant and clinical visits, during the implant procedure, and during follow-up. To our knowledge it is the only one of its kind that offers treatment monitoring and data comparison across borders and across treatment modalities.

The concept of the database is:

- A database that tracks implant use, independent of manufacturer and implant type.
- A cloud-based database software independent of computer platform.
- Secure, encrypted, GDPR compliant database globally accessible via the internet.
- Encrypted data storage and full safety of data in the cloud.
- Legally approved by the national authorities in Denmark
- Each treatment center / country responsible for data safety, legal approval and control of own data and database access.
- The data structure in all database mirrors is generic and directly compatible for all who use the database. This lays all the framework for national and international comparative studies on the use of neuromodulation implants.

A multinational, generic database is the only way to amass sufficient, high-quality data for real-life monitoring and analysis of treatment effect and safety. The data in a large, continually used registry will provide solid documentation for these all-important factors, increasing awareness of neuromodulation therapies among patients and decision makers.

This is a crucial step not only in ensuring the continued support of neuromodulation treatments from authorities and insurance companies but also to increase penetrance of the therapies.

Recently, the Neurizon Neuromodulation Database has been approved by the German TÜV regulatory body as a tool for mandatory post-market surveillance of a new lead for Occipital Nerve Stimulation.

## Example of data reports

The data report below is an example of some of the data that can be extracted and analyzed from the Neurizon Neuromodulation Database.

The report contains both local and multicenter data from Denmark

Thanks to the structured data output of the database, the data analyses are immediately applicable to larger datasets.

IPG manufacturer: Market share (stacked bars)

*Data from Aarhus, Aalborg, and Odense University Hospitals 2015-2016*

IPGs replaced by IPG from a different manufacturer (table)

*Data from Aarhus, Aalborg, and Odense University Hospitals 2012-2016*

Implanted IPGs: Model (pie chart)

*Data from Aarhus University Hospital 2015*

Basic demographic data for patients receiving an IPG (table)

*Data from Aarhus University Hospital 2015*

IPG geographical distribution: Implanted IPGs per municipality (map)

*Data from Aarhus, Aalborg, and Odense University Hospitals 2015-2016*

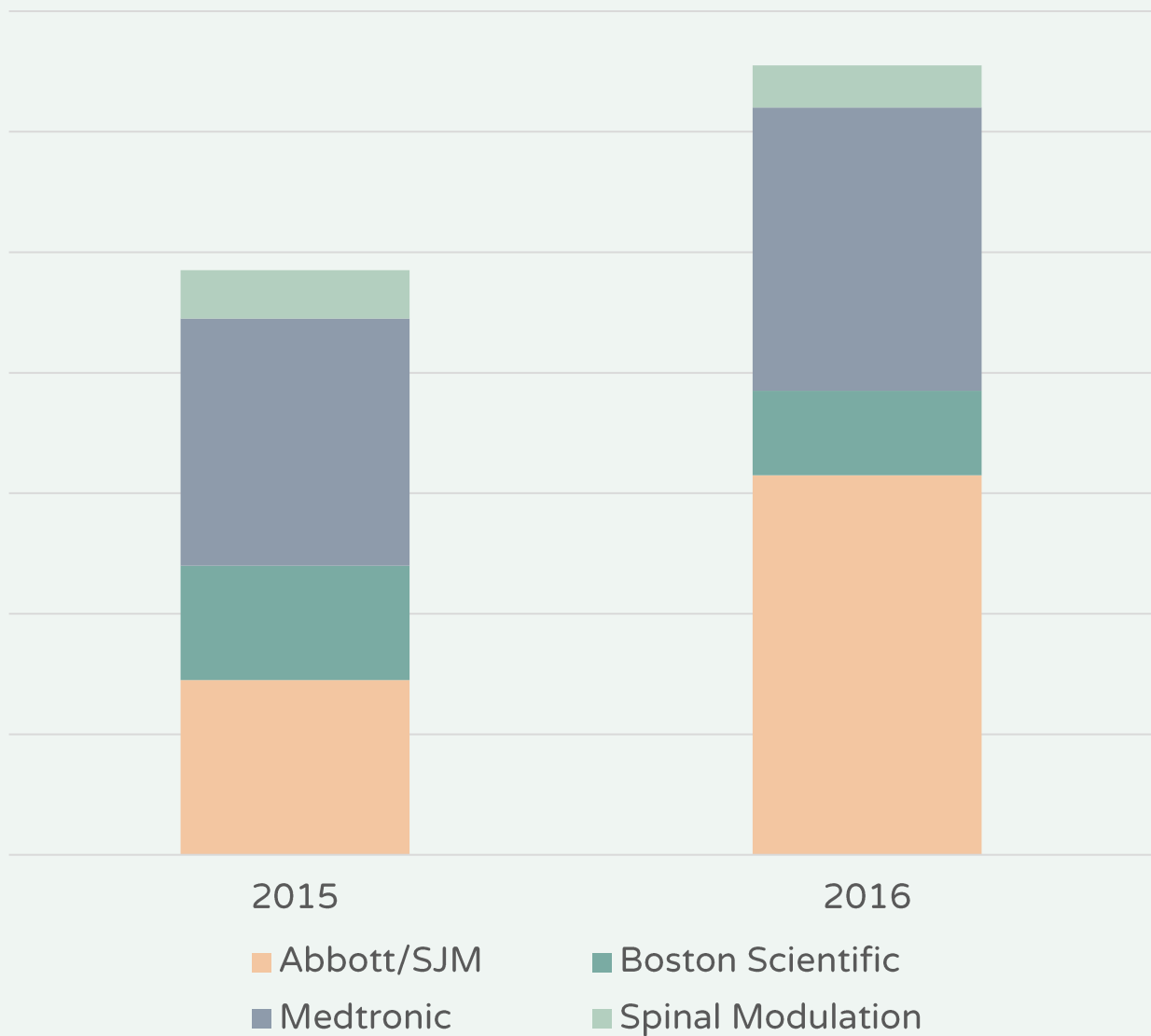
IPG explants: Registered reasons for explantation (pie chart)

*Data from Aarhus, Aalborg, and Odense University Hospitals 2015-2016*

Implanted IPGs per year: Replacement vs new implants (stacked bars)

*Data from Aarhus University Hospital 2012-2016*

## Market Share



Market share of 4 manufacturers of neuromodulation implants.  
 Data are from 2015 and 2016 from Aarhus, Aalborg, and Odense University  
 Hospitals, Denmark.  
 Market share is calculated based on number of implanted IPGs.

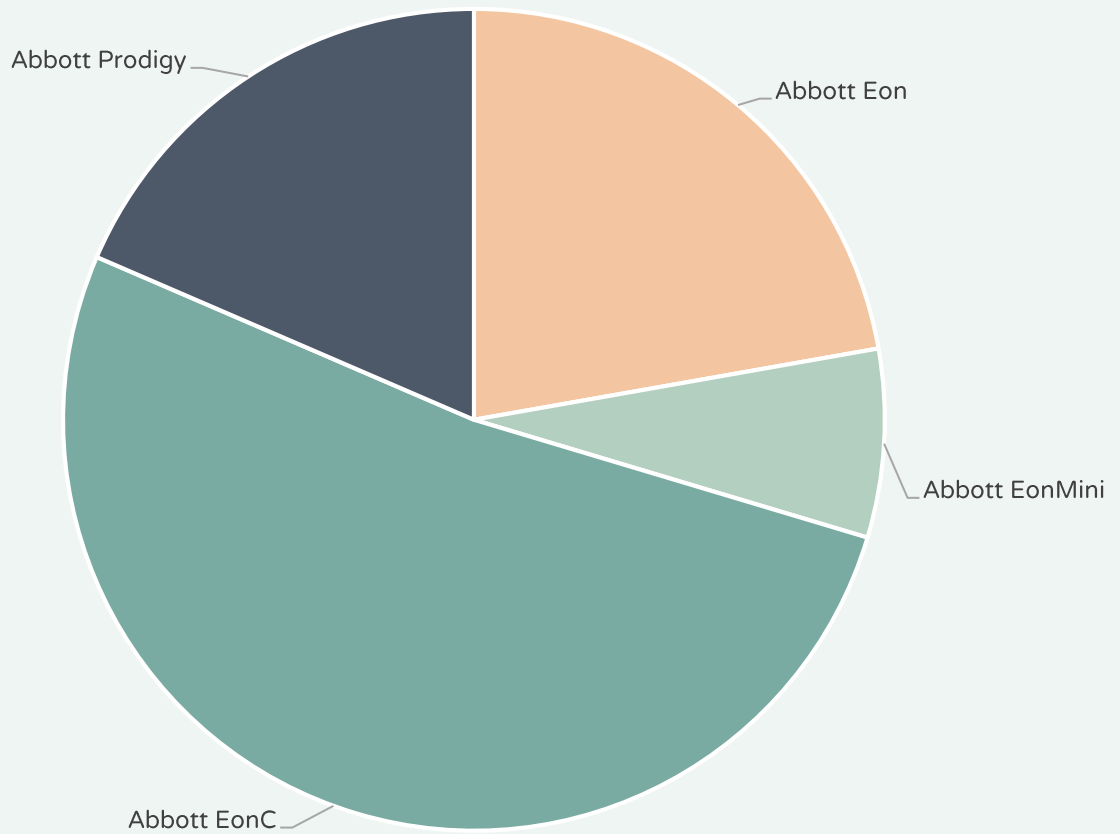
Abbott to Boston Scientific	1
Abbott to Medtronic	1
Medtronic to Abbott	5
Medtronic to Boston Scientific	1
Medtronic to Spinal Modulation	1
Spinal Modulation to Boston Scientific	1

IPGs replaced by IPG from a different manufacturer.  
*Data from Aarhus, Aalborg, and Odense University Hospitals 2012-2016.*

<b>Gender</b>	Male: 63%	Female: 37%
<b>Age</b>	Mean: 51.2y	sd: 12.5
<b>SCS treatment duration</b>	Mean: 2.7y	sd: 2.8
<b>New vs replacement</b>	New: 41%	Replacement: 59%

*Basic demographic data for patients receiving an IPG at a single center in a single year.*  
*Data from Aarhus University Hospital 2015.*

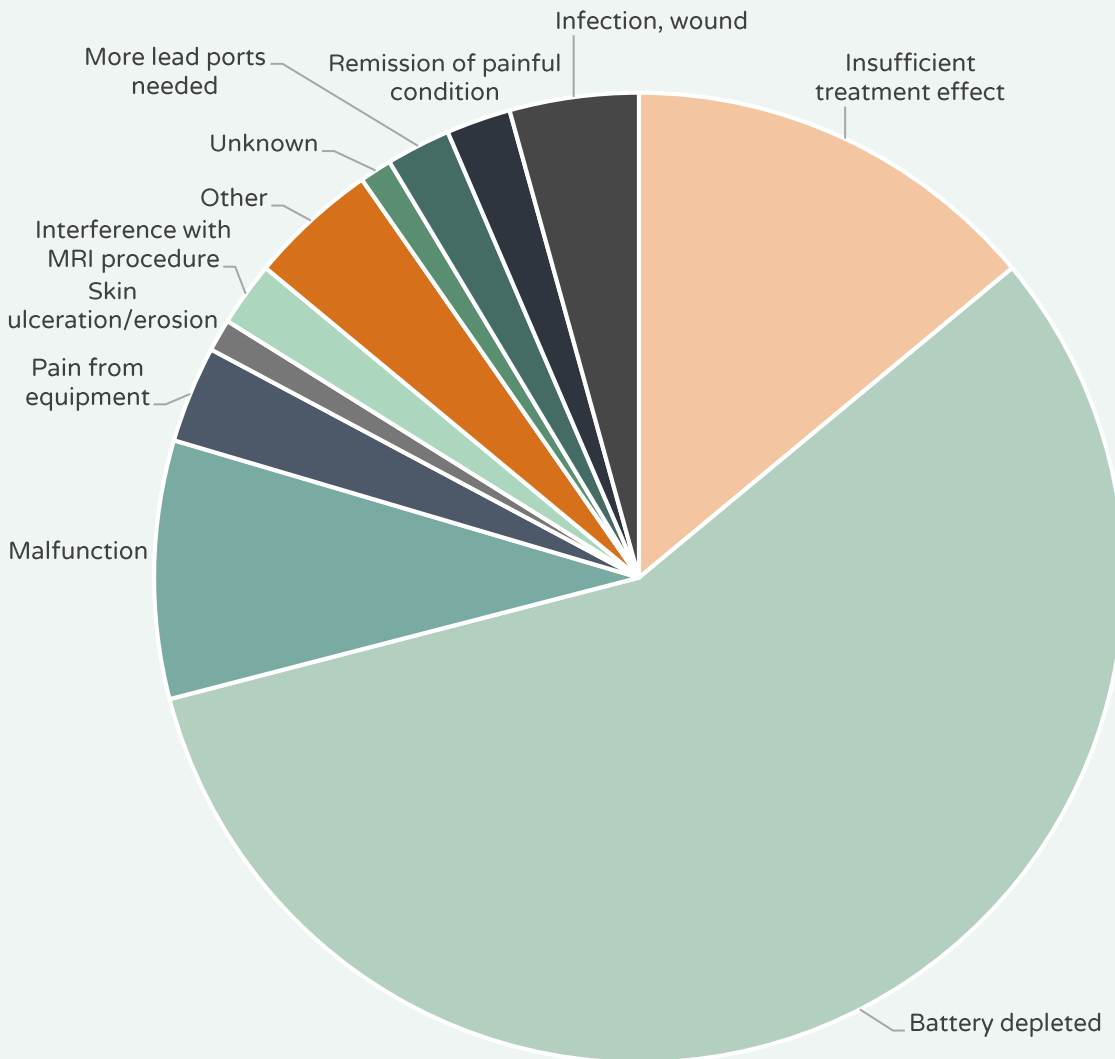
## IPG model



*Distribution of implanted IPGs at a single year in a single center.  
Data from Aarhus University Hospital 2015.*



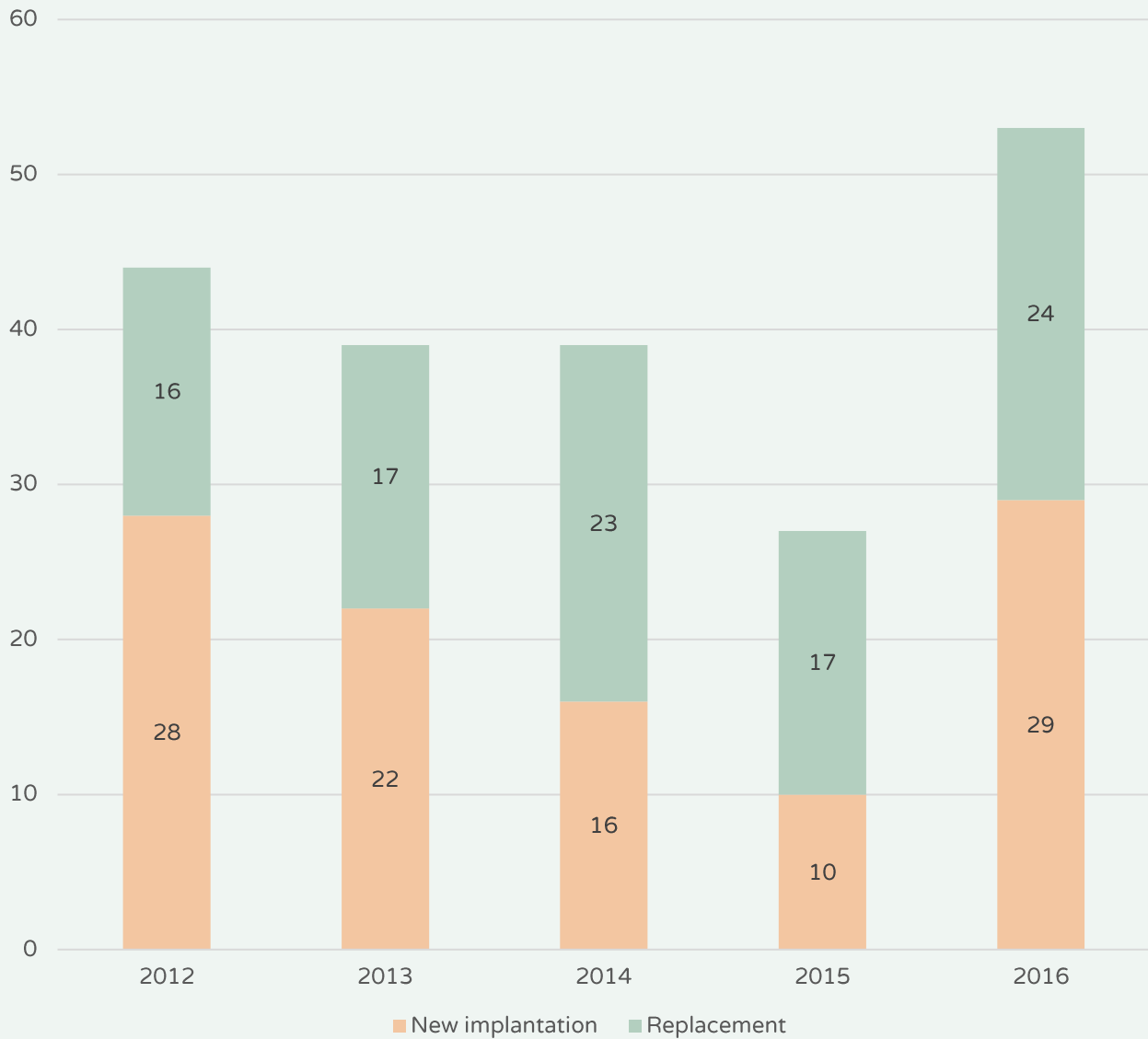
### IPG Explantations, reasons



IPG explants: Registered reasons for explantation.  
*Data from Aarhus, Aalborg, and Odense University Hospitals 2015-2016.*



### IPG implantations, reasons



IPG implants: Registered reasons for implantations at a single center.  
*Data from Aarhus University Hospital 2012-2016.*

## Appendix I: Neurizon Board and CXOs

### *CEO*

Kaare Meier, MD PhD

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Staff specialist, Dept. of Neurosurgery, Aarhus University Hospital

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### *COO*

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### *CTO*

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Jens Chr. Hedemann Sørensen, MD PhD DMSc

Clinical professor, Dept. of Neurosurgery, Aarhus University Hospital

Vice Chair of Research, Department of Clinical Medicine, Aarhus University

## Appendix II: Neurizon Neuromodulation Database Additional information

Neurizon web page:  
<http://neurizon.org/>

Neurizon Neuromodulation Database tutorials:  
<http://neurizon.org/tutorials/>

Neurizon Neuromodulation Database FAQ:  
<http://neurizon.org/faq/>

Server host:  
NIANet  
<https://nianet.dk/om-nianet/uk>

Database documentation:  
*Meier K et al.: The Aarhus Neuromodulation Database; Neuromodulation. 2013 Nov-Dec;16(6):506-13*  
<https://www.ncbi.nlm.nih.gov/pubmed/22882331>

Danish Data Protection Agency file:  
2013-41-2667

## Appendix III: GDPR at Neurizon

The new European General Data Protection Regulation (GDPR) includes changes to existing protection and privacy laws, including extended notification duty and increased responsibility for handling and processing data, as well as enhanced individual rights to access personal data, e.g. the individual's "right to be removed" etc.

Neurizon have implemented the required changes to our systems, processes and policies needed to comply with the GDPR requirements.

Neurizon will refer any requests regarding personal data in Neurizon Neuromodulation Databases to the responsible care givers.

For more information, please contact us: [info@neurizon.org](mailto:info@neurizon.org)

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