Danish Pacemaker and ICD Register
Annual Report
2017-2018

Preface

The Danish Pacemaker Register was founded in 1982 by physicians from all Danish hospitals where pacemakers were implanted. When the first implantable cardioverter defibrillator (ICD) was implanted in 1989, these devices were also included in the register as well as cardiac resynchronization therapy pacemakers and ICDs (CRT-P and CRT-D). The register have since the very start in 1982 recorded details on implant and explant including hardware and survival status of the patients and an annual report have been published. The register holds data on 110350 pacemaker- and 20780 ICD implants as of 31. December 2018.

Data collection and reporting have since 2007 been based on online reporting from all the implanting hospitals. The last printed annual report was issued in 2012, but despite that all data are accessible online, there is still a need for a commented report, which this collection of data represents.

In the past, the annual report was based on a calendar year. The quality data on infection requires 365 days of follow-up, hence the report was published a later to allow for sufficient follow-up time. This is changed in the current report, so this report contains data predominantly from 2018, but the data on infection is derived from 2017. This reorganizing of the report has delayed the current report, and still the main quality indicators require 120 days of follow-up. Therefore the 2019 report should be ready May/June 2020, and will thus contain implant data from 2019 including quality indicators, expect for surgical site infection, which will be the 2018 data.

Odense, December, 2019

On behalf of the steering committee

Jens Brock Johansen

Address

Danish Pacemaker and ICD Register

Department of Cardiology B | Odense University Hospital | DK 5000 Odense C |Denmark

www.icddata.dk | support@icddata.dk

Content

1 Introduction

1.1 Organisation

The register has previously been a private research database, but is now an official clinical quality database and part of the Danish Clinical Registries (RKKP). The steering committee consists of a physician from all implanting hospitals and is rooted in the Danish Society of Cardiology working group for cardiac arrhythmias and device treatment. The daily management of the register is located at Department of Cardiology, Odense University Hospital, by physician Ole Dan Jørgensen (management and development of database), nurse-technician Lisbeth Skov Nielsen (data entry and support), engineer Roy Guldberg (issuing pacemaker ID cards) and physician Jens Brock Johansen (chairman).

The steering committee consists of (as of December 2019):

- Søren Højbjerg, Bispebjerg Hospital, Copenhagen
- Ulrik Hintze, South-West Jutland Hospital, Esbjerg
- Jens Harboe, Gentofte Hospital, Copenhagen
- Jerzy Malczinsky, Regional Hospital West Jutland, Herning
- Michael Dilou, Nordsjællands Hospital, Hillerød
- Jens Brock Johansen, Odense University Hospital, Odense
- Berit Philbert, Rigshospitalet, Copenhagen
- Thomas Melchior, Roskilde Hospital, Roskilde
- Thomas Fischer, Hospital Little Belt, Vejle
- Per Dahl Christensen, Regional Hospital of Viborg, Viborg
- Lene Svendstrup, South Jutland Hospital, Aabenraa
- Sam Riahi, Aalborg University Hospital, Ålborg
- Jens Cosedis Nielsen, Aarhus University Hospital, Aarhus.

All device manufacturers on the Danish market funds the activities of the register by a fee for each sold device and lead, and they have access to aggregated anonymous data in the register.

Data are entered online by the treating physician at implant and explant. Survival status is checked in the civil registration system and users have access to all data in a web based format at the URL address www.icddata.dk. Data is also provided for research purposes after approval of the steering committee and The Danish Clinical Registries (RKKP).

1.2 Comments on implant activity in Denmark 2018

Pacemaker and ICD implantation in Denmark is done in 14 public hospitals and one private hospital (Mølholm).

Institution	Pacemaker	CRT-P	ICD (VVI/DDD)	CRT-D	Lead extraction	Pediatrics GUCH
Bispebjerg	X					
Esbjerg	X					
Gentofte	X	X	X	X		
Herning	X					
Hillerød	X					
Nuuk	X*					
Odense	X	X	X	X	X	
Rigshospitalet	X	X	X	X	X	X
Roskilde	X		X			
Mølholm	X					
Vejle	X					
Viborg	X					
Aabenraa	X					
Ålborg	X	X	X	X	X	
Aarhus	X	X	X	X	X	

Table 1.1 Pacemaker and ICD implantation in Danish hospitals 2018
*Only VVI pacemakers.

The vast majority of institutions were high volume centers except for Nuuk and Mølholm. The intention is to aim for at least 50 device implants per year per operator.

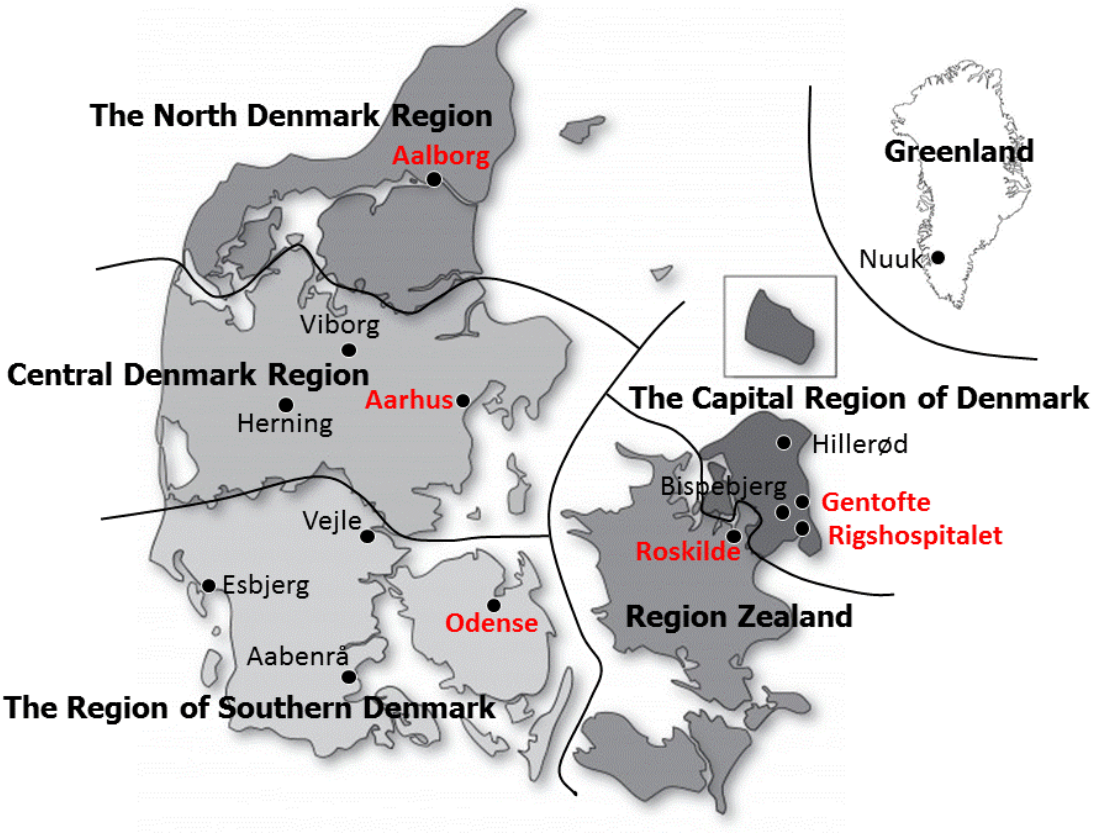

Figure 1.1 Device Implanting hospitals in Denmark

1.2.1 Pacemaker

The majority of first pacemaker implants was dual chamber (n=3050, 70.6%) and about one quarter was single chamber right ventricle pacemakers (n=1055, 24.4%). An increasing number (n=89) compared to 2015 and 2016, of the single chamber right ventricle were lead-less Micra pacemakers. Biventricular pacemakers were implanted in a smaller percentage (n=205, 4.7%) and an even smaller number (n=10, 0.2%) were single chamber atrial pacemakers (See table 2.1).
The pacemaker replacements and system up-/downgrades took up 11.0% of the total number of implants in 2016 (See table 2.2 and table 2.3).

1.2.2 ICD

The predominant pacing mode in first ICD implants was VVI (n=752, 65.9%) while DDD (n=148, 13.0%) and CRT-D (n=241, 21.2%) was only used in a smaller number. Total subcutaneous ICD was implanted in 12 cases (See table 2.4).

The ICD replacements and system up-/downgrades took up 43.5% of the total number of ICD implants in 2018 (See table 2.5 and table 2.6), which is an increase compared to previous years.

The indication for first ICD implant was primary prophylactic in 47.6% in all first implants (See Table 2.12 and Figure 2.5), and the predominant etiology for ICD implant was ischemic heart disease (60.8%) (See table 2.14 and figure 2.6). This represents a decline compared to previous years, and is probably a reflection of publication of the DANISH study on primary prophylactic ICD in dilated cardiomyopathy (Køber L. et al (2016). Defibrillator implantation in patients with nonischemic systolic heart failure. N. Engl. J. Med. 375, 1221–1230). Until 2017 primary prophylactic ICD was not been recommended by the Danish Society of Cardiology.

1.2.3 Leads

All low voltage leads for atrial and right ventricle were bipolar active fixation leads. Of n=673 low voltage leads for left ventricular pacing, n=656 (97%) were quadripolar and n=17 (3%) bipolar (See table 2.9)

Similarly all high voltage leads (except for a small number of leads used for subcutaneous defibrillation) were active fixation leads. Of n=1381 right ventricular defibrillation leads n=1163 (84%) were single coil leads and n=218 (16%) were dual coil leads (See table 2.10). The decreased use of dual coil defibrillation leads is marked compared to previous years.

1.3 Comments on pacemaker and ICD patients

The largest group of patients for first pacemaker implant was between 75-79 years of age for DDD pacemakers and 85-89 years for VVI pacemakers (see table 3.1 and figure 3.1).

Female patients consisted of 40.8% of all first pacemaker patients (See Table 3.2).

For ICD patients, the largest group was 70-74 years of age, with only a limited number above 80 years of age at time of implant (n=46, 4.0%) (See table 3.3 and figure 3.3).

Male patients were dominating in first ICD implants (n=927, 81.2%) (See Table 3.4 and Figure 3.4).

At the end of 2018 30571 pacemaker- and 10808 ICD patients were in treatment and alive (See table 3.5 and table 3.6).

1.4 Comments on trends in implant activity 2000-2018

1.4.1 Number of implants

The number of first pacemaker implants has increased from 440 per million citizens in 2000 to 745 per million citizens in 2018. Currently, this increase does not seem to reach a plateau (See Table 4.1 and Figure 4.1). On the other hand, first ICD implants increased dramatically from 43 per million citizens in 2000 to 219

per million citizens in 2012, but has now decreased slightly to 197 per million citizens in 2018 (See Table 4.2 and Figure 4.2). The implantation rate seems to have reached a plateau. In this context, it is important to recognize that primary prophylactic indication in ischemic heart disease was endorsed in Denmark in 2006 and only recently (in 2017) in dilated cardiomyopathy.

There seems to be some regional differences in number of implants with The Capital Region and Region Zealand implanting 173.5 ICDs per million citizens and The Region of Southern Denmark 227.7 per million citizens (See Table 4.3). These figures are not corrected for regional differences in cardiovascular morbidity.

1.4.2 Pacing modes

In first pacemaker implants DDD pacing mode was used in 62.2% in 2000 but this has increased to 70.6% in 2018. Single lead atrial pacing (AAI) has almost disappeared; whereas VVI pacing has remained constant from 22.8% in 2000 to 24.4 in 2018 (See Table 4.4 and Figure 4.3).

In first ICD implants VVI pacing mode was used in 61.3% in 2000 and is almost unchanged to 65.9% in 2018. CRT-D and DDD-ICD were more often implanted previously (highest in 2011), but after a decrease they now constitute 21.2% (CRT-D) 13.0% (DDD-ICD) of all first implants (See Table 4.5 and Figure 4.4).

1.5 Comments on Quality in device treatment 2017-18

Complications related to all device implantations within 120 days after implant were categorized according to a previous work from the register (Kirkfeldt et al, EHJ 2013) and divided in major and minor complications, where “major” either have major clinical impact or results in re-operation. Only major complications are reported. The predefined goal was a frequency of less than 5% of both surgical related complications as well as generator/lead related complications leading to re-operation.

Across all institutions, there seems to be an equal distribution of complications, and all institutions now fulfil these criteria (See Table 5.1). First implant had a higher risk of generator/lead related complication (1.85%) compared to device replacement (0.42%) and up-/downgrade (1.63%) (See Table 5.2).
It is important to recognize that these numbers don’t take late infections into account, as surgical site infection in implant surgery is defined as infection within 365 days after implant operation. This issue is covered in Table 5.5, where it is shown that infection rate does not exceed 2% at any institutions, which is satisfactory. These frequencies are not adjusted for differences in patient population and operation type, which is known to have an impact on the susceptibility to infection. This may explain why infection is more prevalent at institutions which have more complex patients.

The trends in surgical and generator/lead related complications are shown in Table 5.3 and Table 5.4. There has been a consistent overall decrease in both types of complications since 2015 (see Figure 5.1 and Figure 5.2), which demonstrates the value of continued focus on quality assurance both nationally and on an institutional level. The registry offers opportunity for on-line access for users to monitor each institutions own quality indicators.

Surgical site infection, i.e. local pocket infection/skin erosion or systemic infection/endocarditis leading to removal of the CIED system within 365 days after implant, has been stable since 2015, and well below 1% (see Table 5.6 and Figure 5.3). Hospitals implanting CRT systems seems to have a somewhat higher rate of infection, which is well explained in the current literature, that identify patients for CRT implants, either first- or upgrade implants, as in higher risk of infection.

The Danish Board of Health has suggested an annual minimum number of cases for maintaining operator experience (https://www.sst.dk/da/nyheder/2014/~/media/0232471983BF4C23A241080E82243512.ashx). The majority of centers comply with these recommendations (see Table 5.8). In some teaching hospitals, operators in training may not achieve the suggested minimum number of procedures during their first year in training.

Lead access via puncture of the subclavian vein is related to pneumothorax, and it is thus recommended to use the cephalic cut-down technique. This is well taken at all institutions but with some variations between hospitals (See Table 5.7 and Figure 5.3).

2 Implant activity in Denmark 2018

2.1 Pacemaker

2.1.1 First pacemaker implantation: (Institution|pacing mode)

	Operation | First implant					
	Actual device					
Institution	PM-AAI	PM-VVI	PM-VVI leadless	PM-DDD	CRT-P	First Implant Total
Bispebjerg	3	69		247		319
Esbjerg		39		177		216
Gentofte	1	186	7	325	16	535
Herning		55		169		224
Hillerød		45	21	161		227
Nuuk		18				18
Odense		50	41	361	92	544
Rigshospitalet	1	13	14	128	43	199
Roskilde	1	183		399		583
Varde		1		1		2
Vejle		67		176		243
Viborg		37		130		167
Aabenraa	1	38		110		149
Ålborg	1	61		309	12	383
Aarhus	2	104	6	357	42	511
Grand Total	10	966	89	3050	205	4320

Table 2.1 First pacemaker implantations in Denmark 2018 for each institution and pacing mode

2.1.2 Pacemaker replacement: (Institution|pacing mode)

	Operation | Replacement						
	Actual Device						
Institution	PM-AAI	PM-VVI	PM-VVI leadless	PM-VDD	PM-DDD	CRT-P	Replacement Total
Bispebjerg	1	14			45		60
Esbjerg		5			26		31
Gentofte	8	15	1	2	73	15	114
Herning	4	7			58		69
Hillerød	10	12			52		74
Nuuk		1					1
Odense	1	11	7		74	31	124
Rigshospitalet	4	8	1		41	28	82
Roskilde	5	19			76		100
Vejle	4	10			40		54
Viborg	1	9			53	1	64
Aabenraa	6	8			33		47
Ålborg	2	10			68	4	84
Aarhus		3	1		31	14	49
Grand Total	46	132	10	2	670	93	953

Table 2.2 Pacemaker replacements in Denmark 2018 for each institution and pacing mode

2.1.3 Pacemaker Up-/downgrade: (Institution|pacing mode)

	Operation | Up-/downgrade					
	Actual Device					
Institution	PM-AAI	PM-VVI	PM-VVI leadless	PM-DDD	CRT-P	Up/downgrd. Total
Bispebjerg						
Esbjerg		8		2		10
Gentofte		7		2	9	18
Herning		12				12
Hillerød		0	1	2		3
Odense	1	8	13	2	21	45
Rigshospitalet		1	1	5	17	24
Roskilde		9		7		16
Vejle		7		4		11
Viborg		1		3		4
Aabenraa		2		2		4
Ålborg		9		7	7	23
Aarhus		4	5	3	26	38
Grand Total	1	68	20	39	80	208

Table 2.3 Pacemaker up-/downgrades in Denmark 2018 for each institution and pacing mode

2.2 ICD

2.2.1 First ICD implantation (Institution|pacing mode)

	Operation | First implant			
	Actual device			
Institution	VVI-ICD*	DDD-ICD	CRT-D	First Implant Total
Gentofte	68	9	17	94
Odense	204	11	63	278
Rigshospitalet	158	26	70	254
Roskilde	92	21		113
Ålborg	72	41	29	142
Aarhus	158	40	62	260
Grand Total	752	148	241	1141

Table 2.4 First ICD implantations in Denmark 2018 for each institution and pacing mode
*Of 752 VVI-ICD 12 (1.6%) were subcutaneous ICD, 8 implanted at Odense and 4 at Rigshospitalet.

2.2.2 ICD replacement: (Institution|pacing mode)

	Operation | Replacement			
	Actual device			
Institution	VVI-ICD*	DDD-ICD	CRT-D	First Implant Total
Gentofte	60	17	36	113
Odense	104	27	41	172
Rigshospitalet	100	34	52	186
Roskilde	24	3		27
Ålborg	26	20	20	66
Aarhus	82	27	51	160
Grand Total	396	128	200	724

Table 2.5 ICD replacements in Denmark 2018 for each institution and pacing mode
*Of 396 VVI-ICD 13 (3.2%) were subcutaneous ICD, 2 replaced at Gentofte, 7 at Odense, 3 at Rigshospitalet and 1 at Ålborg.

2.2.3 ICD Up-/downgrade: (Institution|pacing mode)

	Operation | Up-/downgrade			
	Actual device			
Institution	VVI-ICD	DDD-ICD	CRT-D	Up/downgrad. Total
Gentofte		3	9	12
Odense	8	3	32	43
Rigshospitalet	2	8	31	41
Roskilde	3	3		6
Ålborg		4	7	11
Aarhus	3	5	35	43
Grand Total	16	26	114	156

Table 2.6 ICD up-/downgrade in Denmark 2018 for each institution and pacing mode

2.3 Manufacturer

2.3.1 Pacemaker (manufacturer|pacing mode)

	Actual device						
Manufacturer	PM-AAI	PM-VVI	PM-VDD	PM-DDD	CRT-P	Grand Total	Percent [%]
Biotronik	15	375		1124	79	1593	29.0
Boston Scientific	7	174	3	453	29	666	12.1
Medtronic	14	200		90	8	312	5.7
Sorin		38		41		79	1.4
St. Jude Medical	18	423		1928	263	2632	48.0
Vitatron	3	75		128		206	3.8
Grand Total	57	1285	3	3764	379	5488	100.0

Table 2.7 Manufacturer of pacemakers implanted in Denmark 2018 for each pacing mode

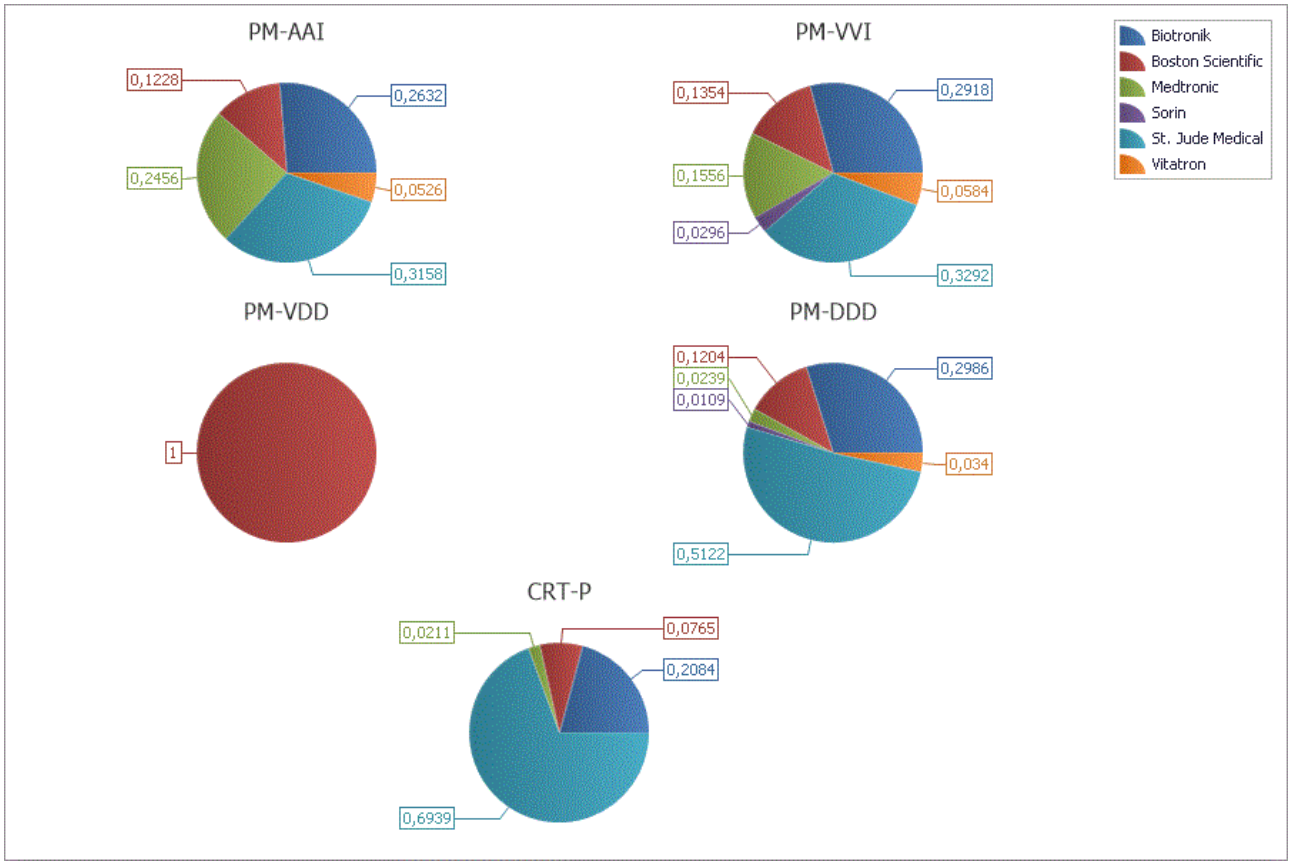

Figure 2.1 Manufacturer of pacemakers implanted in Denmark 2018 for each pacing mode

2.3.2 ICD (manufacturer|pacing mode)

	Actual device				
Manufacturer	VVI-ICD	DDD-ICD	CRT-D	First Implant Total	Percent [%]
Biotronik	228	74	112	414	20.3
Boston Scientific	287	39	68	394	19.3
Medtronic	200	87	76	363	17.8
St. Jude Medical	451	105	300	856	42.0
Grand Total	1166	305	556	2027	100.5

Table 2.8 Manufacturer of ICD´s implanted in Denmark 2018 for each pacing mode

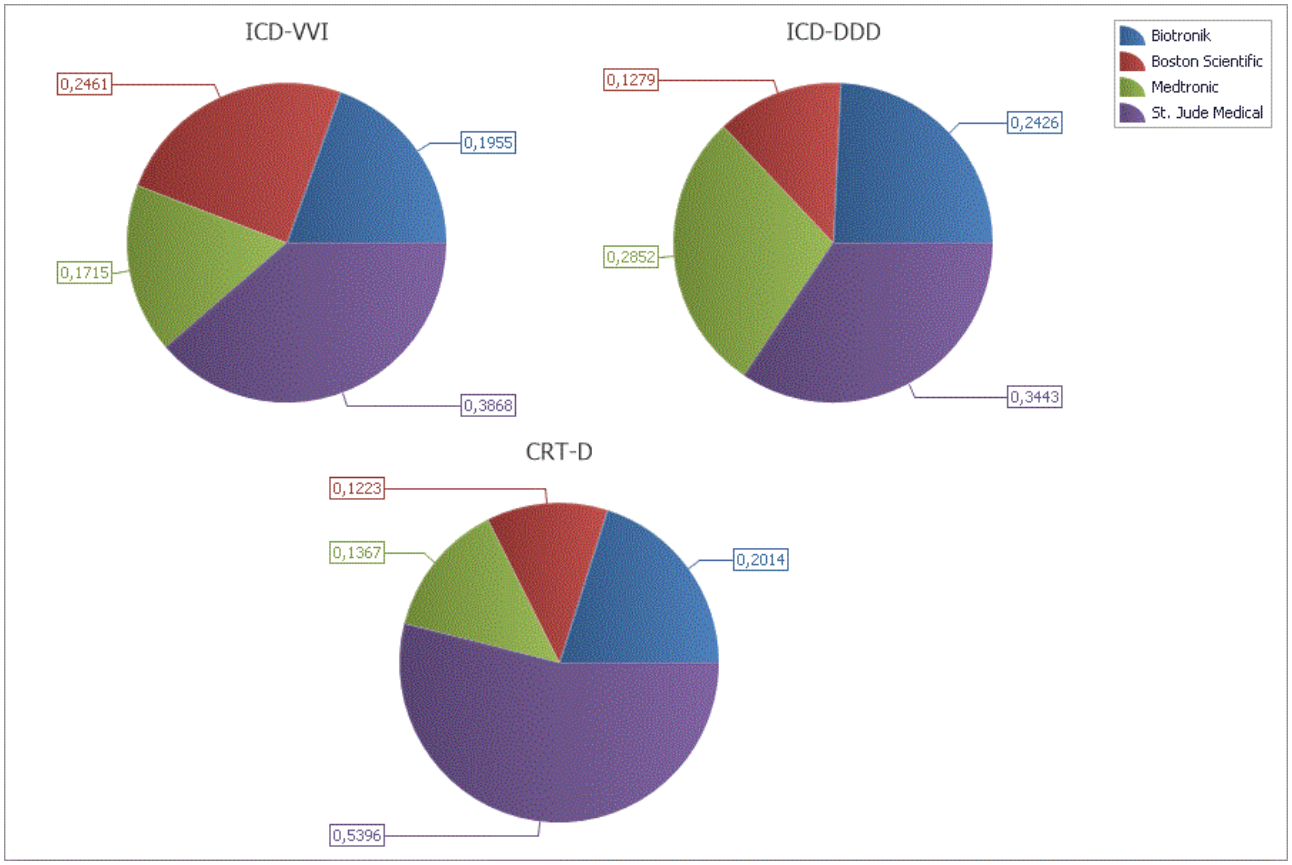

Figure 2.2 Manufacturer of ICD´s implanted in Denmark 2018 for each pacing mode

2.4 Leads

2.4.1 Low voltage leads (atrial, left ventricular, suppl. right ventricular pace/sense | manufacturer)

	Atrial	Left ventricular*	Right ventricular	Suppl. RV pace/sense	Grand Total	Percent [%]
Biotronik	181	17	228	2	428	4.7
Boston Scientific	43		46		89	1.0
Medtronic	56	21	79	14	170	1.9
St. Jude Medical	3566	635	4130	8	8339	92.4
Grand Total	3846	673	4483	24	9026	100.0

Table 2.9 Manufacturer of low voltage leads implanted in Denmark 2018
*Of 842 low voltage leads for left ventricular pacing, 656 (97%) were quadripolar and 17 (3%) bipolar.

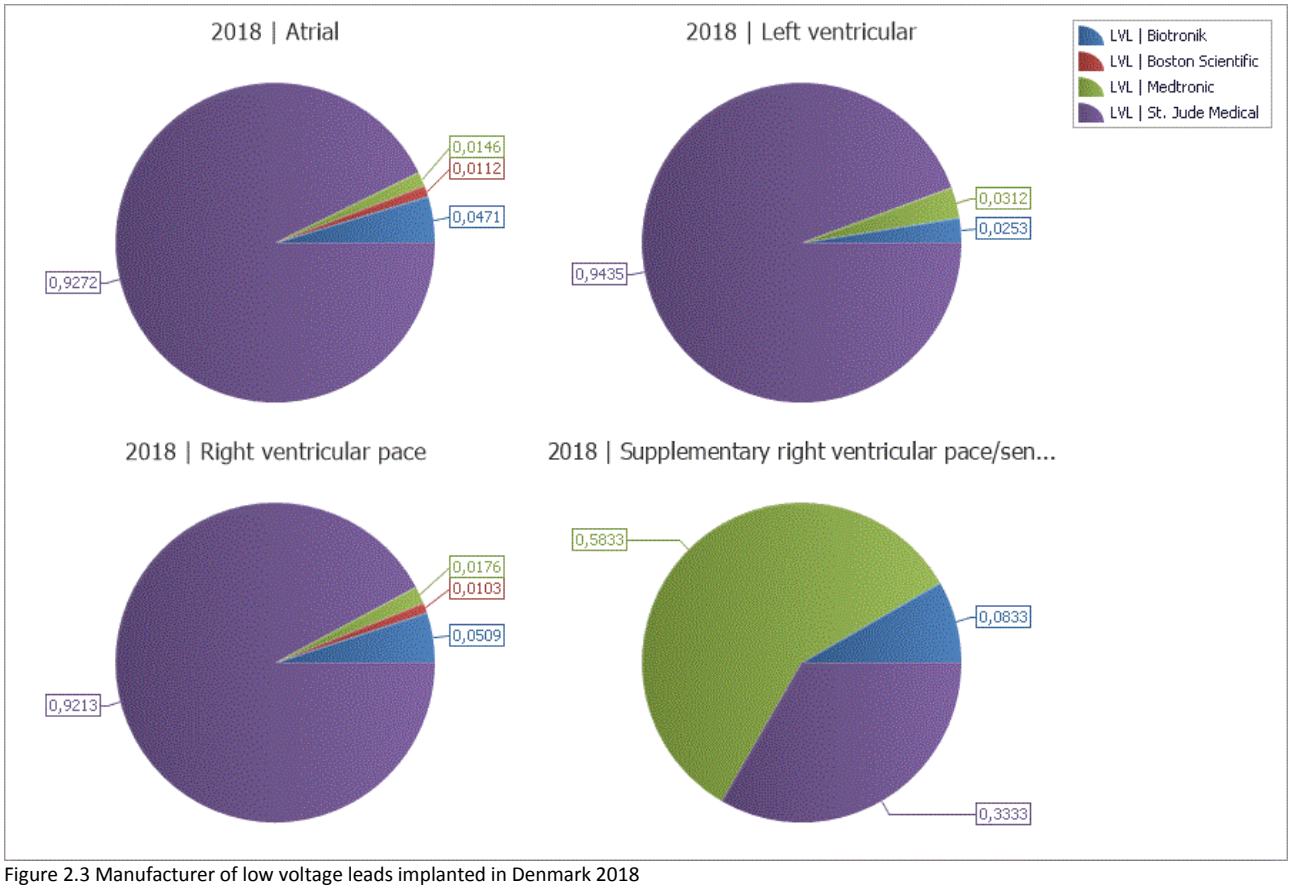

Figure 2.3 Manufacturer of low voltage leads implanted in Denmark 2018

2.4.2 High voltage leads (Right ventricular defibrillation, supplementary defibrillation|manufacturer)

	Right ventricular defibrillation	Supplementary defibrillation	Grand Total	Percent [%]
Biotronik	318		318	22.9
Boston Scientific	293	2	295	21.2
Medtronic	176	6	182	13.1
St. Jude Medical	594	1	595	42.8
Grand Total	1381	9	1390	100.0

Table 2.10 Manufacturer of high voltage leads implanted in Denmark 2018
*Of 1381 right ventricular leads 1163 (84%) were single coil leads and 218 (16%) were dual coil leads.

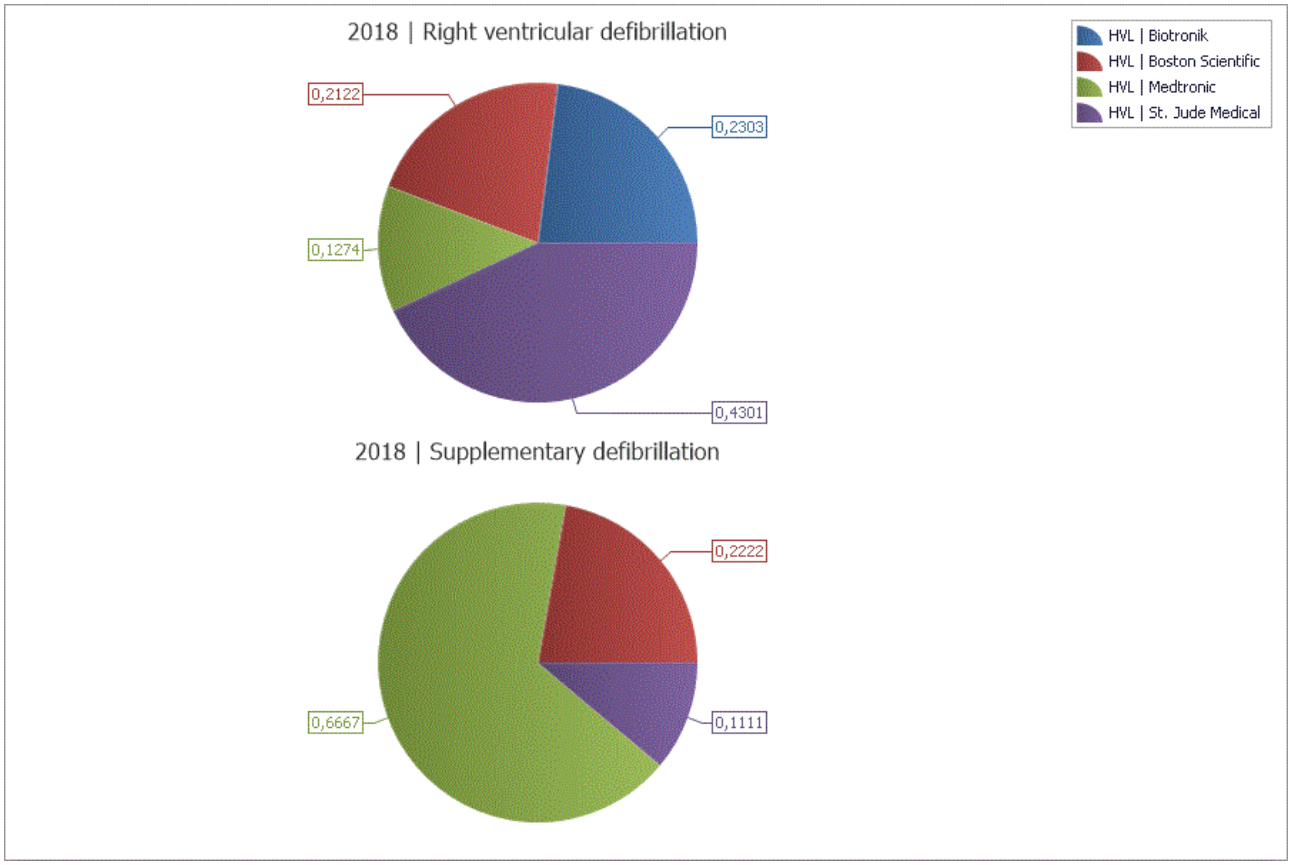

Figure 2.4 Manufacturer of high voltage leads implanted in Denmark 2018

2.5 Indication

2.5.1 Pacemaker (First implant|ECG indication)

Indication	Operation | First Implant	Percent [%]
Arrhythmia not documented	6	0.14
Atrial arrhythmias without sinus dysfunction	12	0.28
AV block - 1°	19	0.44
AV block - 2:1	163	3.77
AV block - 2°. advanced type	150	3.47
AV block - 2° type I	52	1.20
AV block - 2° type II	230	5.32
AV block - 3°	1441	33.31
AV conduction impaired - status unknown	27	0.62
Bradycardia - Tachycardia syndrome	450	10.40
Bundle branch block, unspecified	99	2.29
Chronic atrial fibrillation & AV block - 3°	185	4.28
Chronic atrial fibrillation & bradycardia	240	5.55
Left bundle branch block	137	3.17
Other	32	0.74
Right bundle branch block	80	1.85
Sinus node dysfunction unspec. + impaired AV conduction	26	0.60
Sinus node dysfunction unspecified	48	1.11
Sinus node dysfunction with pause	739	17.08
Sinus node dysfunction without pause	123	2.84
Unknown	67	1.55
Grand Total	4326	100.00

Table 2.11 ECG indication, first pacemaker implantation Denmark 2018

2.5.2 ICD (First implant|ECG indication)

Indication	Operation | First Implant	Percent [%]
Other	1	0.1
Prophylactic (none documented / induced)	546	47.6
Syncope with inducible VT or VF	8	0.7
Unknown	19	1.7
Ventricular Fibrillation	305	26.6
VT - monomorphic Non-sustained	87	7.6
VT - monomorphic Sustained	162	14.1
VT - Polymorphic w. long QT (Torsades des pointes)	11	1.0
VT - polymorphic (with normal QT interval)	7	0.6
Wide complex tachycardia unspecified	1	0.1
Grand Total	1147	100

Table 2.12 ECG indication, first ICD implantation Denmark 2018

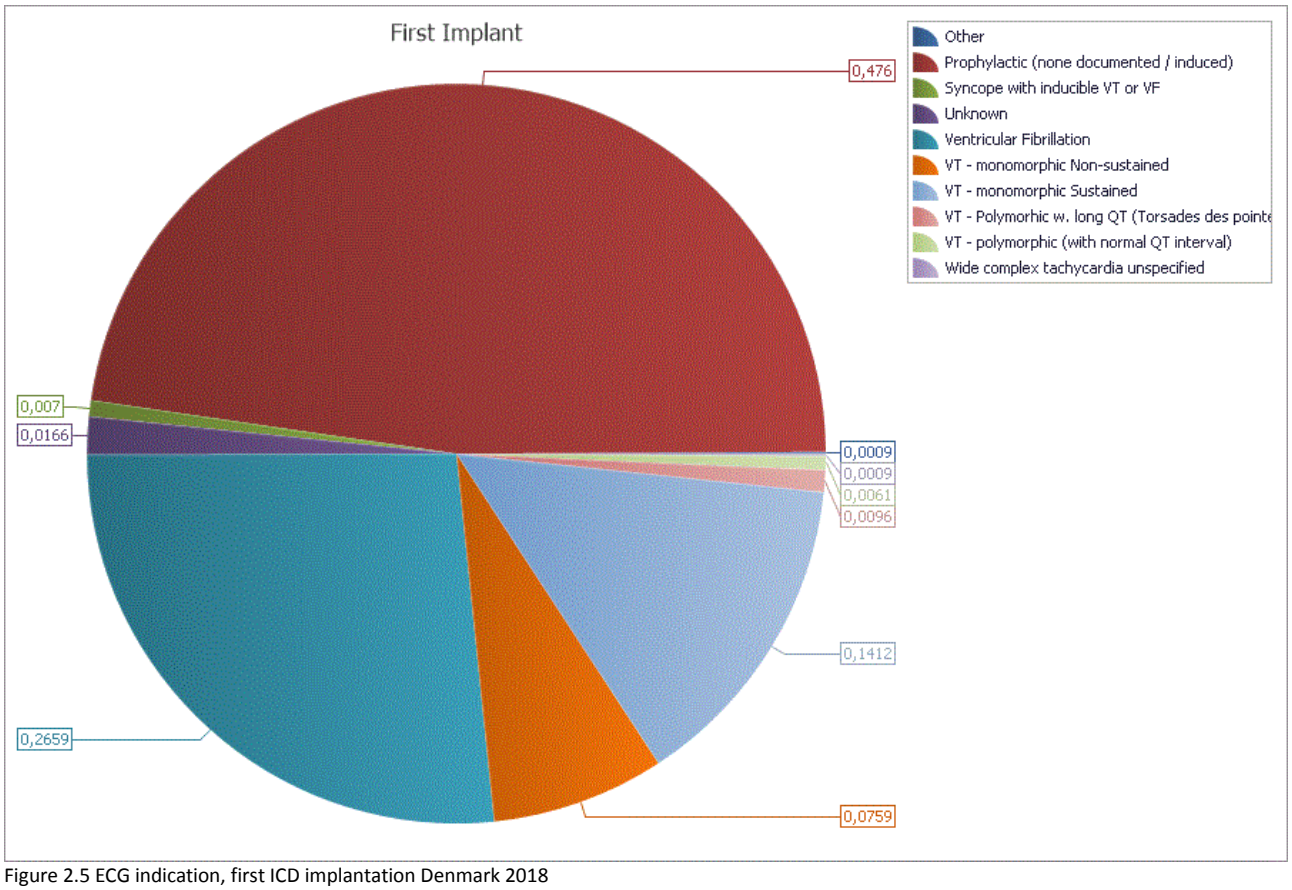

Figure 2.5 ECG indication, first ICD implantation Denmark 2018

2.6 Etiology

2.6.1 Pacemaker (First implant|Etiology)

Diagnosis	Operation | First Implant	Percent [%]
Autonomic dysfunction, other	4	0.1
AV node ablation, complication	3	0.1
AV node ablation, therapeutic	17	0.4
Cardiomyopathy - dilated	90	2.1
Cardiomyopathy - hypertrophic	4	0.1
Cardiomyopathy - other	15	0.3
Carotid sinus syndrome	92	2.1
Conduction tissue disease	2968	68.6
Congenital AV block	5	0.1
Congenital heart disease	5	0.1
Drug induced	12	0.3
Endocarditis	7	0.2
Heart transplant	2	0.0
Ischemic heart disease	136	3.1
Myocarditis	1	0.0
Other	66	1.5
Primary electrical disease	1	0.0
Surgical complication	123	2.8
Surgical therapeutic	4	0.1
Unknown	713	16.5
Valvular heart disease	46	1.1
Vasovagal syncope	12	0.3
Grand Total	4326	100

Table 2.13 Etiology, first pacemaker implantation Denmark 2018

2.6.2 ICD (First implant|Etiology)

Diagnosis	Operation | First Implant	Percent [%]
Arrhythmogenic right ventricle	5	0.4
Brugada syndrome	6	0.5
Cardiomyopathy - dilated	230	20.1
Cardiomyopathy - hypertrophic	30	2.6
Cardiomyopathy - other	37	3.2
Congenital heart disease	7	0.6
Congenital long QT	7	0.6
Idiopathic ventricular fibrillation	42	3.7
Ischemic heart disease	697	60.8
Other	14	1.2
Primary electrical disease - other	11	1.0
Unknown	47	4.1
Valvular heart disease	14	1.2
Grand Total	1147	100

Table 2.14 Etiology, first ICD implantation, Denmark 2018

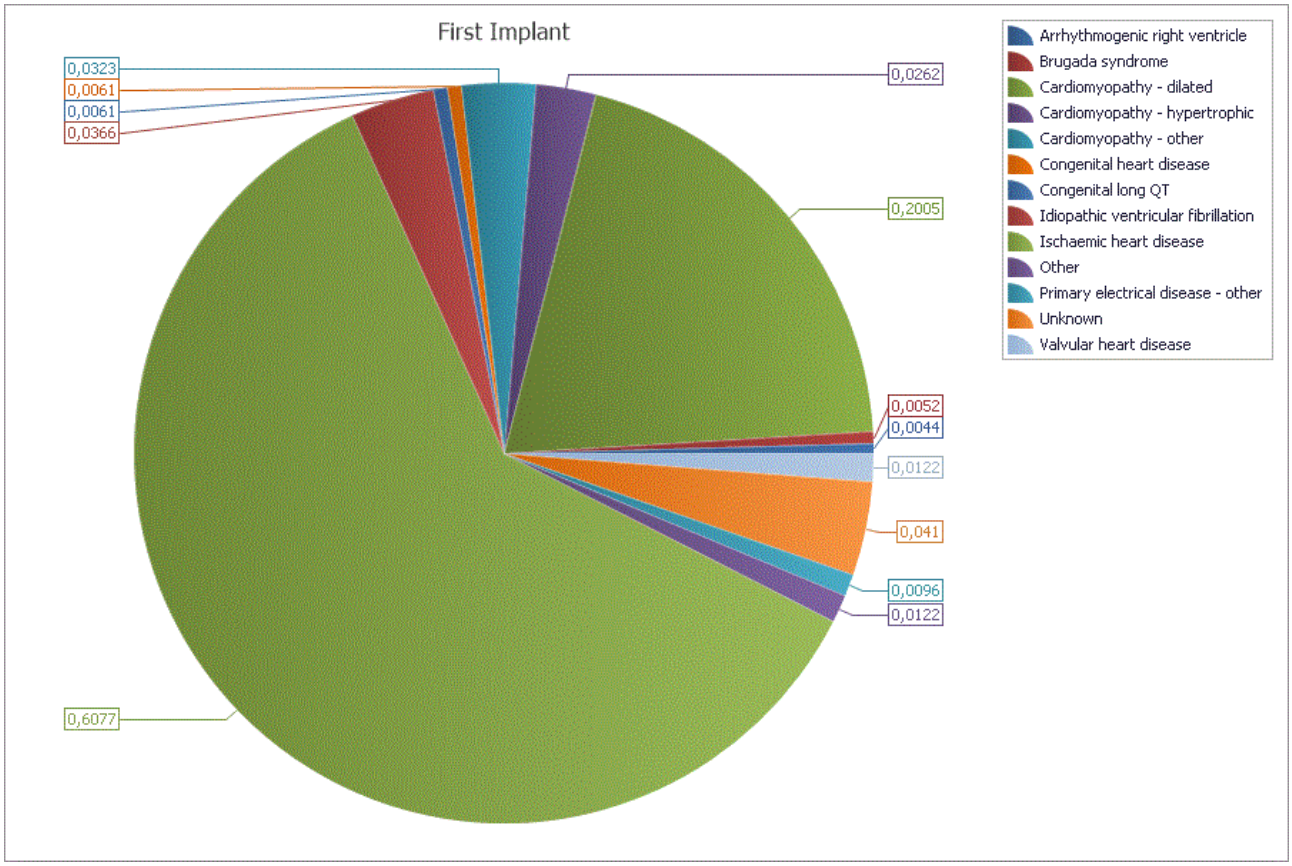

Figure 2.6 Etiology, first ICD implantation, Denmark 2018

3 Patients

3.1 Age and sex

3.1.1 First pacemaker implant (Age group|pacing mode)

	Age at first implant																					
Actual Device	0-4	5-9	10-14	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50-54	55-59	60-64	65-69	70-74	75-79	80-84	85-89	90-94	95-99	100 104	Grand Total
PM-AAI								1	2				2		1	3	1					10
PM-VVI					1	1	2		3	5	7	13	20	45	111	155	205	266	169	49	3	1055
PM-VDD														1								1
PM-DDD	4	1	2	5	3	6	10	12	22	36	74	102	207	298	595	624	608	320	109	14	2	3054
CRT-P											3	4	15	22	43	60	46	12	1			206
Grand Total	4	1	2	5	4	7	12	13	27	41	84	119	244	366	750	842	860	598	279	63	5	4326

Table 3.1 Age group in first pacemaker implantation, Denmark 2018

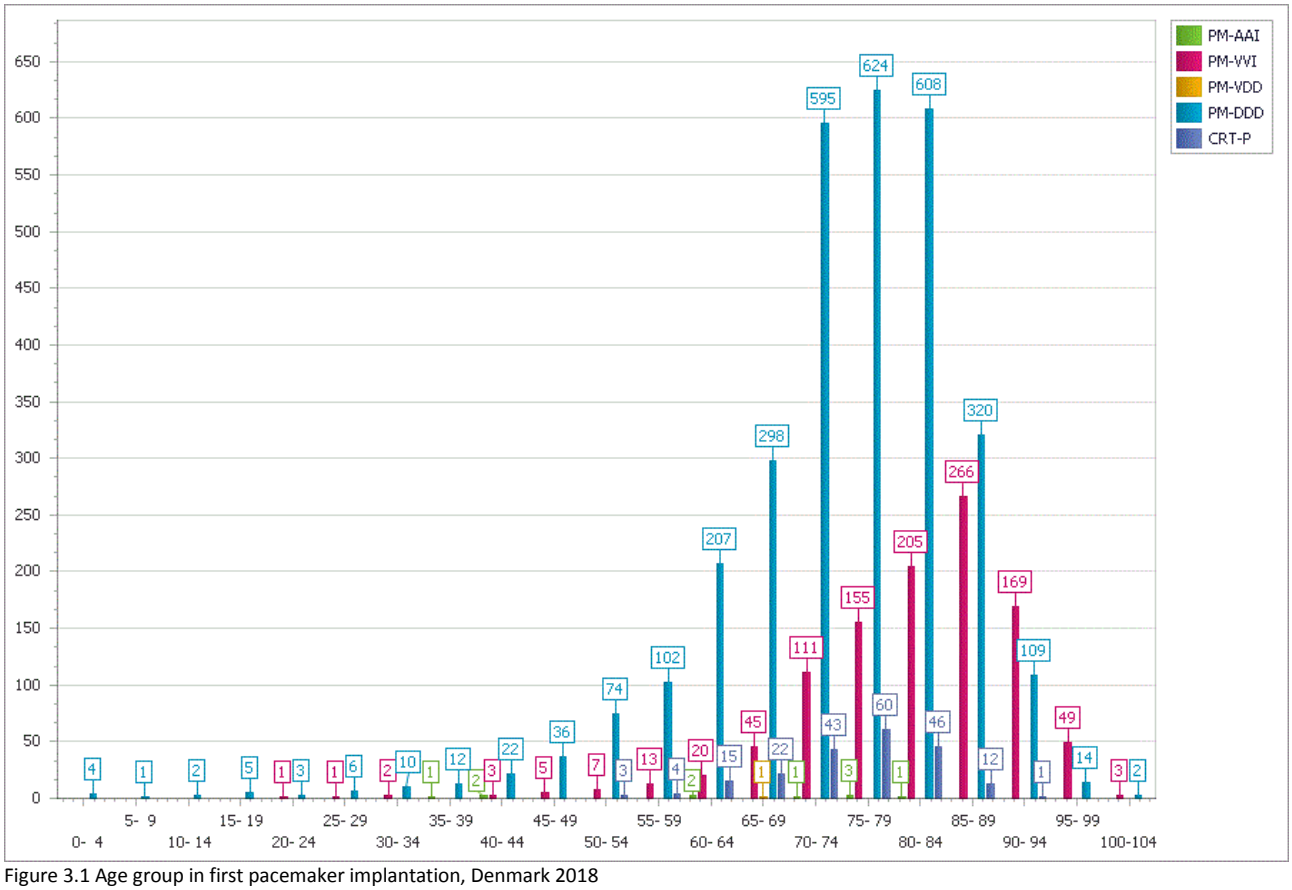

Figure 3.1 Age group in first pacemaker implantation, Denmark 2018

3.1.2 First pacemaker implant (Sex|pacing mode)

	Sex		
Actual device	Female	Male	Grand Total
PM-AAI	3 (30.0%)	7 (70.0%)	10
PM-VVI	424 (40.2%)	631 (59.8%)	1055
PM-VDD		1 (100.0%)	1
PM-DDD	1259 (41.2%)	1795 (58.8%)	3054
CRT-P	78 (37.9%)	128 (62.1%)	206
Grand Total	1764 (40.8%)	2562 (59.2%)	4326

Table 3.2 Sex in first pacemaker implantation in each pacing mode, Denmark 2018

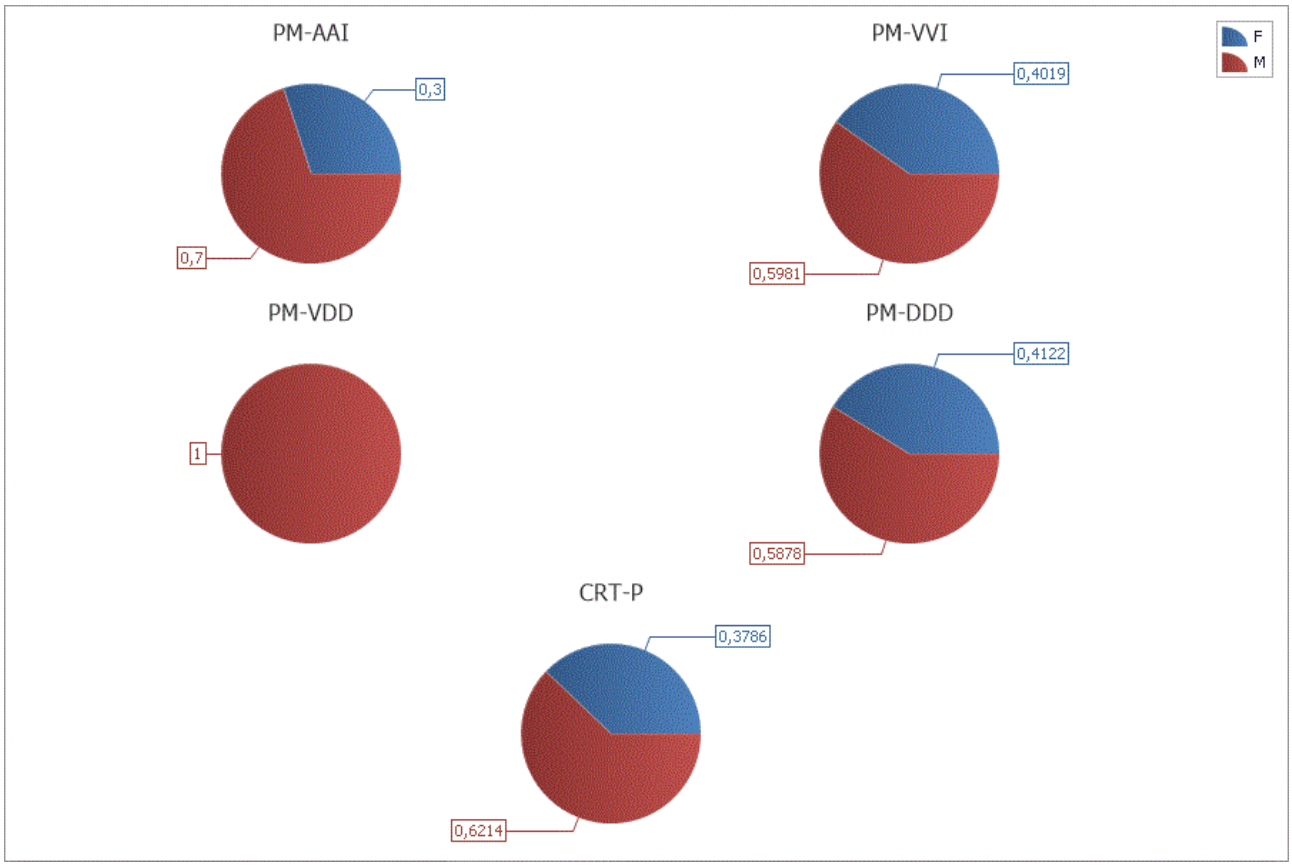

Figure 3.2 Sex in first pacemaker implantation in each pacing mode, Denmark 2018

3.1.3 First ICD implant (Age group | pacing mode)

	Age at first implant																
Actual Device	10-14	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50-54	55-59	60-64	65-69	70-74	75-79	80-84	85-89	Grand Total
ICD-VVI	4	4	3	6	10	18	21	48	70	86	119	113	128	94	24	6	754
ICD-DDD			1	1		3	5	11	8	18	24	22	33	18	7		151
CRT-D		2		1			5	7	18	33	50	49	43	25	9		242
Grand Total	4	6	4	8	10	21	31	66	96	137	193	184	204	137	40	6	1147

Table 3.3 Age group in first ICD implantation, Denmark 2018

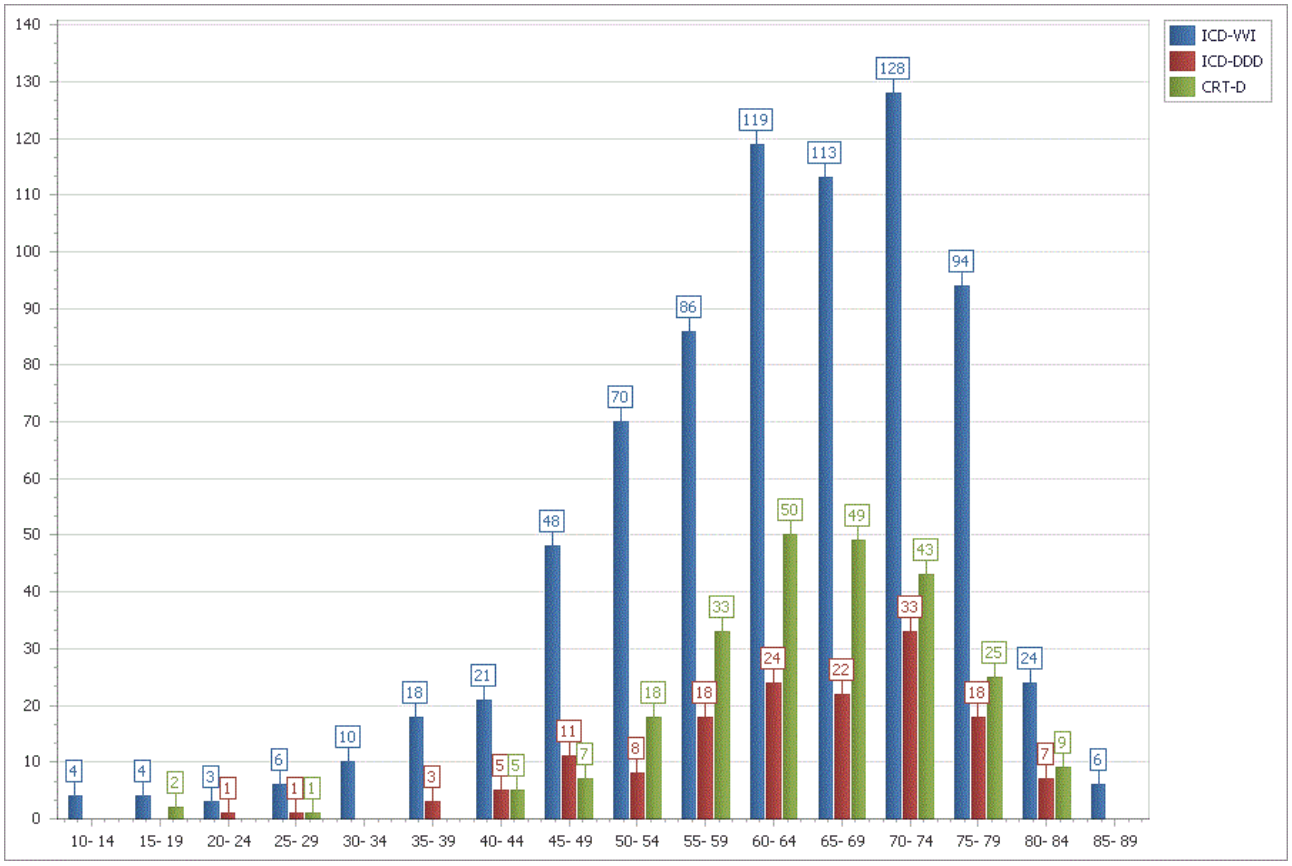

Figure 3.3 Age group in first ICD implantation, Denmark 2018

3.1.4 First ICD implant (Sex|pacing mode)

	Sex		
Actual device	Female	Male	Grand Total
ICD-VVI	122 (16.2%)	630 (83.8%)	716
ICD-DDD	36 (24.3%)	112 (75.7%)	148
CRT-D	56 (23.2%)	185 (76.8%)	241
Grand Total	214 (18.8%)	927 (81.2%)	1147

Table 3.4 Gender in first ICD implantation in each pacing mode, Denmark 2018

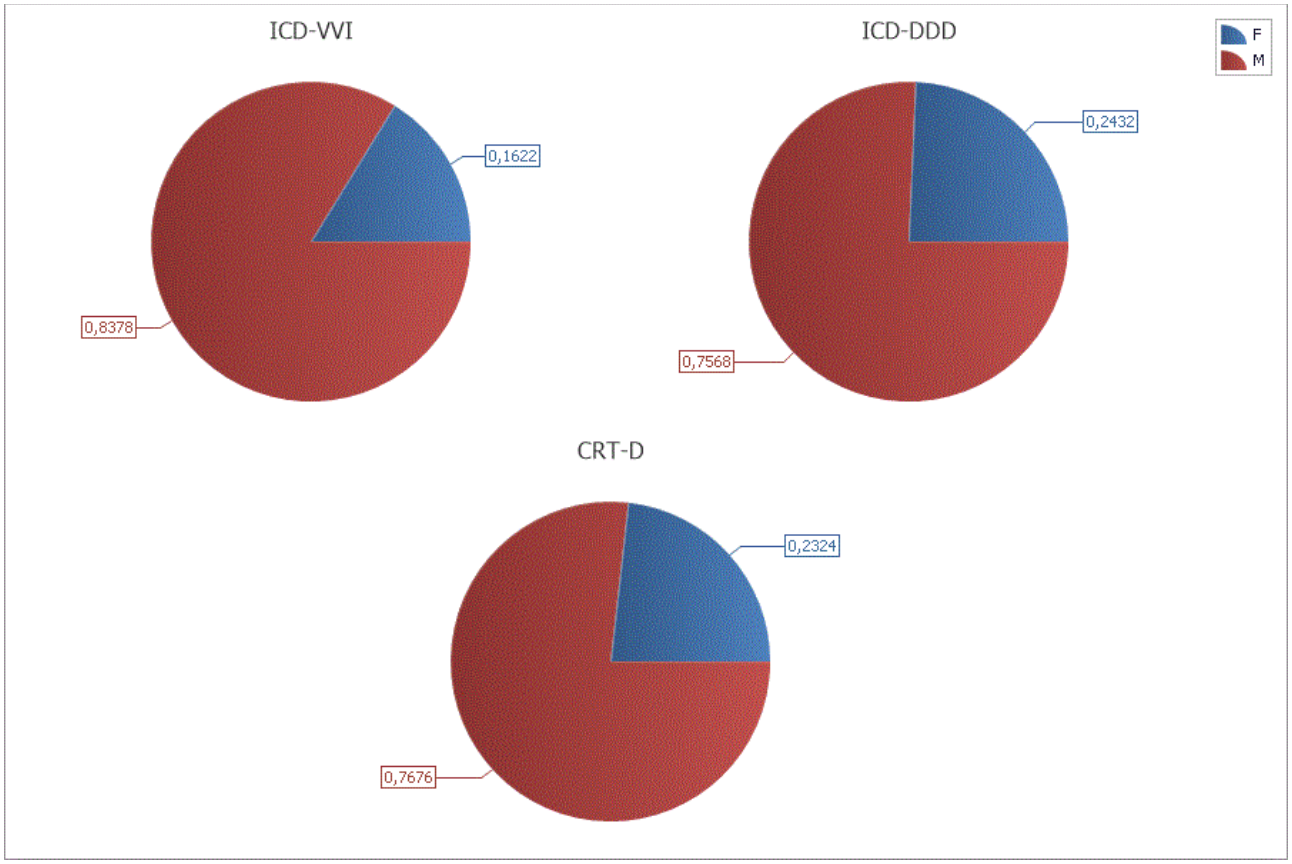

Figure 3.4 Sex in first ICD implantation in each pacing mode, Denmark 2018

3.2 Patients in treatment

3.2.1 All pacemaker patients in treatment | 31. December 2018 | last implant institution

		Actual Device					
Period	Last Institution	PM-AAI	PM-VVI	PM-VDD	PM-DDD	CRT-P	**Grand Total**
End 2018	Bispebjerg	41	384		1766		2191
	Esbjerg	14	151		1073	14	1252
	Gentofte	91	875	32	2368	257	3623
	Herning	46	286		1312		1644
	Hillerød	68	378	2	1205		1653
	Nuuk	1	150				151
	Odense	61	432		2239	535	3267
	Rigshospitalet	36	188		943	482	1649
	Roskilde	88	755	1	2737		3581
	Vejle	93	434		1433		1960
	Viborg	13	201		1032	15	1261
	Aabenraa	36	226		937		1199
	Ålborg	63	394		2362	178	2997
	Aarhus	40	505		3109	489	4143
End 2018 Total		691	5359	35	22516	1970	30571

Table 3.5 All danish pacemaker patients in treatment and alive 31. December 2018 according to last implant institution

3.2.2 All ICD patients in treatment | 31. December 2018 | last implant institution

		Actual Device			
Period	Last Institution	ICD-VVI	ICD-DDD	CRT-D	Grand Total
End 2018	Gentofte	948	235	378	1561
	Odense	1438	237	650	2325
	Rigshospitalet	1528	465	738	2731
	Roskilde	397	156		553
	Ålborg	513	310	258	1081
	Aarhus	1273	529	755	2557
End 2018 Total		6097	1932	2779	10808

Table 3.6 All danish ICD patients in treatment and alive 31. December 2018 according to last implant institution

4 Trends in implant activity 2000 - 2018

4.1 Total number of first implants | number of devices per million citizens

4.1.1 First pacemaker implants 2000 - 2018

	Operation | First Implant																		
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Implants Total	2346	2449	2477	2605	2652	2883	2932	2780	3006	3080	3328	3386	3664	3733	3861	4042	4176	4181	4326
Implants per mill. citizens*	440	458	461	484	491	533	540	510	549	559	601	609	657	666	686	714	732	727	745

Table 4.1 Number of first pacemaker implants in Denmark 2000 - 2018 and number of pacemakers per million citizens
*Data on population based on data from Statistics Denmark

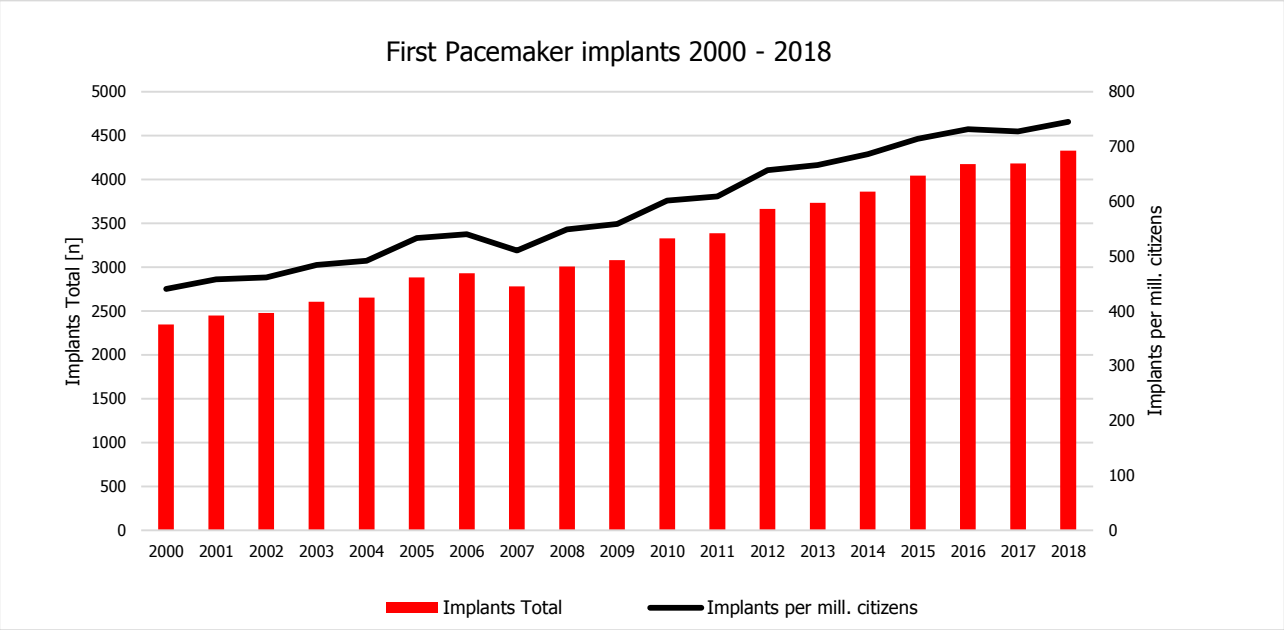

Figure 4.1 Number of first pacemaker implants in Denmark 2000 - 2018 and number of pacemakers per million citizens

4.1.2 First ICD implants 2000 - 2018

	Operation | First Implant																		
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Implants Total	230	231	301	331	397	510	574	725	918	1013	1090	1160	1224	1180	1117	1088	1147	1309	1141
Implants per mill. citizens*	43	43	56	61	74	94	106	133	168	184	197	209	219	211	198	192	201	228	197

Table 4.2 Number of first ICDs implants in Denmark 2000 - 2018 and number of ICDs per million citizens
*Data on population based on data from Statistics Denmark

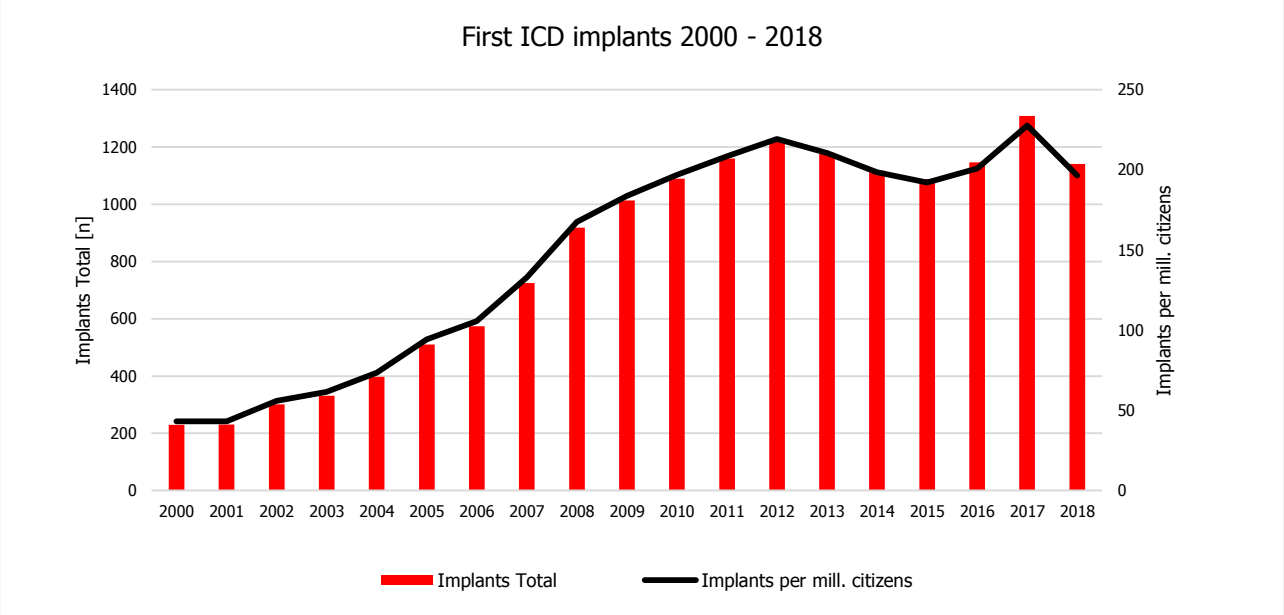

Figure 4.2 Number of first ICDs implants in Denmark 2000 - 2018 and number of ICDs per million citizens

4.1.3 First ICD implants 2018 | million citizens | Region

	Operation | First Implant						
	Actual Device			First Implant Total	**Region**	Citizens 1. January 2018	First ICD implants per mill. citizens
Institution	ICD-VVI	ICD-DDD	CRT-D				
Gentofte	68	9	17	94	The Capital Region of Denmark and Region Zealand	2,657,683	**173.5**
Roskilde	92	21		113			
Rigshospitalet	158	26	70	254			
Odense	204	11	63	278	The Region of Southern Denmark	1,220,763	**227.7**
Ålborg	72	41	29	142	The North Denmark Region	589,148	**241.0**
Aarhus	158	40	62	260	Central Denmark Region	1,313,596	**197.9**
Grand Total	752	148	241	1141		**5,748,769**	**197.4**

Table 4.3 Number of first ICDs implants in 2018 and number of ICDs per million citizens i different regions in Denmark

4.2 Pacing mode | first implants

4.2.1 Pacemakers 2000-2018

	Operation | First Implant																		First Implant Total
Actual Device	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	
PM-AAI	248	225	230	270	288	279	238	167	128	97	56	19	6	7	13	9	11	1	10	2291
PM-VVI	534	597	564	675	692	757	811	750	821	739	719	722	832	855	906	978	917	1029	1055	12869
PM-VDD	74	63	50	28	36	52	49	41	35	44	20	5	1	1				2	1	499
PM-DDD	1459	1507	1563	1545	1519	1620	1691	1708	1913	2067	2394	2459	2637	2649	2699	2805	2989	2891	3054	35232
CRT-P	31	57	70	87	117	175	143	114	109	133	139	181	188	221	243	250	259	224	206	2516
Grand Total	2346	2449	2477	2605	2652	2883	2932	2780	3006	3080	3328	3386	3664	3733	3861	4042	4176	4147	4326	53407

Table 4.4 Number of first pacemaker implants and pacing modes in Denmark 2000-2018

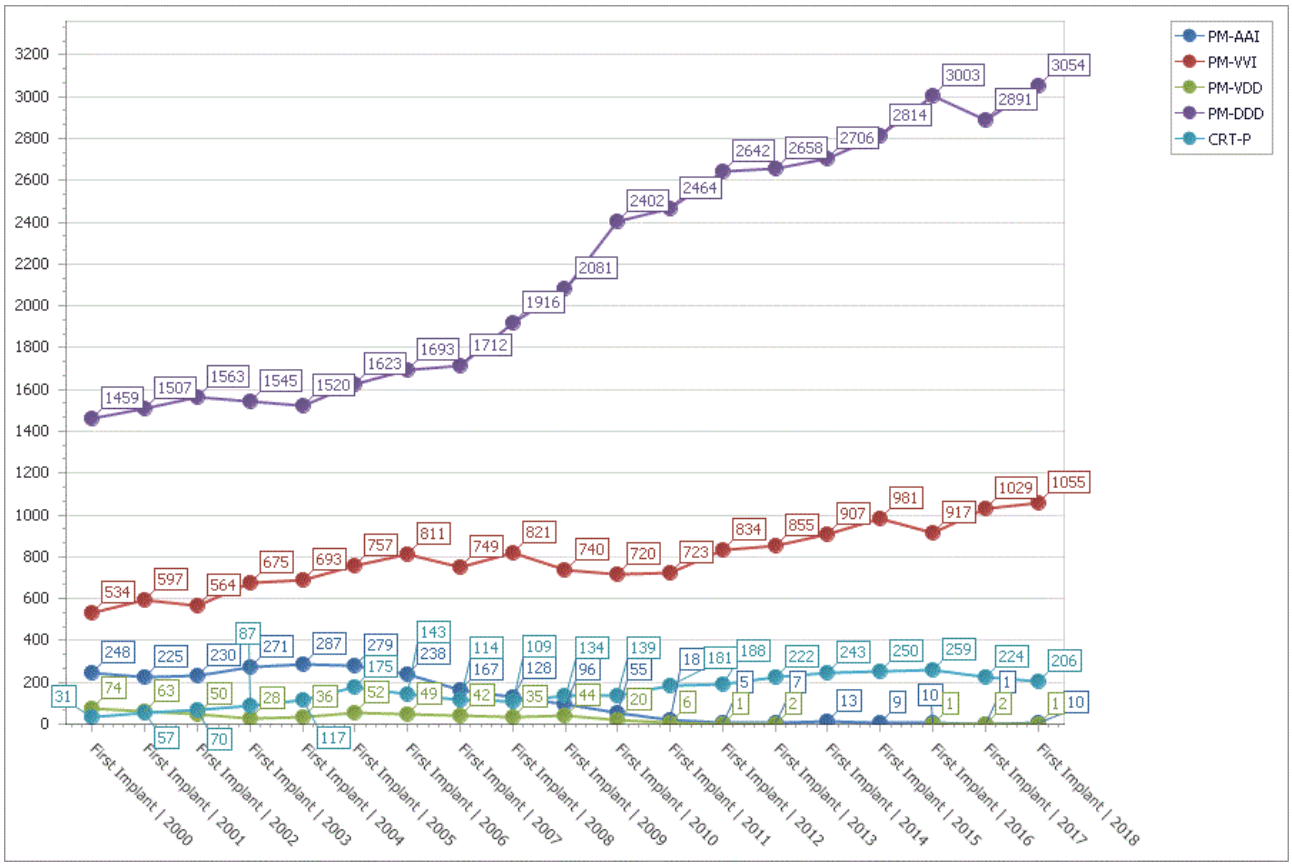

Figure 4.3 Number of first pacemaker implants and pacing modes in Denmark 2000-2018

4.2.2 ICDs 2000 - 2018

	Operation | First Implant																			First Implant Total
Actual Device	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	
ICD-VVI	141	150	177	229	270	303	327	476	571	540	531	534	640	694	691	694	712	832	752	9260
ICD-DDD	77	75	99	73	88	117	143	128	191	247	297	295	257	211	185	178	154	169	148	3135
CRT-D	12	6	25	29	39	90	104	121	156	226	262	331	327	275	241	216	272	305	241	3282
Grand Total	230	231	301	331	397	510	574	725	918	1013	1090	1160	1224	1180	1117	1088	1138	1306	1141	15677

Table 4.5 Number of first ICD implants and pacing modes in Denmark 2000-2018

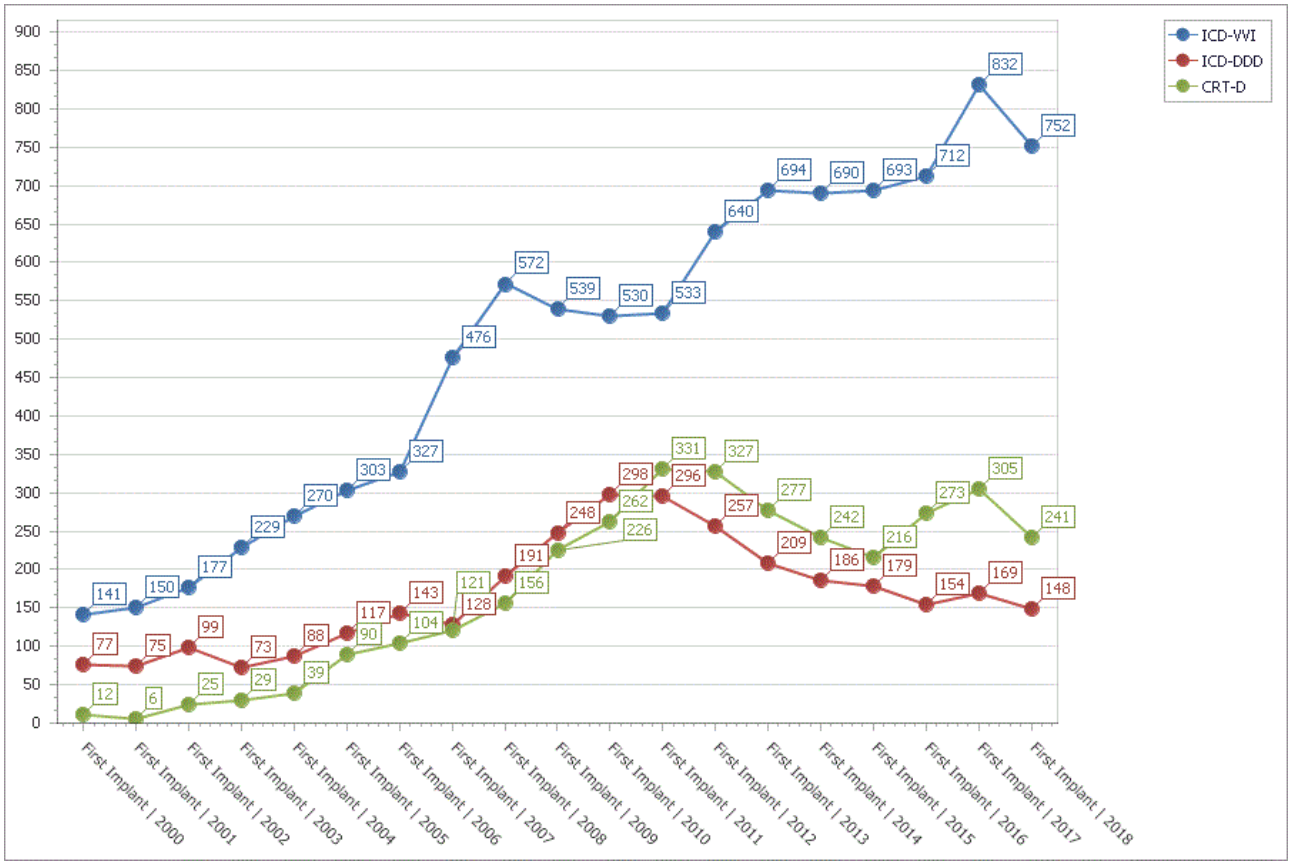

Figure 4.4 Number of first ICD implants and pacing modes in Denmark 2000-2018

5 Quality in device treatment 2017 - 2018

5.1 Complications after all operations in 2018

5.1.1 Major complications per institution up to 120 days after implant

Complications with major clinical impact or resulting in reoperation within 120 days after implant operation in 2018

Complication type	Institution													
Surgical related	Bispebjerg	Esbjerg	Gentofte	Herning	Hillerød	Odense	Rigshosp	Roskilde	Vejle	Viborg	Aabenrå	Ålborg	Aarhus	**Total**
Cardiac perforation not req. pericardiocentesis		1	2	1		3	2	1	1	2	1	1	1	16
Cardiac perforation req. pericardiocentesis			3	1						1		2	1	8
Deep venous thrombosis			1		1	3			1				1	7
Haemothorax req. drainage						1	1							2
Local pocket infection / Skin erosion	1			3		1	1	1	1			4	9	21
Pneumothorax not req. drainage			1		1			3			1		1	7
Pneumothorax req. drainage	1			1		3		3			1	2	3	14
Systemic infection / endocarditis	2	2		1	1	2	1	2		2		1	2	16
Total number of surgical related complications	4	3	7	7	3	12	5	10	3	5	3	10	18	91
Total number of operations	381	259	898	306	304	1214	800	846	308	238	200	722	1078	7554
Frequency pr. institution	**1.05**	**1.16**	**0.78**	**2.29**	**0.99**	**0.99**	**0.63**	**1.18**	**0.97**	**2.10**	**1.50**	**1.39**	**1.67**	**1.20**

Generator/lead related complications leading to re-operation	Bispebjerg	Esbjerg	Gentofte	Herning	Hillerød	Odense	Rigshosp	Roskilde	Vejle	Viborg	Aabenrå	Ålborg	Aarhus	**Total**
Connector failure						1								1
Conductor break														0
Displacement	6	4	7	4	4	7	9	12	10	2	1	5	11	82
Extracardiac stimulation								1	1			1		3
Generator-lead interface problem									1					1
High defibrillation threshold							1							1
High pacing threshold		3		1		1	3	2			1		3	14
Insulation failure							1							1
Sensing / pacing failure				1		1		1	1					4
Twiddler's syndrome		1				2		1						4
Undersensing							1	1					1	3
Generator failure, other						1								1
Total number of lead/generator complications leading to re-operation	6	8	7	6	4	13	15	18	13	2	2	6	15	115
Total number of operations	381	259	898	306	304	1214	800	846	308	238	200	722	1078	7554
Frequency pr. institution	**1.57**	**3.09**	**0.78**	**1.96**	**1.32**	**1.07**	**1.88**	**2.13**	**4.22**	**0.84**	**1.00**	**0.83**	**1.39**	**1.52**

Table 5.1 Major surgical- and generator/lead related complications within 120 days after all operations in 2018

5.1.2 Major complications per operation type up to 120 days after implant

Complications with major clinical impact or resulting in reoperation within 120 days after implant operation in 2018

Complication type	Operation type			
Surgical related	**First implant**	**Replacement**	**Up-Downgrade**	**Total**
Cardiac perforation not req. pericardiocentesis	15	0	1	16
Cardiac perforation req. pericardiocentesis	7	0	1	8
Deep venous thrombosis	5	2	0	7
Haemothorax req. drainage	1	1	0	2
Local pocket infection / Skin erosion	7	12	2	21
Pneumothorax not req. drainage	5	0	2	7
Pneumothorax req. drainage	11	3	0	14
Systemic infection / endocarditis	9	4	3	16
Total number of complications	60	22	9	91
Total number of operations	5447	1677	430	7554
Frequency of surgical related complications pr. operation type	**1.10**	**1.31**	**2.09**	**1.20**

Generator/lead related complications leading to re-operation	**First implant**	**Replacement**	**Up-Downgrade**	**Total**
Connector failure	0	1	0	1
Conductor break	0	0	0	0
Displacement	74	2	6	82
Extracardiac stimulation	3			3
Generator-lead interface problem	1			1
Failure to defibrillate	1			1
High pacing threshold	12	1	1	14
Insulation failure	1			1
Sensing / pacing failure	3	1		4
Twiddler's syndrome	3	1		4
Undersensing	3			3
Generator failure, other		1		1
Total number of complications	115	4	5	124
Total number of operations	5447	1677	430	7554
Frequency of generator/lead related complications pr. operation type	**1.85**	**0.42**	**1.63**	**1.52**

Table 5.2 Major surgical related complications within 120 days according to type of operations in 2018

5.1.3 Trends in major complications (either major clinical impact or resulting in re-operation) per operation type up to 120 days after implant

Surgical related complications* within 120 days after implant operation 2015 - 2018

Frequency pr. Institution

	Bispebjerg	Esbjerg	Gentofte	Herning	Hillerød	Odense	Rigshosp	Roskilde	Vejle	Viborg	Aabenrå	Ålborg	Aarhus	Total
2015	0.93	1.19	1.43	0.68	1.86	1.09	2.16	2.11	0.75	0.53	1.74	3.94	2.08	**1.80**
2016	0.51	2.38	0.37	1.43	1.38	0.93	1.02	1.93	1.82	0.44	3.24	1.55	1.67	**1.31**
2017	0.60	0.45	0.87	1.47	1.89	0.71	1.82	3.50	0.99	0.43	2.23	1.87	1.04	**1.44**
2018	1.05	1.16	0.78	2.29	0.99	0.99	0.63	1.18	0.97	2.10	1.50	1.39	1.67	**1.20**

Table 5.3 Major surgical complications within 120 days after implant operations in 2015-2018 (*See Table 5.1 for definition of Surgical related complications)

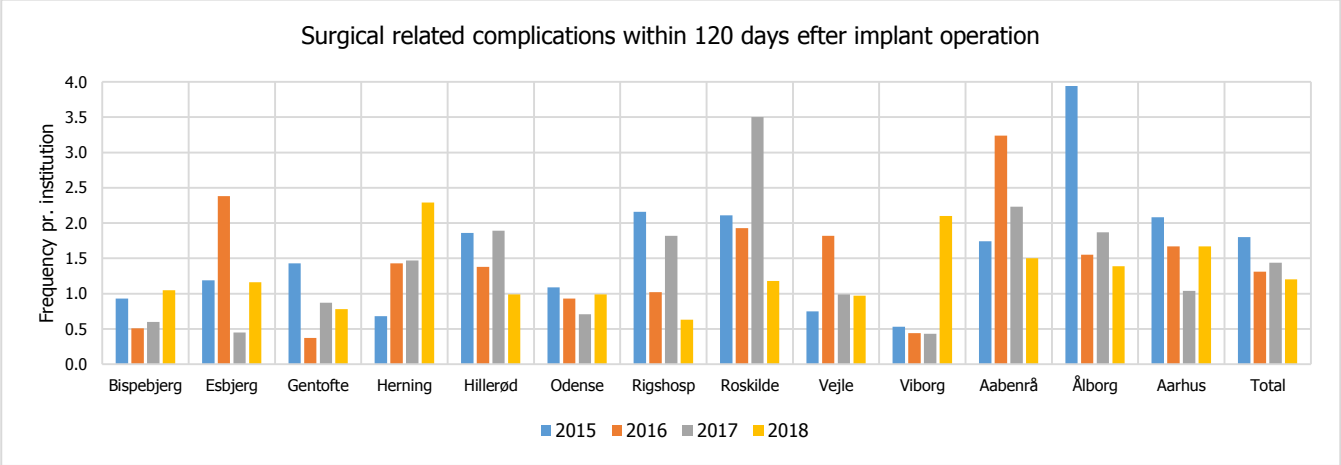

Figure 5.1 Major surgical complications within 120 days after implant operations in 2015-2018

Generator/lead related complications* within 120 days after implant operation 2015 - 2018

Frequency pr. institution

	Bispebjerg	Esbjerg	Gentofte	Herning	Hillerød	Odense	Rigshosp	Roskilde	Vejle	Viborg	Aabenrå	Ålborg	Aarhus	**Total**
2015	1.63	3.56	1.19	3.07	2.60	1.64	3.05	2.86	0.75	2.12	1.16	2.33	1.09	**2.00**
2016	0.51	7.54	1.46	1.08	2.07	1.39	2.30	2.54	0.36	1.32	0.00	0.56	1.75	**1.71**
2017	0.60	5.43	0.99	0.37	2.21	1.51	1.46	1.87	1.99	1.73	1.68	1.20	1.47	**1.54**
2018	1.57	3.09	0.78	1.96	1.32	1.07	1.88	2.13	4.22	0.84	1.00	0.83	1.39	**1.52**

Table 5.4 Generator/lead related complications within 120 days after implant operations in 2015-2018 (*See Table 5.1 for definition of generator/lead related complications)

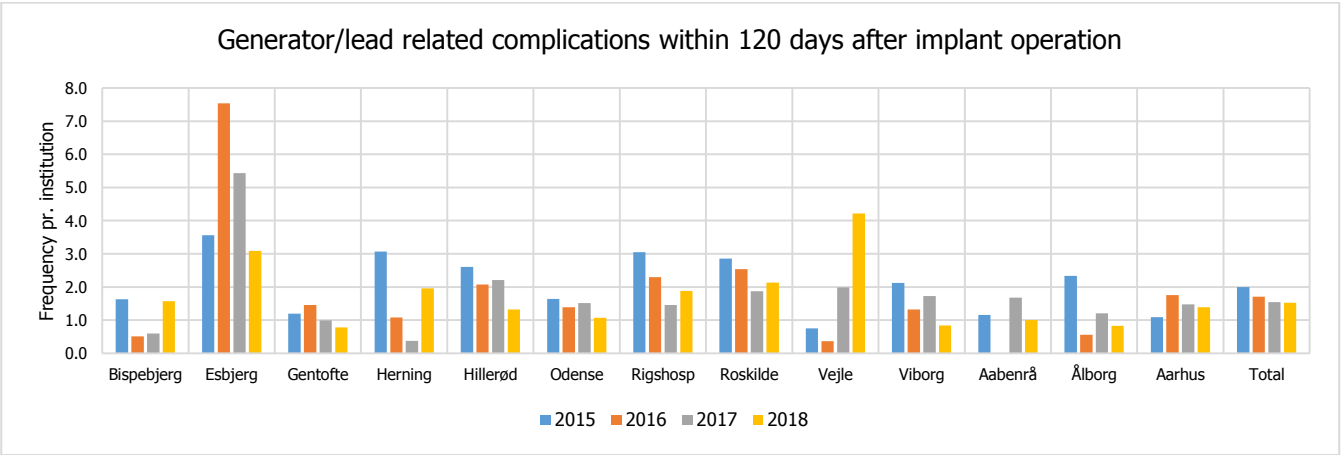

Figure 5.2 Generator/lead related complications within 120 days after implant operations in 2015-2018

5.2 CIED infection

5.2.1 Removal of system due to infection up to 365 days after implant

Infection leading to removal of the CIED system within 365 days after implant operation in 2017

	Institution													
Infection type	Bispebjerg	Esbjerg	Gentofte	Herning	Hillerød	Odense	Rigshosp	Roskilde	Vejle	Viborg	Aabenrå	Ålborg	Aarhus	**Total**
Local pocket infection / Skin erosion		1	2	1	2	2	2	3	3	1	2	7	5	31
Systemic infection / endocarditis	2		3	4	0	6	7	4				4	2	32
All infections	2	1	5	5	2	8	9	7	3	1	2	11	7	63
Total number of operations	333	221	806	273	317	1124	822	801	302	232	179	749	1153	7312
Frequency of infection leading to removal of CIED system	0.60	0.45	0.62	1.83	0.63	0.71	1.09	0.87	0.99	0.43	1.12	1.47	0.61	**0.86**

Table 5.5 Infection leading to removal of the CIED system within 365 days after implant operation in 2017

5.2.2 Trend in CIED infection 2015 - 2017

Infection (either local pocket infection/skin erosion or systemic infection/endocarditis) leading to removal of the CIED system within 365 days after implant operation in 2015 - 2017

	Institution													
Frequency pr. institution	Bispebjerg	Esbjerg	Gentofte	Herning	Hillerød	Odense	Rigshosp	Roskilde	Vejle	Viborg	Aabenrå	Ålborg	Aarhus	**Total**
2015	0.70	0.00	0.60	0.34	0.37	0.66	1.15	0.75	0.37	0.00	0.58	1.02	1.72	**0.84**
2016	0.26	0.79	0.12	1.08	0.34	0.74	1.41	0.60	1.46	0.44	0.54	1.83	1.75	**0.98**
2017	0.60	0.45	0.62	1.83	0.63	0.71	1.09	0.87	0.99	0.43	1.12	1.47	0.61	**0.86**

Table 5.6 Infection (either local pocket infection/skin erosion or systemic infection/endocarditis) leading to removal of the CIED system within 365 days after implant operation in 2015-2017

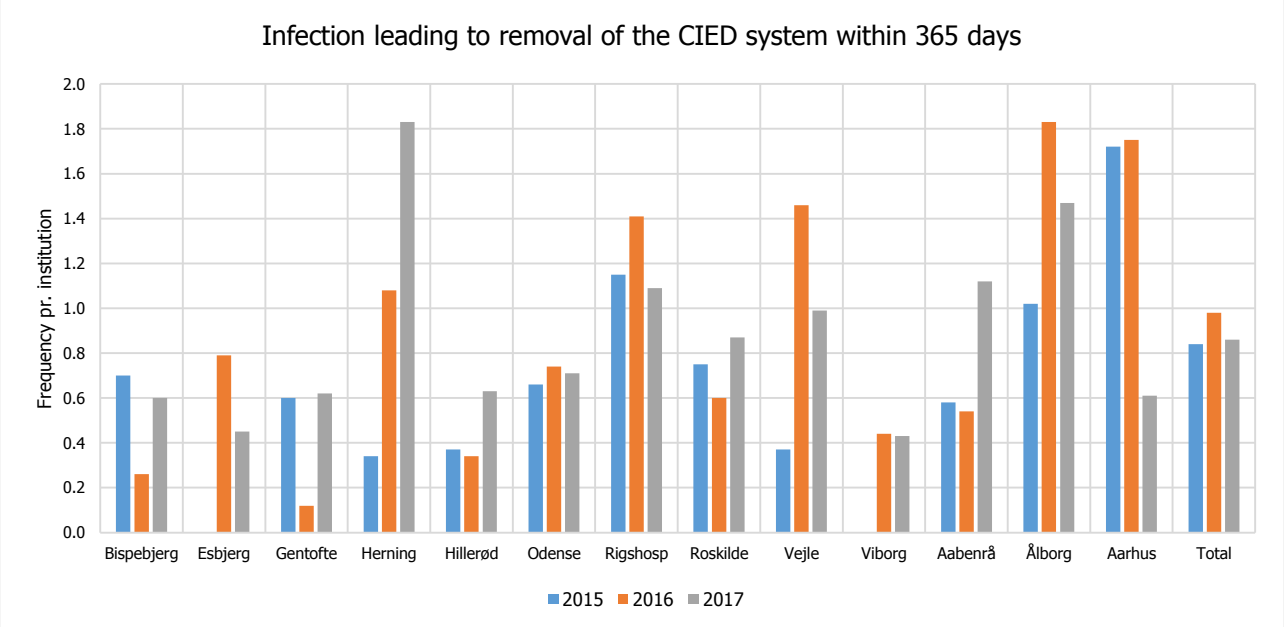

Figure 5.3 Infection (either local pocket infection/skin erosion or systemic infection/endocarditis) leading to removal of the CIED system within 365 days after implant

5.3 Lead access

5.3.1 Ratio of cephalic vein cut-down to subclavian vein puncture in lead implants during first device implants

Lead access in first implants in 2018
Ratio of cephalic | subclavian vein

	Institution													
Lead type	Bispebjerg	Esbjerg	Gentofte	Herning	Hillerød	Odense	Rigshosp	Roskilde	Vejle	Viborg	Aabenrå	Ålborg	Aarhus	**Total**
Atrial	3.02	2.87	3.89	1.66	2.16	3.34	1.21	2.47	1.20	2.33	3.63	2.06	2.02	2.33
Right ventricular pace	3.38	3.17	4.50	1.77	2.64	3.49	3.01	2.74	1.18	2.55	3.63	2.50	2.17	2.72
Right ventricular defibrillation			5.86			5.18	4.12	3.04				2.50	2.22	3.28
Left ventricular pacing			0			0.86	0.06					0	0.27	0.29
Total	3.21	3.03	3.68	1.72	2.41	3.03	1.53	2.66	1.19	2.45	3.63	1.92	1.80	**2.32**

Table 5.7 Ratio of cephalic cut-down to subclavian vein puncture in lead access during first device implant in 2018

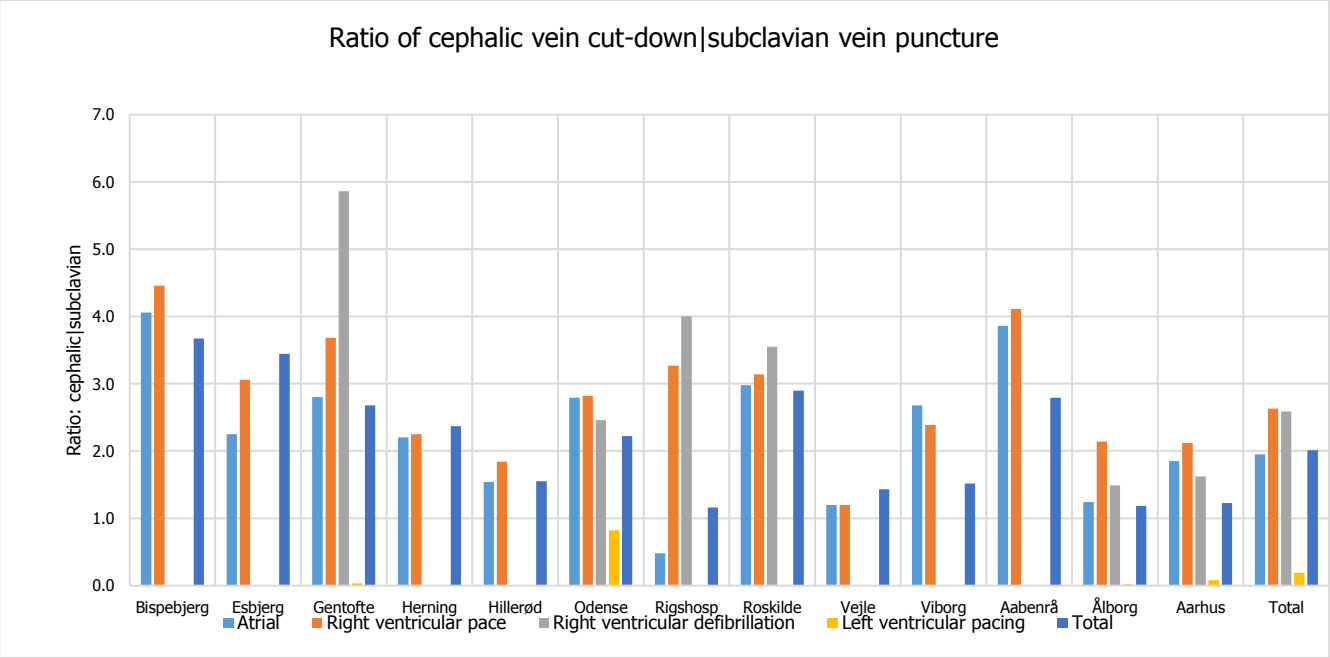

Figure 5.4 Ratio of cephalic cut-down to subclavian vein puncture in lead access during first device implant in 2018

5.4 Operator experience

5.4.1 Number of operators fulfilling annual operator experience as recommended by the Danish National Board of Health

Operators fulfilling recommended annual operator experience out of total number of operators
(Figure in brackets denotes number of operators in training)

	Institution												
Device type	Bispebjerg	Esbjerg	Gentofte	Herning	Hillerød	Odense	Rigshosp	Roskilde	Vejle	Viborg	Aabenrå	Ålborg	Aarhus
Pacemaker, ≥50/year	3/3	3/3	3/7(1)	3/4	3/4	5/6(1)	4/5	5/7(1)	4/4	3/4(1)	3/3	4/6(1)	8/9(1)
ICD, ≥50/year	-	-	3/5(1)	-	-	5/6(1)	4/5	2/3	-	-	-	3/6(1)	5/8
Biventricular device, ≥25/year	-	-	3/3	-	-	5/5	3/5	-	-	-	-	1/4	6/8

Table 5.8 Number of operators fulfilling annual operator experience as recommended by the Danish National Board of Health