

# Danish Pacemaker and ICD Register

## Annual Report

### 2016



## 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 99597 pacemaker- and 20780 ICD implants as of 31. December 2016.

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.

Odense, May-2018

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](http://www.icddata.dk) | [support@icddata.dk](mailto:support@icddata.dk)

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## 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 May 2018):

- 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](http://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 2016

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

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			
Varde	X					
Vejle	X					
Viborg	X					
Aabenraa	X					
Ålborg	X	X	X	X	X	
Aarhus	X	X	X	X	X	X

Table 1.1 Pacemaker and ICD implantation in Danish hospitals 2016

\*Only VVI pacemakers.

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

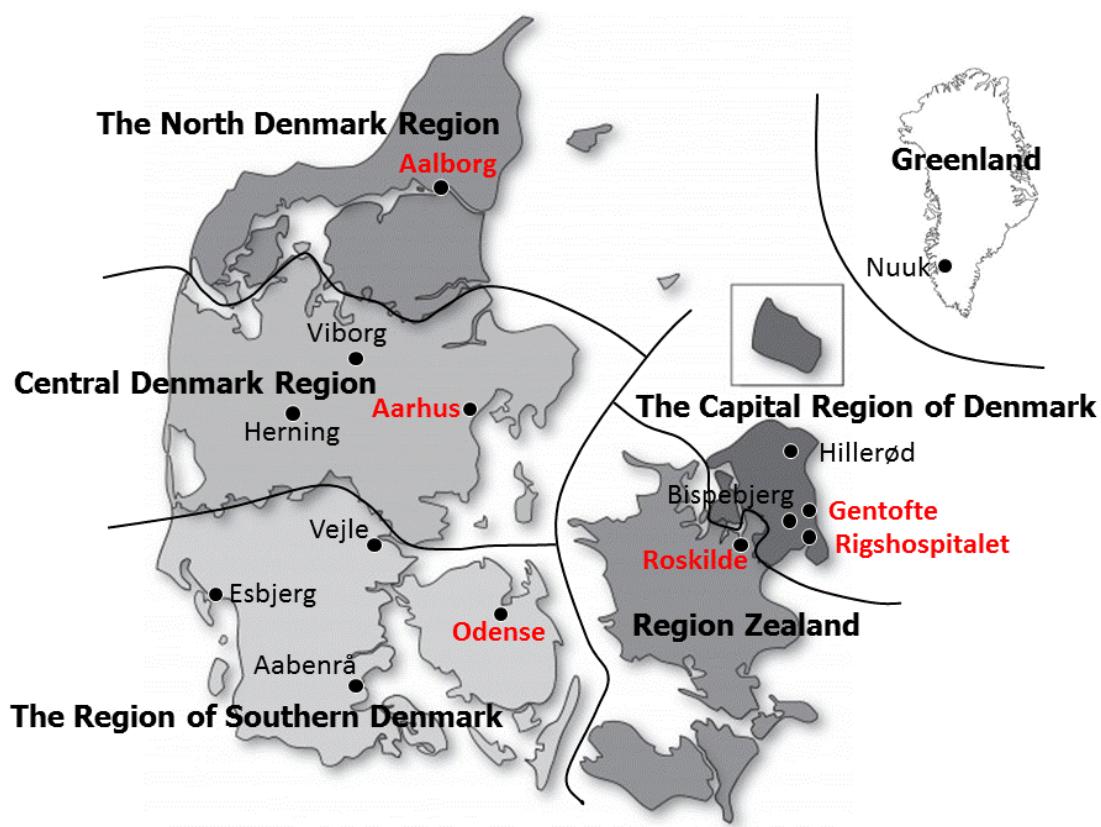


Figure 1.1 Device Implanting hospitals in Denmark

### 1.2.1 Pacemaker

The majority of first pacemaker implants was dual chamber (n=2989, 69.2%) and about one quarter was single chamber right ventricle pacemakers (n=917, 22.0%). A small number (n=47), but increasing compared to 2015, of the single chamber right ventricle were lead-less Micra pacemakers. Biventricular pacemakers were implanted in a smaller percentage (n=259, 6.2%) and an even smaller number (n=11, 0.3%) were single chamber atrial pacemakers (See table 2.1).

The pacemaker replacements and system up-/downgrades took up 21.5% 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=712, 62.6%) while DDD (n=154, 13.5%) and CRT-D (n=272, 23.9%) was only used in a smaller number. Total subcutaneous ICD was implanted in 13 cases (See table 2.4).

The ICD replacements and system up-/downgrades took up 38.5% of the total number of ICD implants in 2016 (See table 2.5 and table 2.6).

The indication for first ICD implant was primary prophylactic in 45.7% in all first implants (See Table 2.12 and Figure 2.5), and the predominant etiology for ICD implant was ischemic heart disease (76.1%) (See table 2.14 and figure 2.6).

### 1.2.3 Leads

All low voltage leads for atrial and right ventricle were bipolar active fixation leads. Of n=842 low voltage leads for left ventricular pacing, n=792 (94%) were quadripolar and n=50 (6%) 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=1420 right ventricular defibrillation leads n=843 (60%) were single coil leads and n=577 (40%) were dual coil leads (See table 2.10).

## 1.3 Comments on pacemaker and ICD patients

The largest group of patients for first pacemaker implant were 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 40.2% 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=69, 6.0%) (See table 3.3 and figure 3.3).

Male patients were dominating in first ICD implants (n=940, 82.0%) (See Table 3.4 and Figure 3.4).

At the end of 2016 29667 pacemaker- and 9881 ICD patients were in treatment and alive (See table 3.5 and table 3.6).

## 1.4 Comments on trends in implant activity 2000-2016

### 1.4.1 Number of implants

The number of first pacemaker implants has increased from 440 per million citizens in 2000 to 732 per million citizens in 2016. 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 192 per million citizens in 2015 (See Table 4.2 and Figure 4.2), but showed a slight increase in 2016 to 201 per million citizens. In this context, it is important to recognize that primary prophylactic indication in ischemic heart disease was endorsed in Denmark in 2006.

There seems to be minor regional differences in number of implants with The Capital Region and Region Zealand implanting 184.5 ICDs per million citizens and The Region of Southern Denmark 223 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 69.2% in 2016. Single lead atrial pacing (AAI) has almost disappeared, whereas VVI pacing has remained constant from 22.8% in 2000 to 22.0 in 2016 (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 62.6% in 2016. CRT-D and DDD-ICD were more often implanted previously (highest in 2011), but after a decrease they now constitute 23.9% (CRT-D) 13.5% (DDD-ICD) of all first implants (See Table 4.5 and Figure 4.4). However, the numbers of CRT-D has increased from 19.6% in 2015.

### 1.5 Comments on Quality in device treatment 2016

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 fulfil these criteria with the exception of one institution, with a frequency of 7.54% of lead/generator complications leading to reoperation (See Table 5.1). First implant had a higher risk of generator/lead related complication (2.17%) compared to device replacement (0.29%) and up-/downgrade (0.85%) (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 5.3, 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.

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 5.4 and Figure 5.1).

## 2 Implant activity in Denmark 2016

### 2.1 Pacemaker

#### 2.1.1 First pacemaker implantation: (Institution|pacing mode)

Institution	Operation   First implant					First Implant Total
	Actual device					
PM-AAI	PM-VVI	PM-VVI leadless	PM-DDD	CRT-P		
Bispebjerg	4	71		262		337
Esbjerg		29		182		211
Gentofte		161	8	248	36	453
Herning	2	51		152		205
Hillerød	1	47	7	181		236
Nuuk		16				16
Odense		29	20	348	79	476
Rigshospitalet	2	23	1	134	56	216
Roskilde		174		403		577
Varde				2	1	3
Vejle		59		162		221
Viborg		31		124		155
Aabenraa		36		107		143
Ålborg	1	67		277	42	387
Aarhus	1	76	11	407	45	540
Grand Total	11	870	47	2989	259	4176

Table 2.1 First pacemaker implantations in Denmark 2016 for each institution and pacing mode

#### 2.1.2 Pacemaker replacement: (Institution|pacing mode)

Institution	Operation   Replacement						Replacement Total
	Actual Device						
PM-AAI	PM-VVI	PM-VVI leadless	PM-VDD	PM-DDD	CRT-P		
Bispebjerg	5	11			36		52
Esbjerg	2	9			24		35
Gentofte	5	12	1	12	46	6	81
Herning	4	8			48		60
Hillerød	3	6			33		42
Nuuk		1					1
Odense	3	10	2		75	25	113
Rigshospitalet		4			36	21	61
Roskilde	8	10			88		106
Vejle	6	9			24		39
Viborg	3	8			48	2	61
Aabenraa	2	8			24		34
Ålborg	1	8			69	10	88
Aarhus	1	6	2		48	33	88
Grand Total	43	110	5		599	97	861

Table 2.2 Pacemaker replacements in Denmark 2016 for each institution and pacing mode

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

Institution	Operation   Up-/ downgrade					Up/downgrd. Total
	Actual Device					
	PM-AAI	PM-VVI	PM-VVI leadless	PM-DDD	CRT-P	
Bispebjerg		1				1
Esbjerg		1		4		5
Gentofte		3	1	4	11	19
Herning	1	10		1		12
Hillerød		9	1	1		11
Odense		12	8	5	33	58
Rigshospitalet		2		7	22	31
Roskilde		10		13		23
Vejle		11		3		14
Viborg		11		1		12
Aabenraa		6				6
Ålborg		15		5	13	33
Aarhus	2	10	4	8	35	59
Grand Total	3	101	14	52	114	284

Table 2.3 Pacemaker up-/downgrades in Denmark 2016 for each institution and pacing mode

## 2.2 ICD

### 2.2.1 First ICD implantation (Institution|pacing mode)

Institution	Operation   First implant			
	Actual device			
	VVI-ICD*	DDD-ICD	CRT-D	First Implant Total
Gentofte	105	15	29	149
Odense	190	2	80	272
Rigshospitalet	143	33	68	244
Roskilde	71	23		94
Ålborg	60	39	20	119
Aarhus	143	42	75	260
Grand Total	712	154	272	1138

Table 2.4 First ICD implantations in Denmark 2016 for each institution and pacing mode

\*Of 712 VVI-ICD 13 (1.4%) were subcutaneous ICD, 8 implanted at Odense and 5 at Rigshospitalet.

### 2.2.2 ICD replacement: (Institution|pacing mode)

Institution	Operation   First implant			
	Actual device			
	VVI-ICD*	DDD-ICD	CRT-D	First Implant Total
Gentofte	29	11	25	65
Odense	40	18	29	87
Rigshospitalet	78	37	38	153
Roskilde	8	7		15
Ålborg	11	12	23	46
Aarhus	34	33	62	129
Grand Total	200	118	177	495

Table 2.5 ICD replacements in Denmark 2016 for each institution and pacing mode

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

Institution	Operation   Up-/ downgrade			
	Actual device			
	VVI-ICD*	DDD-ICD	CRT-D	Up/downgrad. Total
Gentofte	4	8	20	32
Odense	7	7	50	64
Rigshospitalet	7	9	46	62
Roskilde				
Ålborg		5	12	17
Aarhus	3	13	26	42
Grand Total	21	42	154	217

Table 2.6 ICD up-/downgrade in Denmark 2016 for each institution and pacing mode

## 2.3 Manufacturer

### 2.3.1 Pacemaker (manufacturer|pacing mode)

Manufacturer	Actual device					Grand Total	Percent [%]
	PM-AAI	PM-VVI	PM-VDD	PM-DDD	CRT-P		
Biotronik	5	127		516	10	658	12,3
Boston Scientific	8	141	12	440	106	707	13,2
Medtronic	26	366		748	16	1156	21,7
Pacesetter		3				3	0,1
Sorin	1	66		153		220	4,1
St. Jude Medical	17	444		1793	338	2592	48,6
Grand Total	57	1147	12	3650	470	5336	100

Table 2.7 Manufacturer of pacemakers implanted in Denmark 2016 for each pacing mode

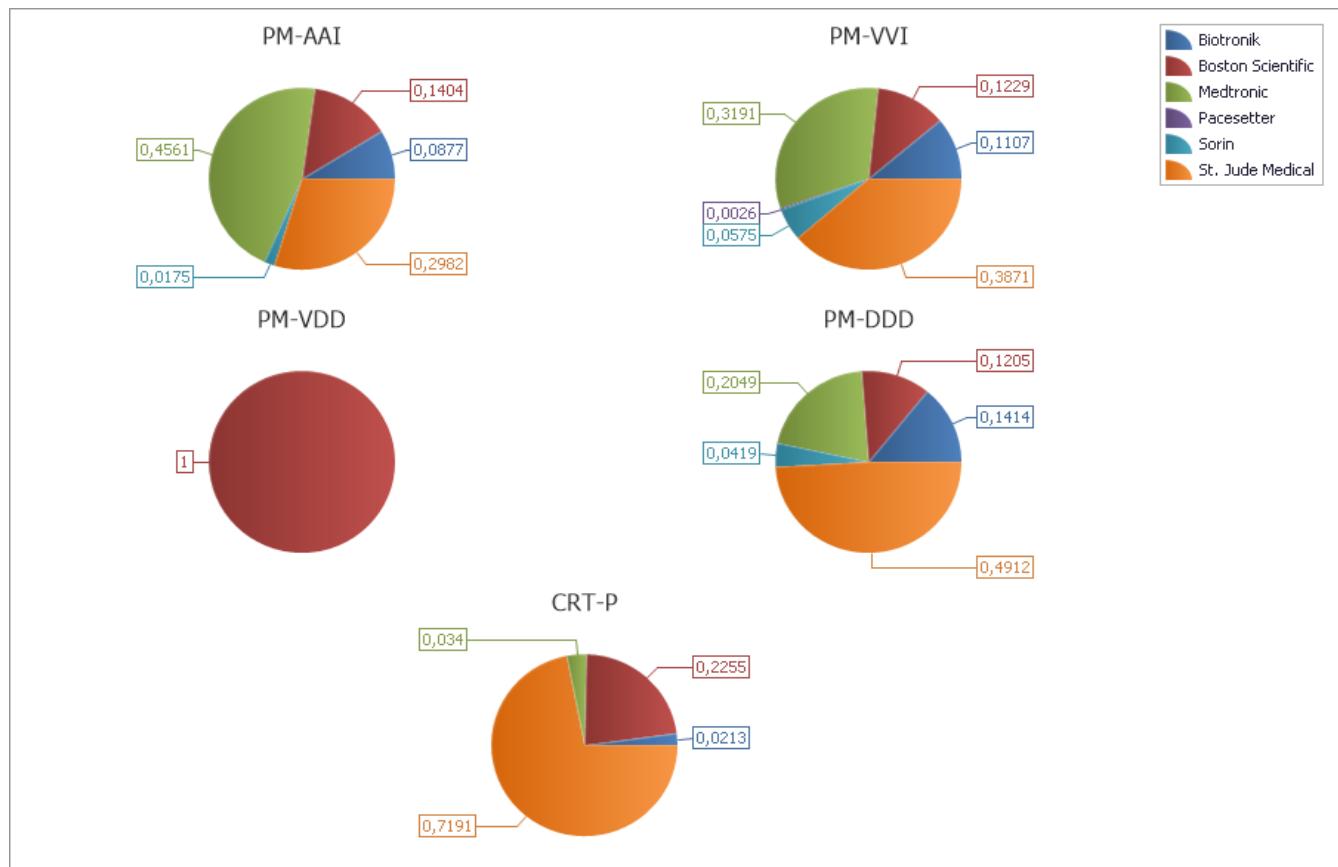


Figure 2.1 Manufacturer of pacemakers implanted in Denmark 2016 for each pacing mode

### 2.3.2 ICD (manufacturer|pacing mode)

Manufacturer	Operation   Up-/downgrade			First Implant Total	Percent [%]
	Actual device				
Biotronik	182	65	81	328	17.6
Boston Scientific	150	39	47	236	12.7
Medtronic	258	105	172	535	28.8
St. Jude Medical	347	108	305	760	40.9
Grand Total	937	317	605	1859	100.0

Table 2.8 Manufacturer of ICD's implanted in Denmark 2016 for each pacing mode

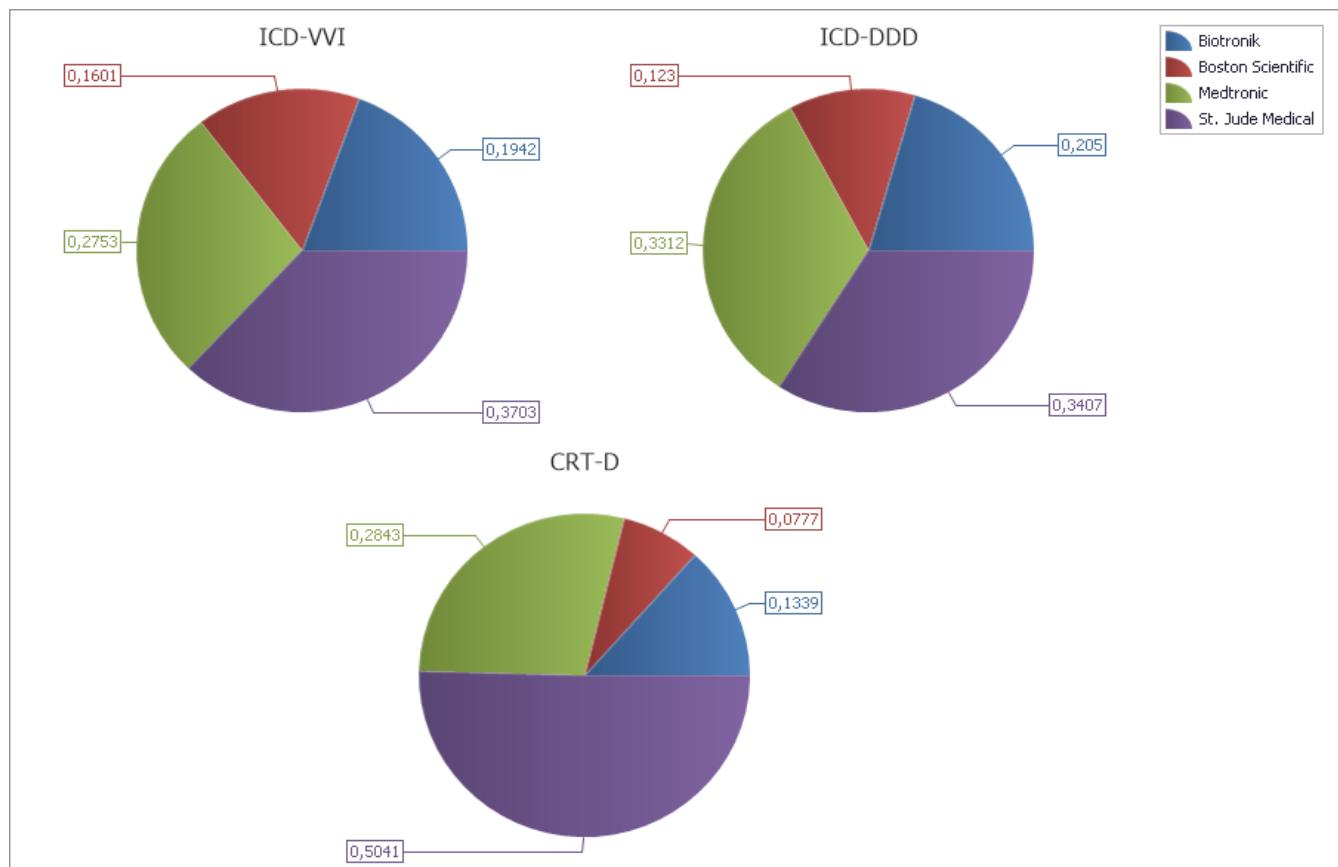


Figure 2.2 Manufacturer of ICD's implanted in Denmark 2016 for each pacing mode

## 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	126	15	501	1	643	7.0
Boston Scientific	142	5	131		278	3.0
Medtronic	18	20	19	1	58	0.6
St. Jude Medical	3646	802	3737	9	8194	89.3
Grand Total	3932	842	4388	11	9173	100.0

Table 2.9 Manufacturer of low voltage leads implanted in Denmark 2016

\*Of 842 low voltage leads for left ventricular pacing, 792 (94%) were quadripolar and 50 (6%) bipolar.



Figure 2.3 Manufacturer of low voltage leads implanted in Denmark 2016

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

	Right ventricular defibrillation	Supplementary defibrillation	Grand Total	Percent [%]
Biotronik	323		323	22.7
Boston Scientific	225	3	228	16.1
Cameron Health	1		1	0.1
Medtronic	119	11	127	8.9
St. Jude Medical	741		741	52.2
Grand Total	1409*	11	1420	100.0

Table 2.10 Manufacturer of high voltage leads implanted in Denmark 2016

\*Of 1420 right ventricular leads 843 (60%) were single coil leads and 577 (40%) were dual coil leads.

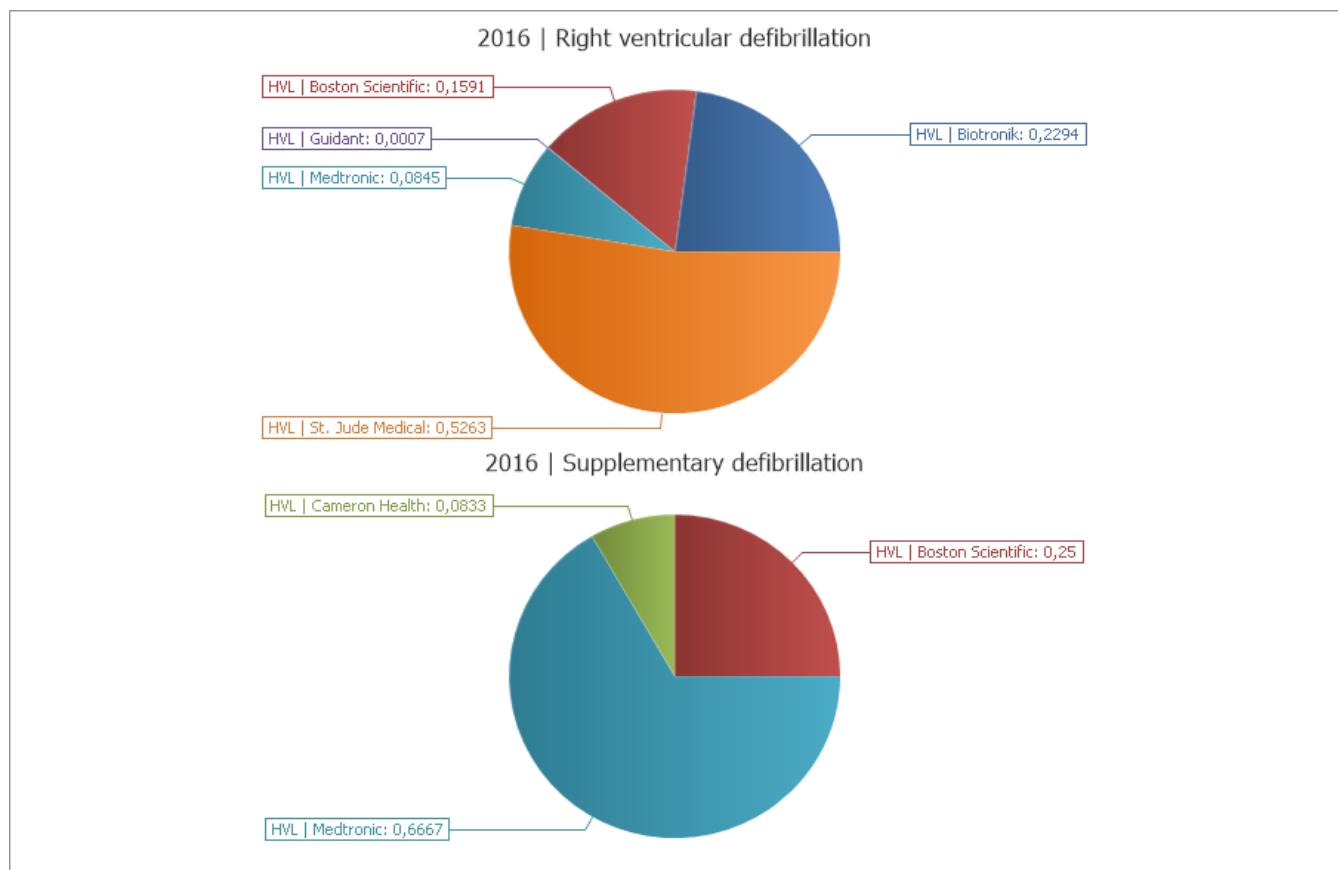


Figure 2.4 Manufacturer of high voltage leads implanted in Denmark 2016

## 2.5 Indication

### 2.5.1 Pacemaker (First implant|ECG indication)

Indication	Operation   First Implant	Percent [%]
Arrhythmia not documented	7	0.2
Atrial arrhythmias without sinus dysfunction	18	0.4
AV block - 1°	28	0.7
AV block - 2:1	96	2.3
AV block - 2° . advanced type	128	3.1
AV block - 2° type I	51	1.2
AV block - 2° type II	235	5.6
AV block - 3°	1364	32.6
AV conduction impaired - status unknown	25	0.6
Bradycardia - Tachycardia syndrome	512	12.2
Bundle branch block, unspecified	79	1.9
Chronic atrial fibrillation & AV block - 3°	197	4.7
Chronic atrial fibrillation & bradycardia	268	6.4
Left bundle branch block	171	4.1
Other	37	0.9
Polymorphic VT /Torsades des pointes	4	0.1
Right bundle branch block	74	1.8
Sinus node dysfunction unspec. + impaired AV conduction	37	0.9
Sinus node dysfunction unspecified	35	0.8
Sinus node dysfunction with pause	659	15.7
Sinus node dysfunction without pause	99	2.4
Unknown	62	1.5
Grand Total	4186	100.0

Table 2.11 ECG indication, first pacemaker implantation Denmark 2016

## 2.5.2 ICD (First implant|ECG indication)

Indication	Operation   First Implant	Percent [%]
Other	7	0.6
Prophylactic (none documented / induced)	524	45.7
Syncope with inducible VT or VF	15	1.3
Unknown	26	2.3
Ventricular Fibrillation	306	26.7
VT - monomorphic Non-sustained	74	6.5
VT - monomorphic Sustained	179	15.6
VT - Polymorphic w. long QT (Torsades des pointes)	12	1.0
VT - polymorphic (with normal QT interval)	3	0.3
Wide complex tachycardia unspecified	1	0.1
Grand Total	1147	100.0

Table 2.12 ECG indication, first ICD implantation Denmark 2016

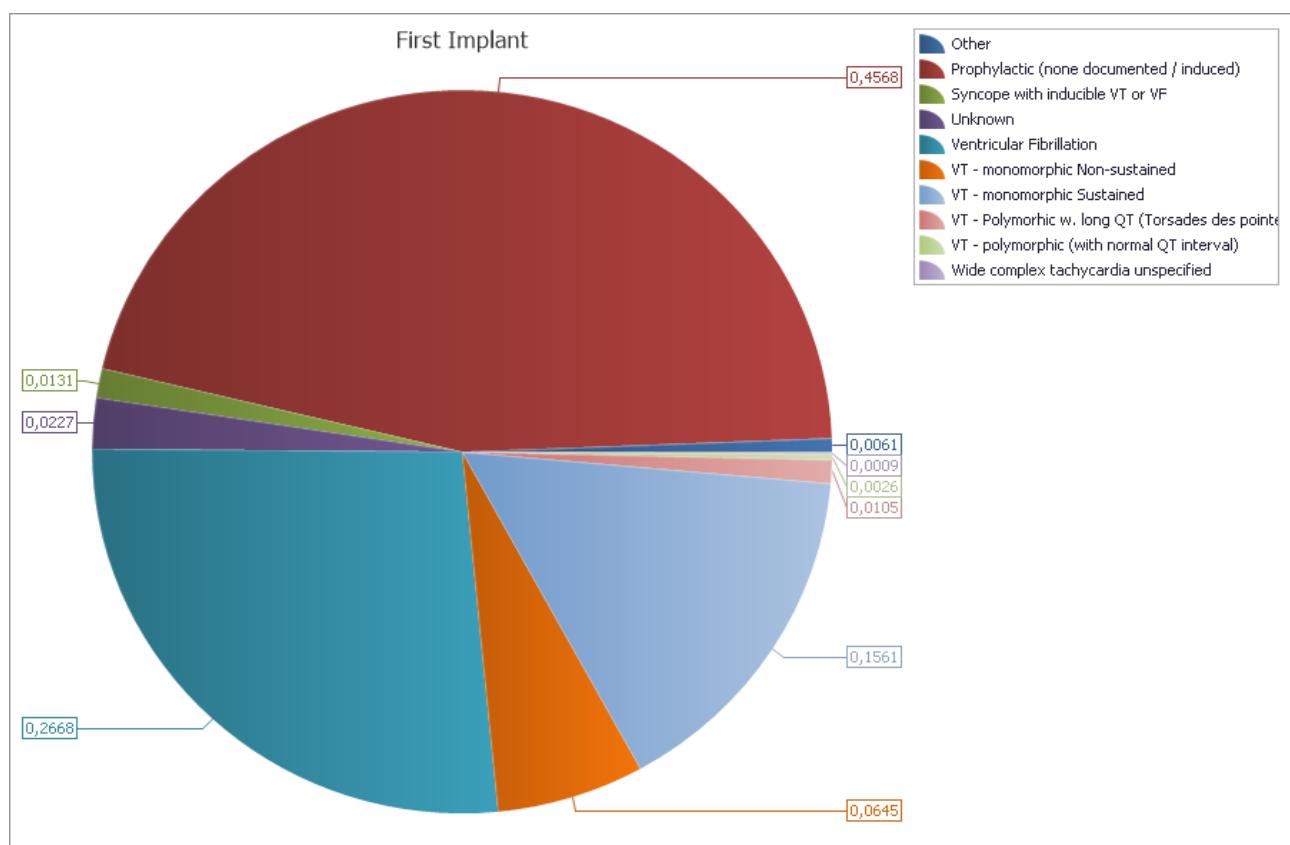


Figure 2.5 ECG indication, first ICD implantation Denmark 2016

## 2.6 Etiology

### 2.6.1 Pacemaker (First implant) | Etiology

Diagnosis	Operation   First Implant	Percent [%]
Autonomic dysfunction, other	10	0.2
AV node ablation, complication	2	0.0
AV node ablation, therapeutic	25	0.6
Cardiomyopathy - dilated	143	3.4
Cardiomyopathy - hypertrophic	8	0.2
Cardiomyopathy - other	22	0.5
Carotid sinus syndrome	72	1.7
Conduction tissue disease	2402	57.4
Congenital AV block	6	0.1
Congenital heart disease	8	0.2
Drug induced	12	0.3
Endocarditis	4	0.1
Heart transplant	1	0.0
Ischaemic heart disease	204	4.9
Myocarditis	1	0.0
Other	241	5.8
Primary electrical disease - other	77	1.8
Surgical complication	110	2.6
Unknown	770	18.4
Valvular heart disease	56	1.3
Vasovagal syncope	12	0.3
Grand Total	4186	100.0

Table 2.13 Etiology, first pacemaker implantation Denmark 2016

## 2.6.2 ICD (First implant|Indication)

Diagnosis	Operation   First Implant	Percent [%]
Arrhythmogenic right ventricle	10	0.9
Brugada syndrome	7	0.6
Cardiomyopathy - dilated	98	8.5
Cardiomyopathy - hypertrophic	27	2.4
Cardiomyopathy - other	51	4.4
Congenital heart disease	5	0.4
Congenital long QT	8	0.7
Idiopathic ventricular fibrillation	28	2.4
Ischaemic heart disease	815	71.1
Other	13	1.1
Primary electrical disease - other	15	1.3
Unknown	57	5.0
Valvular heart disease	13	1.1
<b>Grand Total</b>	<b>1147</b>	<b>100.0</b>

Table 2.14 Etiology, first ICD implantation, Denmark 2016

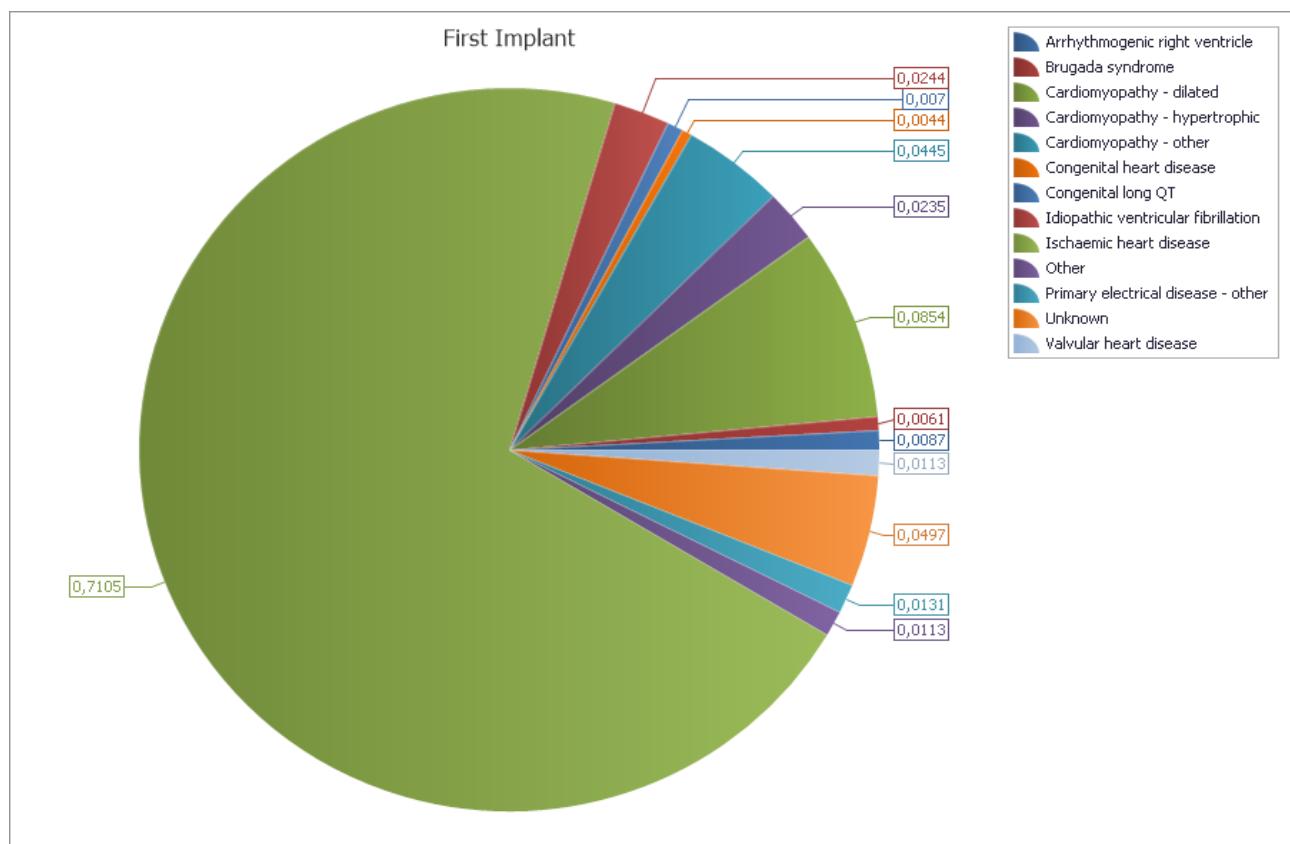


Figure 2.6 Etiology, first ICD implantation, Denmark 2016

### 3 Patients

#### 3.1 Age and sex

##### 3.1.1 First pacemaker implant (Age group|pacing mode)

Actual Device	Age at first implant																			Grand Total		
	0-4	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	105-109	
PM-AAI				1									1		1	3		4		1		11
PM-VVI	2			2	1		2	1		4	10	17	34	108	141	195	212	142	41	4	1	917
PM-DDD	4	1	4	7	9	5	7	37	29	88	106	190	336	568	592	514	363	120	18	1		2999
CRT-P						1		1	3	14	20	26	42	53	46	35	18					259
Grand Total	6	1	4	10	10	6	9	39	32	106	137	233	413	732	779	748	593	263	59	5	1	4186

Table 3.1 Age group in first pacemaker implantation, Denmark 2016

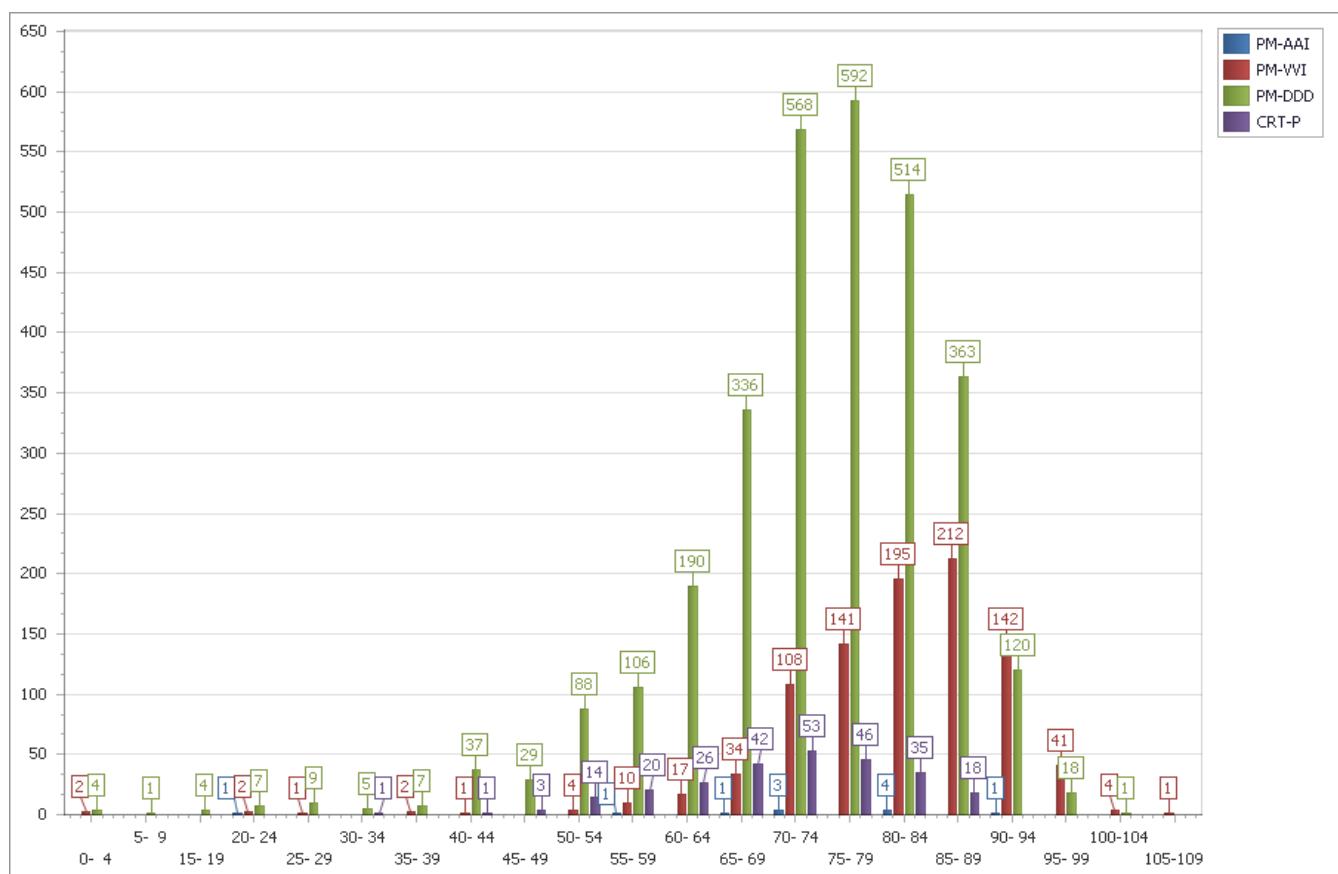


Figure 3.1 Age group in first pacemaker implantation, Denmark 2016

### 3.1.2 First pacemaker implant (Sex|pacing mode)

Sex			
Actual Device	Female	Male	Grand Total
PM-AAI	5 (45.5%)	6 (54.5%)	11
PM-VVI	369 (40.2%)	548 (59.8%)	917
PM-DDD	1221 (40.7%)	1778 (59.3%)	2999
CRT-P	86 (33.2%)	173 (66.8%)	259
Grand Total	1681 (40.2%)	2505 (59.8%)	4186

Table 3.2 Gender in first pacemaker implantation in each pacing mode, Denmark 2016

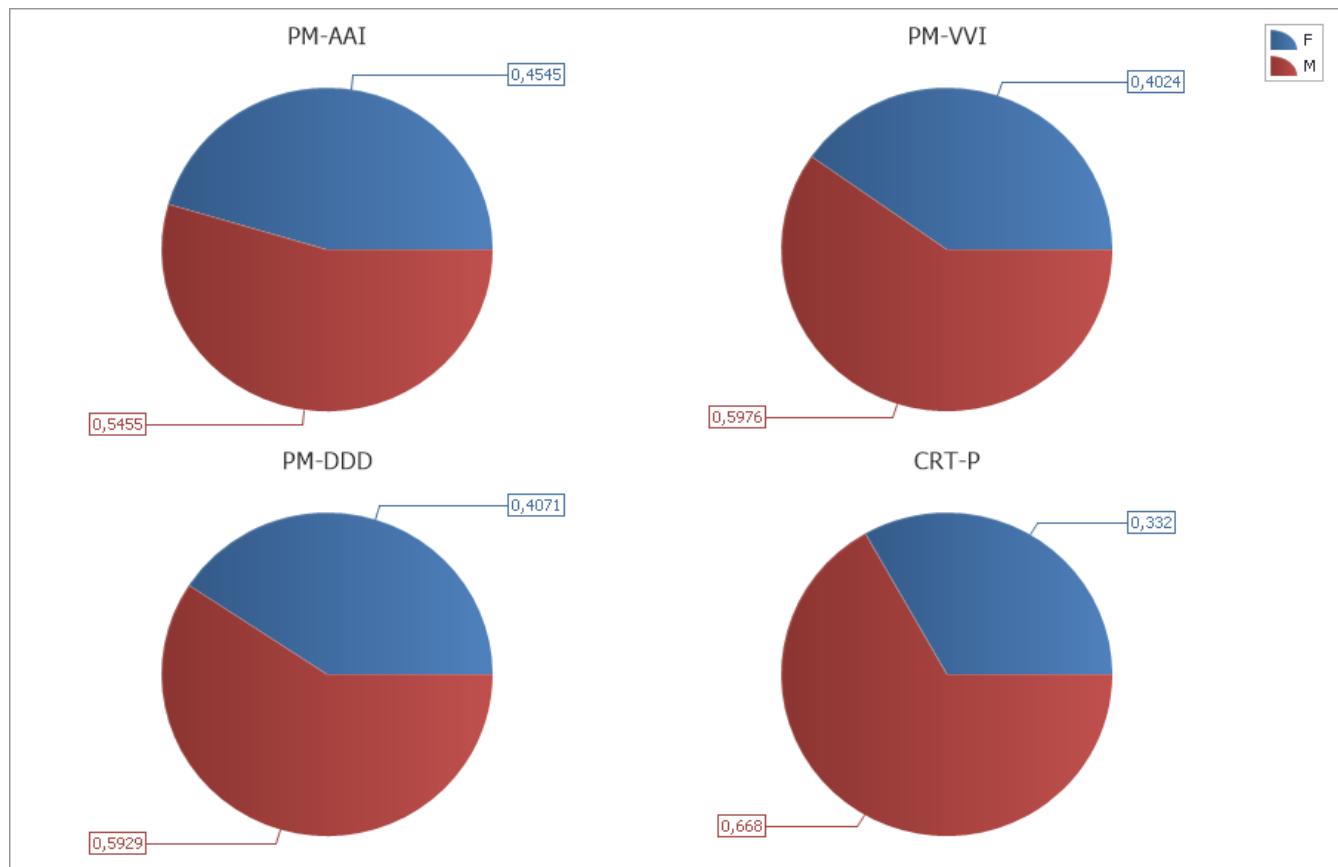


Figure 3.2 Gender in first pacemaker implantation in each pacing mode, Denmark 2016

### 3.1.3 First ICD implant (Age group | pacing mode)

Actual Device	Age at first implant																		Grand Total
	0-4	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	95-99	
ICD-VVI	3	3	4	4	6	7	9	21	33	63	87	107	114	139	79	34	3		716
ICD-DDD				1	3	2	1	4	12	14	10	21	23	29	21	12	3	1	157
CRT-D						1	1	13	8	15	28	34	52	54	52	16			274
Grand Total	3	3	4	5	9	10	11	38	53	92	125	162	189	222	152	62	6	1	1147

Table 3.3 Age group in first ICD implantation, Denmark 2016

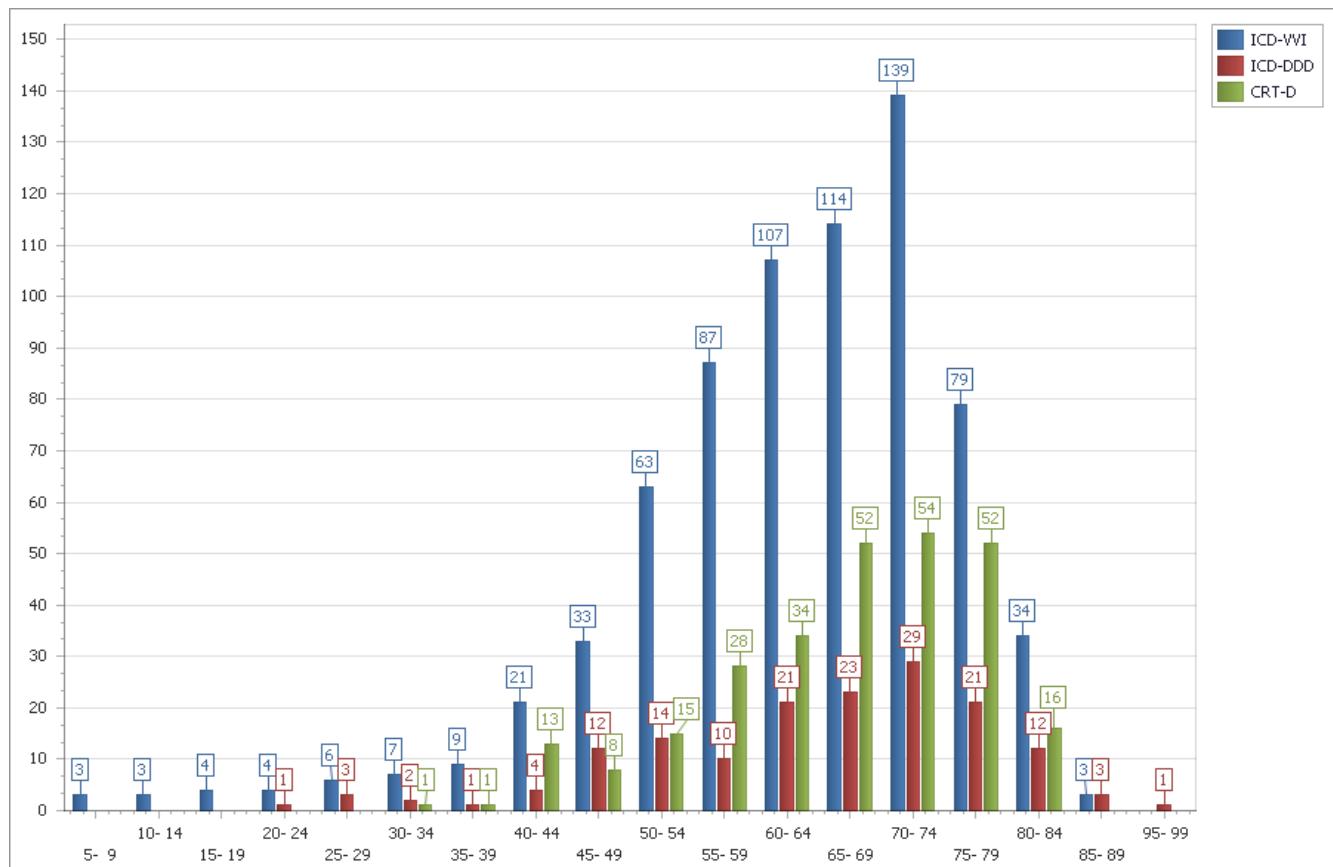


Figure 3.3 Age group in first ICD implantation, Denmark 2016

### 3.1.4 First ICD implant (Sex|pacing mode)

Actual Device	Sex		
	Female	Male	Grand Total
ICD-VVI	118 (16.5%)	598 (83.5%)	716
ICD-DDD	37 (23.6%)	120 (76.4%)	157
CRT-D	52 (19.0%)	222 (81.0%)	274
Grand Total	207 (18.0%)	940 (82.0%)	1147

Table 3.4 Gender in first ICD implantation in each pacing mode, Denmark 2016

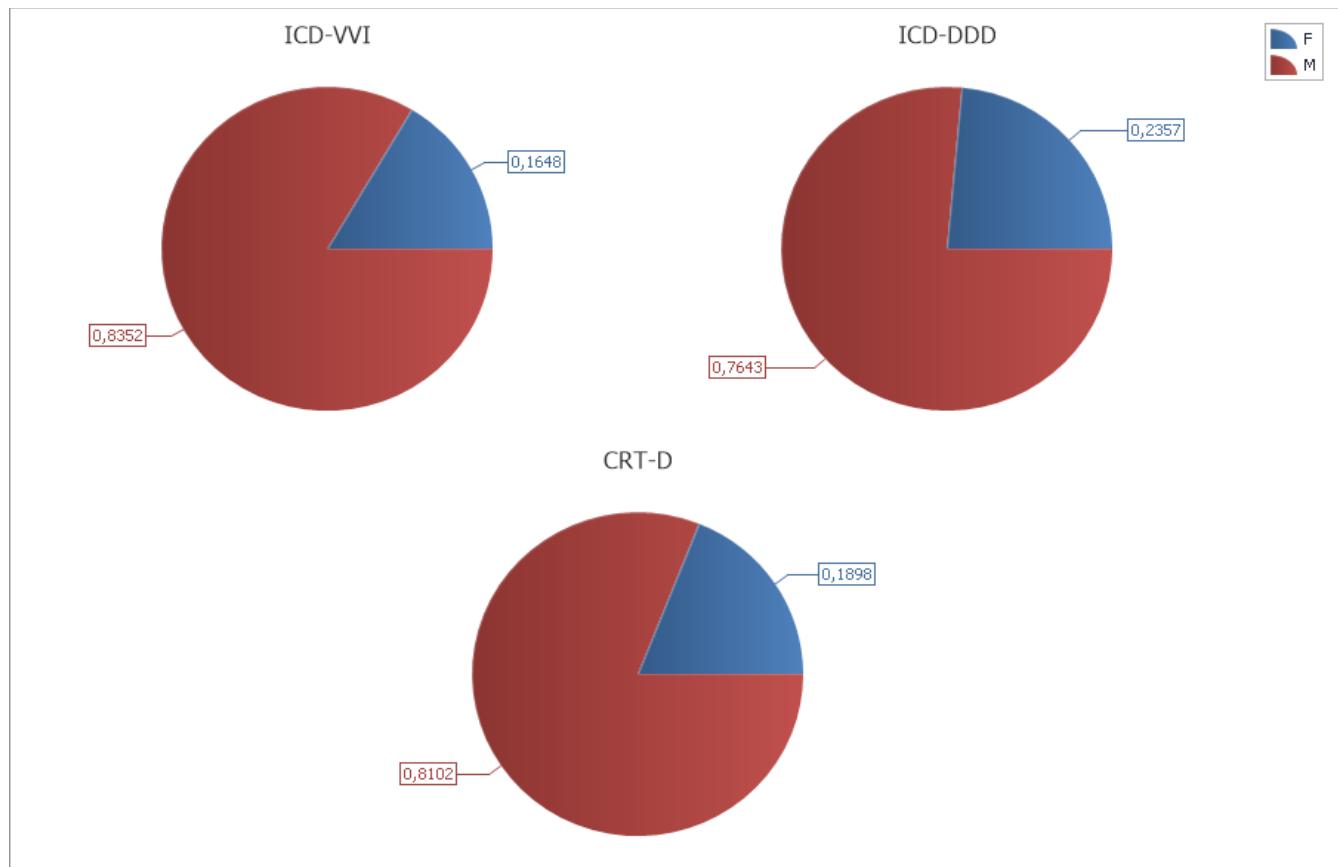


Figure 3.4 Gender in first ICD implantation in each pacing mode, Denmark 2016

### 3.2 Patients in treatment

#### 3.2.1 All pacemaker patients in treatment and alive at 31. December 2016 according to last implant institution

Period	Last Institution	Actual Device					<b>Grand Total</b>
		PM-AAI	PM-VVI	PM-VDD	PM-DDD	CRT-P	
End 2016	Bispebjerg	48	402		1735		<b>2185</b>
	Esbjerg	19	150		935		<b>1104</b>
	Gentofte	113	765	51	2221	381	<b>3531</b>
	Herning	50	250		1220		<b>1520</b>
	Hillerød	75	381	2	1103		<b>1561</b>
	Nuuk	1	153				<b>154</b>
	Odense	71	425	1	2057	582	<b>3136</b>
	Rigshospitalet	43	185		899	642	<b>1769</b>
	Roskilde	102	710	3	2524		<b>3339</b>
	Vejle	112	436		1331		<b>1879</b>
	Viborg	17	185		944		<b>1146</b>
	Aabenraa	42	213		893		<b>1148</b>
	Ålborg	80	415		2170	224	<b>2889</b>
	Aarhus	55	487	1	3043	705	<b>4291</b>
End 2016 Total		<b>828</b>	<b>5157</b>	<b>58</b>	<b>21090</b>	<b>2534</b>	<b>29667</b>

Table 3.5 All danish pacemaker patients in treatment and alive 31. December 2016 according to last implant institution

#### 3.2.2 All ICD patients in treatment and alive at 31. December 2016 according to last implant institution

Period	Last Institution	Actual Device			Grand Total
		ICD-VVI	ICD-DDD	CRT-D	
End 2016	Gentofte	921	253	381	<b>1555</b>
	Odense	1254	256	582	<b>2092</b>
	Rigshospitalet	1443	474	642	<b>2559</b>
	Roskilde	264	122		<b>386</b>
	Ålborg	474	295	224	<b>993</b>
	Aarhus	1096	495	705	<b>2296</b>
End 2016 Total		<b>5452</b>	<b>1895</b>	<b>2534</b>	<b>9881</b>

Table 3.6 All danish ICD patients in treatment and alive 31. December 2016 according to last implant institution

## 4 Trends in implant activity 2000-2016

### 4.1 Total number of first implants and number of devices per million citizens

#### 4.1.1 First pacemaker implants 2000-2016

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

Table 4.1 Number of first pacemaker implants in Denmark 2000-2016 and number of pacemakers per million citizens

\*Data on population based on data from Statistics Denmark

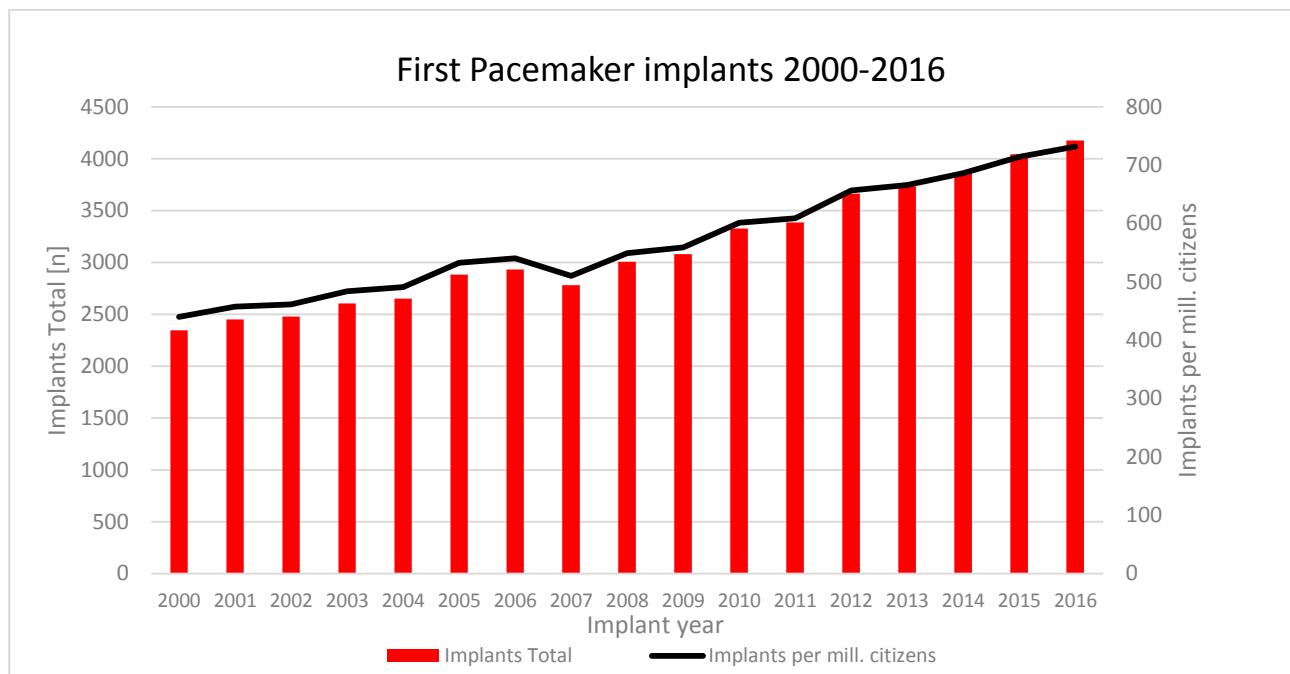


Figure 4.1 Number of first pacemaker implants in Denmark 2000-2016 and number of pacemakers per million citizens

#### 4.1.2 First ICD implants 2000-2016

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

Table 4.2 Number of first ICDs implants in Denmark 2000-2016 and number of ICDs per million citizens

\*Data on population based on data from Statistics Denmark

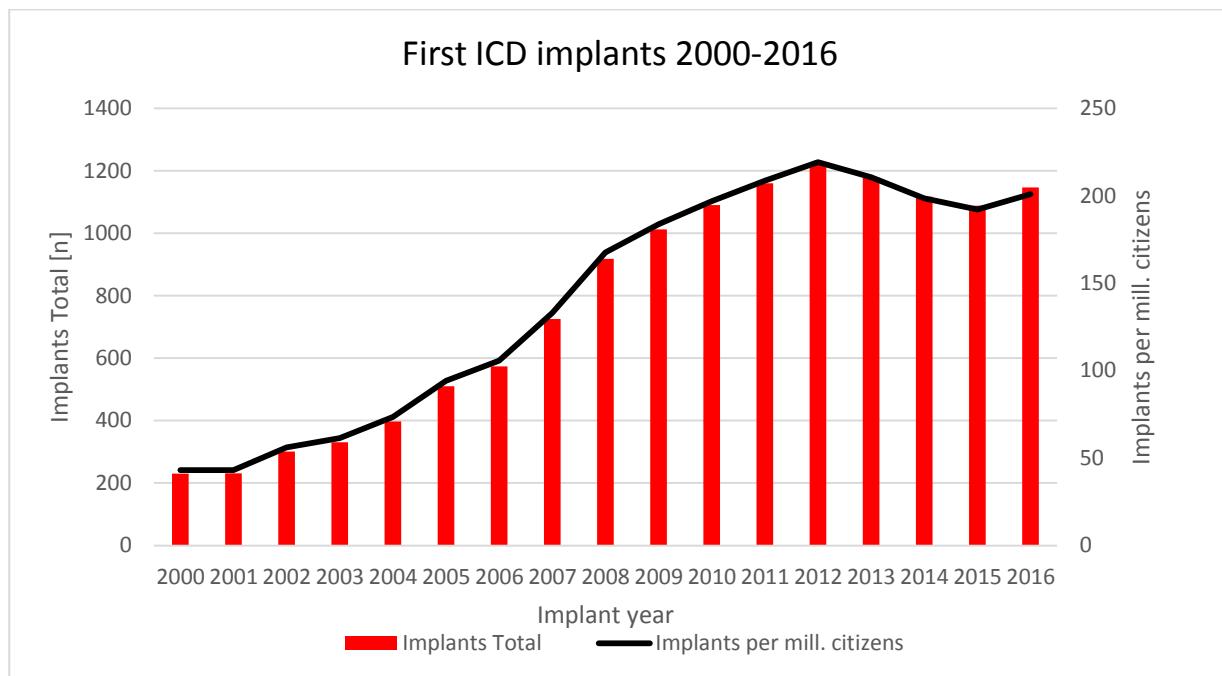


Figure 4.2 Number of first ICDs implants in Denmark 2000-2016 and number of ICDs per million citizens

#### 4.1.3 First ICD implants 2016 per million citizens per Region

Institution	Operation   First Implant			First Implant Total	Region	Citizens (1. January 2016)	First ICD implants per mill. citizens
	ICD-VVI	ICD-DDD	CRT-D				
Gentofte	105	15	29	149	The Capital Region of Denmark and Region Zealand	2,639,957	<b>184.5</b>
Roskilde	71	23		94			
Rigshospitalet	143	33	68	244			
Odense	190	2	80	272	The Region of Southern Denmark	1,217,224	<b>223.5</b>
Ålborg	60	39	20	119	The North Denmark Region	587,335	<b>202.6</b>
Aarhus	143	42	75	260	Central Denmark Region	130,4253	<b>199.3</b>
<b>Grand Total</b>	<b>712</b>	<b>154</b>	<b>272</b>	<b>1138</b>		<b>5,748,769</b>	<b>198.0</b>

Table 4.3 Number of first ICDs implants in 2016 and number of ICDs per million citizens i different regions in Denmark

## 4.2 Pacing mode in first implants

### 4.2.1 Pacemakers 2000-2016

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

Table 4.4 Number of first pacemaker implants and pacing modes in Denmark 2000-2016

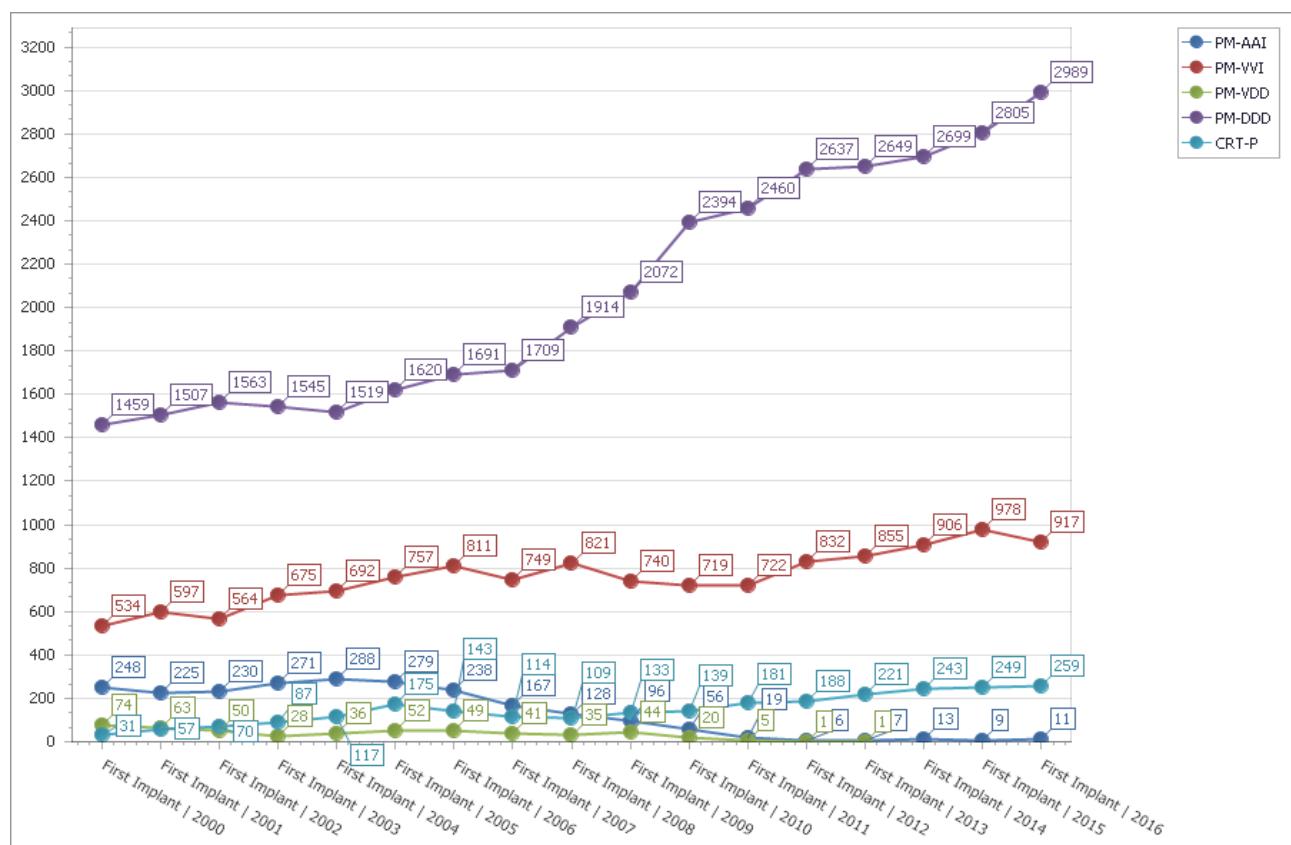


Figure 4.3 Number of first pacemaker implants and pacing modes in Denmark 2000-2016

#### 4.2.2 ICDs 2000-2016

Actual Device	Operaton   First Implant															First Implant Total		
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015		
ICD-VVI	141	150	177	229	270	303	327	476	571	540	531	534	640	694	691	712	7678	
ICD-DDD	77	75	99	73	88	117	143	128	191	247	297	295	257	211	185	178	154	2817
CRT-D	12	6	25	29	39	90	104	121	156	226	262	331	327	275	241	216	272	2733
Grand Total	230	231	301	331	397	510	574	725	918	1013	1090	1160	1224	1180	1117	1088	1138	13228

Table 4.5 Number of first ICD implants and pacing modes in Denmark 2000-2016

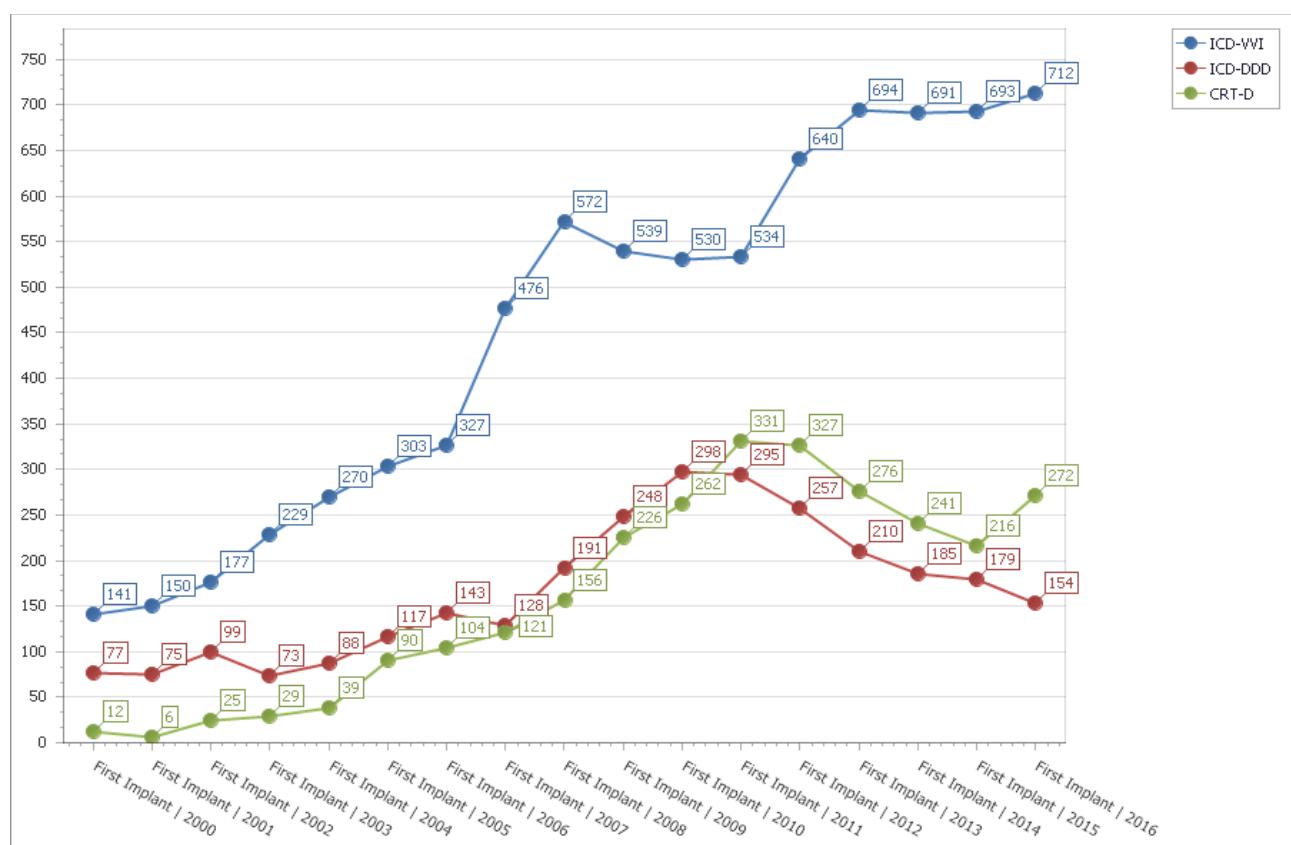


Figure 4.4 Number of first ICD implants and pacing modes in Denmark 2000-2016

## 5 Quality in device treatment 2016

### 5.1 Complications after all operations in 2016

#### 5.1.1 Major complications (either major clinical impact or resulting in reoperation) per institution up to 120 days after implant

##### Complications within 120 days after implant operation in 2016

Complication type <b>Surgical related complications</b>	Institution													<b>Total</b>
	Bispebjerg	Esbjerg	Gentofte	Herning	Hillerød	Odense	Rigshosp	Roskilde	Vejle	Viborg	Aabenrå	Ålborg	Aarhus	
Cardiac perforation not req. pericardiocentesis		2		1		1					1		5	10
Cardiac perforation req. pericardiocentesis		1					1							2
Deep venous thrombosis		2			1		1		2		2			8
Haemothorax req. drainage						1					1			2
Local pocket infection / Skin erosion				1		2	3	4	3	1		5	9	28
Pneumothorax not req. drainage	1			1			1	2				2	1	8
Pneumothorax req. drainage	1	1	3		2	2		10			2	1	2	24
Systemic infection / endocarditis				1	1	4	2					3	2	13
Total number of surgical related complications	2	6	3	4	4	10	8	16	5	1	6	11	19	95
Total number of operations	392	252	820	279	290	1076	781	827	274	228	185	709	1140	7253
<b>Frequency pr. institution</b>	<b>0.51</b>	<b>2.38</b>	<b>0.37</b>	<b>1.43</b>	<b>1.38</b>	<b>0.93</b>	<b>1.02</b>	<b>1.93</b>	<b>1.82</b>	<b>0.44</b>	<b>3.24</b>	<b>1.55</b>	<b>1.67</b>	<b>1.31</b>

##### Generator/lead related complications leading to re-operation

Generator/lead related complications leading to re-operation	Institution													<b>Total</b>
	Bispebjerg	Esbjerg	Gentofte	Herning	Hillerød	Odense	Rigshosp	Roskilde	Vejle	Viborg	Aabenrå	Ålborg	Aarhus	
Connector failure			1					1						2
Conductor break													1	1
Displacement	1	11	9		6	11	10	14	1	2		2	12	79
Extracardiac stimulation		1					1							2
Generator-lead interface problem		1				1		1						3
Failure to defibrillate								1						1
High pacing threshold	1	3	1	2		1	5	2				2	5	22
Insulation failure			1										1	2
Sensing / pacing failure			1	1		1		1		1				5
Twiddler's syndrome		1				1								2
Undersensing			1					1	1				1	4
Generator failure, other								1						1
Total number of lead/generator complications leading to re-operation	2	19	12	3	6	15	18	21	1	3	0	4	20	124
Total number of operations	392	252	820	279	290	1076	781	827	274	228	185	709	1140	7253
<b>Frequency pr. institution</b>	<b>0.51</b>	<b>7.54</b>	<b>1.46</b>	<b>1.08</b>	<b>2.07</b>	<b>1.39</b>	<b>2.30</b>	<b>2.54</b>	<b>0.36</b>	<b>1.32</b>	<b>0.00</b>	<b>0.56</b>	<b>1.75</b>	<b>1.71</b>

Table 5.1 Major surgical- and generator/lead related complications within 120 days after all operations in 2016

#### 5.1.2 Major complications (either major clinical impact or resulting in reoperation) per operation type up to 120 days after implant

Table 5.2 Major surgical related complications within 120 days according to type of operations in 2016

## **Complications within 120 days after operation in 2016**

Complication type		Operation type			
Surgical related		First implant	Replacement	Up-Downgrade	Total
Cardiac perforation not req. pericardiocentesis		8	2		10
Cardiac perforation req. pericardiocentesis		1		1	2
Deep venous thrombosis		7	1		8
Haemothorax req. drainage		2			2
Local pocket infection / Skin erosion		15	8	5	28
Pneumothorax not req. drainage		5	1	2	8
Pneumothorax req. drainage		24			24
Systemic infection / endocarditis		9	3	1	13
Total number of complications		71	15	9	95
Total number of operations		5303	1360	590	7253
Frequency of surgical related complications pr. operation type		1.34	1.10	1.53	1.31

### **Generator/lead related complications leading to re-**

<b>operation</b>	<b>First implant</b>	<b>Replacement</b>	<b>Up-Downgrade</b>	<b>Total</b>
Connector failure	1	1		2
Conductor break	1			1
Displacement	78		1	79
Extracardiac stimulation	2			2
Generator-lead interface problem	2	1		3
Failure to defibrillate	1			1
High pacing threshold	18	1	3	22
Insulation failure	2			2
Sensing / pacing failure	5			5
Twiddler's syndrome	1		1	2
Undersensing	4			4
Generator failure, other		1		1
Total number of complications	115	4	5	124
Total number of operations	5303	1360	590	7253
Frequency of generator/lead related complications pr. operation type	<b>2.17</b>	<b>0.29</b>	<b>0.85</b>	<b>1.71</b>

## 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 2016

Infection type	Bispebjerg	Esbjerg	Gentofte	Herning	Hillerød	Odense	Rigshosp	Roskilde	Vejle	Viborg	Aabenrå	Ålborg	Aarhus	Total
Local pocket infection / Skin erosion				2		4	5	5	4	1	1	11	16	49
Systemic infection / endocarditis	1	2	1	1	1	4	6					2	4	22
All infections	1	2	1	3	1	8	11	5	4	1	1	13	20	71
Total number of operations	392	252	820	279	290	1076	781	827	274	228	185	709	1140	7253
<b>Frequency of infection leading to removal of CIED system</b>	<b>0.26</b>	<b>0.79</b>	<b>0.12</b>	<b>1.08</b>	<b>0.34</b>	<b>0.74</b>	<b>1.41</b>	<b>0.60</b>	<b>1.46</b>	<b>0.44</b>	<b>0.54</b>	<b>1.83</b>	<b>1.75</b>	<b>0.98</b>

Table 5.3 Infection leading to removal of the CIED system within 365 days after implant operation in 2016

## 5.3 Lead access

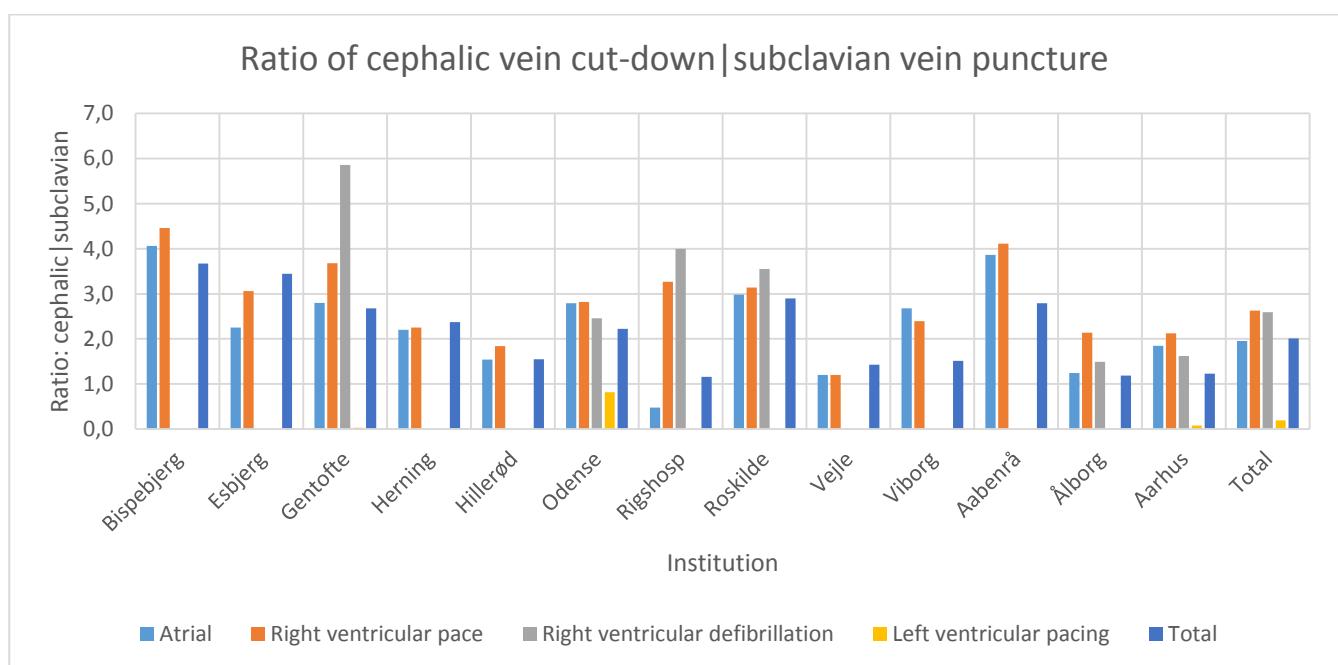
### 5.3.1 Ratio of cephalic vein cut-down to subclavian vein puncture in lead implants during first device implants

#### Lead access in first implants in 2016

Ratio of cephalic|subclavian vein

Lead type	Bispebjerg	Esbjerg	Gentofte	Herning	Hillerød	Odense	Rigshosp	Roskilde	Vejle	Viborg	Aabenrå	Ålborg	Aarhus	Total
Atrial	4.06	2.25	2.8	2.2	1.54	2.79	0.48	2.98	1.2	2.68	3.86	1.24	1.85	1.95
Right ventricular pace	4.46	3.06	3.68	2.25	1.84	2.82	3.27	3.14	1.2	2.39	4.11	2.14	2.12	2.63
Right ventricular defibrillation			5.86			2.46	4	3.55				1.49	1.62	2.59
Left ventricular pacing			0.03			0.82	0.01					0.02	0.08	0.19
<b>Total</b>	<b>3.67</b>	<b>3.45</b>	<b>2.68</b>	<b>2.37</b>	<b>1.55</b>	<b>2.22</b>	<b>1.16</b>	<b>2.90</b>	<b>1.43</b>	<b>1.52</b>	<b>2.79</b>	<b>1.18</b>	<b>1.23</b>	<b>2.01</b>

Table 5.4 Ratio of cephalic cut-down to subclavian vein puncture in lead access during first device implant in 2016



Figur 5-1 Ratio of cephalic cut-down to subclavian vein puncture in lead access during first device implant in 2016