### 2019 Questionnaire Survey Report

#### on

### Incidents, Accidents, and Safety Procedures Related to Cardiopulmonary Bypass and Cardiopulmonary Support Systems

Safety Control Committee Japanese Society of Extra-Corporeal Technology in Medicine (JaSECT)

#### **Objectives & Target Years of the Survey**

#### Objectives

To enhance the awareness of safety management, promote the advancement of extra-corporeal technology, and improve the medical standards and patient safety by gathering and compiling information on incidents/accidents related to cardiopulmonary bypass (CPB) and cardiopulmonary support (CPS) systems.

#### Target years

2017 and 2018

#### **Background of the Survey**

Prior questionnaire surveys (and target years) on incidents/accidents conducted by JaSECT Safety Control Committee:

2010: CPB (2008, 2009) 2011: CPS (2009, 2010) 2013: CPB & CPS (2011, 2012) 2015: CPB & CPS (2013, 2014) 2017: CPB & CPS (2015, 2016)

This survey is a continuation of ongoing research. 2019: CPB & CPS (2017, 2018)

#### <u>Subjects</u>

#### 684 medical institutions with JaSECT members

#### <u>Responses</u>

Response rate: 65.5 % (448/684 institutions)

<u>15 institutions</u> replied but were unable to answer the questions due to a managerial decision and thus <u>excluded from aggregation</u>.

Valid response rate: 63.3% (433 institutions)

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#### **Levels of Impact on Patients**

Level	Impact on patients
Level 0	Errors and/or failures were found in pharmaceuticals and/or medical devices that were not used on patient.
Level 1	Errors and/or failures were found in pharmaceuticals and/or medical devices that were used on patient but had no impact on the patient.
Level 2	Caused changes in patient's vital signs and/or necessitated medical examination.
Level 3a	Necessitated minor treatment or procedure (disinfection, cooling, administration of analgesics, etc.).
Level 3b	Necessitated major treatment or procedure (unplanned procedure or treatment, hospitalization, extension of hospital stay, etc.)
Level 4	Resulted in permanent disability.
Level 5	Resulted in death (excluding that caused by natural course of primary disease).

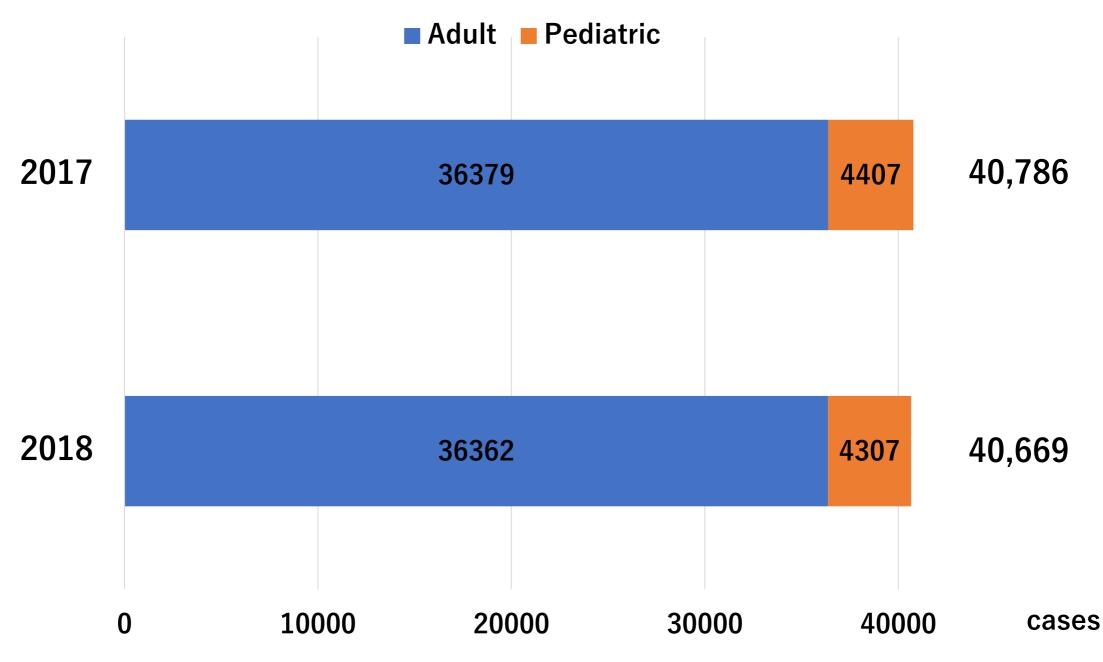


### **Aggregation Results**

### Cardiopulmonary Bypass (CPB)

#### **CPB-Related Accidents/Incidents by Demographics**

Total CPB-related cases: 81,455 (Adult: 72,741 Pediatric: 8,714)

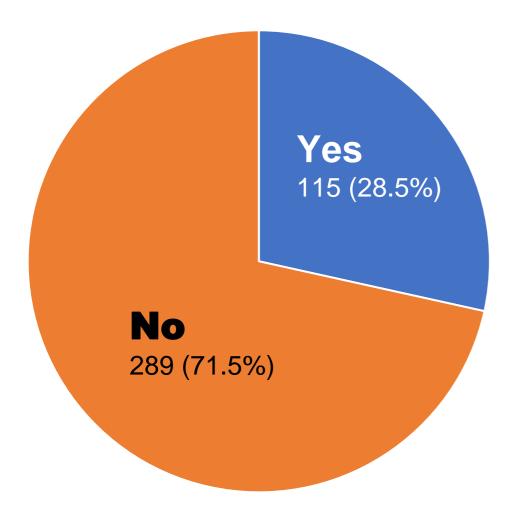


n = 416 insts.

#### **CPB-Related Accidents/Incidents & Rates**

	2019 Survey			2017 Survey			2015 Survey		
	2017	2018	Total	2015	2016	Total	2013	2014	Total
CPB cases	40,786	40,669	81,455	42,303	44,180	86,483	37,573	38,643	76,216
Impact level (0)	379 0.93%	393 0.97%	772 0.95%	431 1.02%	440 1.00%	871 1.01%	480 1.28%	554 1.43%	1,034 1.36%
Impact level (1 – 3a)	340 0.83%	345 0.85%	685 0.84%	265 0.63%	274 0.62%	539 0.62%	251 0.67%	291 0.75%	542 0.71%
Impact level (3b – 5)	16 0.04%	22 0.05%	38 0.05%	24 0.06%	26 0.06%	50 0.06%	23 0.06%	22 0.06%	45 0.06%
Total	735 1.80%	760 1.87%	1,495 1.84%	720 1.70%	740 1.67%	1,460 1.69%	754 2.01%	867 2.24%	1,621 2.13%

# Did you experience an incident/accident involving a <u>CPB Device?</u>



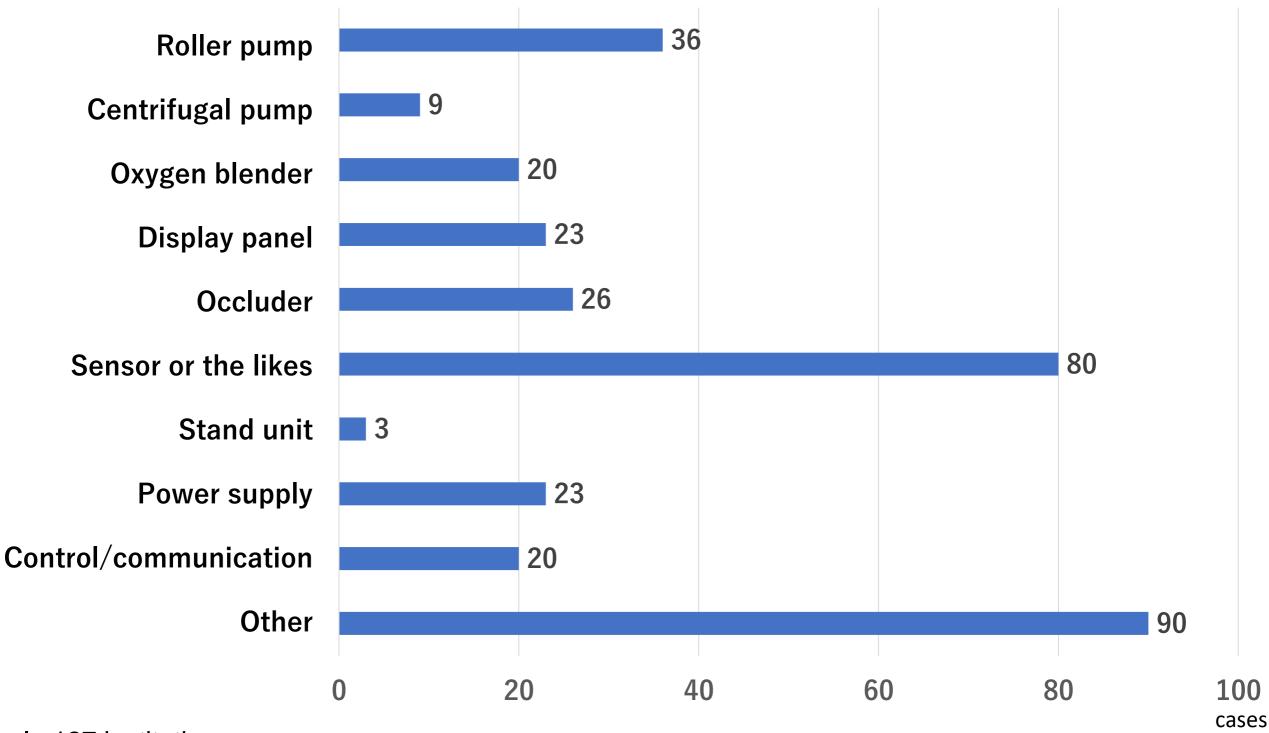
Impact level	No. of cases	Frequency*
0	199	0.24%
1 – 3a	117	0.14%
3b – 5	6	0.01%

No answer: 11 insts.

\*Among 81,455 CPB cases occurring during the 2-year period.

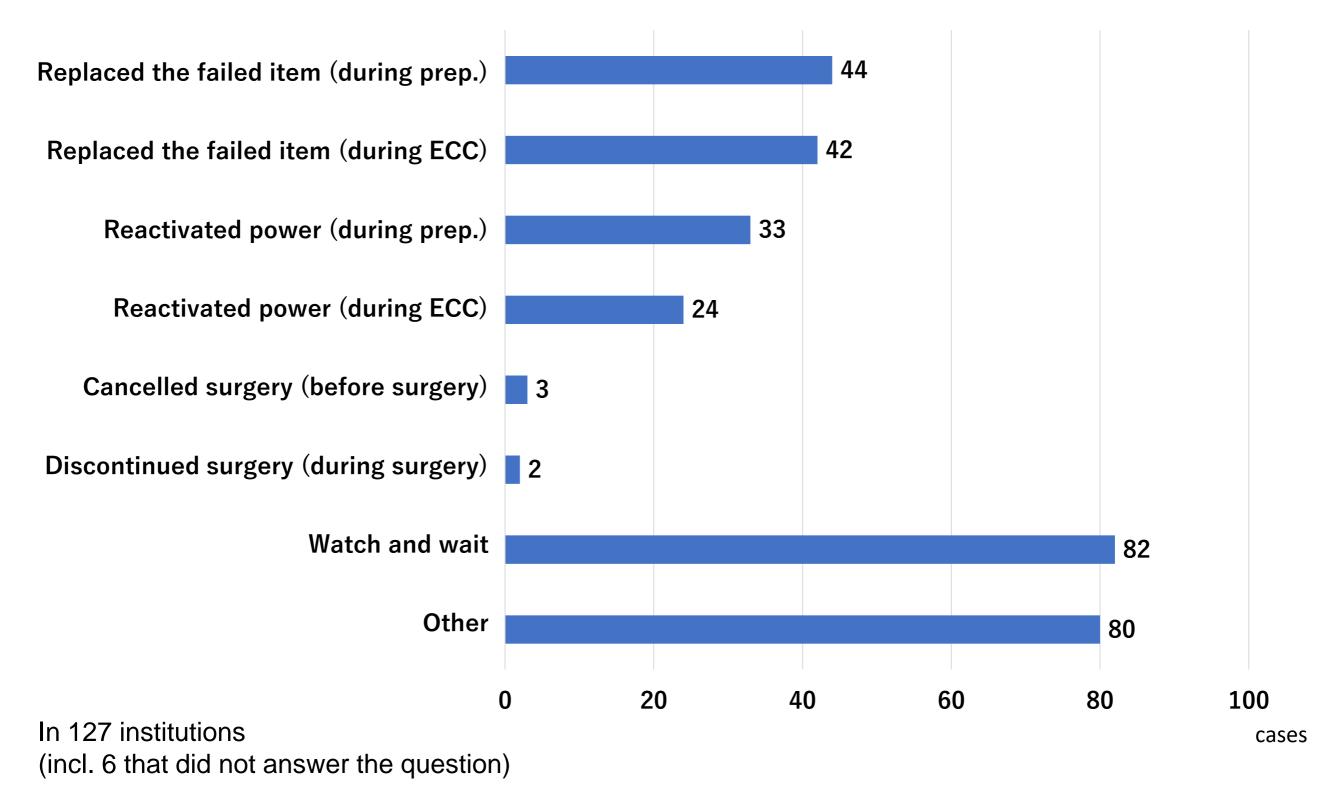
n = 416 (no answer: 12 insts.)

## Which of the following was involved in the incident/accident and how many times? (Please choose all that apply.)



In 127 institutions (incl. 9 that did not answer the question)

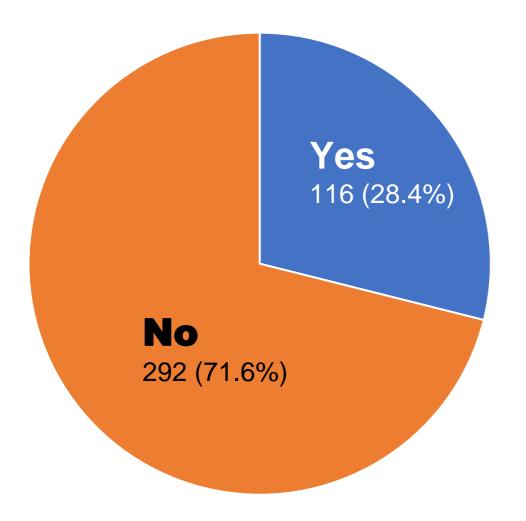
## Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



#### **CPB Device-Related Incidents & Rates**

	2019 Survey		2019 Survey 2017 Survey		2015 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	199	0.24%	278	0.32%	179	0.23%
1 – 3a	117	0.14%	65	0.08%	104	0.14%
3b — 5	6	0.01%	12	0.01%	5	0.01%
	No answer: 18 insts.		Ν	lo answer: 16	Ν	lo answer: 11
	*Among 81,455 cases		**Am	ong 86,483 cases	***Am	ong 76,216 cases

### Did you experience an incident/accident involving an Oxygenator?



Impact level	No. of cases	Frequency*
0	89	0.11%
1 – 3a	120	0.15%
3b – 5	12	0.01%

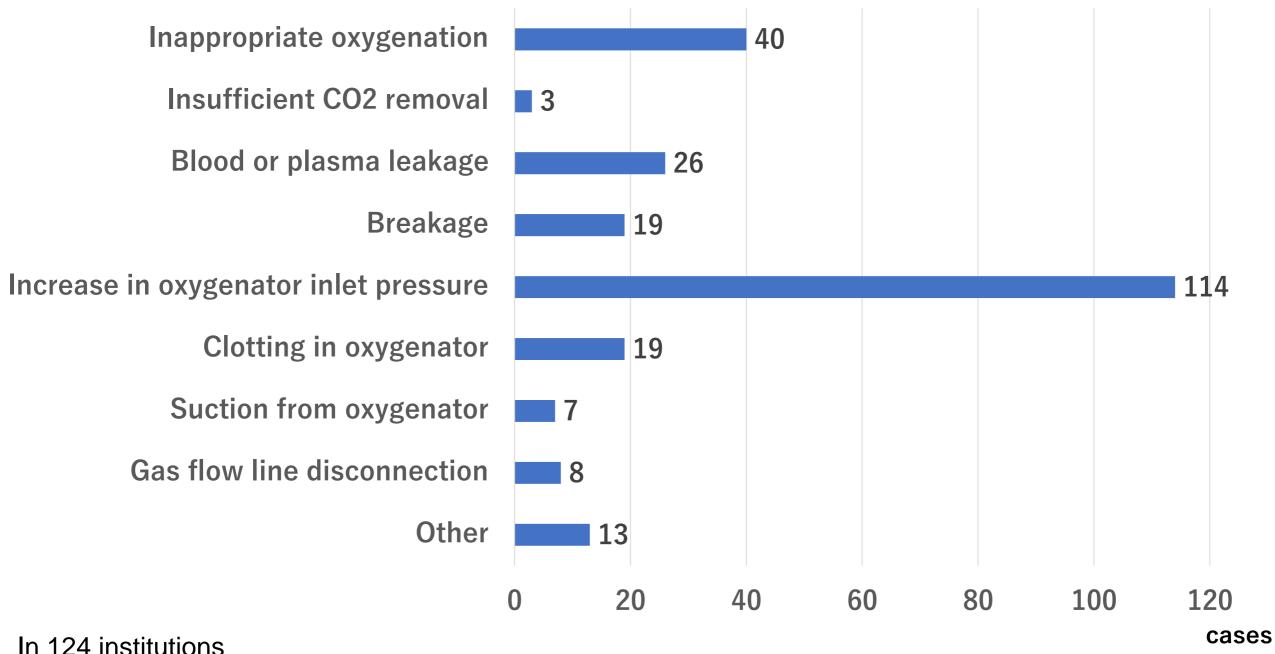
No answer: 11 insts.

\*Among 81,455 CPB cases occurring during the 2-year period.

n = 416 (no answer: 8 insts.)

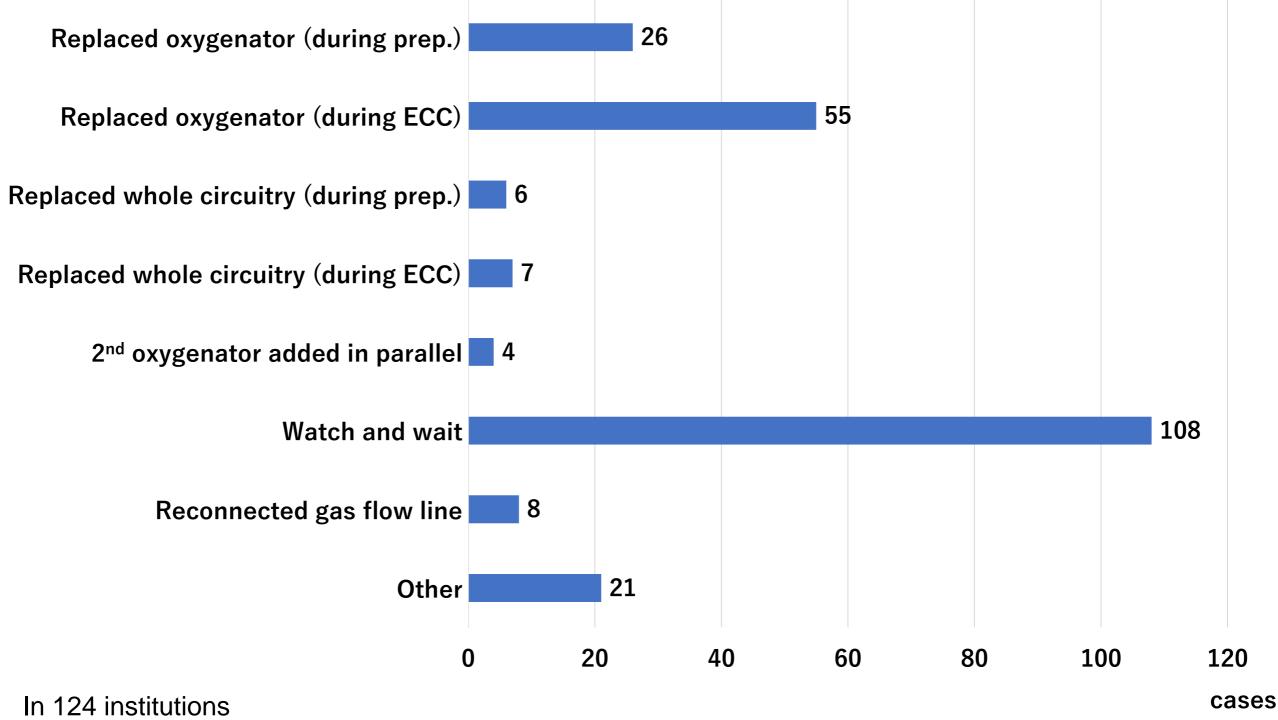


# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



(incl. 6 that did not answer the question)

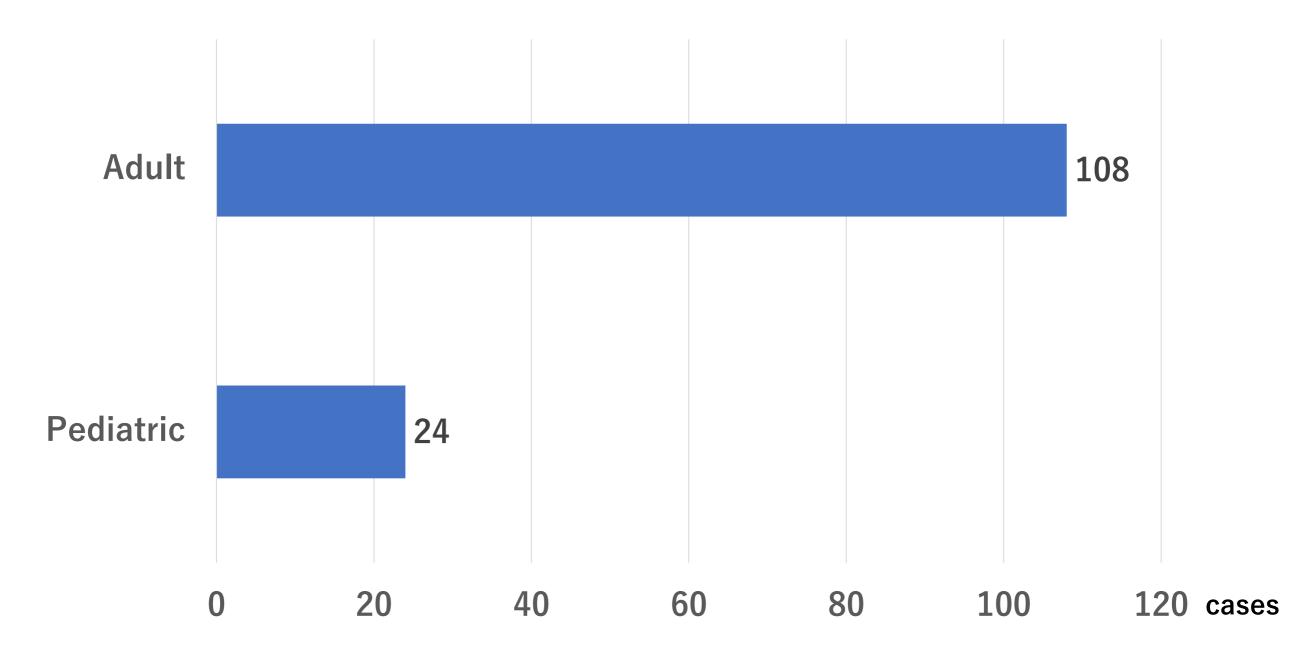
## Which of the following actions did you take in response to the incident/accident? (Please choose all that apply.)



(incl. 6 that did not answer the question)

#### No. of Cases by Demographics

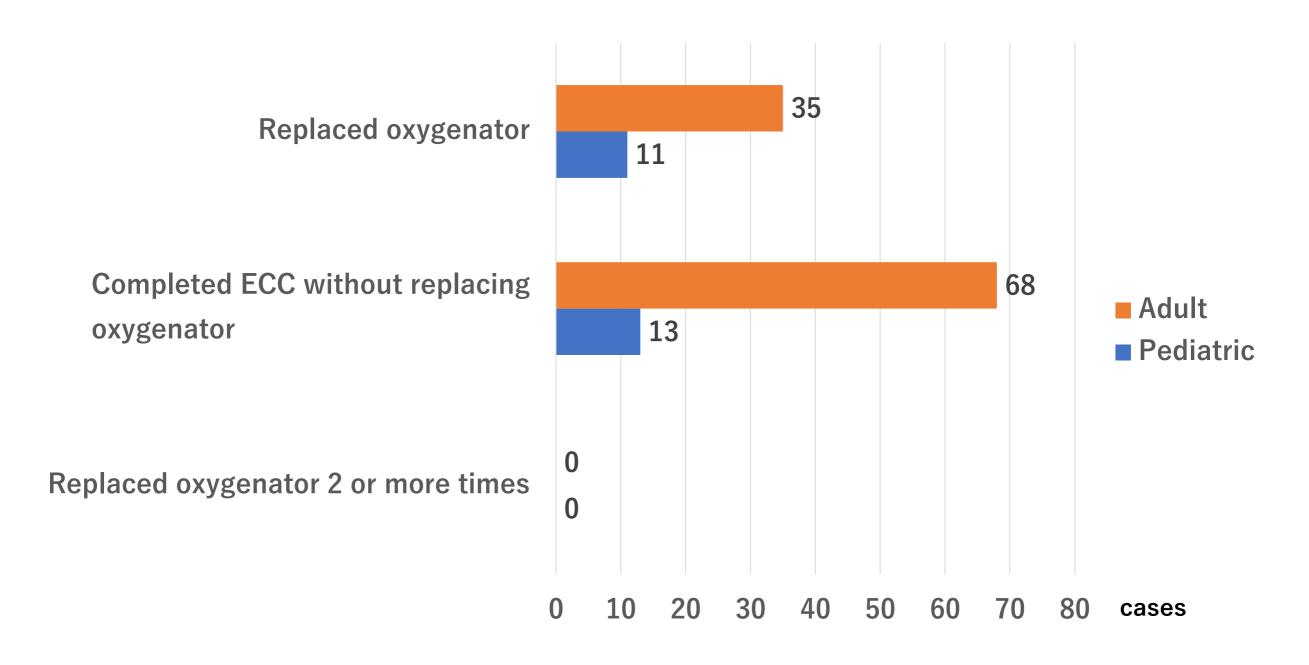
(66 institutions that experienced "increase in oxygenator inlet pressure" and/or "clotting")



In 66 institutions (incl. 1 that did not answer the question)

#### Did you replace the oxygenator? (Please choose all that apply.)

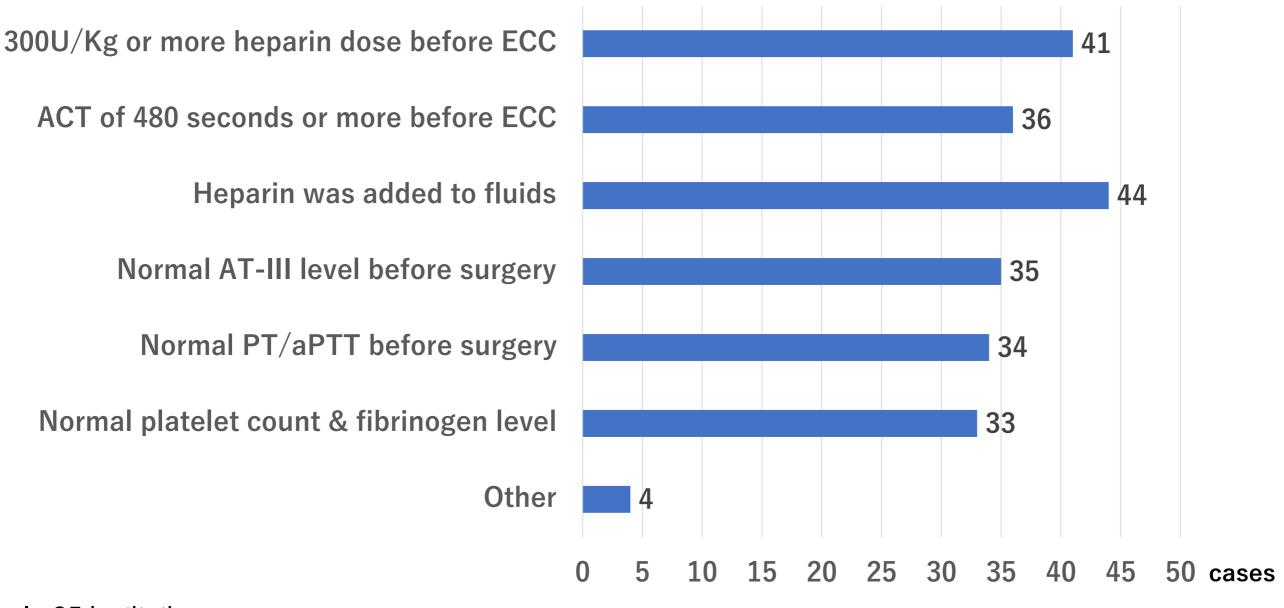
(66 institutions that experienced "increase in oxygenator inlet pressure" and/or "clotting")



In 66 institutions (incl. 4 that did not answer the question)



# What was the state of the patient when you replaced the oxygenator? (Please choose all that apply.)

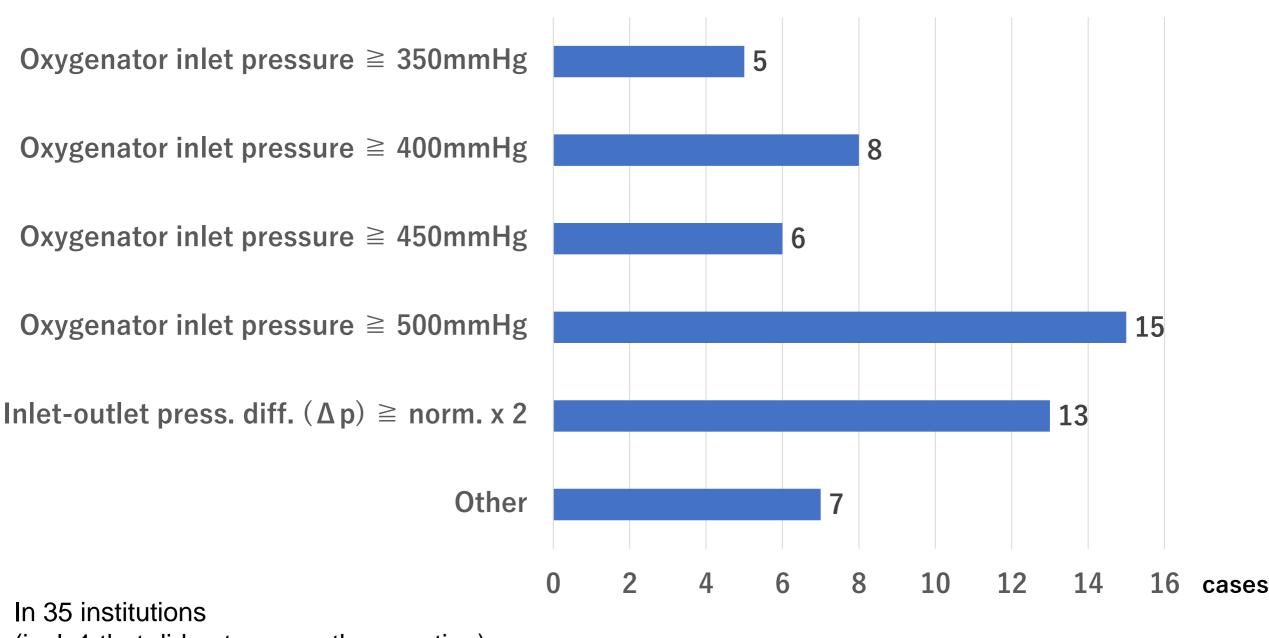


In 35 institutions (incl. 3 that did not answer the question)



#### What was reason for replacing the oxygenator?

(Please choose all that apply.) (35 institutions that replaced oxygenator 1 or more times)



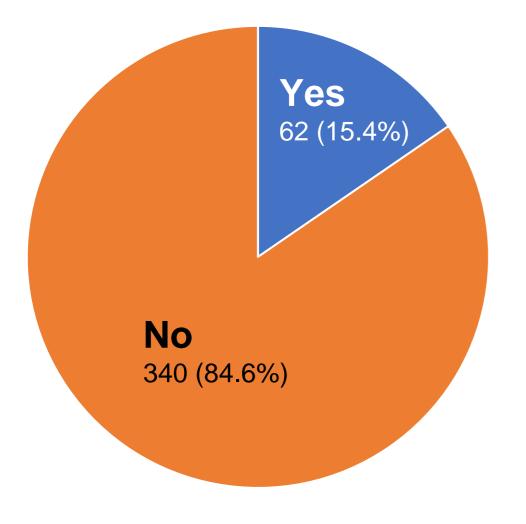
(incl. 1 that did not answer the question)

#### **Oxygenator-Related Incidents & Rates**

	2019 Survey		2019 Survey 2017 Survey		2015 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	89	0.11%	96	0.11%	83	0.11%
1 – 3a	120	0.15%	132	0.15%	154	0.20%
3b – 5	12	0.01%	13	0.02%	16	0.02%
	No answer: 11 insts.		Ν	lo answer: 10		No answer: 7
	* Among 81,455 cases		** Am	ong 86,483 cases	*** Arr	nong 76,216 cases



### Did you experience an incident/accident involving a <u>Venous or Cardiotomy Reservoir?</u>



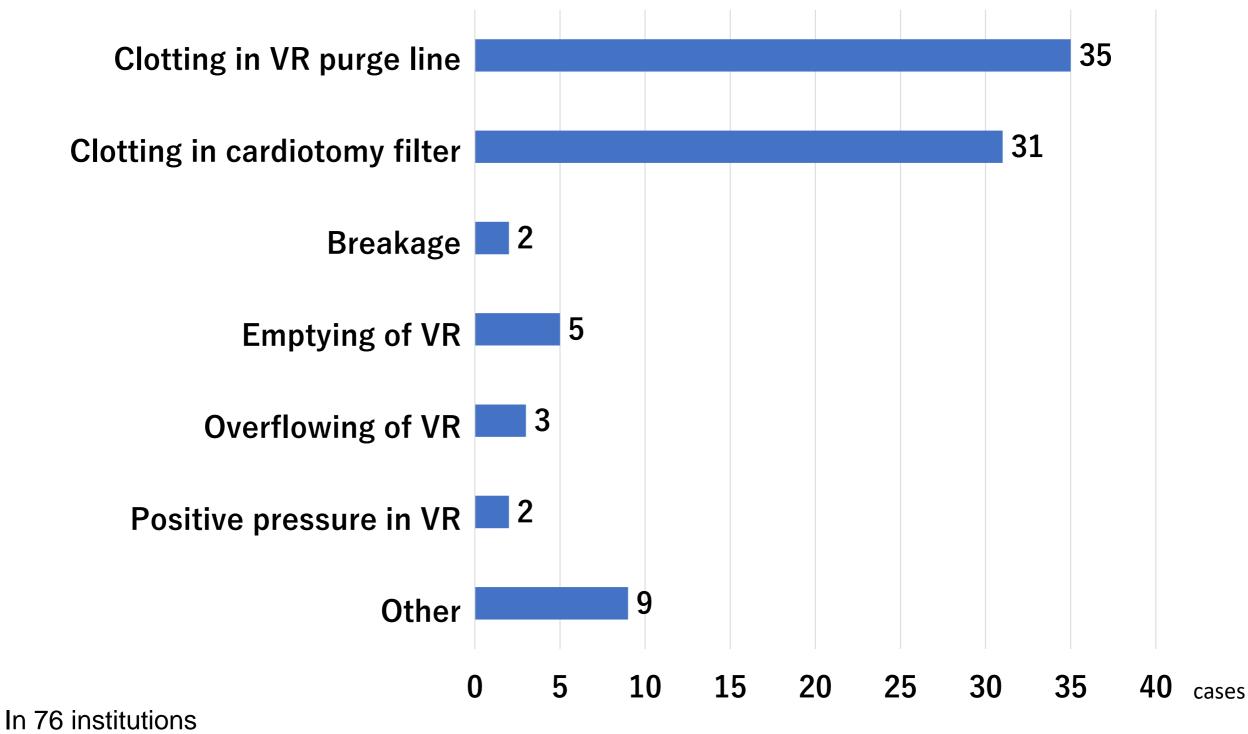
Impact level	No. of cases	Frequency*
0	46	0.06%
1 – 3a	36	0.04%
3b – 5	4	< 0.01%

No answer: 13 insts.

\*Among 81,455 CPB cases occurringg during the 2-year period.

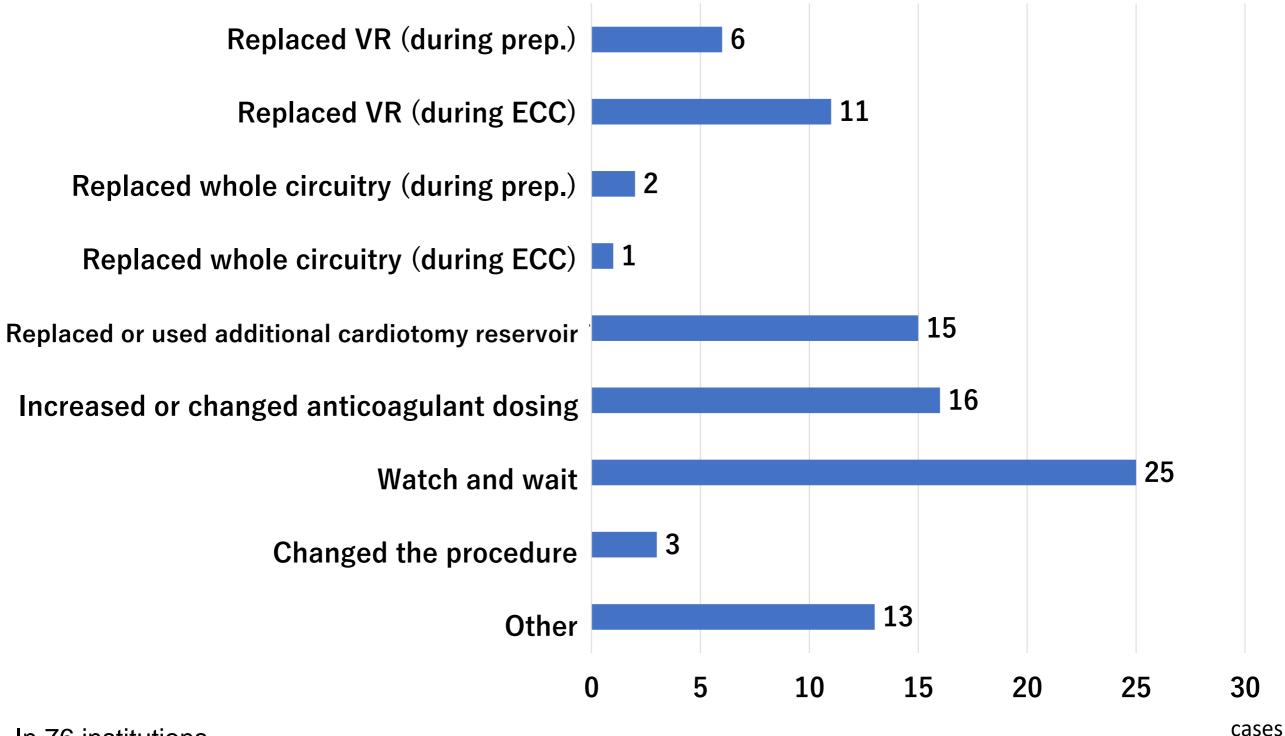
n = 416 (no answer: 14 insts.)

# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



(incl. 15 that did not answer the question)

## Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



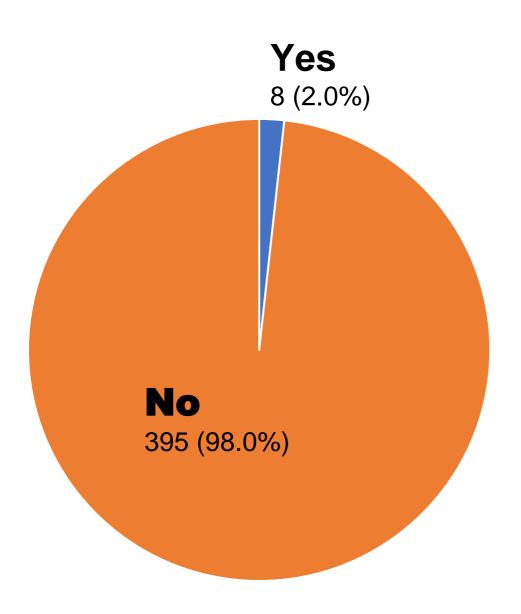
In 76 institutions (incl. 14 that did not answer the question)



#### **Venous-Reservoir-Related Incidents & Rates**

	2019 Survey		2017	Survey	2015	Survey
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	46	0.06%	52	0.06%	76	0.10%
1 – 3a	36	0.04%	28	0.03%	53	0.07%
3b – 5	4	< 0.01%	2	< 0.01%	2	< 0.01%
	No answer: 14 insts.		N	lo answer: 11		No answer: 5
	* Among 81,455 cases		** Am	ong 86,483 cases	*** Arr	ong 76,216 cases

### Did you experience an incident/accident involving an Arterial Line Filter? (excluding oxygenators with built-in filters)



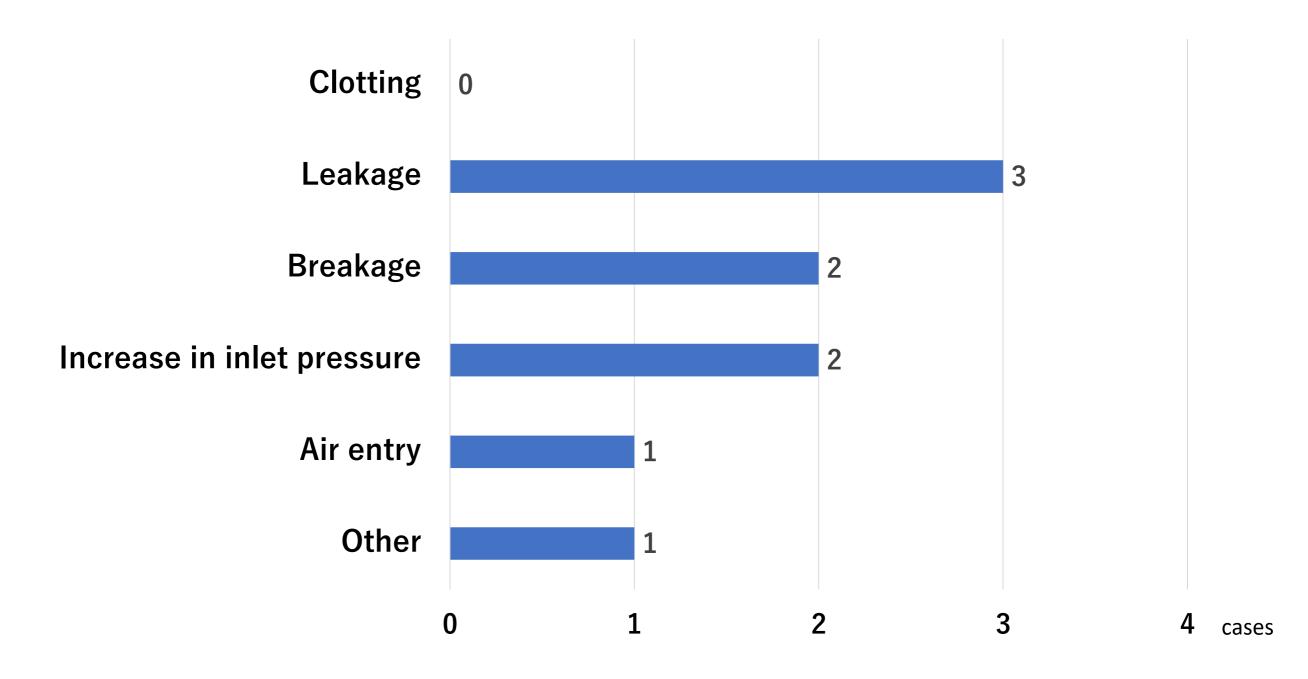
Impact level	No. of cases	Frequency*		
0	6	< 0.01%		
1 – 3a	3	< 0.01%		
3b – 5	0	0%		
	No answer: 13 insts.			

\*Among 81,455 CPB cases occurring during the 2-year period.

n = 416 (no answer: 13 insts.)

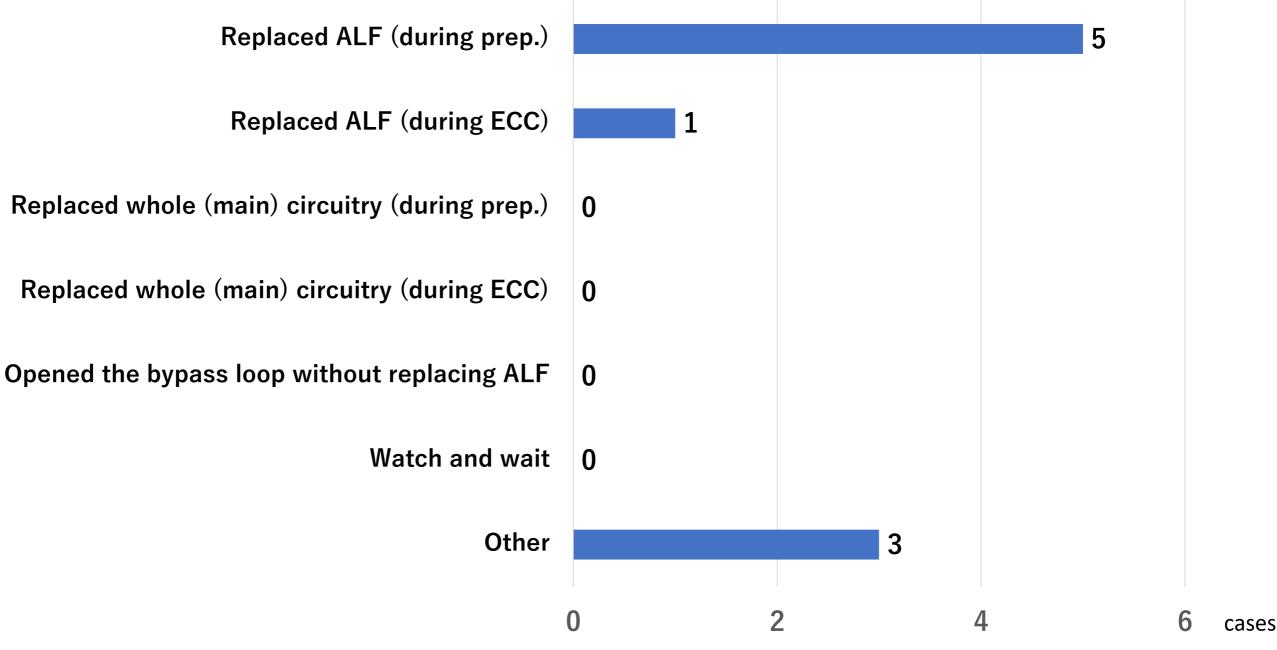


# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



In 21 institutions (incl. 13 that did not answer the question)



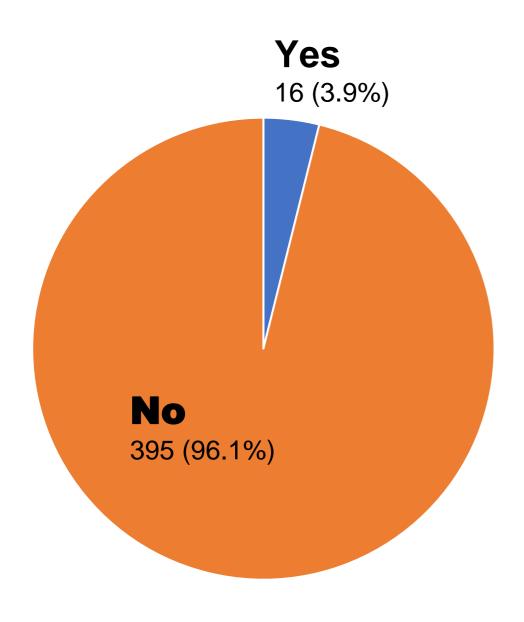


In 21 institutions (incl. 13 that did not answer the question)

#### **Arterial-Filter-Related Incidents & Rates**

	2019 Survey		2019 Survey 2017 Survey		2015 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	6	< 0.01%	17	0.02%	32	0.04%
1 – 3a	3	< 0.01%	3	< 0.01%	2	< 0.01%
3b – 5	0	0%	0	0%	0	0%
	No answer: 13 insts.		N	lo answer: 17	٩	lo answer: 14
	* Among 81,455 cases		** Am	ong 86,483 cases	*** Arr	ong 76,216 cases

#### Did you experience an incident/accident related to Blood Supply Interruption due to Blood Pump Failure?

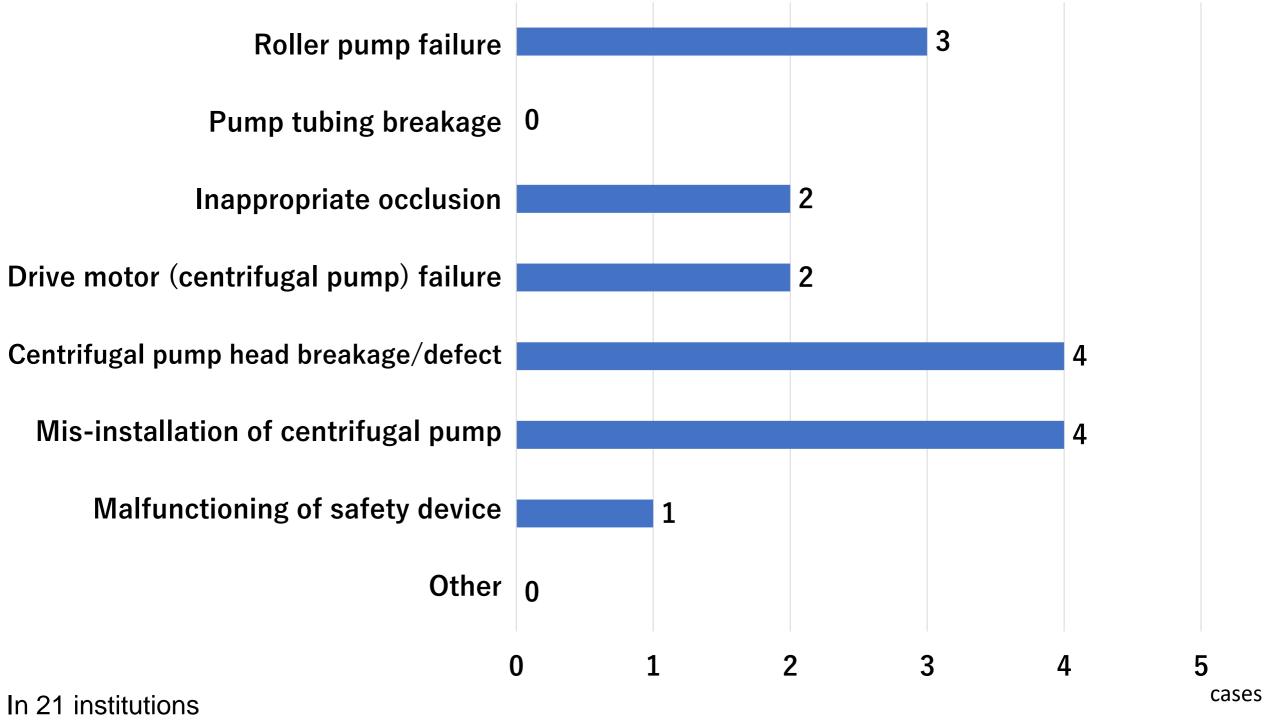


Impact level	No. of cases	Frequency*
0	8	< 0.01%
1 – 3a	7	< 0.01%
3b – 5	0	0%
	No a	inswer: 7 insts.

\*Among 81,455 CPB cases occurring during the 2-year period.

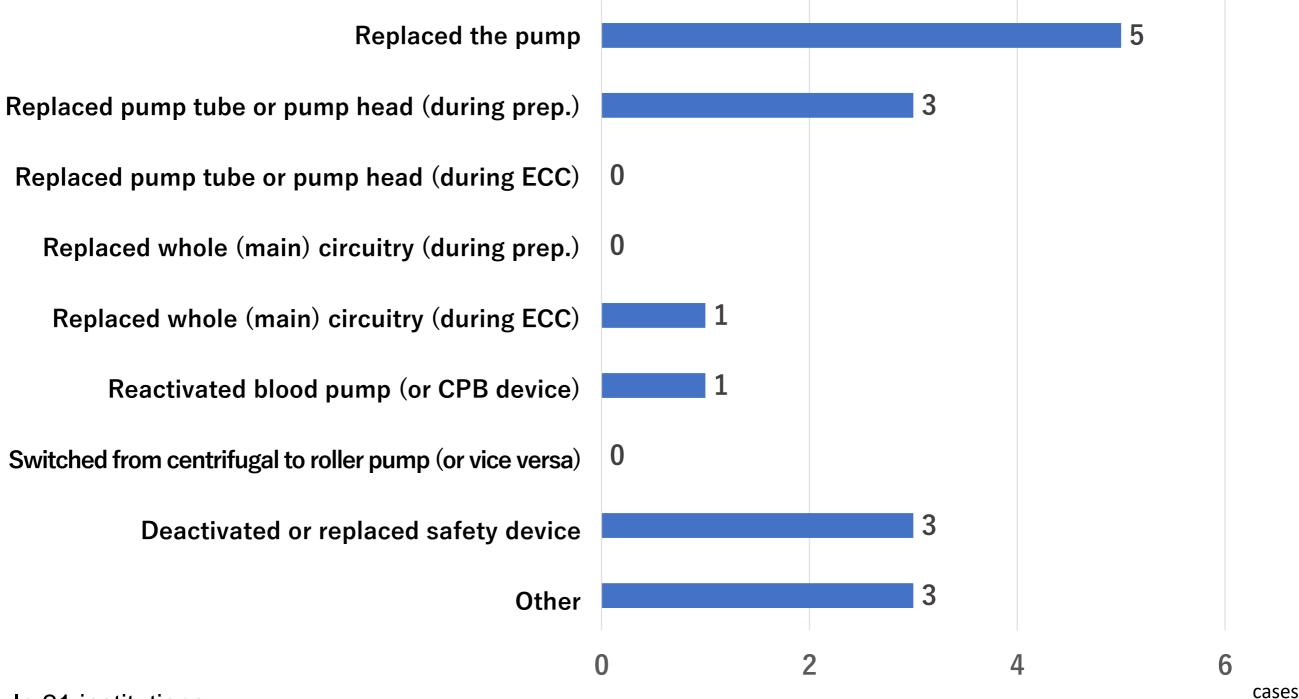
n = 416 (no answer: 5 insts.)

## How many times did you experience the following incidents/accidents? (Please choose all that apply.)



(incl. 14 that did not answer the question)

## Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



In 21 institutions (incl. 12 that did not answer the question)

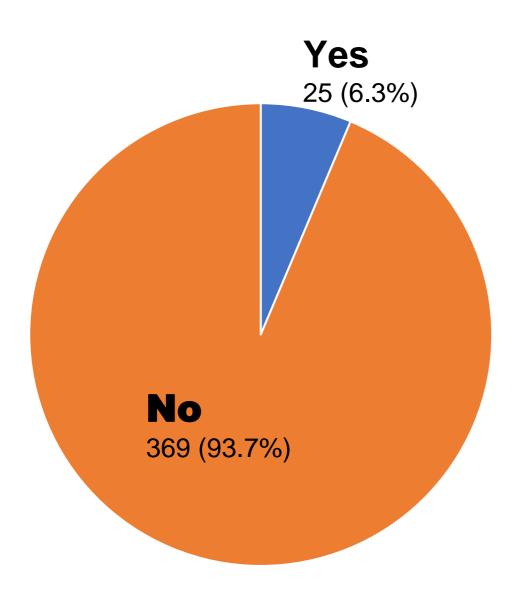


#### Blood Supply Interruption Incidents & Rates due to Blood Pump Failure

	2019 Survey		2019 Survey 2017 Survey		2015 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	7	< 0.01%	16	0.02%	21	0.03%
1 – 3a	7	< 0.01%	8	0.01%	16	0.02%
3b – 5	0	0%	0	0%	0	0%
	No answer: 7 insts.		Ν	lo answer: 11		No answer: 5
	* Among 81,455 cases		** Am	ong 86,483 cases	*** Arr	ong 76,216 cases



### Did you experience an incident/accident caused by Mishandling of Blood Pump?



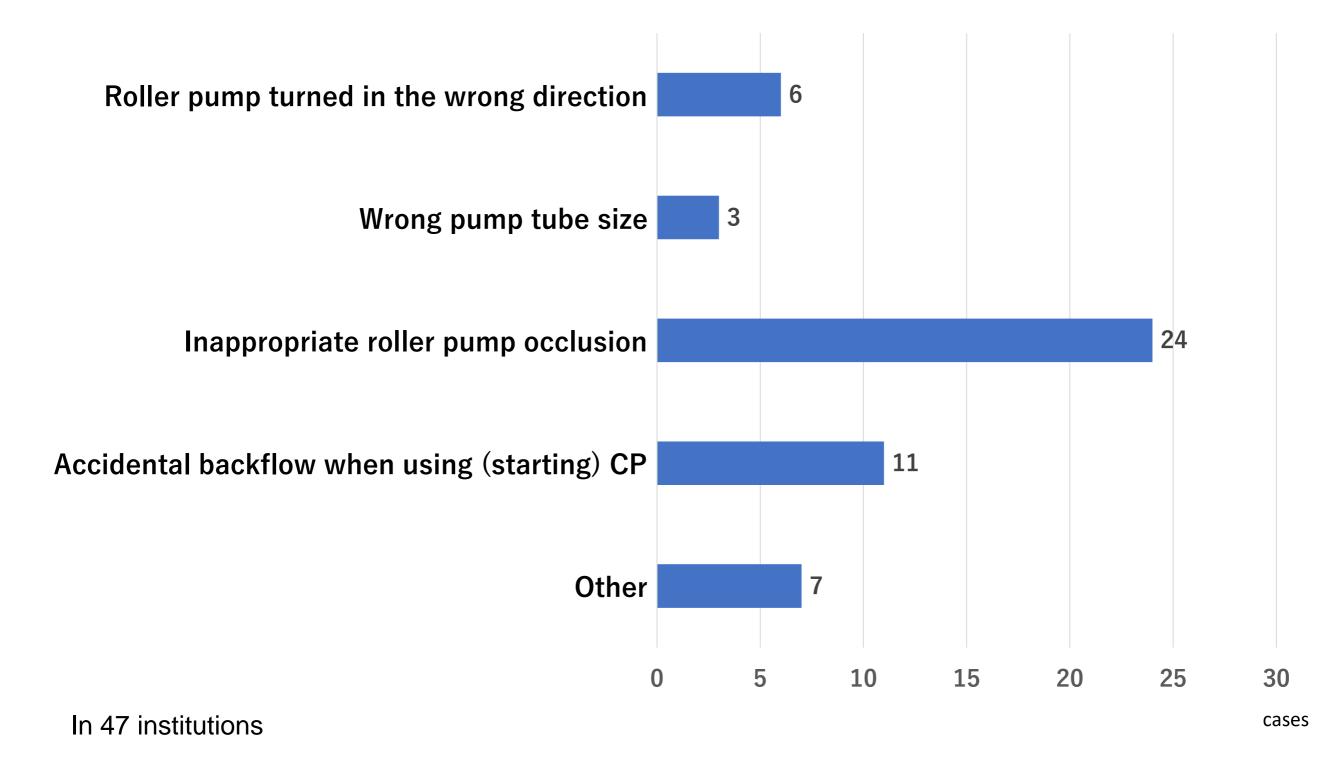
Impact level	No. of cases	Frequency*	
0	12	0.01%	
1 – 3a	39	0.05%	
3b – 5	0	0%	
	No opowary 02 inote		

No answer: 23 insts.

\*Among 81,455 CPB cases occurring during the 2-year period.

n = 416 (no answer: 22 insts.)

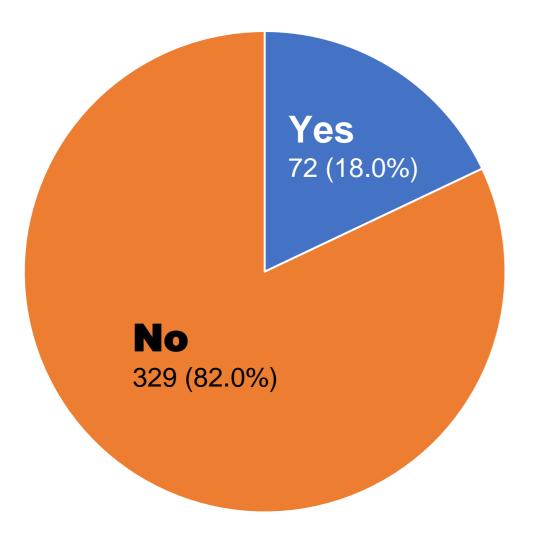
# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



#### **Blood Pump Mishandling Incidents & Rates**

	2019 Survey		2017 Survey		2015 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	12	0.01%	23	0.03%	30	0.04%
1 – 3a	39	0.05%	15	0.02%	10	0.01%
3b – 5	0	0 %	1	< 0.01%	0	0%
	No answer: 23 insts.		Ν	lo answer: 10	٩	lo answer: 10
	* Among 81,455 cases		** Am	ong 86,483 cases	*** Am	ong 76,216 cases

# Did you experience an incident/accident involving a <u>Meter or Alarm Device?</u>

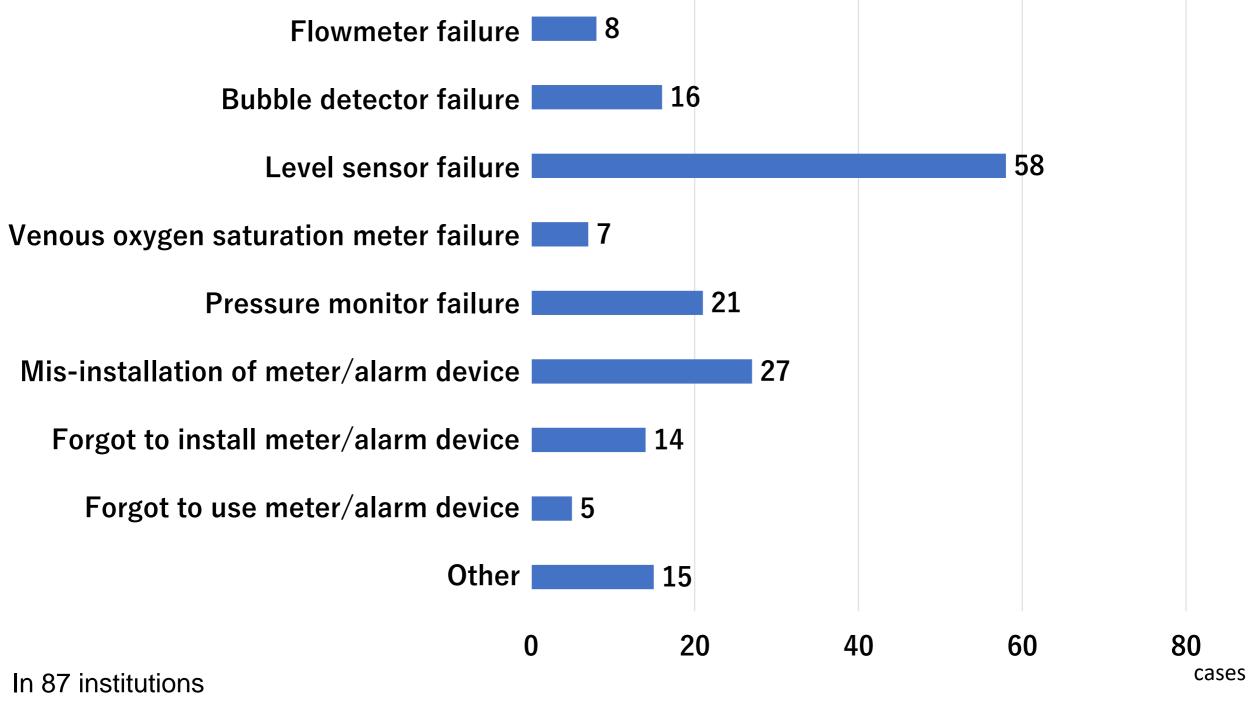


Impact level	No. of cases	Frequency*	
0	134	0.16%	
1 – 3a	28	0.03%	
3b – 5	0	0%	
	No answer: 20 insts.		

\*Among 81,455 CPB cases occurring during the 2-year period.

n = 416 (no answer: 15 insts.)

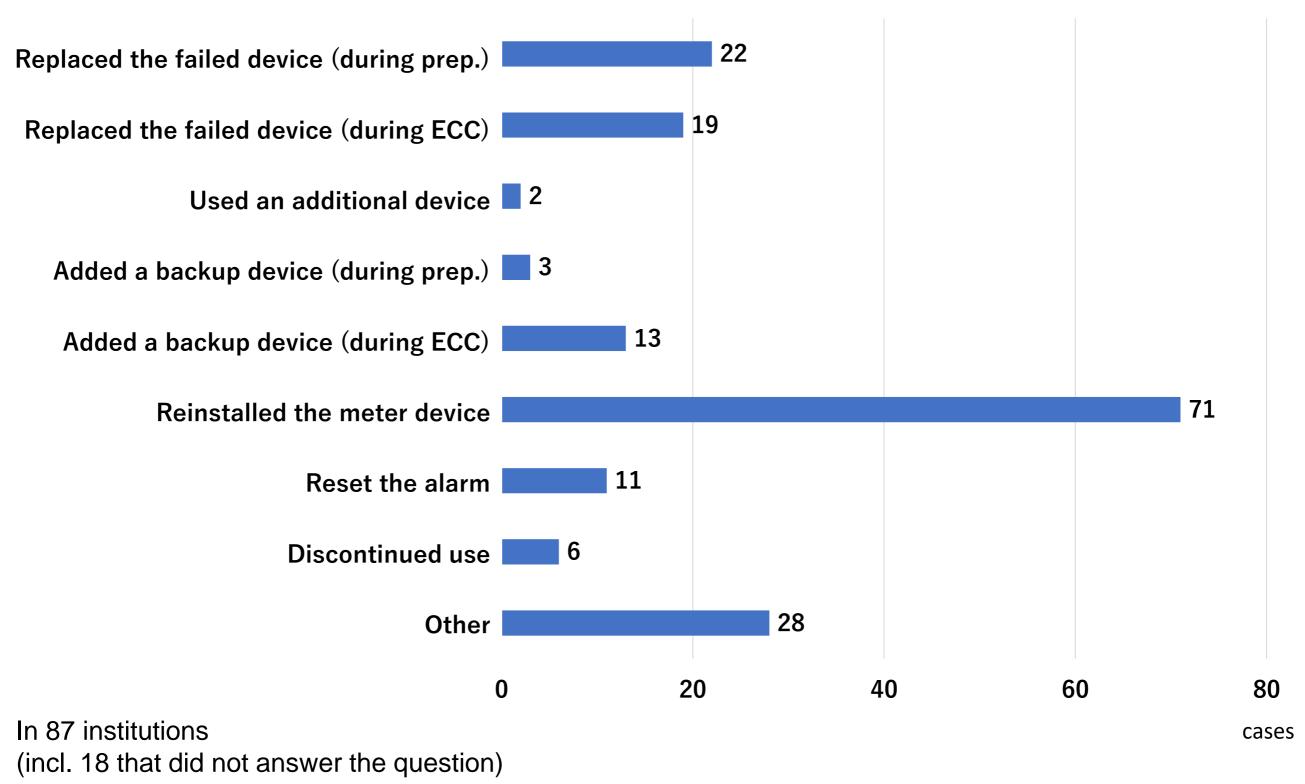
# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



(incl. 15 that did not answer the question)



## Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)

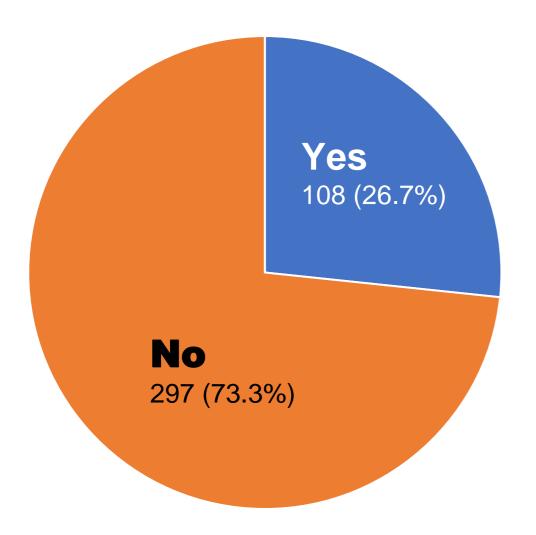


#### **Meter/Alarm-Related Incidents & Rates**

	2019	Survey	2017	Survey	2015	Survey
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	134	0.16%	167	0.19%	162	0.21%
1 – 3a	26	0.03%	28	0.03%	27	0.04%
3b – 5	0	0%	0	0%	0	0%
	No ans	wer: 20 insts.	N	lo answer: 29	Ν	lo answer: 16
	* Among 81,455 cases		** Am	ong 86,483 cases	*** Am	ong 76,216 cases



### Did you experience an incident/accident involving <u>CPB Circuit?</u> (excl. blood pump, oxygenator & arterial filter)

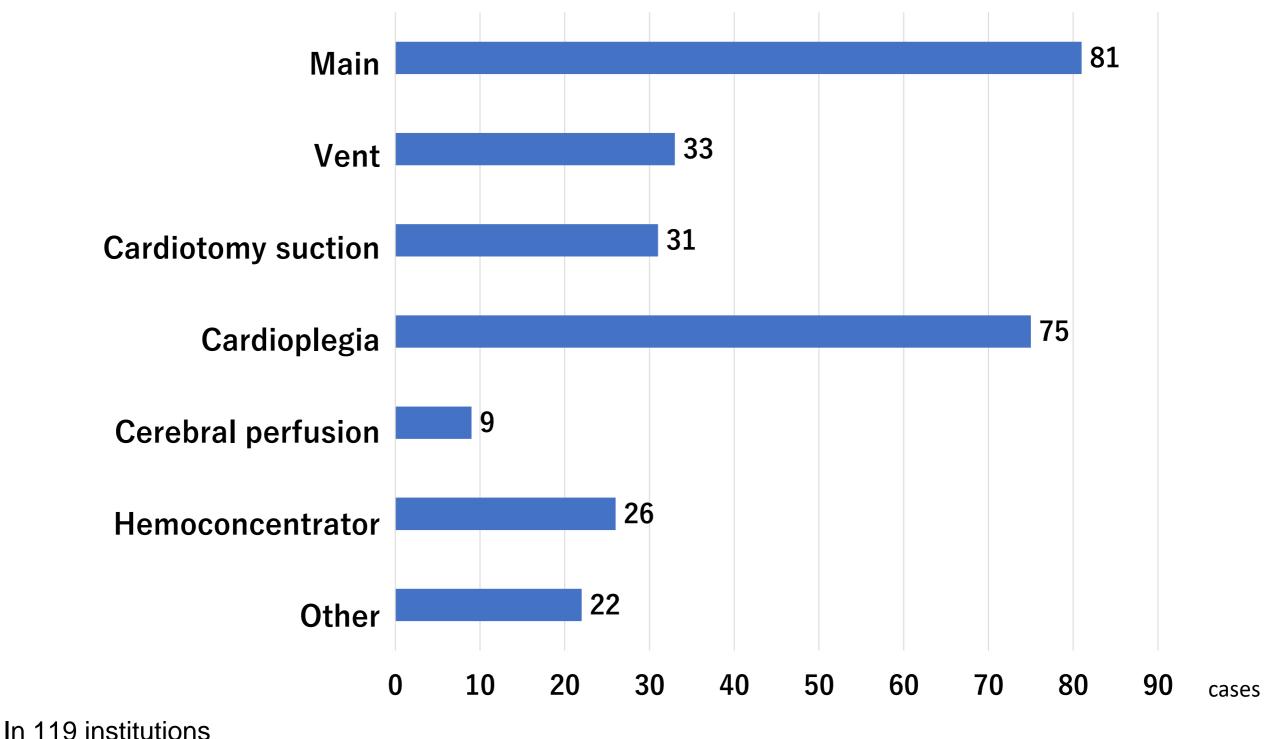


Impact level	No. of cases	Frequency*	
0	145	0.18%	
1 – 3a	110	0.14%	
3b – 5	2	< 0.01%	
	No answer: 18 insts.		

\*Among 81,455 CPB cases occurring during the 2-year period.

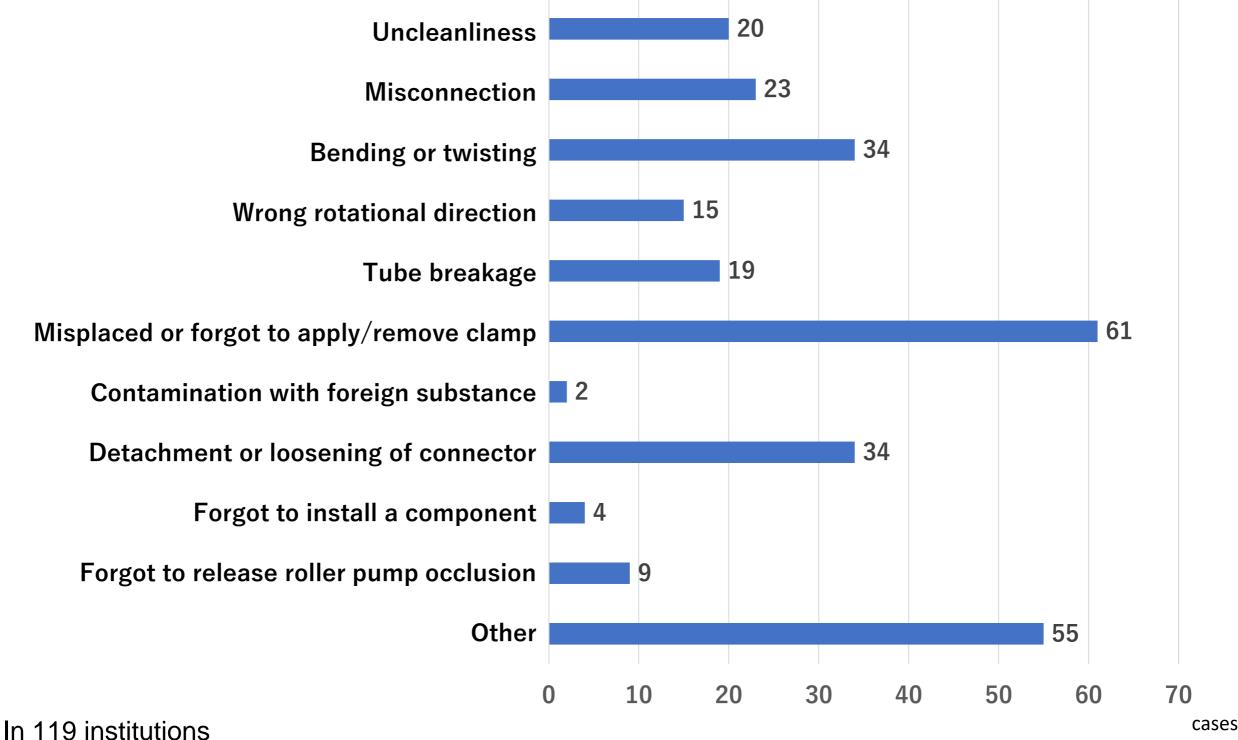
n = 416 (no answer: 11 insts.)

# Which of the following circuit/line was involved in the accident/incident and how many times? (Please choose all that apply.)



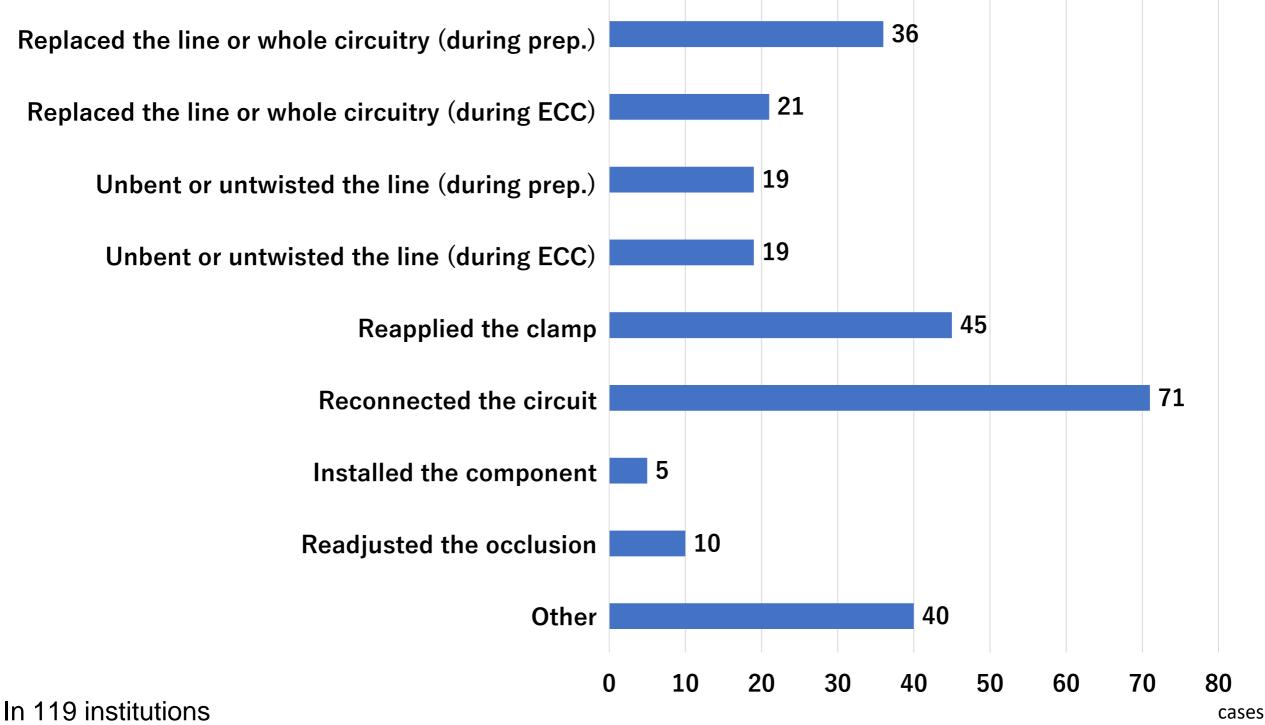
(incl. 10 that did not answer the question)

## Which of the following causes was responsible for the accident/incident and how many times? (Please choose all that apply.)



(incl. 9 that did not answer the question)

## Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)

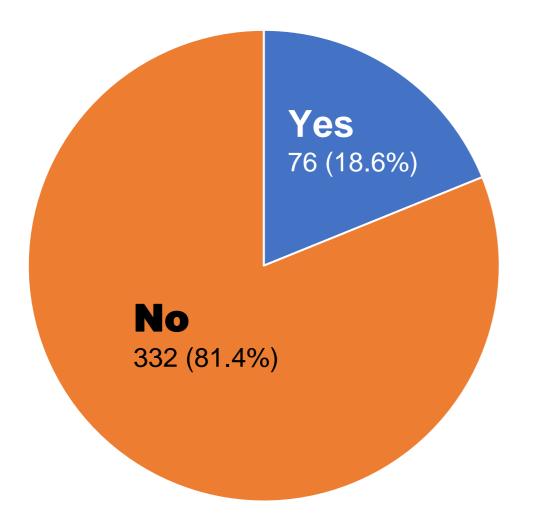


(incl. 12 that did not answer the question)

#### **CPB-Circuitry-Related Incidents & Rates**

	2019	Survey	2017	Survey	2015	Survey
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	145	0.18%	176	0.20%	242	0.32%
1 – 3a	110	0.14%	74	0.09%	55	0.07%
3b — 5	2	< 0.01%	6	0.01%	4	0.01%
	No ans	wer: 18 insts.	N	lo answer: 17	٩	lo answer: 19
	* Amo	ong 81,455 cases	** Am	ong 86,483 cases	*** Am	ong 76,216 cases

# Did you experience an incident/accident involving a <u>Cannula?</u>

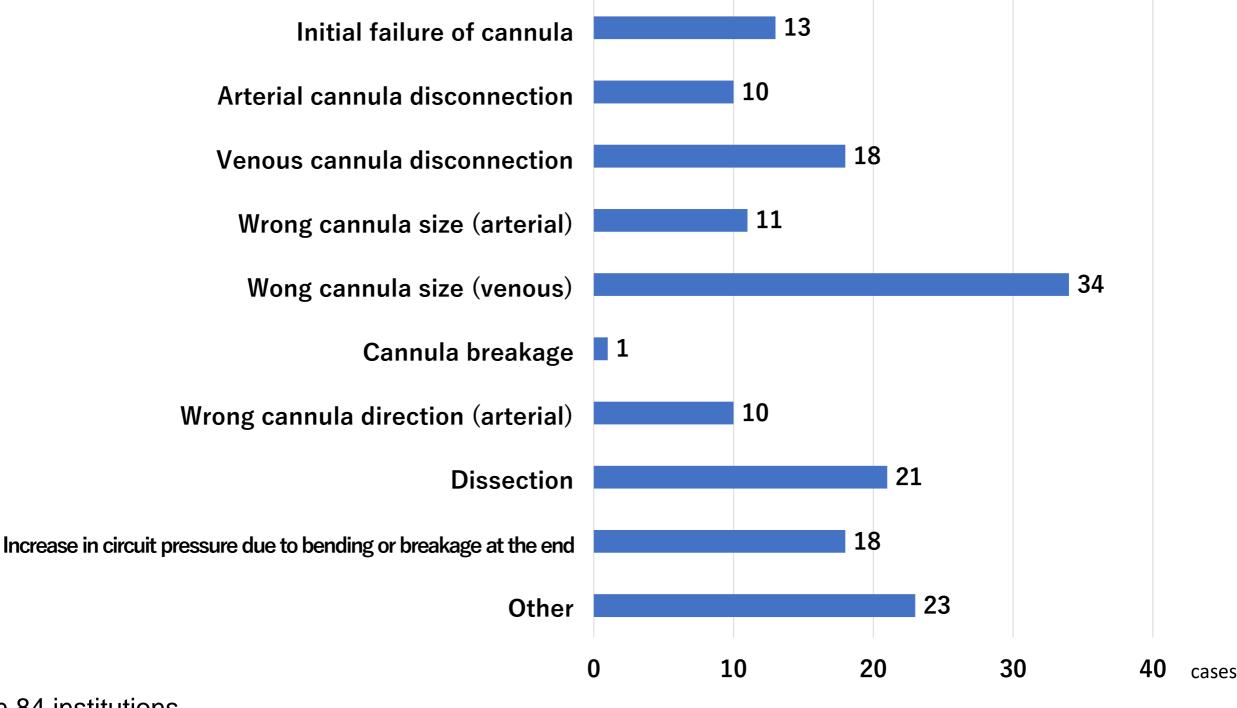


Impact level	No. of cases	Frequency*	
0	41	0.05%	
1 – 3a	92	0.11%	
3b – 5	16	0.02%	
	No answer: 14 insts.		

\*Among 81,455 CPB cases occurring during the 2-year period.

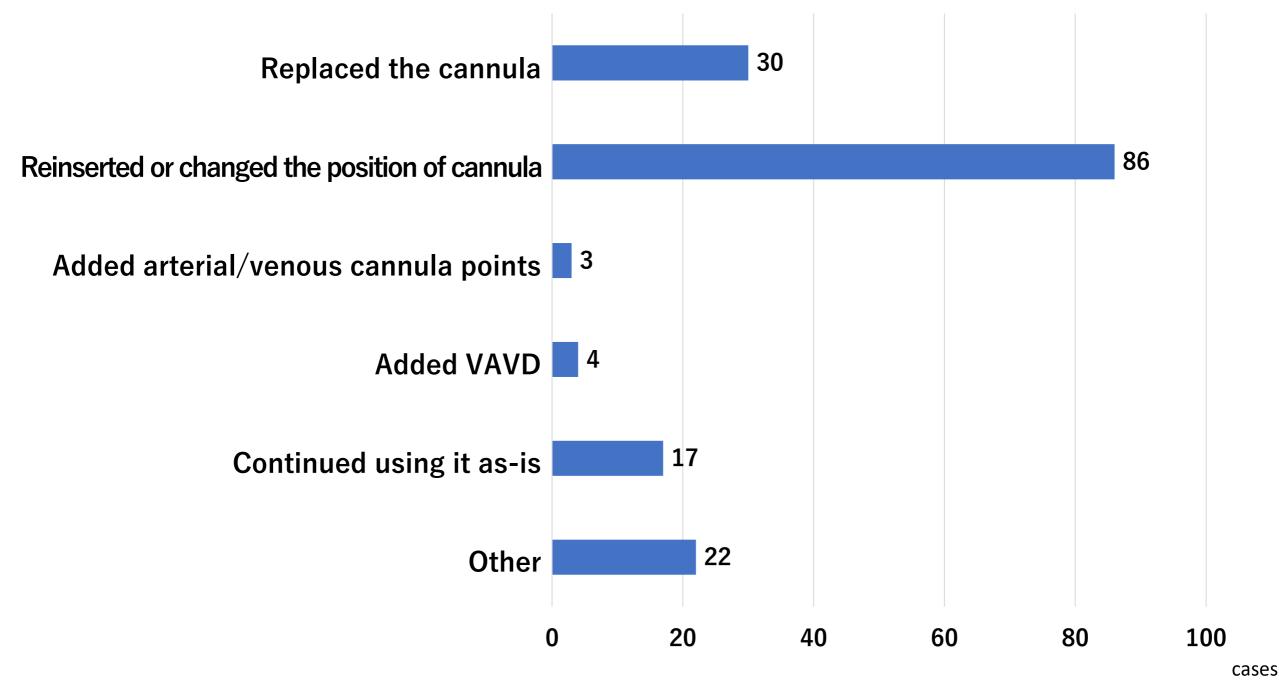
n = 416 (no answer: 8 insts.)

# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



In 84 institutions (incl. 9 that did not answer the question)

## Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)

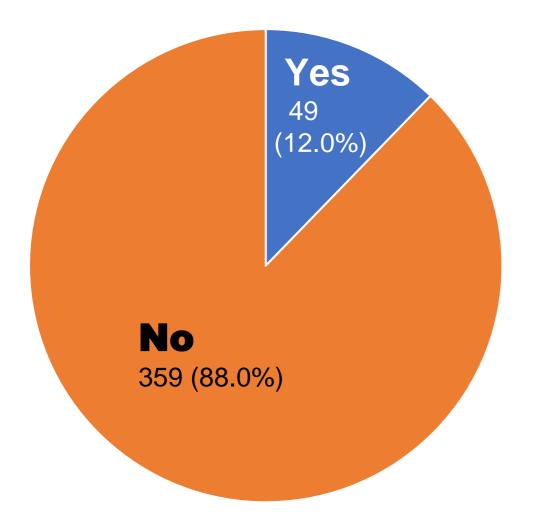


In 84 institutions (incl. 10 that did not answer the question)

#### **Cannula-Related Incidents & Rates**

	2019	Survey	2017	Survey	2015	Survey
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	41	0.05%	55	0.06%	79	0.10%
1 – 3a	92	0.11%	67	0.08%	78	0.10%
3b – 5	16	0.02%	12	0.01%	30	0.04%
	No ans	wer: 14 insts.		No answer: 7	Ν	lo answer: 10
	* Am	ong 81,455 cases	** Am	ong 86,483 cases	*** Am	ong 76,216 cases

### Was there an instance of Forgetting to Supply Oxygen at the start of ECC?



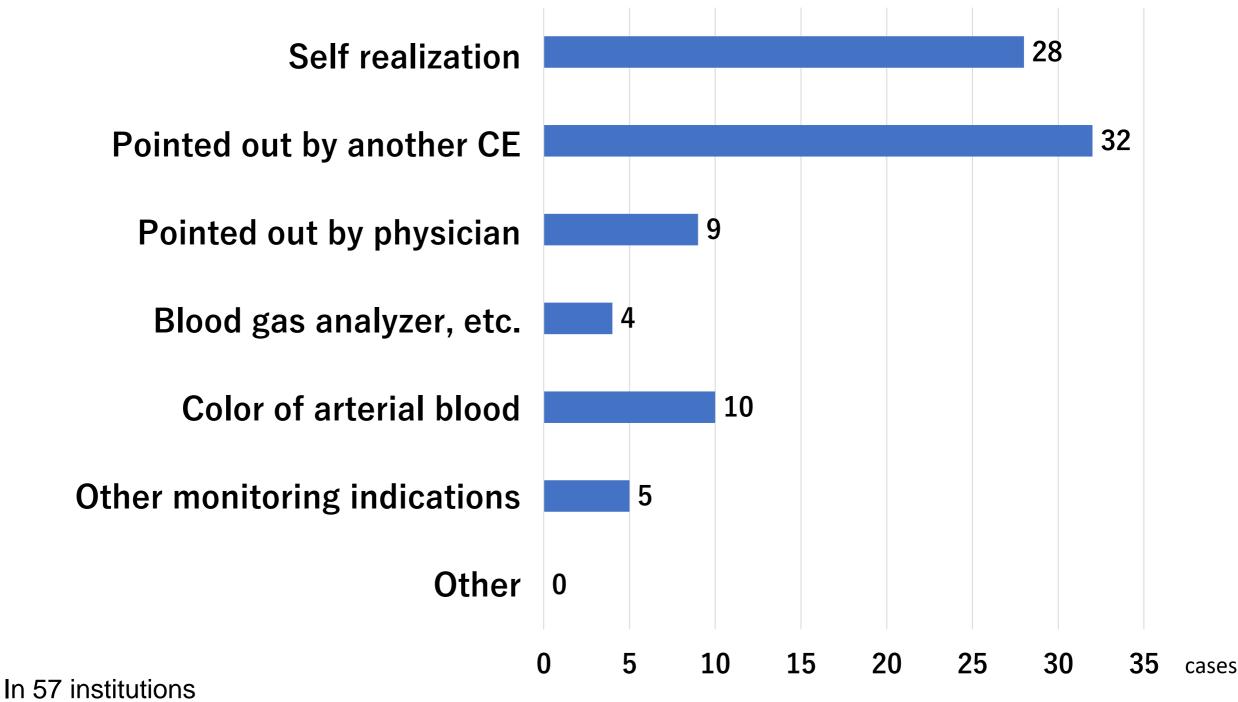
Impact level	No. of cases	Frequency*
0	44	0.06%
1 – 3a	34	0.04%
3b – 5	0	0%
	No a	nswer: 8 insts.

\*Among 81,455 CPB cases occurring during the 2-year period.

n = 416 (no answer: 8 insts.)



# What made you realize that you forgot to supply oxygen? (Please choose all that apply.)



(incl. 7 that did not answer the question)

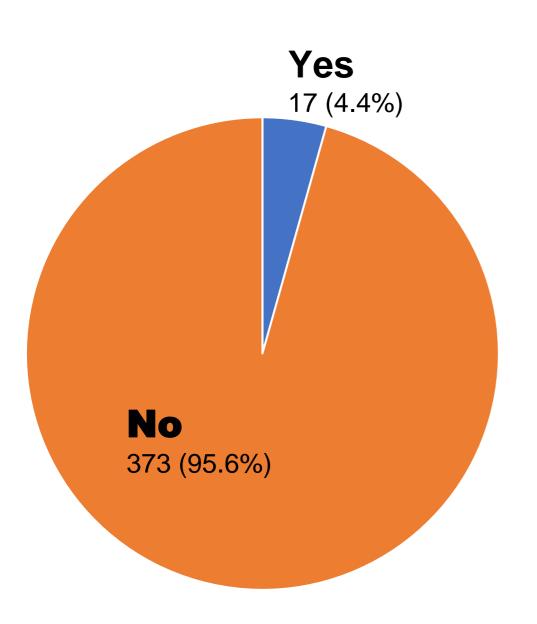


#### Incidents & Rates of Forgetting to Supply Oxygen at the Start of ECC

	2019	Survey	2017	Survey	2015	Survey
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	44	0.06%	65	0.08%	76	0.10%
1 – 3a	34	0.04%	46	0.05%	41	0.05%
3b – 5	0	0%	0	0%	0	0%
	No an	swer: 8 insts.		No answer: 6		No answer: 7
	* Am	ong 81,455 cases	** Am	ong 86,483 cases	*** Arr	ong 76,216 cases



### Did you experience an Inadvertent Air Entry into the Bloodstream?



Impact level	No. of cases	Frequency*	
1 – 3a	16	0.02%	
3b – 5	2	< 0.01%	
	No answer: 26 insts.		

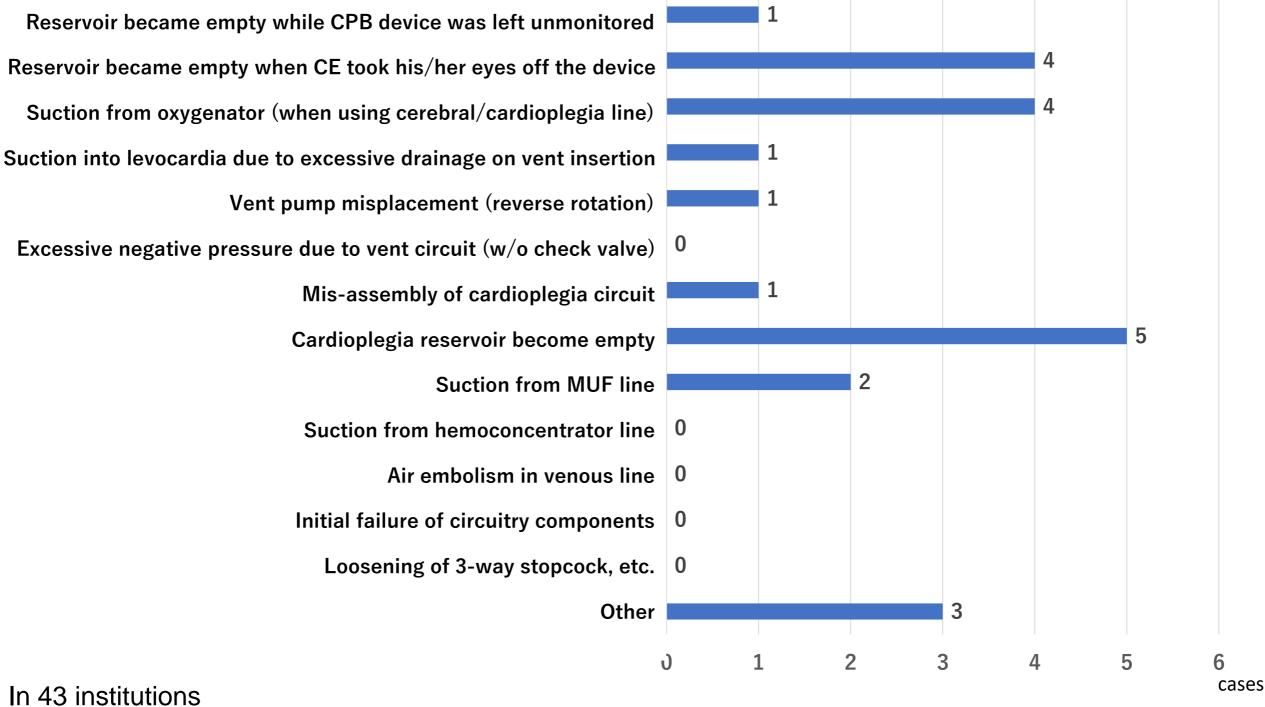
\*Among 81,455 CPB cases occurring during the 2-year period.

n = 416 (no answer: 26 insts.)

JaSECT Safety Control Committee



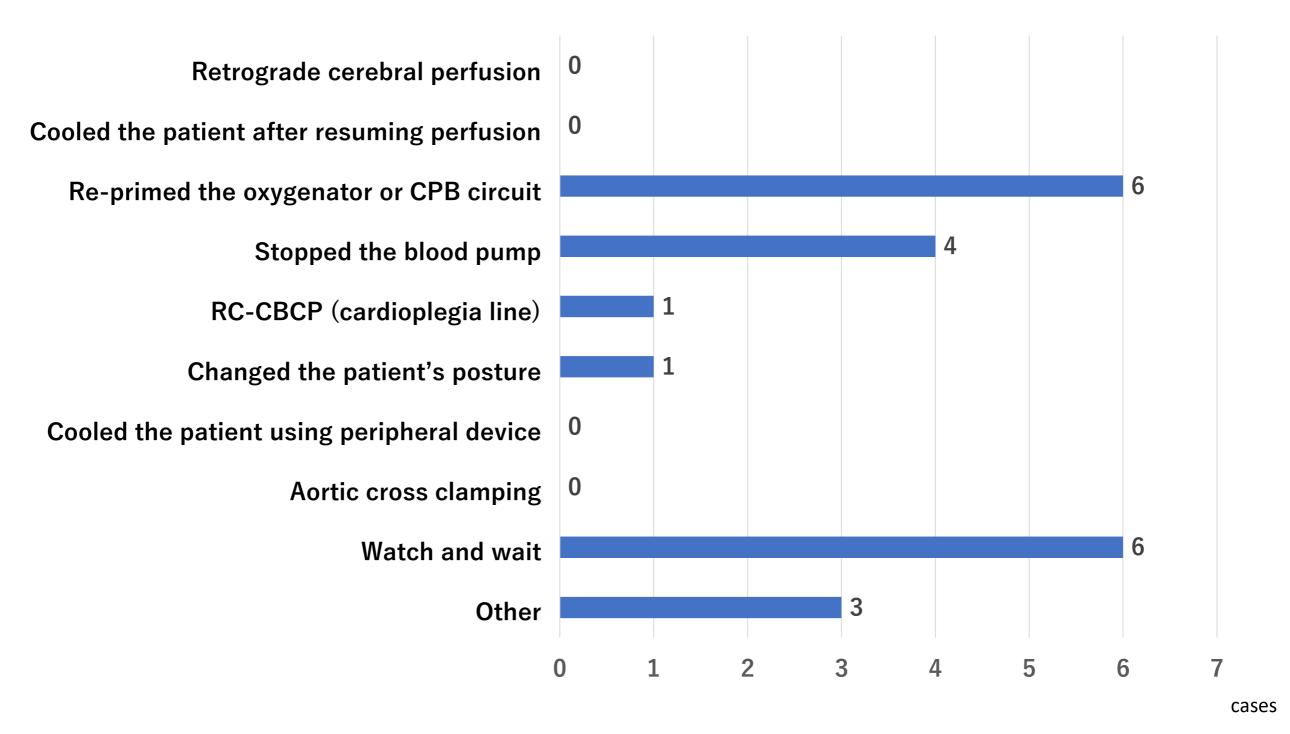
# Which of the following caused the air entry and how may times? (Please choose all that apply.)



(incl. 24 that did not answer the question)



# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



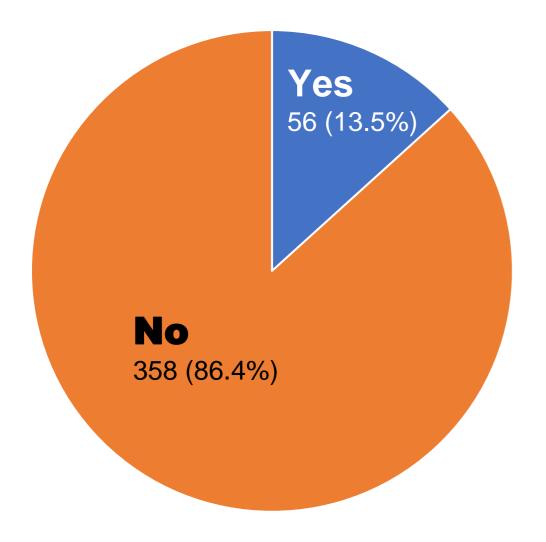
In 43 institutions (incl. 24 that did not answer the question)

#### **Incidents & Rates of Inadvertent Air Entry**

	2019	Survey	2017	Survey	2015	Survey
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	—	—	—	—	10	0.01%
1 – 3a	17	0.02%	16	0.02%	16	0.02%
3b – 5	2	< 0.01%	5	0.01%	3	< 0.01%
	No ans	wer: 26 insts.	Ν	lo answer: 27	٨	lo answer: 16
	* Am	ong 81,455 cases	** Am	ong 86,483 cases	*** Am	ong 76,216 cases



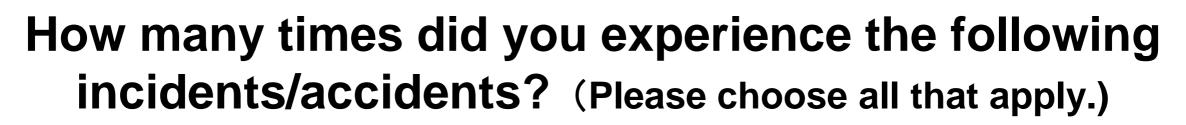
### Was there an instance of <u>Unexpected Drainage</u> <u>from Arterial or Venous Cannula</u> after ECC?

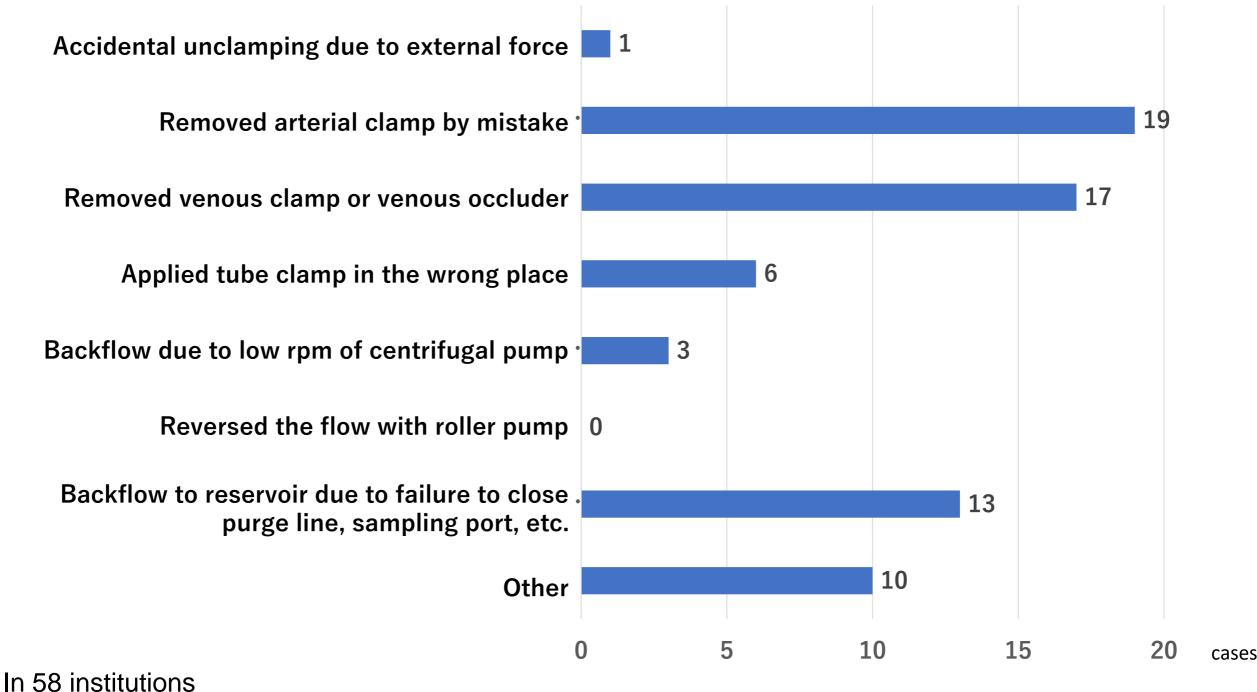


Impact level	No. of cases	Frequency*
1 – 3a	65	0.08%
3b – 5	4	< 0.01%
	No a	nswer: 4 insts.

\*Among 81,455 CPB cases occurring during the 2-year period.

n = 416 (no answer: 2 insts.)

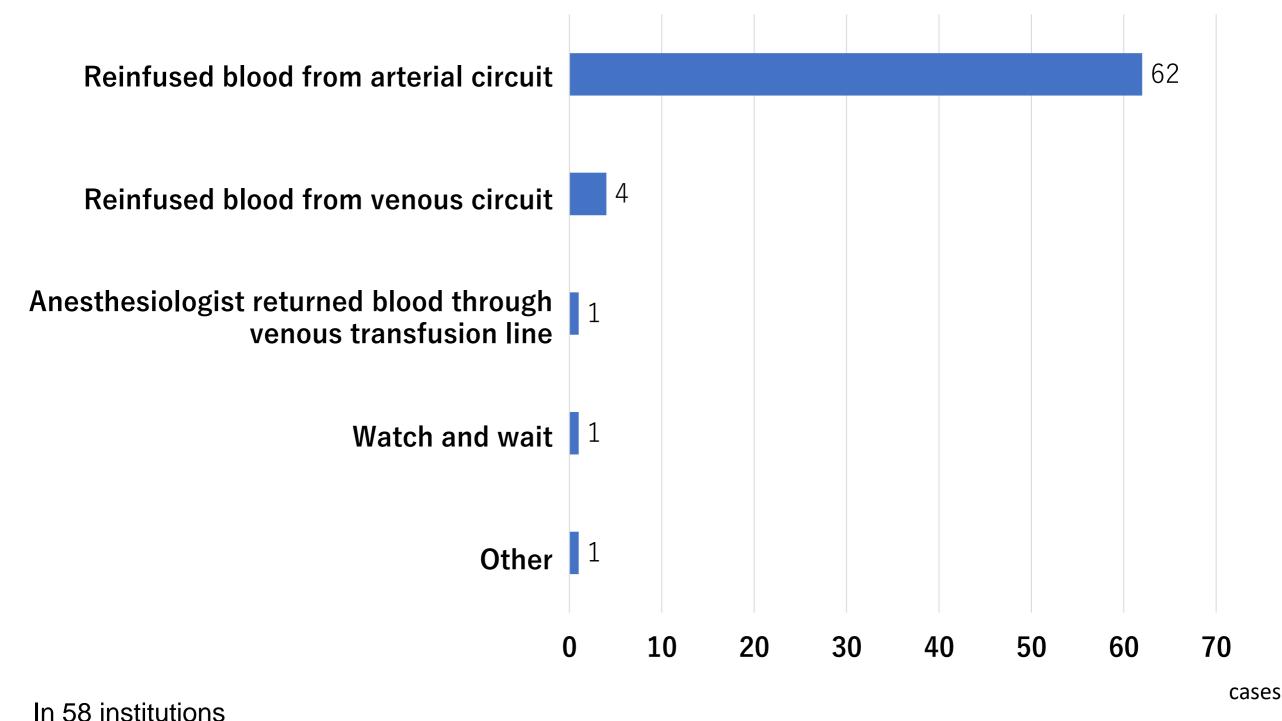




(incl. 2 that did not answer the question)



# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



(incl. 2 that did not answer the question)

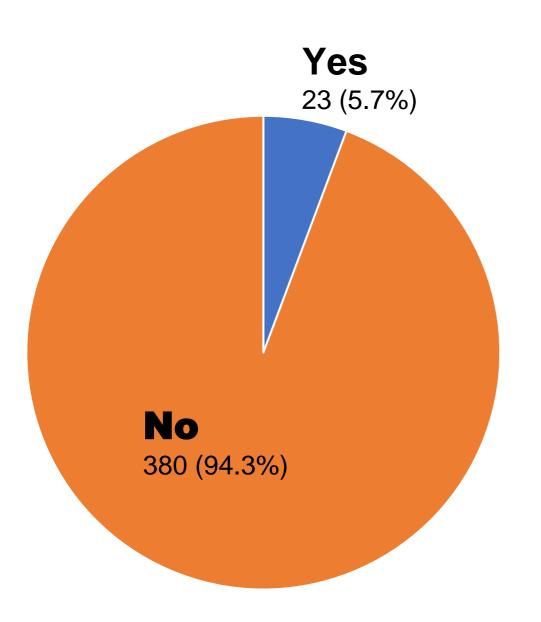


#### Incidents & Rates of Unexpected Blood Drainage after ECC

	2019	Survey	2017	Survey	2015	Survey
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	—	_	—	—	33	0.04%
1 – 3a	65	0.08%	74	0.09%	69	0.09%
3b – 5	4	< 0.01%	2	< 0.01%	3	< 0.01%
	No an	swer: 4 insts.	Ν	lo answer: 11		No answer: 3
	* Amo	ong 81,455 cases	** Am	ong 86,483 cases	*** Am	ong 76,216 cases

### Did you experience a <u>Medication Error</u>?

(excluding errors in cardioplegia)



Impact level	No. of cases	Frequency*
0	8	0.01%
1 – 3a	19	0.02%
3b – 5	0	0%

No answer: 14 insts.

\*Among 81,455 CPB cases occurring during the 2-year period.

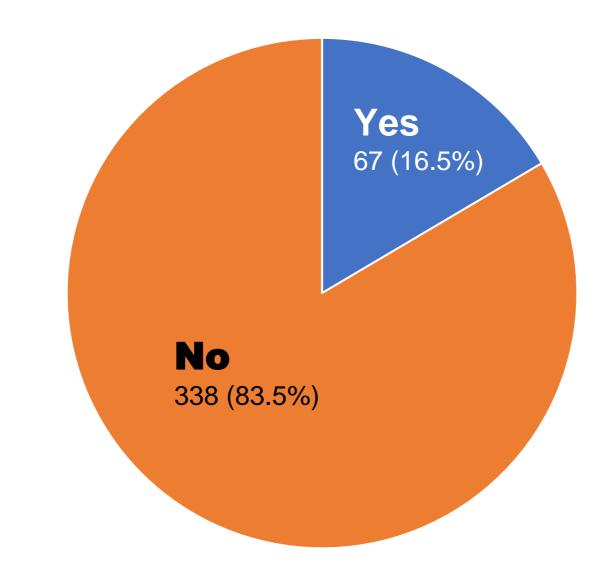
n = 416 (no answer: 13 insts.)

#### **Incidents & Rates of Medication Errors**

	2019 Survey		2017 Survey		2015 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	8	0.01%	17	0.02%	16	0.02%
1 – 3a	19	0.02%	10	0.01%	15	0.02%
3b — 5	0	0%	3	< 0.01%	0	0%
	No answer: 14 insts.			No answer: 1		No answer: 1
	* Among 81,455 cases		** Am	ong 86,483 cases	*** Am	ong 76,216 cases

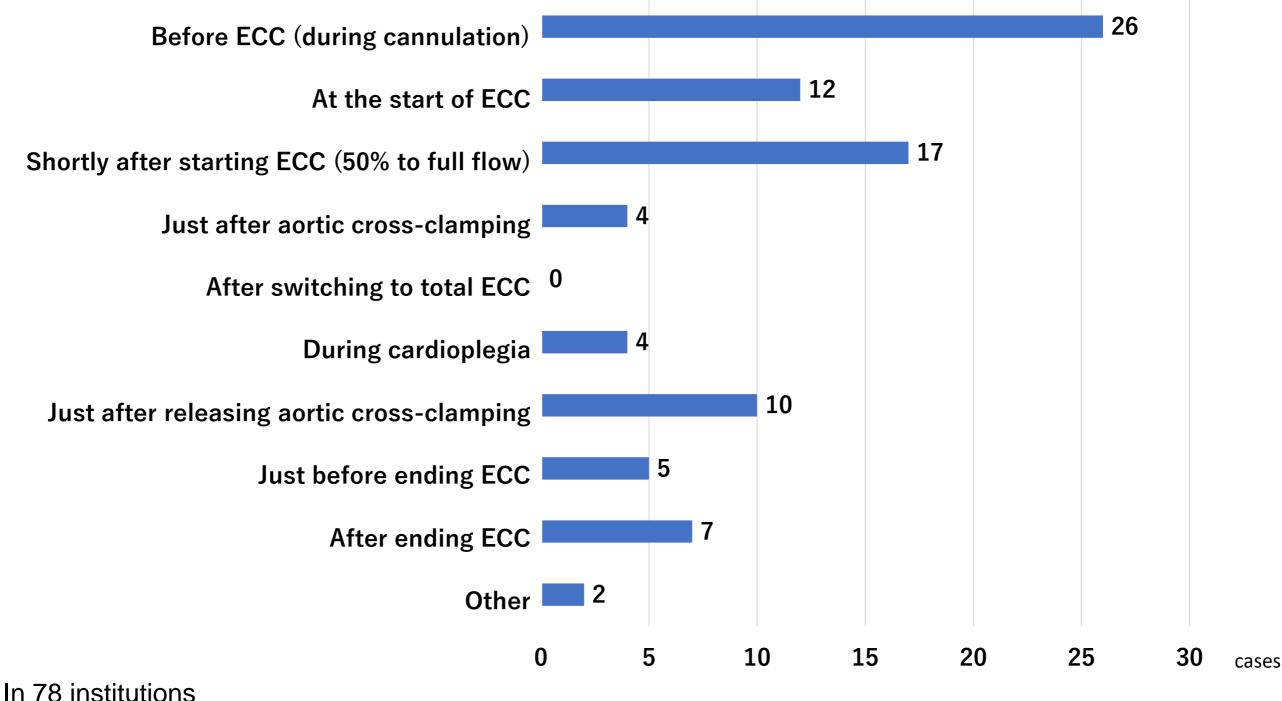
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### Did you experience an Intraoperative Dissection?



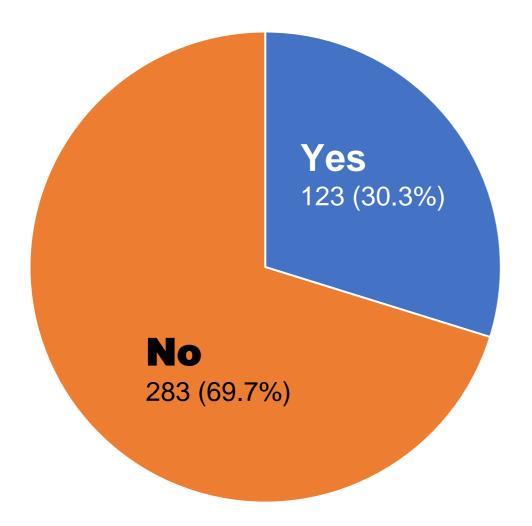
n = 416 (no answer: 11 insts.)

#### When did you notice it? (Please choose all that apply.)



(incl. 11 that did not answer the question)

### Did you experience an incident/accident related to Cardioplegia?



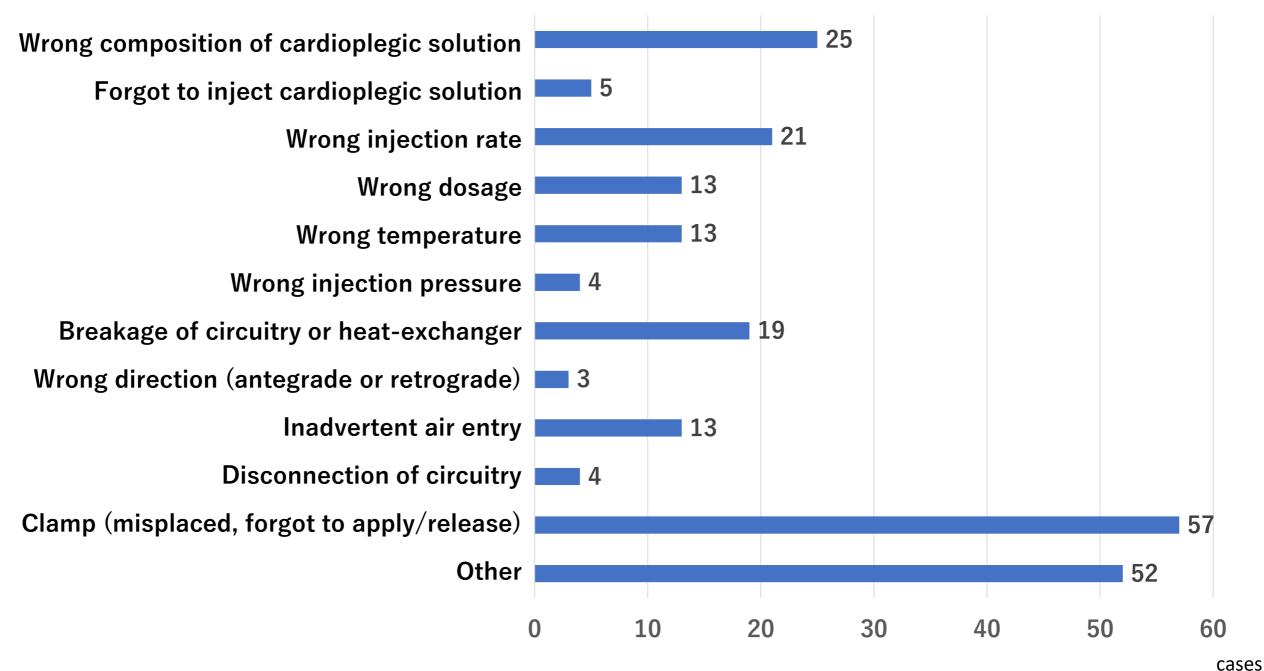
Impact level	No. of cases	Frequency*	
0	136	0.17%	
1 – 3a	114	0.14%	
3b – 5	2	< 0.01%	
	No answer: 10 insts.		

\*Among 81,455 CPB cases occurring during the 2-year period.

n = 416 (no answer: 10 insts.)



# How many times did you experience the following incidents/accidents? (Please choose all that apply.)

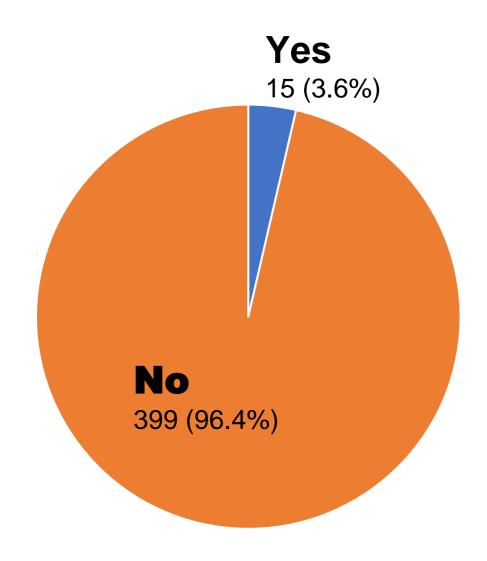


In 133 institutions (incl. 10 that did not answer the question)

#### **Cardioplegia-Related Incidents & Rates**

	2019 Survey		2017 Survey		2015 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	136	0.17%	128	0.15%	127	0.17%
1 – 3a	114	0.14%	80	0.09%	64	0.08%
3b – 5	2	< 0.01%	1	< 0.01%	4	0.01%
	No answer: 10 insts.			No answer: 6		No answer: 9
	* Among 81,455 cases		** Am	ong 86,483 cases	*** Am	ong 76,216 cases

## Did you experience a <u>Power Interruption or Outage</u> during CPB?



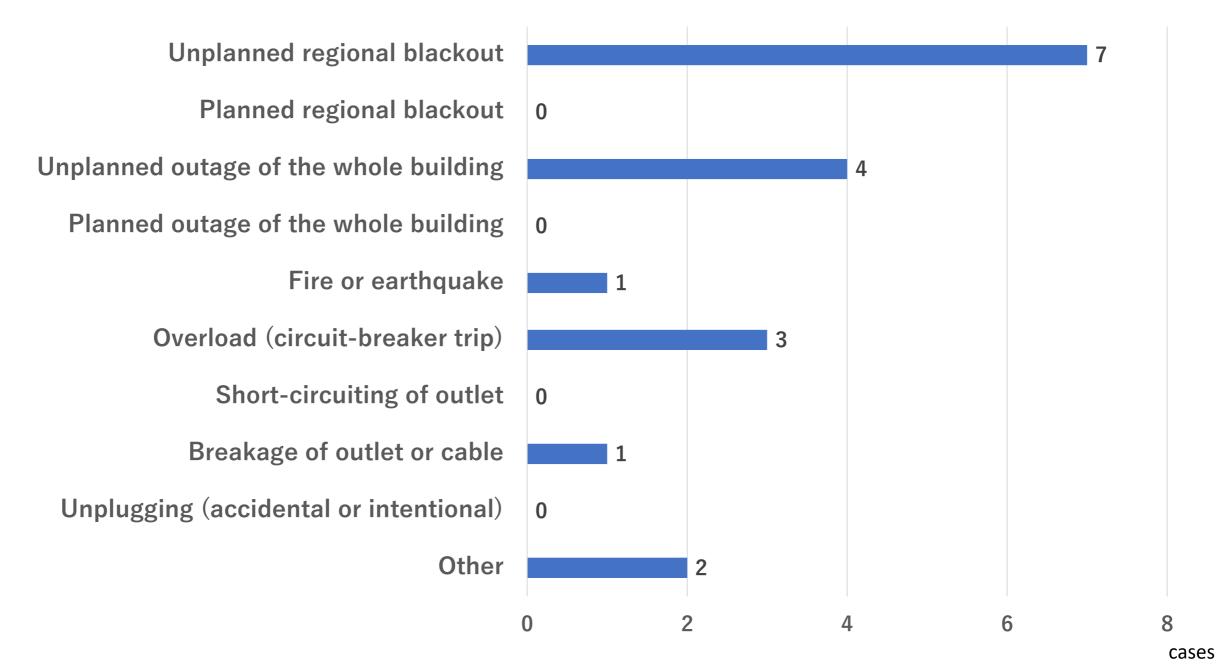
Impact level	No. of cases	Frequency*	
0	11	0.01%	
1 – 3a	5	0.01%	
3b – 5	0	0%	
	No answer: 2 insts.		

\*Among 81,455 CPB cases occurring during the 2-year period.

n = 416 (no answer: 2 insts.)

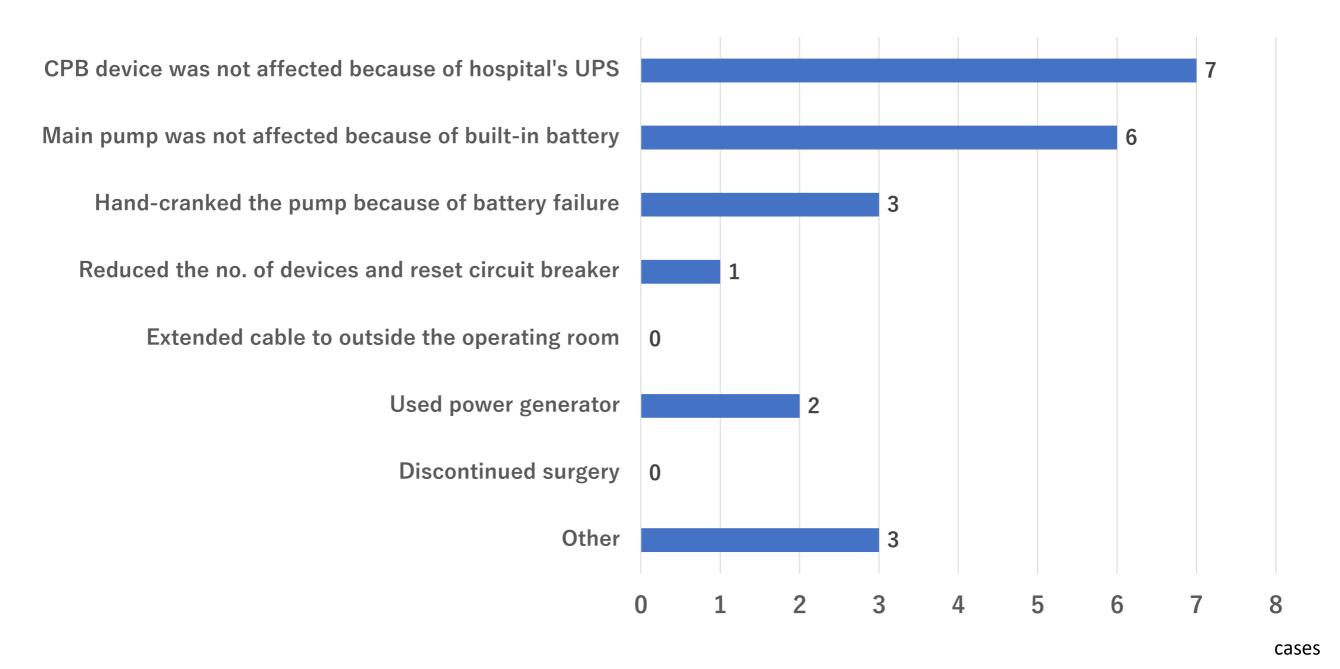


# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



In 17 institutions

## Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



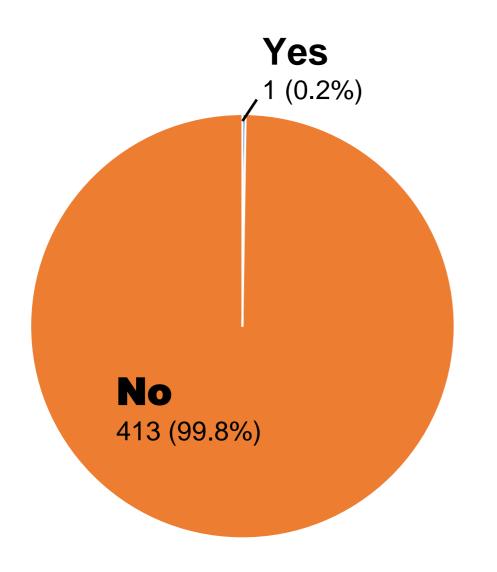
In 17 institutions

#### **Incidents & Rates related to Power Interruption/Outage**

	2019 Survey		2017	2017 Survey		2015 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***	
0	11	0.01%	14	0.02%	11	0.01%	
1 – 3a	5	0.01%	12	0.01%	5	0.01%	
3b – 5	0	0%	0	0%	0	0%	
	No answer: 2 insts.			No answer: 0		No answer: 2	
	* Among 81,455 cases		** Am	ong 86,483 cases	*** Am	iong 76,216 cases	



## Did you experience an Interruption of Medical Gas Supply during CPB?



Impact level	No. of cases	Frequency*
1 – 3a	1	< 0.01%
3b – 5	-	-

No answer: 2 insts.

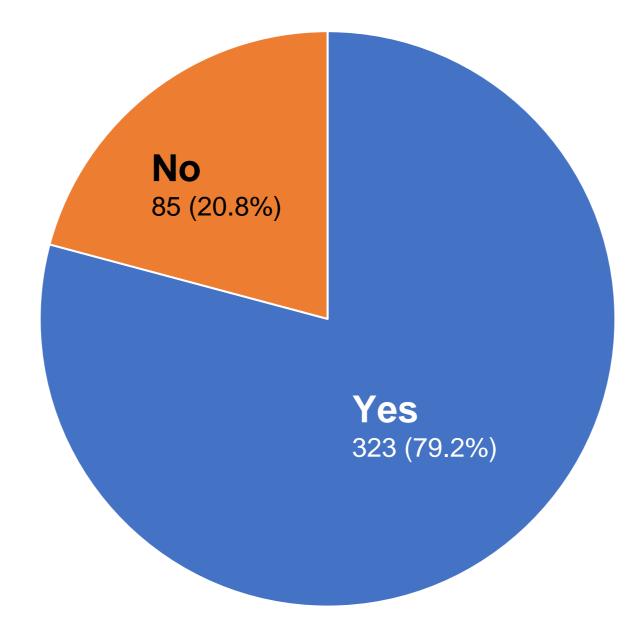
\*Among 81,455 CPB cases occurring during the 2-year period.

n = 416 (no answer: 2 insts.)



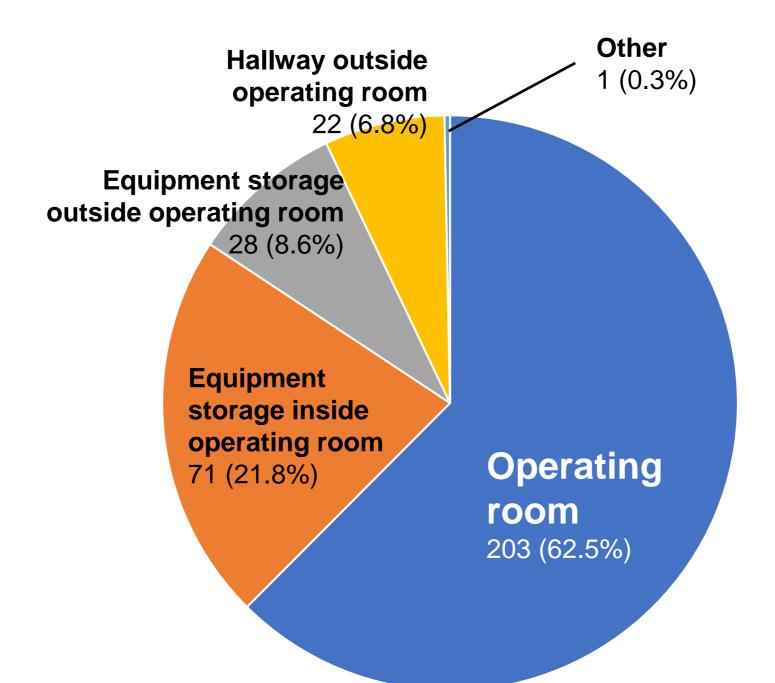
	2019 Survey		2017 Survey		2015 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	-	-	0	0%	2	< 0.01%
1 – 3a	1	< 0.01%	0	0%	0	0%
3b – 5	0	0%	0	0%	0	0%
	No answer: 2 insts.			No answer: 8		No answer: 2
	* Among 81,455 cases		** Am	ong 86,483 cases	*** Am	ong 76,216 cases

### Do you have an emergency kit in place?



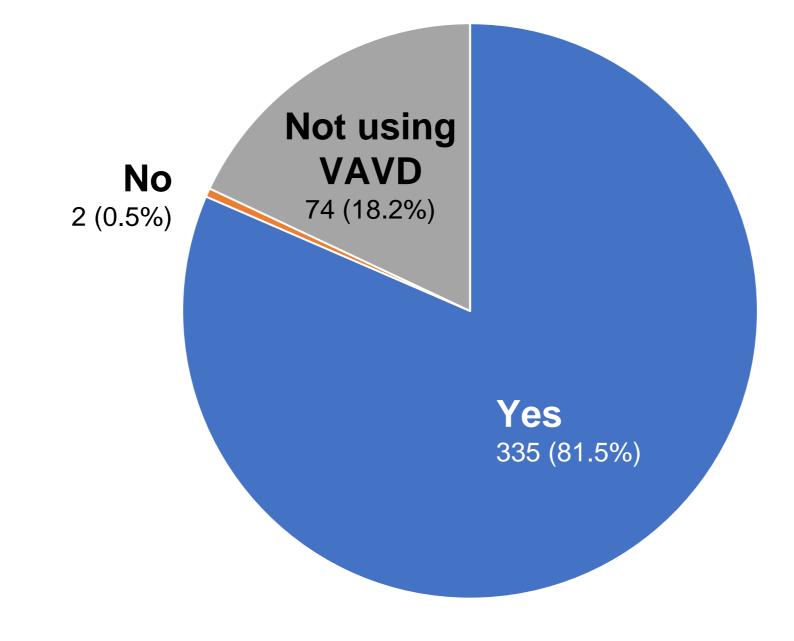
n = 416 (no answer: 8 insts.)

### Where do you store the emergency kit?



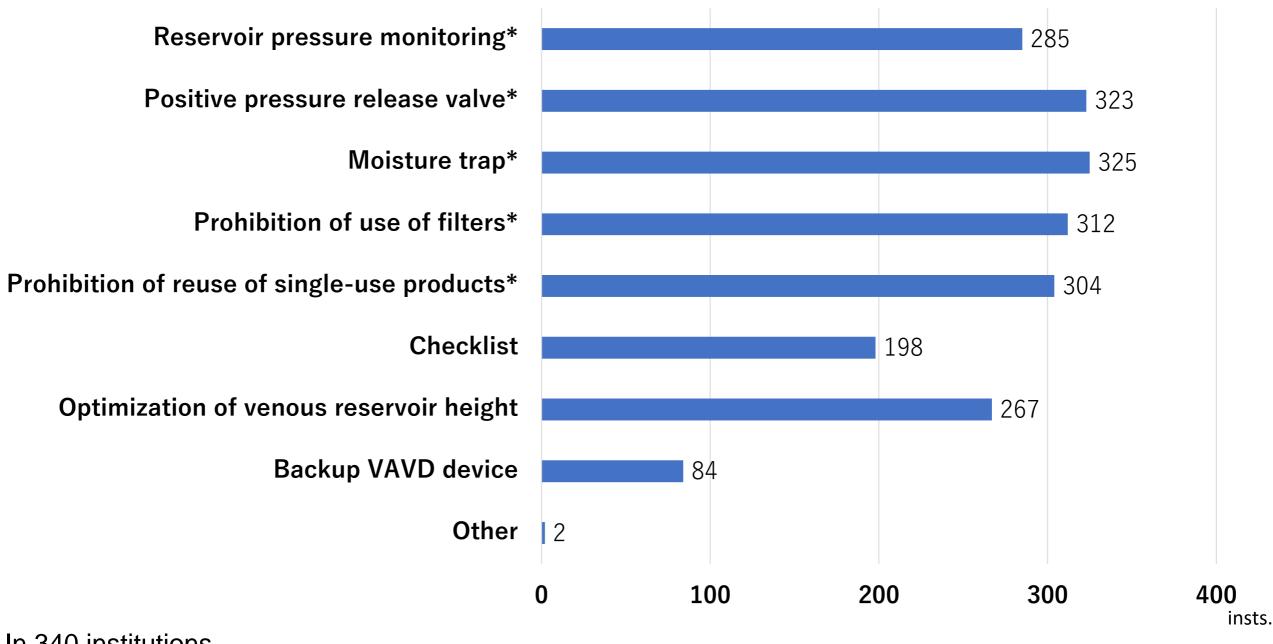
n = 331 (no answer: 6 insts.) Institutions without emergency kit are excluded.

### Do you take safety measures when using VAVD?



n = 416 (no answer: 5 insts.)

## Which of the following safety measures do you take when using VAVD? (Please choose all that apply.)



\*Recommended by 3 academic societies

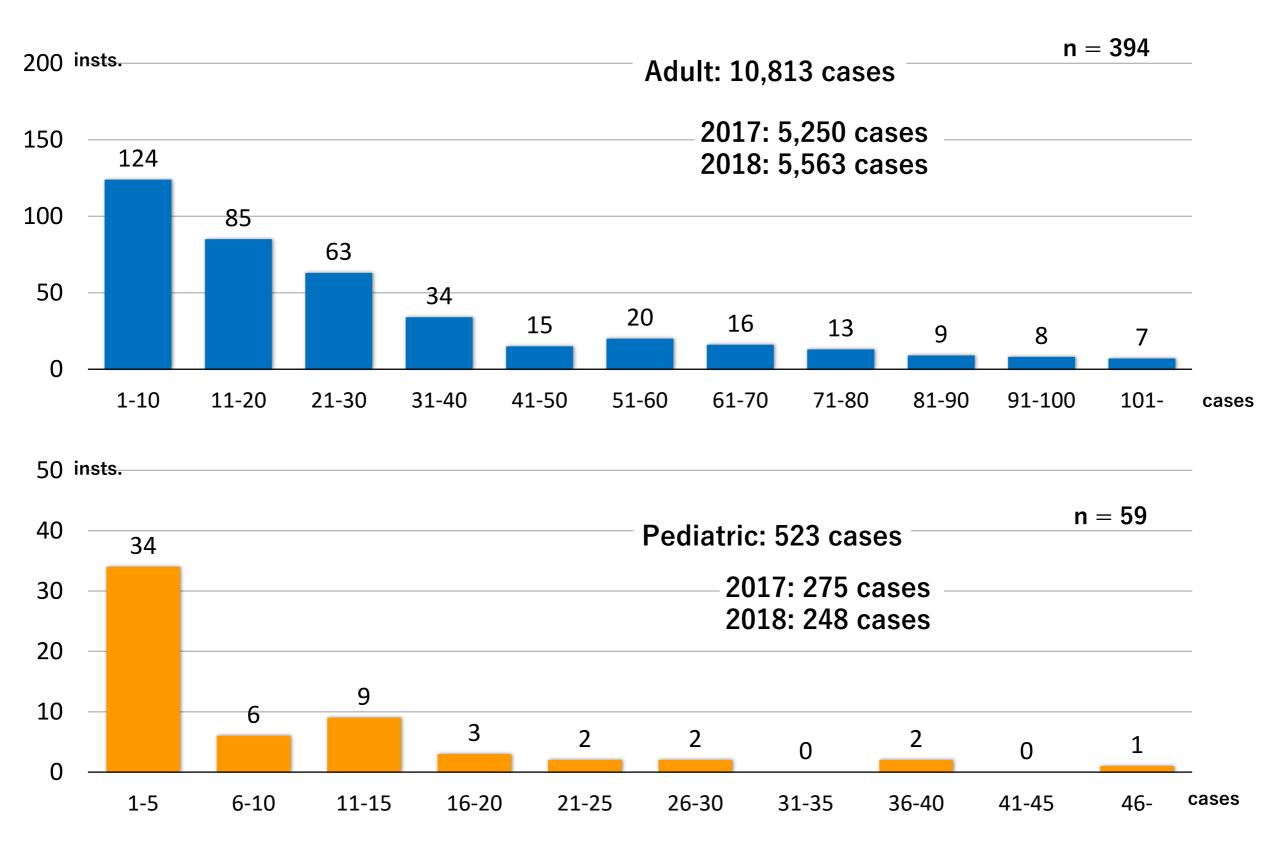
In 340 institutions (incl. 3 that did not answer the question)

Cardiopulmonary Bypass (CPB)



## **Aggregation Results**

#### **PCPS/ECMO-Related Cases by Demographics**

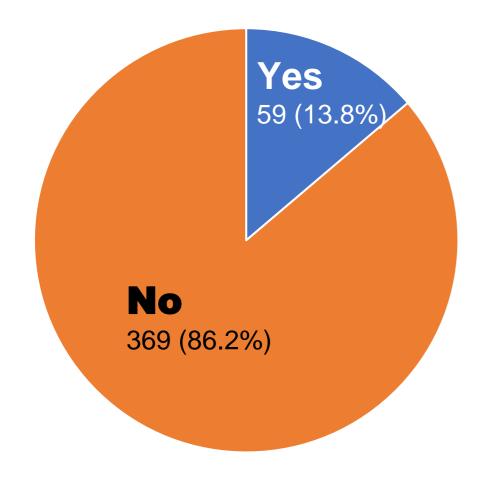




#### **PCPS/ECMO-Related Incidents/Accidents & Rates**

	2019 Survey			2017 Survey			2015 Survey		
	2017	2018	Total	2015	2016	Total	2013	2014	Total
No. of cases	5,525	5,811	11,336	4,921	5,524	10,445	4,375	4,666	9,041
Impact level (0)	57 1.03%	58 1.00%	115 1.01%	51 1.04%	45 0.81%	96 0.92%	94 2.15%	94 2.01%	188 2.08%
Impact level (1 – 3a)	128 2.32%	161 2.77%	289 2.55%	92 1.87%	123 2.23%	215 2.06%	112 2.56%	128 2.74%	240 2.65%
Impact level (3b – 5)	23 0.42%	27 0.46%	50 0.44%	12 0.24%	25 0.45%	37 0.35%	14 0.32%	25 0.54%	39 0.43%
Total	208 3.76%	246 4.23%	454 4.00%	155 3.15%	193 3.49%	348 3.33%	220 5.03%	247 5.29%	467 5.17%

# Did you experience a <u>Sudden Stop or Deceleration of Blood Pump</u>?

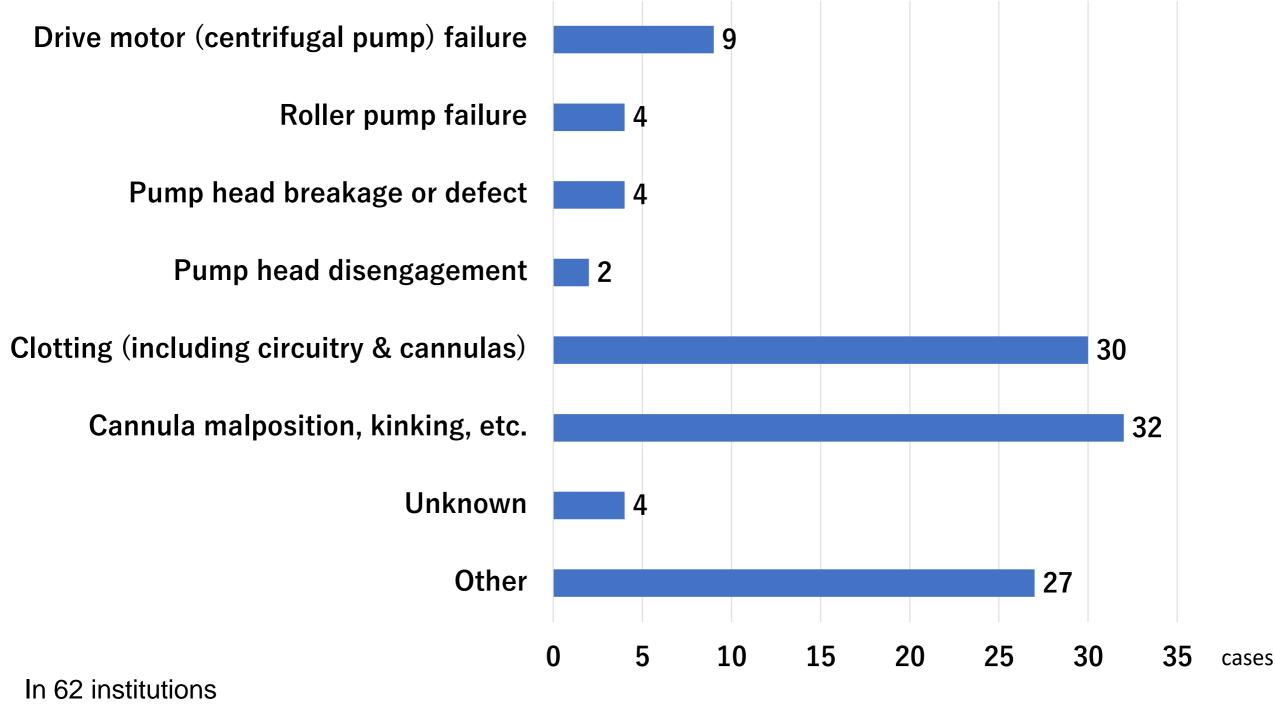


Impact level	No. of cases	Frequency*
1 – 3a	69	0.61%
3b – 5	8	0.07%
	No a	nswer: 9 insts.

\*Among 11,336 CPS cases occurring during the 2-year period.

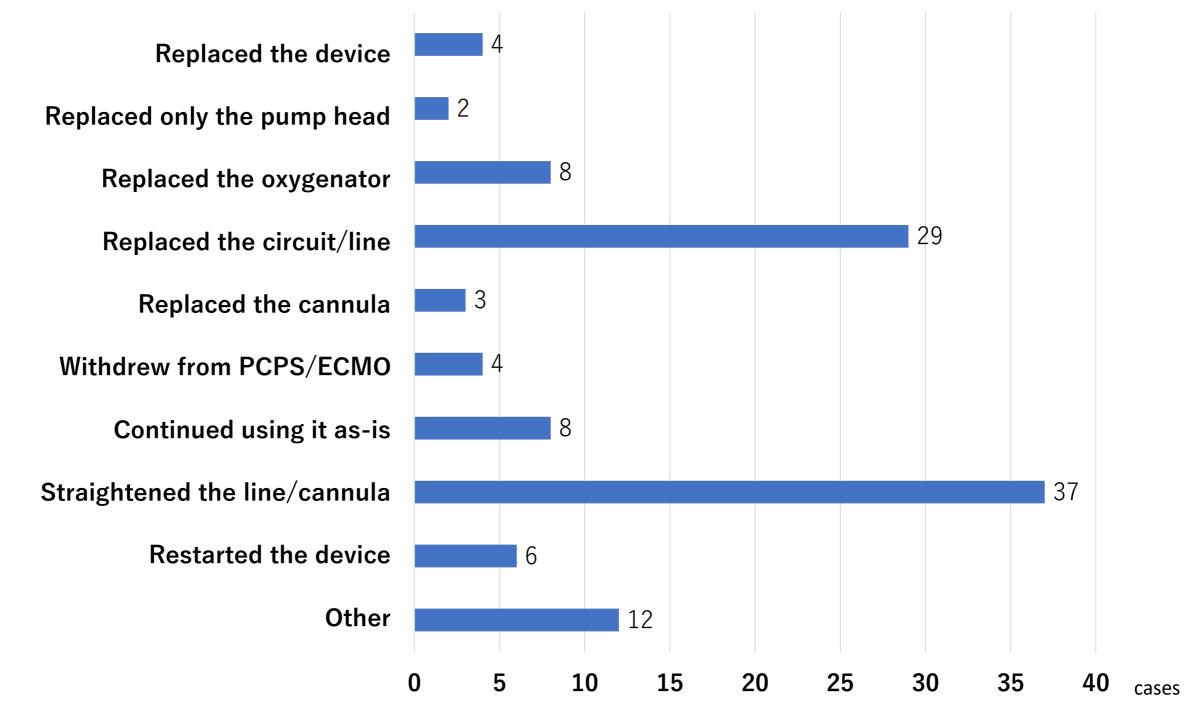
n = 431 (no answer: 3 insts.)

# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



(incl. 4 that did not answer the question)

# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)

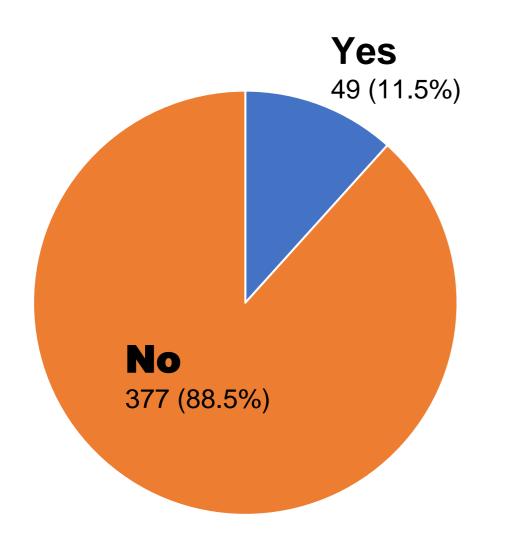


In 62 institutions (incl. 4 that did not answer the question)



	2019	Survey	2017	Survey	2015	Survey
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0					34	0.38%
1 – 3a	69	0.61%	58	0.56%	58	0.64%
3b – 5	8	0.07%	14	0.13%	3	0.03%
	No answer: 9 insts.		N	lo answer: 20	I	No answer: 10
	*Among 11,336 cases		**Am	ong 10,445 cases	***A	mong 9,041 cases

# Did you experience an incident/accident involving an Flow Sensor?



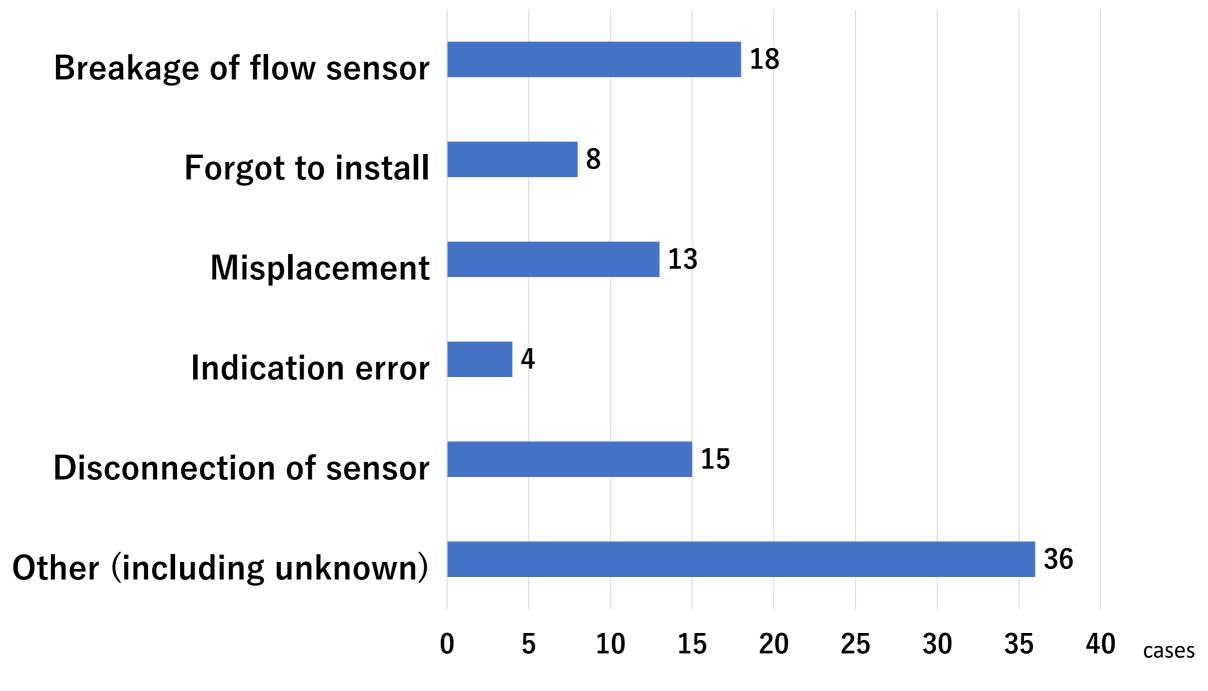
Impact level	No. of cases	Frequency*			
0	53	0.47%			
1 – 3a	34	0.30%			
3b – 5	10	0.01%			
	No answer: 12 insts.				

\*Among 11,336 CPS cases occurring during the 2-year period.

n = 431 (no answer: 5 insts.)

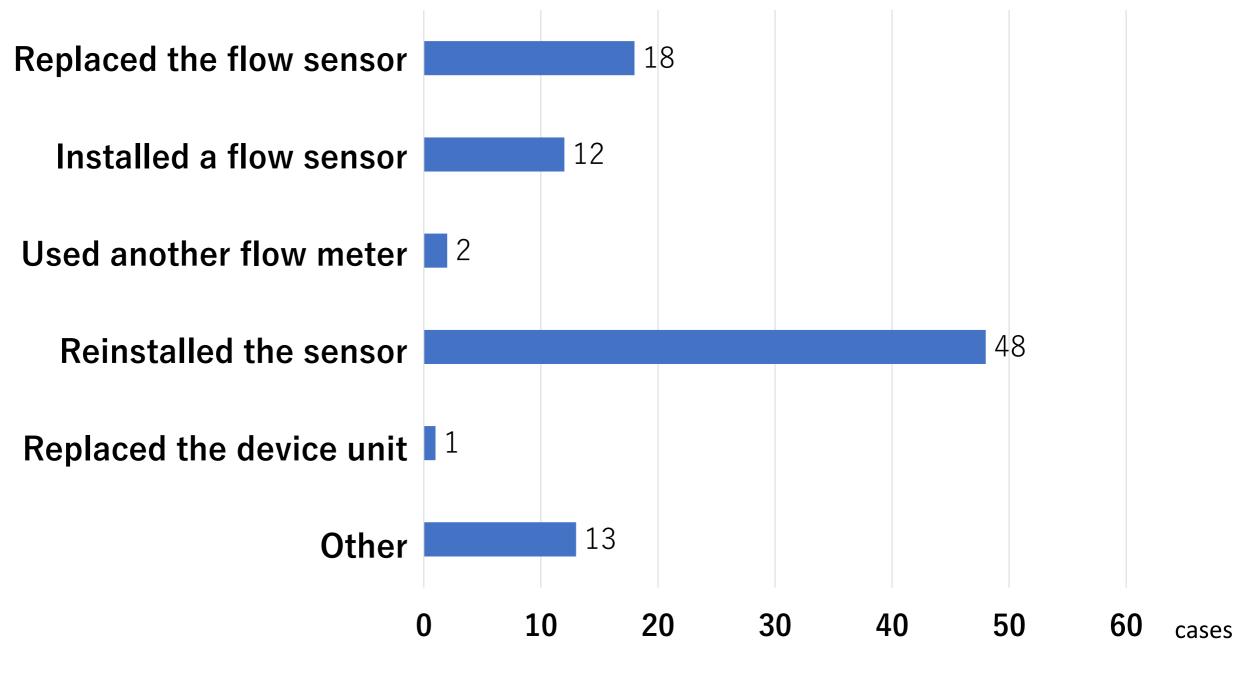


# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



In 54 institutions (incl. 6 that did not answer the question)

## Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



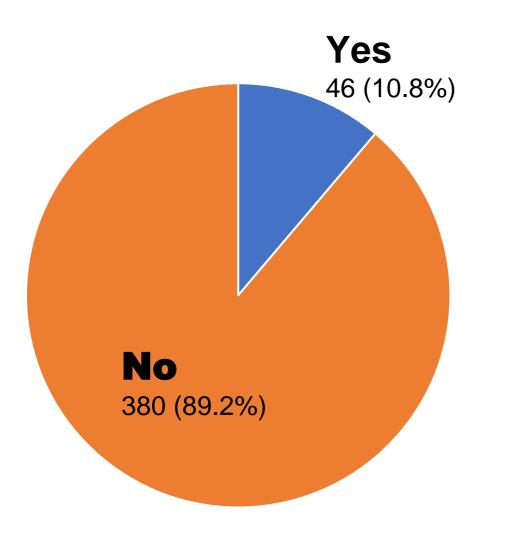
In 54 institutions (incl. 8 that did not answer the question)

#### Incidents & Rates of Related to Flow Sensor

	2019 \$	Survey	2017	Survey	2015	5 Survey
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	53	0.47%	52	0.50%	102	1.13%
1 – 3a	34	0.30%	15	0.14%	22	0.24%
3b — 5	1	0.01%	1	0.01%	0	0%
	No ans	wer: 6 insts.	Ν	lo answer: 11	I	No answer: 13
	*Amor	ng 11,336 cases	**Am	ong 10,445 cases	***A	mong 9,041 cases

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### Did you experience Aspiration of Air Into the Circuit?

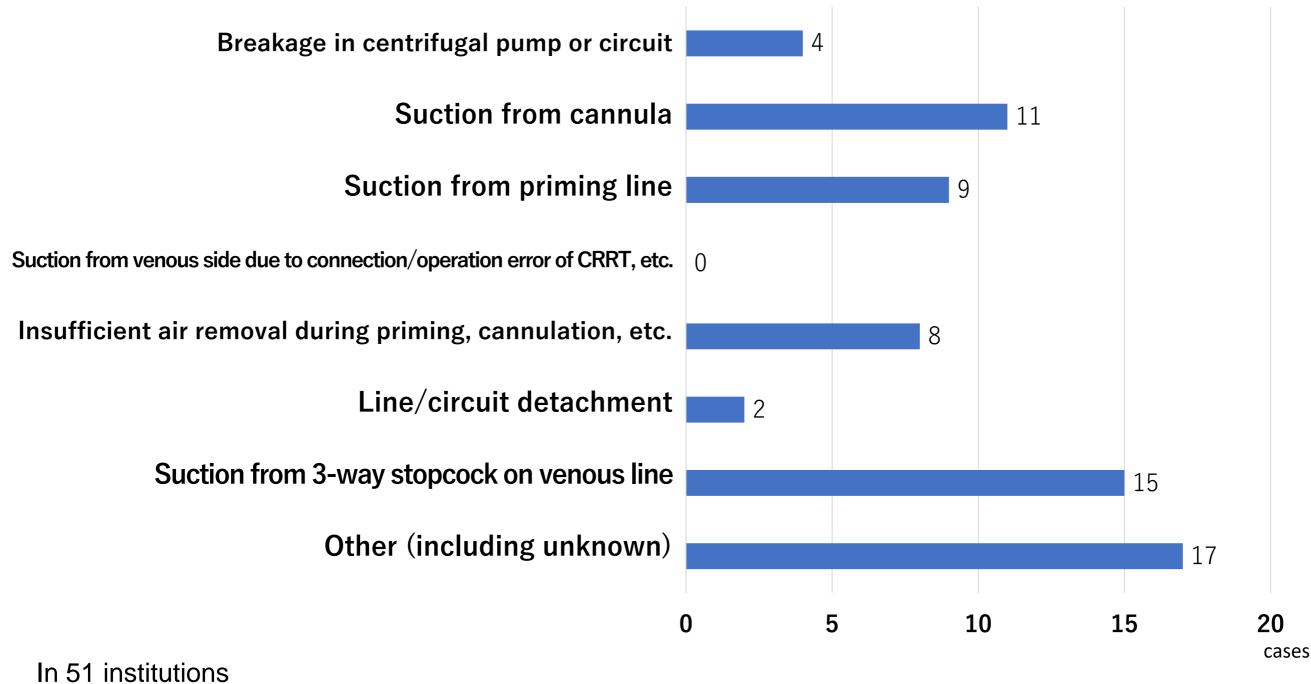


Impact level	No. of cases	Frequency*
1 – 3a	54	0.48%
3b – 5	7	0.06%
	No a	nswer: 5 insts.

\*Among 11,336 CPS cases occurring during the 2-year period.

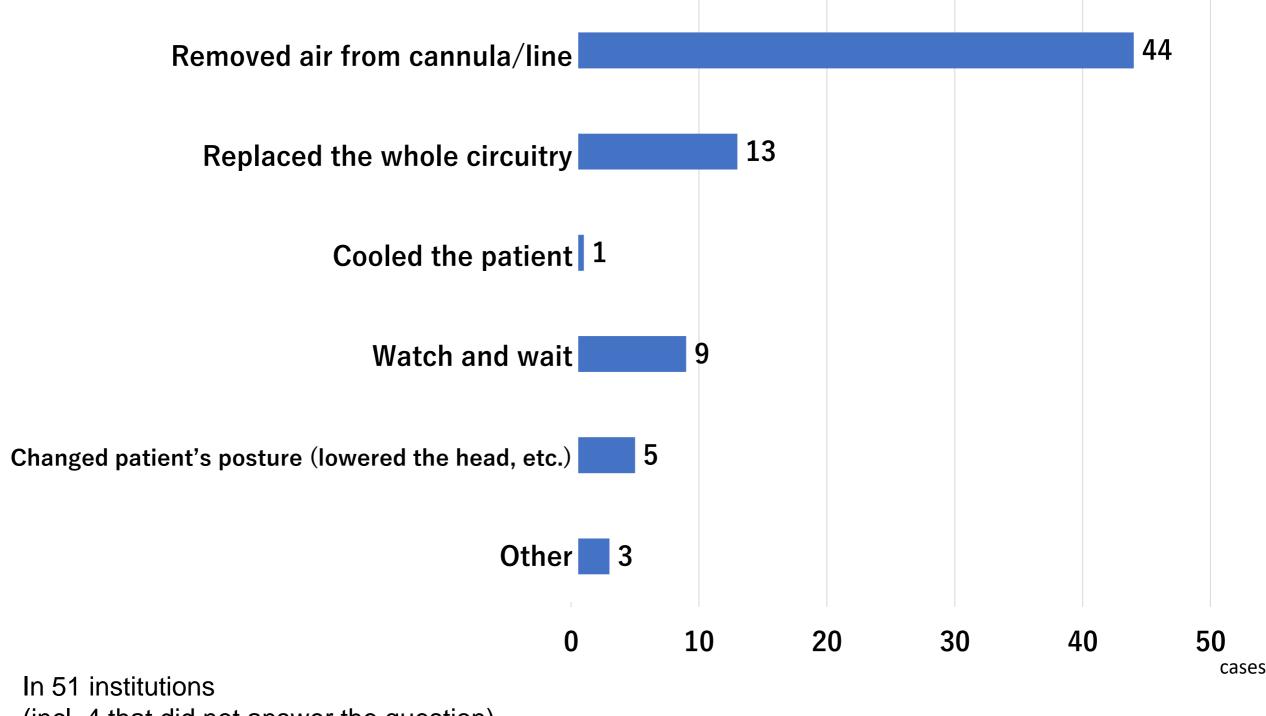
n = 431 (no answer: 5 insts.)

# Which of the following caused the aspiration and how many times? (Please choose all that apply.)



(incl. 3 that did not answer the question)

# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)

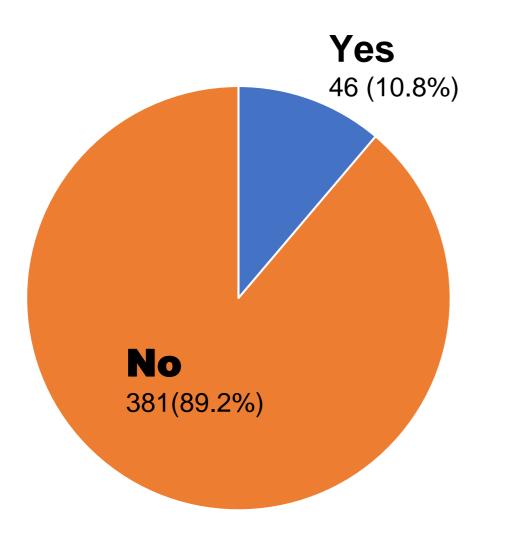


(incl. 4 that did not answer the question)

#### **Incidents & Rates of Air Aspiration into Circuit**

	2019 Survey		2017 Survey		2015 Survey	
Impact level	No. of cases	Frequency *	No. of cases	Frequency**	No. of cases	Frequency***
0	-	-	-	-	28	0.31%
1 – 3a	54	0.48%	49	0.47%	49	0.54%
3b – 5	7	0.06%	9	0.09%	4	0.04%
	No answer: 5 insts.			No answer: 7		No answer: 8
	*Among	g 11,336 cases	**An	nong 10,445 cases	***	Among 9,041 cases

## Did you experience Unexpected Bleeding from the Circuit?

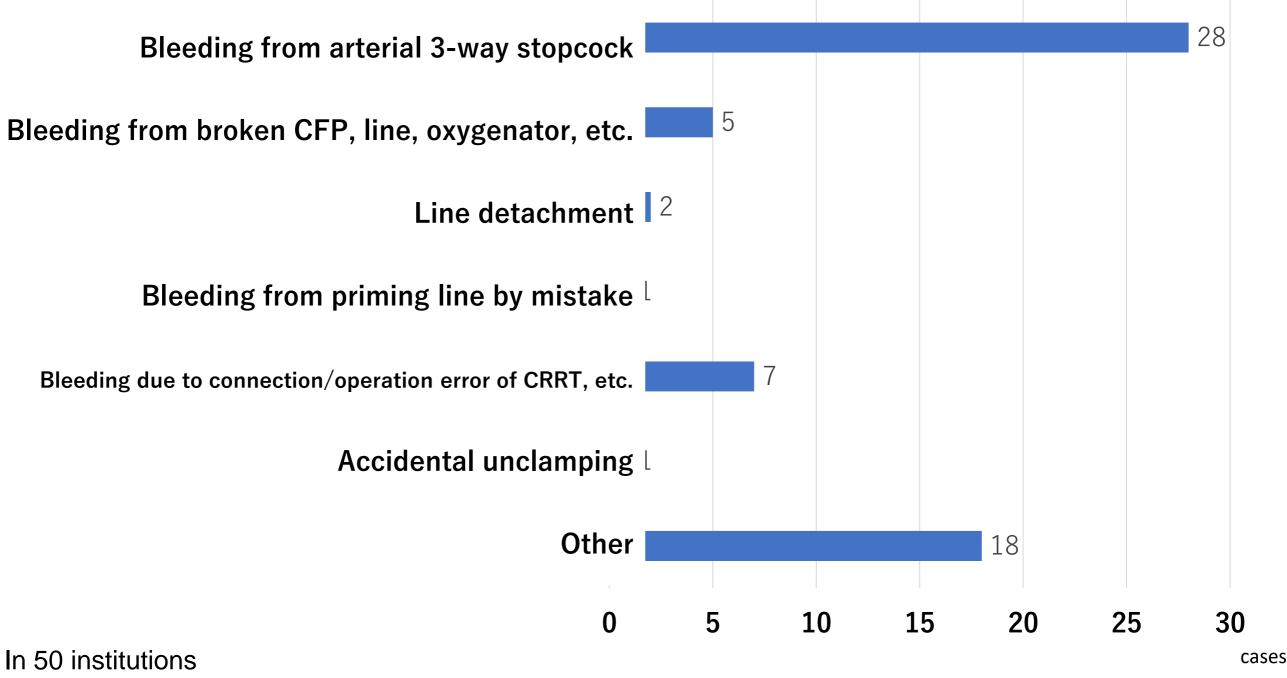


Impact level	No. of cases	Frequency*			
1 – 3a	56	0.49%			
3b – 5	2	0.02%			
	No answer: 8 inst				

\*Among 11,336 CPS cases occurring during the 2-year period.

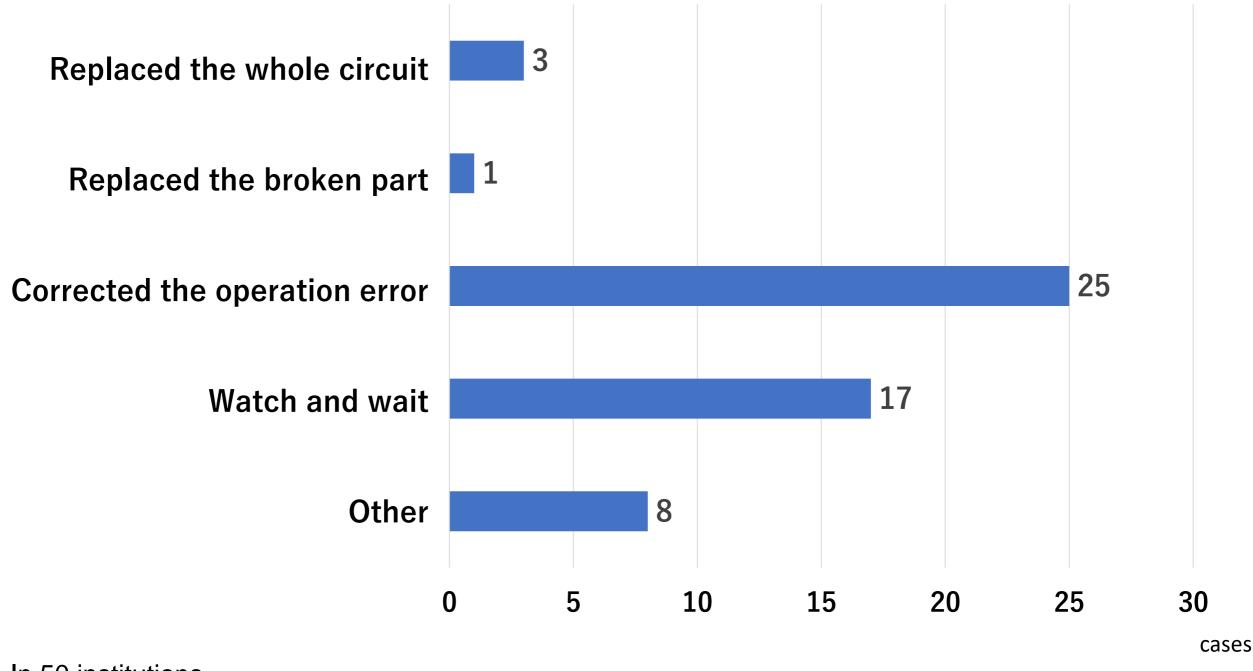
n = 431 (no answer: 4 insts.)

# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



(incl. 5 that did not answer the question)

## Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



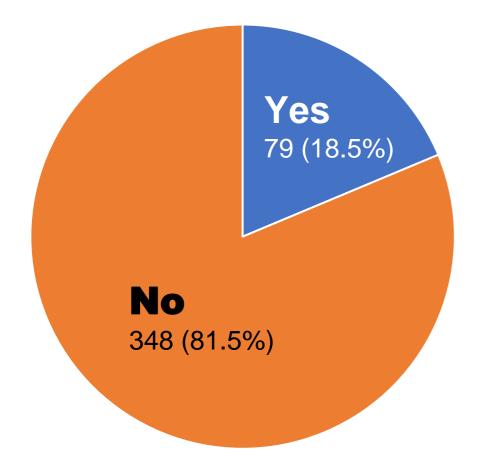
In 50 institutions (incl. 8 that did not answer the question)



#### **Incidents & Rates of Unexpected Bleeding from Circuit**

	2019	Survey	2017	Survey	2015	5 Survey
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	-	-	-	-	25	0.28%
1 – 3a	56	0.49%	58	0.56%	18	0.2%
3b – 5	2	0.02%	4	0.04%	1	0.01%
	No ans	swer: 8 insts.	N	o answer: 10		No answer: 10
	*Amo	ong 11,336 cases	**Amo	ong 10,445 cases	***/	Among 9,041 cases

### Did you experience an incident/accident associated with Cannulation?



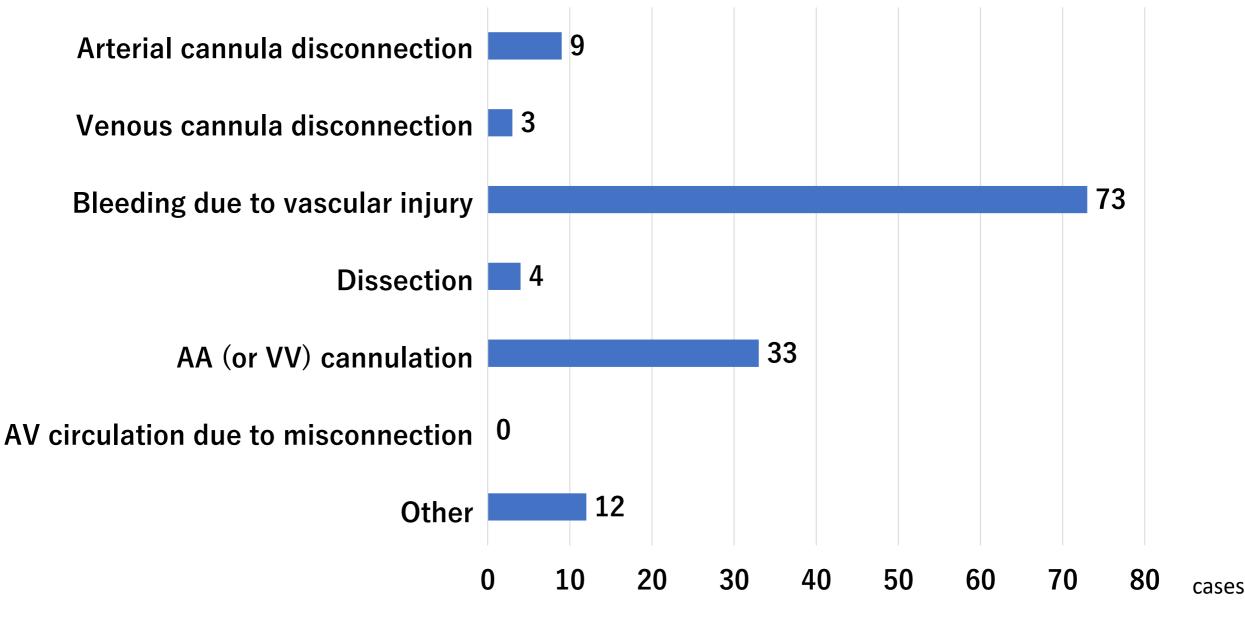
Impact level	No. of cases	Frequency*			
0	16	0.14%			
1 – 3a	74	0.65%			
3b – 5	40	0.35%			
	No answer: 9 insts.				

\*Among 11,336 CPS cases occurring during the 2-year period.

n = 431 (no answer: 4 insts.)

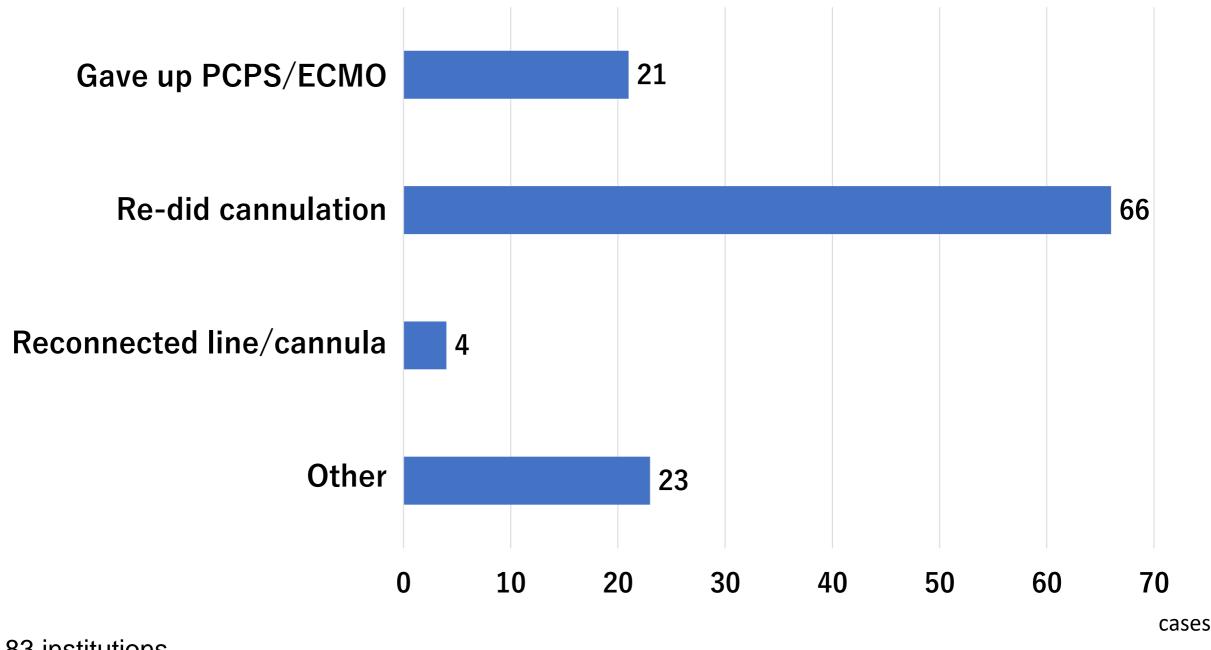


# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



In 83 institutions (incl. 5 that did not answer the question)

## Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)

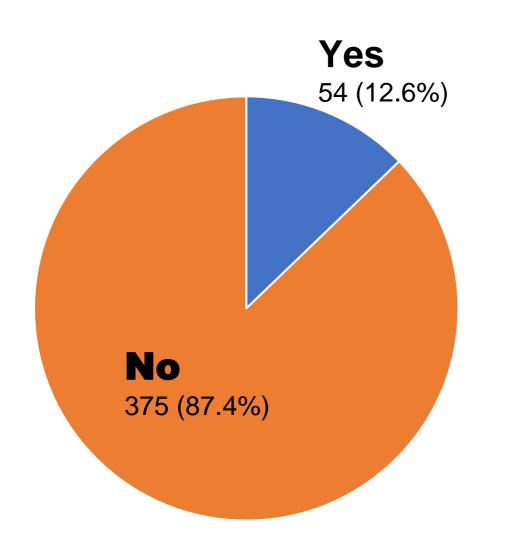


In 83 institutions (incl. 6 that did not answer the question)

#### **Incidents & Rates Related to Cannulation**

	2019	Survey	2017	Survey	2015	5 Survey
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	16	0.14%	13	0.12%	7	0.08%
1 – 3a	74	0.65%	66	0.63%	82	0.91%
3b – 5	40	0.35%	31	0.30%	46	0.51%
	No ans	swer: 9 insts.	N	o answer: 16		No answer: 13
	*Amo	ng 11,336 cases	**Am	ong 10,445 cases	***A	Among 9,041 cases

### Did you experience an incident/accident During Transport to or in CT/Angiography Room?



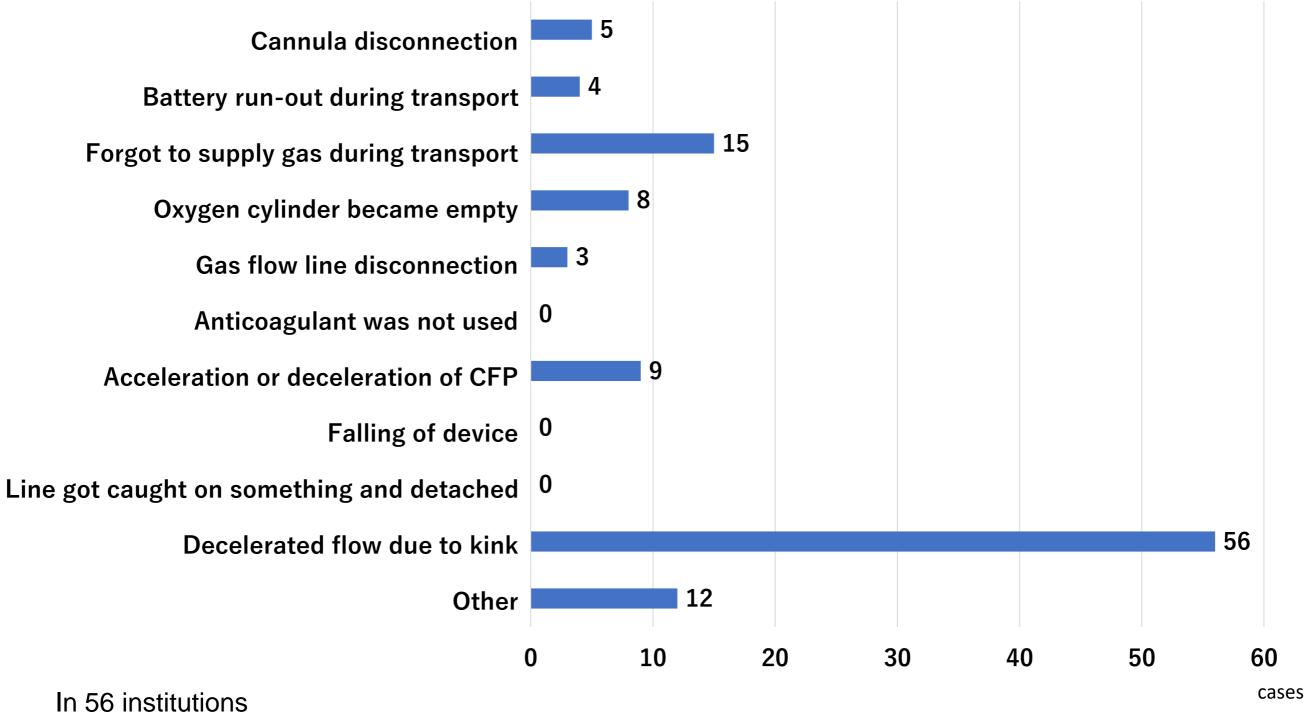
Impact level	No. of cases	Frequency*
1 – 3a	92	0.81%
3b – 5	5	0.04%
	No a	nswer: 3 insts.

\*Among 11,336 CPS cases occurring during the 2-year period.

n = 431 (no answer: 2 insts.)



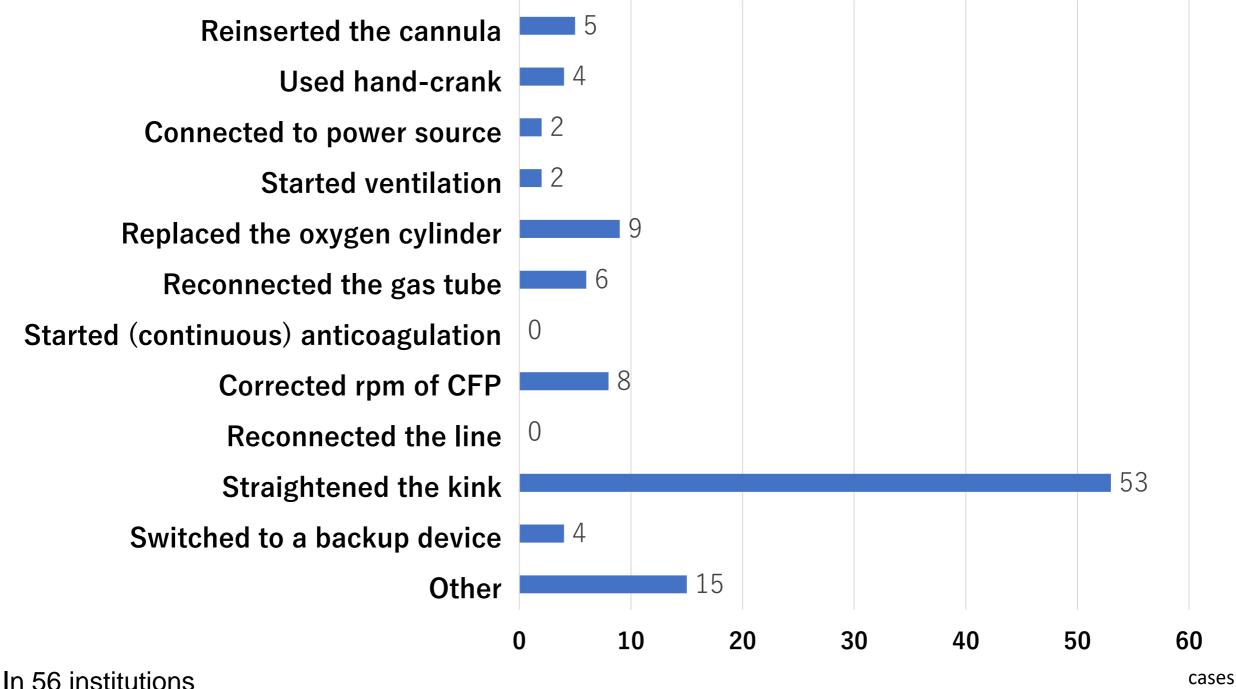
# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



(incl. 1 that did not answer the question)



# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



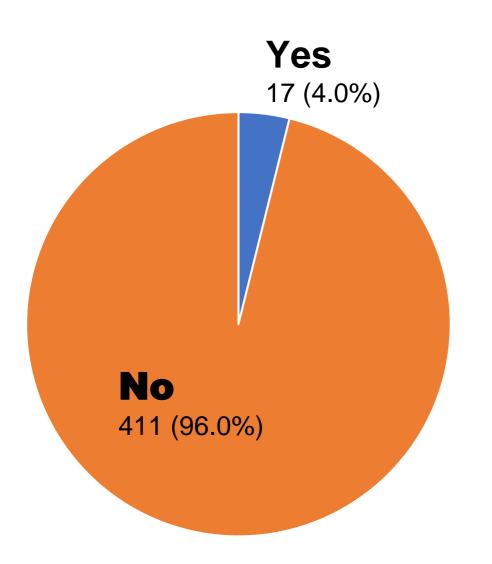
(incl. 3 that did not answer the question)

#### **Incidents & Rates Related to Transport or Destination**

	2019 Survey		2017 Survey		2015 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	-	-	-	-	52	0.58%
1 – 3a	92	0.81%	77	0.74%	50	0.55%
3b – 5	5	0.04%	3	0.03%	2	0.02%
	No answer: 3 insts.		No answer: 7		No answer: 10	
	*Among 11,336 cases		**Am	ong 10,445 cases	***/	Among 9,041 cases



### Did you experience an incident/accident related to <u>Power Outage or Interruption?</u>



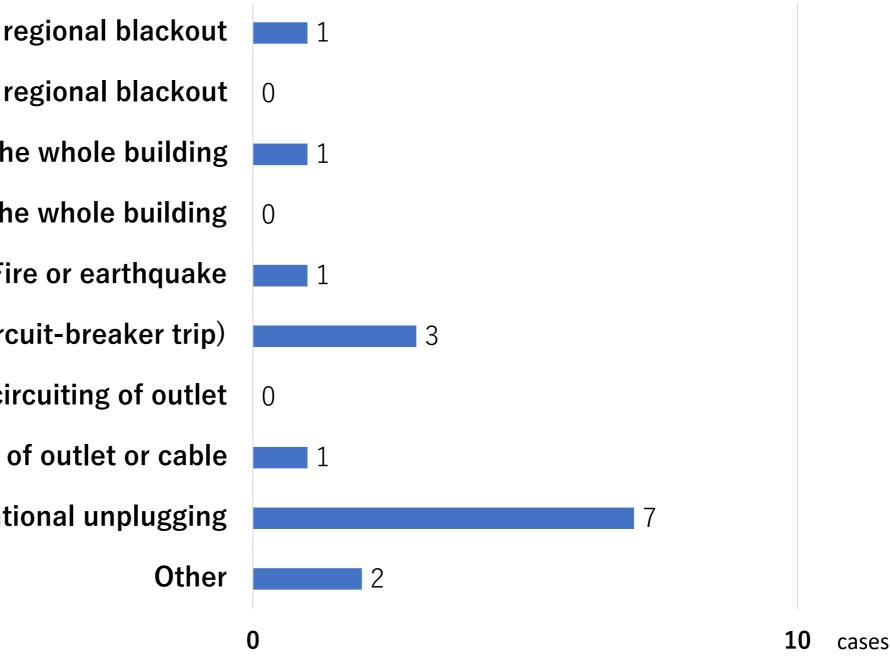
Impact level	No. of cases	Frequency*	
0	5	0.04%	
1 – 3a	9	0.08%	
3b – 5	1	0.01%	
	No answer: 5 insts.		

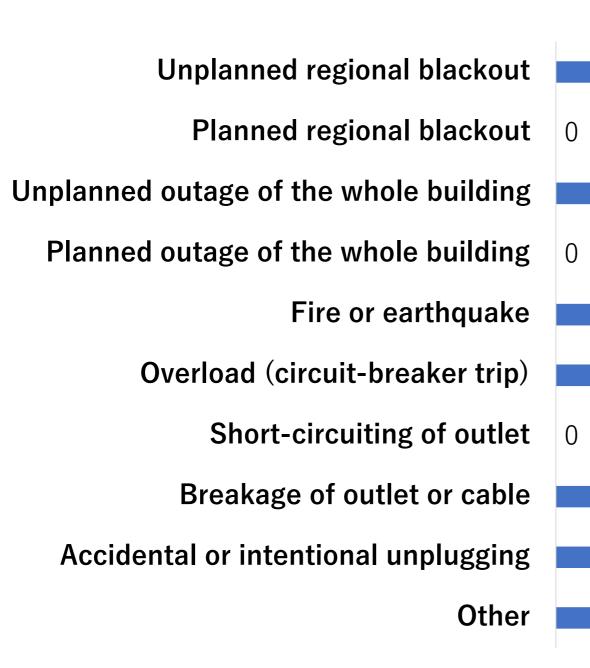
\*Among 11,336 CPS cases occurring during the 2-year period.

n = 431 (no answer: 3 insts.)



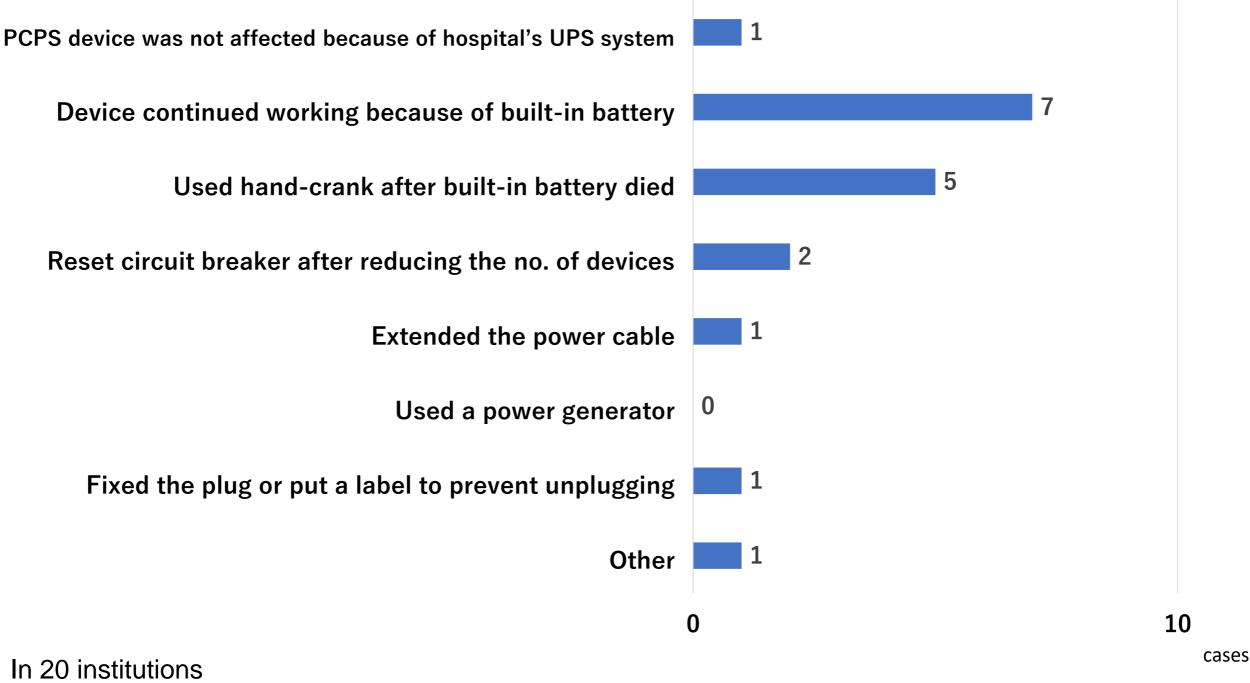
# How many times did you experience the following incidents/accidents? (Please choose all that apply.)





In 20 institutions (incl. 3 that did not answer the question)





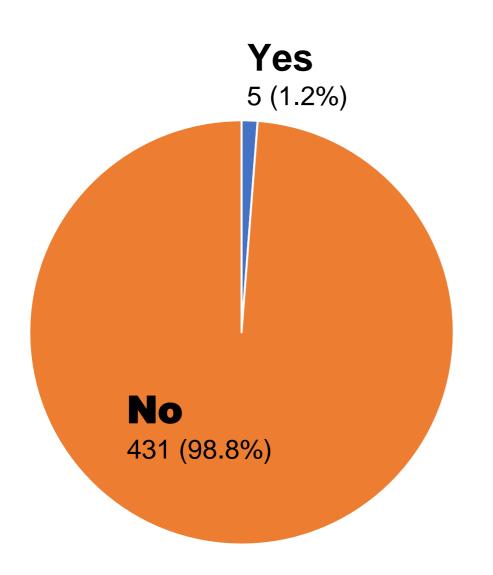
(incl. 5 that did not answer the question)

#### **Incidents & Rates of Power Outage/Interruption**

	2019 Survey		2017 Survey		2015 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	5	0.04%	8	0.08%	11	0.12%
1 – 3a	9	0.08%	9	0.09%	5	0.06%
3b – 5	1	0.01%	1	0.01%	0	0.0%
	No answer: 5 insts.		No answer: 2		No answer: 2	
	*Among 11,336 cases		**Among 10,445 cases		***Among 9,041 cases	



### Did you experience an Interruption of Medical Gas Supply?



Impact level	No. of cases	Frequency*
1 – 3a	5	0.04%
3b – 5	0	0%
	No	answer: 1 inst.

\*Among 11,336 CPS cases occurring during the 2-year period.

n = 431 (no answer: 3 insts.)

#### **Incidents & Rates of Medical Gas Supply Interruption**

	2019 Survey		2017 Survey		2015 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0					3	0.01%
1 – 3a	5	0.04%	2	0.02%	4	0.09%
3b – 5	0	0%	0	0%	1	0.0%
	No answer: 1 inst.		No answer: 3		No answer: 4	
	*Among 11,336 cases		**Among 10,445 cases		***Among 9,041 cases	