ECE 313 Final Project (FDA Adverse event data analysis)
Group Epsilon

Rawaha Ahmed Tariq (tariq3)
Neelabh Gupta (nsgupta2)

Summary

Main Objective: Finding the failure density and hazard rate of various medical devices based on their failure reports from the FDA.

Secondary Objective:
- Finding relationship between different variable to see if they followed any distribution.
- Doing Hypothesis Testing, using "Model number" and "System Flag" as random variables and finding the probability of "Event type" (H1= Death or Injury and H0= Malfunction or Others).
- Use the ML rule to generate alarms.

Motivation: Nowadays medical devices are extensively being used in the field of medicine. Machines have been well known to increase the efficiency of any process and in our project we will be dealing with real data to find the reliability of the devices and the probability that a device fails in the next time interval (Important information to find the reliability of a machine during a surgery).

Data Collection Technique: The data-set for our project consisted of reports received by the FDA regarding failures of various electronic medical instruments. The data was provided to us which was originally obtained from the FDA Website. We moved our data to a database and we first filtered our data by removing the variables that were not required for our analysis. Then we removed those event /instances which had either of the variables missing.

Original Data-set:

id	MDR RE	EVENT KEY	REPORT N	Patient (	Event Narra	REPORT	NUMB	NUMB	DATE RECE	ADVE	PRC	DATE REPORT	DATE OF EVENT	REPOR	INITI	DIS	TY	REPOR'	REI	DATE R	REP(	DATE	SOURCE TYPE	DATE MANUF	DEVICE D/	REN	EVEI	DEVICE E\	BRAND	GENERIC I	MODEL NL	DEVIC	B/	BAS	E	B
1	1 2890524	2787060	2890524	N/A	An err	N/A	U	1	1	12/4/2012	N	Y	11/7/2012	7/10/2012		Y		I	11/7/20	Y	12/4/20					M	2917024	*		INSTRUMEN	*				
2	2 2890369	2786905	2955842-2(	Death	It was	On (b)	M	1	1	12/29/2012	Y	N	10/11/2012	10/11/2012	0	N		I			N		01,07	10/11/2012	7/1/2010	D	2916912	DA VINCI	ENDOSCOP	IS3000 A6.				
3	3 2889862	2786378	2955842-2(	Required I	It was	Accorc	M	1	1	12/28/2012	Y	Y	11/28/2012		0	*		I			N		6	11/28/2012	8/1/2008	IN	2916308	DA VINCI	ENDOSCOP	IS2000 A5.				
4	4 2888137	2784673	2955842-2(	Other	It was	Based	M	1	1	12/27/2012	Y	Y	11/27/2012	11/26/2012	112	*		I			N		05,06	11/27/2012	10/1/2011	IN	2914569	DA VINCI	ENDOSCOP	IS3000 A60				
5	5 2886930	2586549	300485803	Other	Volun (	The cc	M	1	1	8/25/2012	Y	N	8/23/2012	7/6/2012	0	Y		I			N		0	8/21/2012		IN	2915043	DA VINCI	POWERED I	9.0 90				
6	6 2886217	2782753	2886217	N/A	Broker	N/A	U	1	1	10/19/2012	N	Y	10/19/2012	6/1/2012	500	Y		I	10/19/2	Y	10/19/2(					M	2912526	DA VINCI	INSTRUMEN	PK420227	1	DY		
7	7 2884107	2780643	2955842-2(	Required I	On (b)	Isi has	M	1	1	12/21/2012	Y	Y	8/2/2012		1	*		I			N		03,05			IN	2910975	8MM MCS	ENDOSCOP	400180				

Filtered Data-set:

	id	MDR REPORT	MODEL NUMBER	DATE OF EVENT	DEVICE DATE OF MANUFACTURI	EVENT TYPE	OPERATION DAYS	SYSTEM FLAG
1	1	2890369	IS3000 A6.0P6	2012-10-11	2010-07-01	D	833	Y
2	2	2888137	IS3000 A60P7	2012-11-26	2011-10-01	IN	422	Y
3	3	2884091	IS3000 A60.P7	2012-09-24	2011-11-01	O	328	Y
4	4	2883607	IS3000 A60P7	2012-11-27	2012-04-01	IN	240	Y
5	5	2880664	420093-08	2012-11-13	2010-05-01	IN	927	N
6	6	2876728	IS3000 A6.0P6	2012-03-09	2009-06-01	IN	1012	Y
7	7	2873221	IS2000 A5. 1P8	2012-11-13	2007-06-01	O	1992	Y

Some Distributions

Outcomes of device failures

Devices types
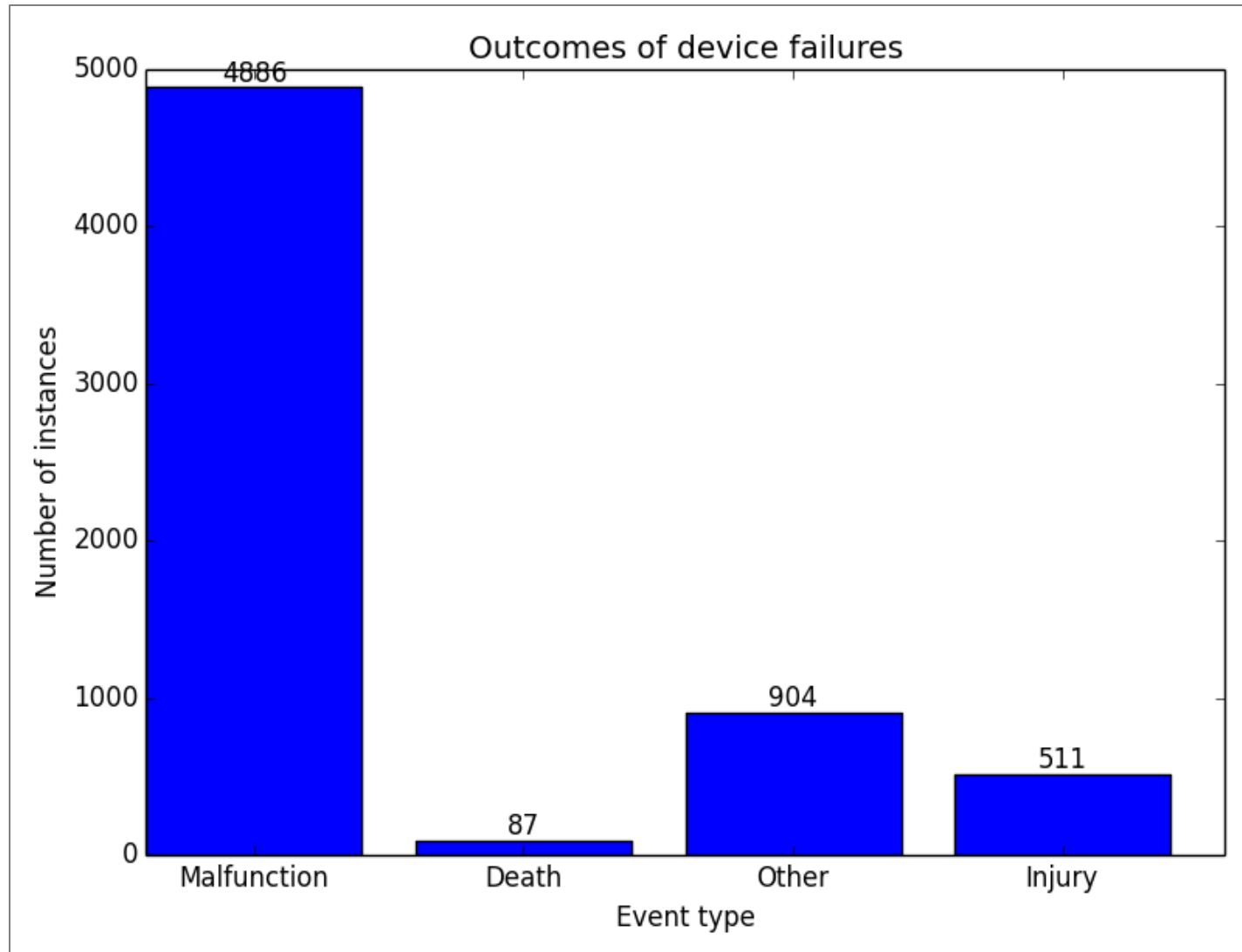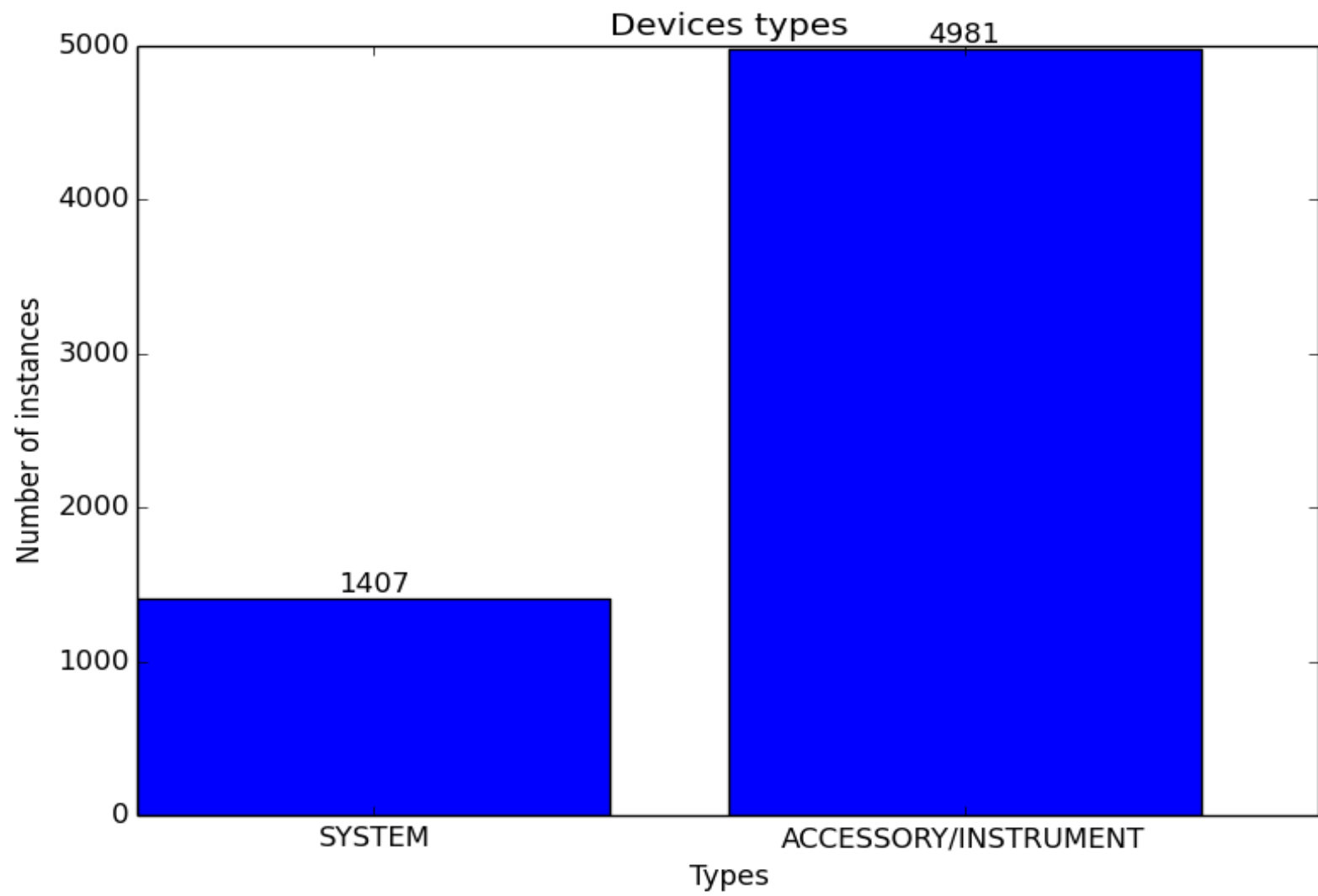
Number of instances corresponding to event and device types
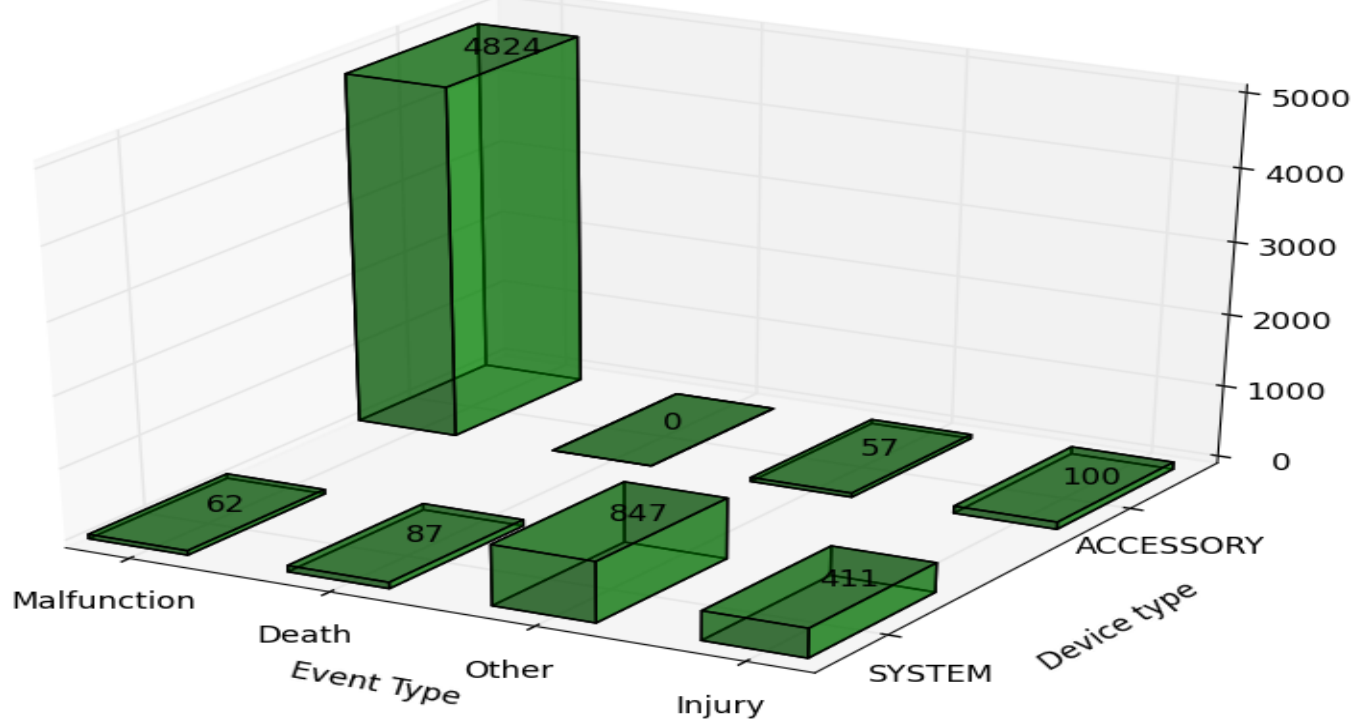
	Accessory	System
Injury	0.02007629	0.2921109
Other	0.01144349	0.60199
Death	0	0.06183369
Malfunction	0.9684802	0.04406539

Model numbers and their frequency (Only >20 shown)
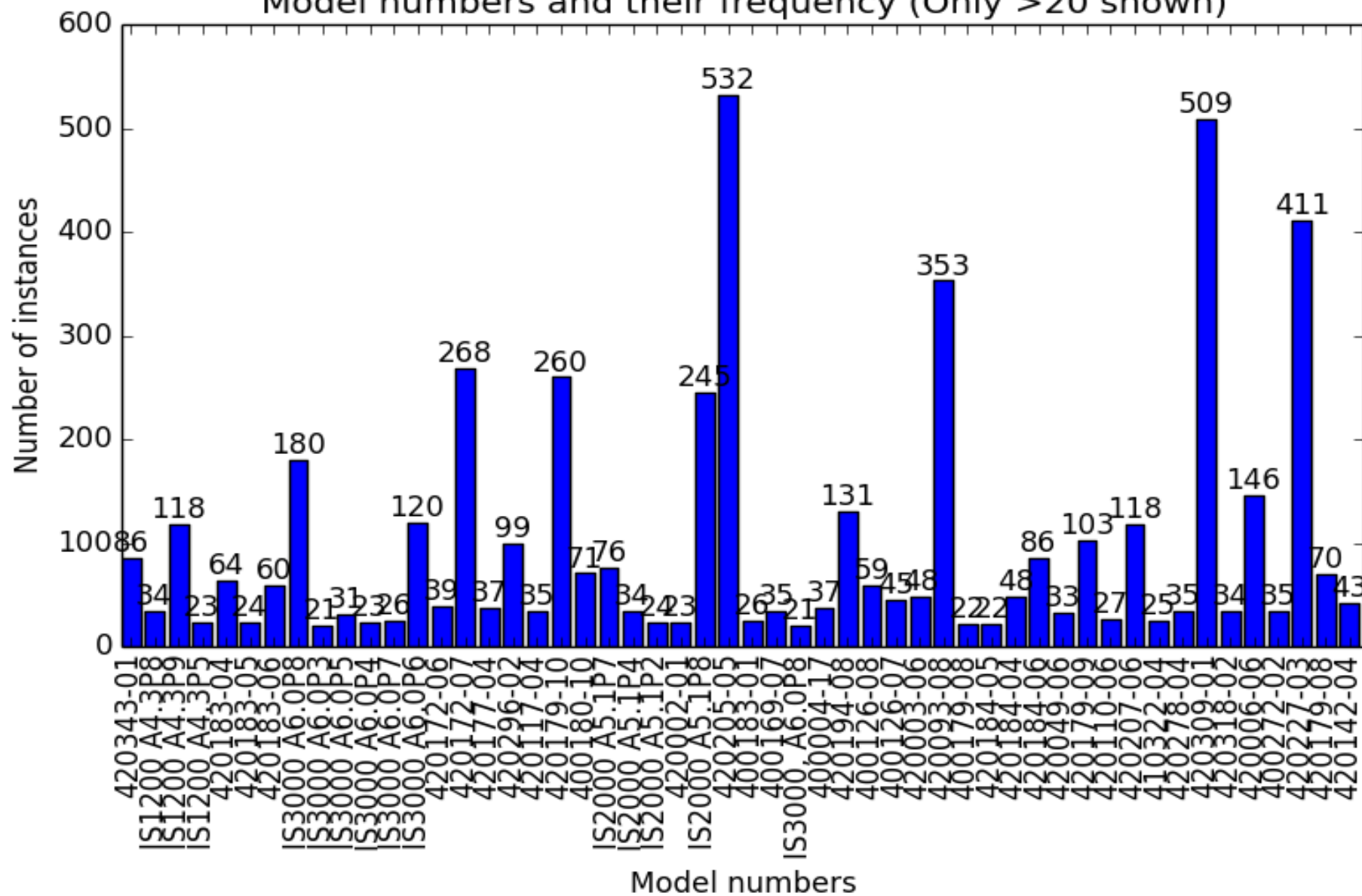
Failure Density and Hazard Rate Calculations

Our data:
- Every row is a Failure event
- Manufacture date
- Event date

Assumptions:
- All devices start at time t = 0.
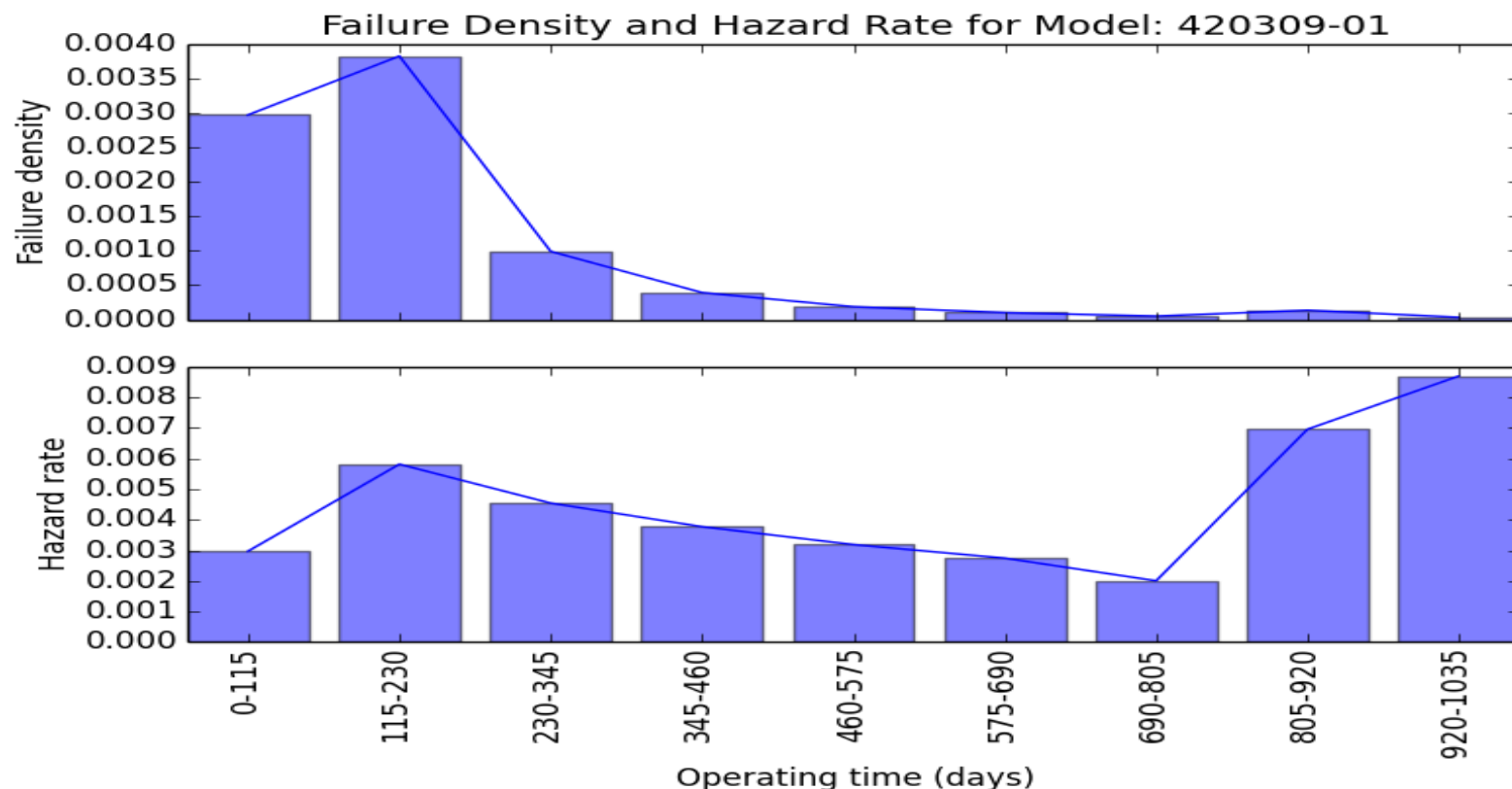- Number of devices = number of failure events
- No replacements of failed devices

Failure Density and Hazard Rate of the top 5 Model Numbers

Interval	Number of failures	Devices remaining	Failure Density	Hazard Rate
0-393	493	532	0.0023579942222	0.0023579942222
393-786	35	39	0.000167403240927	0.00228355190187
786-1179	3	4	1.43488492223e-05	0.00190839694656
1179-1572	0	1	0.0	0.0
1572-1965	0	1	0.0	0.0
1965-2358	0	1	0.0	0.0
2358-2751	0	1	0.0	0.0
2751-3144	0	1	0.0	0.0
3144-3537	0	1	0.0	0.0
3537-3930	1	1	4.78294974076e-06	0.00254452926209

Failure Density and Hazard Rate for Model: 420205-05
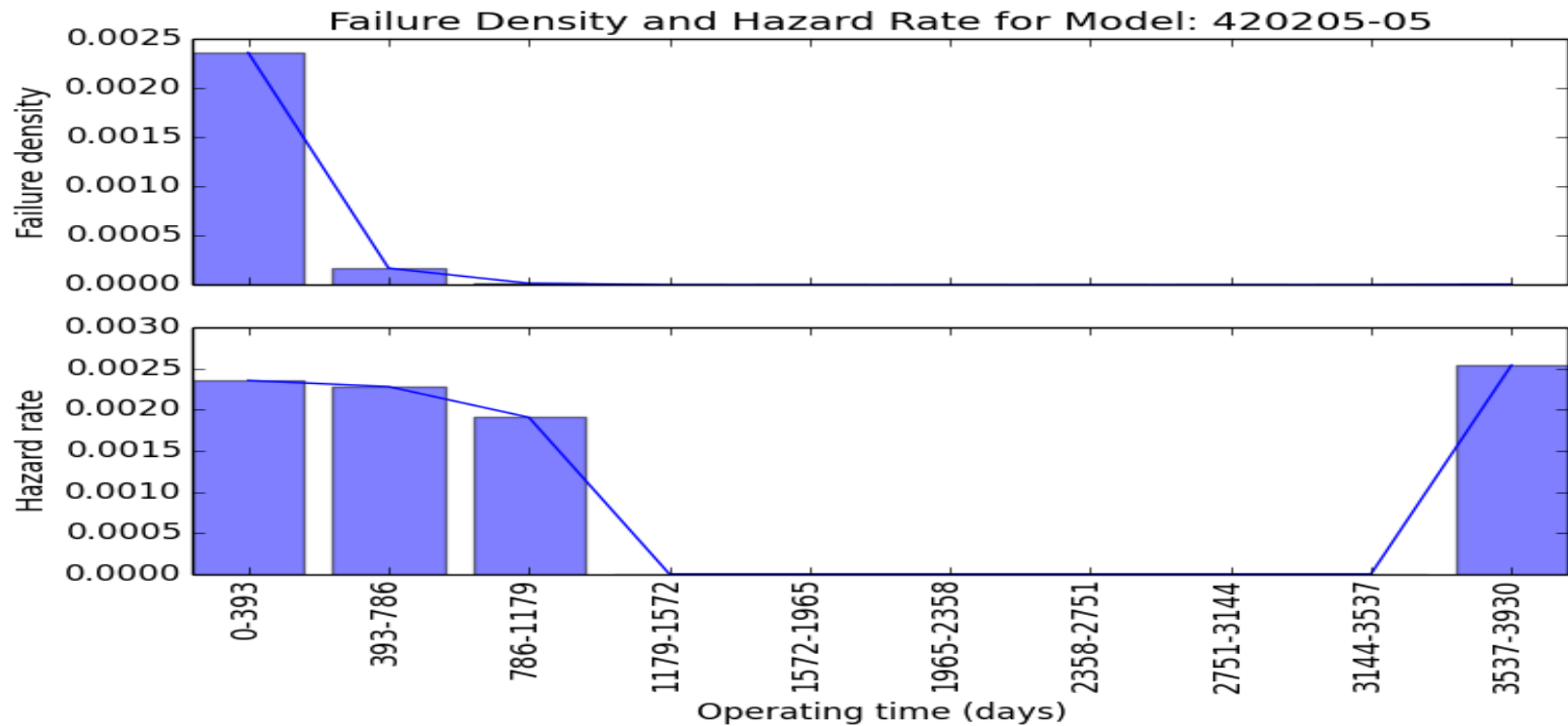
Interval	Number of failures	Devices remaining	Failure Density	Hazard Rate
0–115	174	509	0.00297258050739	0.00297258050739
115–230	224	335	0.00382677030836	0.00581440622972
230–345	58	111	0.00099086016913	0.00454367410889
345–460	23	53	0.000392927308448	0.00377358490566
460–575	11	30	0.000187921756214	0.0031884057971
575–690	6	19	0.000102502776117	0.00274599542334
690–805	3	13	5.12513880584e-05	0.00200668896321
805–920	8	10	0.000136670368156	0.00695652173913
920–1035	2	2	3.4167592039e-05	0.00869565217391

Failure Density and Hazard Rate for Model: 420309-01

Interval	Number of failures	Devices remaining	Failure Density	Hazard Rate
0-380	382	411	0.0024458957613	0.0024458957613
380-760	23	29	0.000147265975157	0.00208711433757
760-1140	4	6	2.56114739403e-05	0.00175438596491
1140-1520	1	2	6.40286848508e-06	0.00131578947368
1520-1900	0	1	0.0	0.0
1900-2280	0	1	0.0	0.0
2280-2660	0	1	0.0	0.0
2660-3040	0	1	0.0	0.0
3040-3420	0	1	0.0	0.0
3420-3800	1	1	6.40286848508e-06	0.00263157894737

Failure Density and Hazard Rate for Model: 420227-03
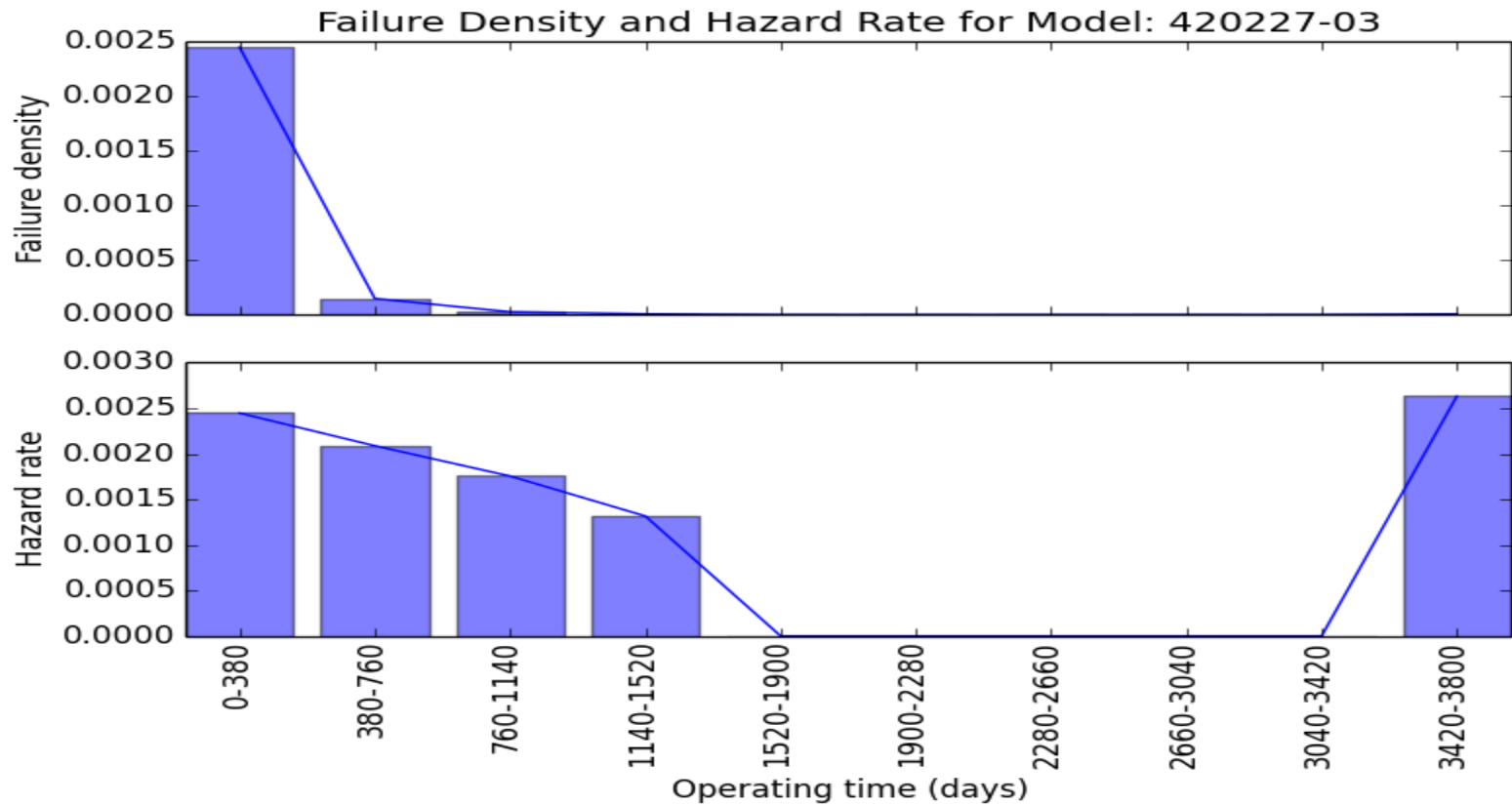
Interval	Number of failures	Devices remaining	Failure Density	Hazard Rate
0-123	181	353	0.00416868191345	0.00416868191345
123-246	112	172	0.00257951588014	0.00529400642844
246-369	39	60	0.000898224279693	0.00528455284553
369-492	12	21	0.000276376701444	0.00464576074332
492-615	6	9	0.000138188350722	0.00542005420054
615-738	0	3	0.0	0.0
738-861	1	3	2.3031391787e-05	0.00271002710027
861-984	0	2	0.0	0.0
984-1107	1	2	2.3031391787e-05	0.00406504065041
1107-1230	1	1	2.3031391787e-05	0.00813008130081

Failure Density and Hazard Rate for Model: 420093-08
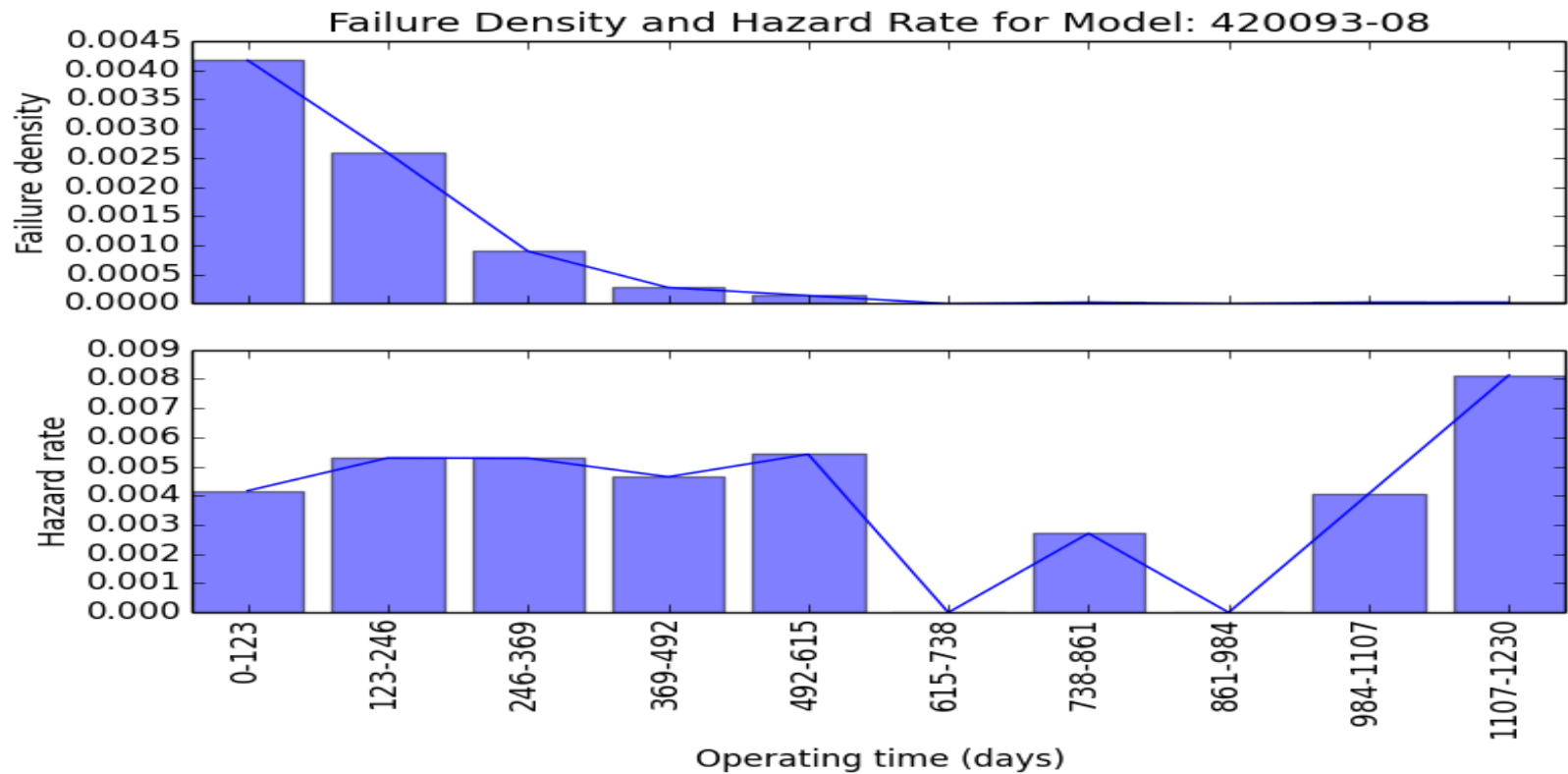
| Interval	Number of failures	Devices remaining	Failure Density	Hazard Rate
0-114	60	268	0.0019638648861	0.0019638648861
114-228	113	208	0.00369861220215	0.00476551956815
228-342	43	95	0.0014074365017	0.00397045244691
342-456	26	52	0.000851008117308	0.00438596491228
456-570	11	26	0.000360041895784	0.00371120107962
570-684	6	15	0.00019638648861	0.00350877192982
684-798	5	9	0.000163655407175	0.00487329434698
798-912	2	4	6.54621628699e-05	0.00438596491228
912-1026	1	2	3.27310814349e-05	0.00438596491228
1026-1140	1	1	3.27310814349e-05	0.00877192982456

Failure Density and Hazard Rate for Model: 420172-07
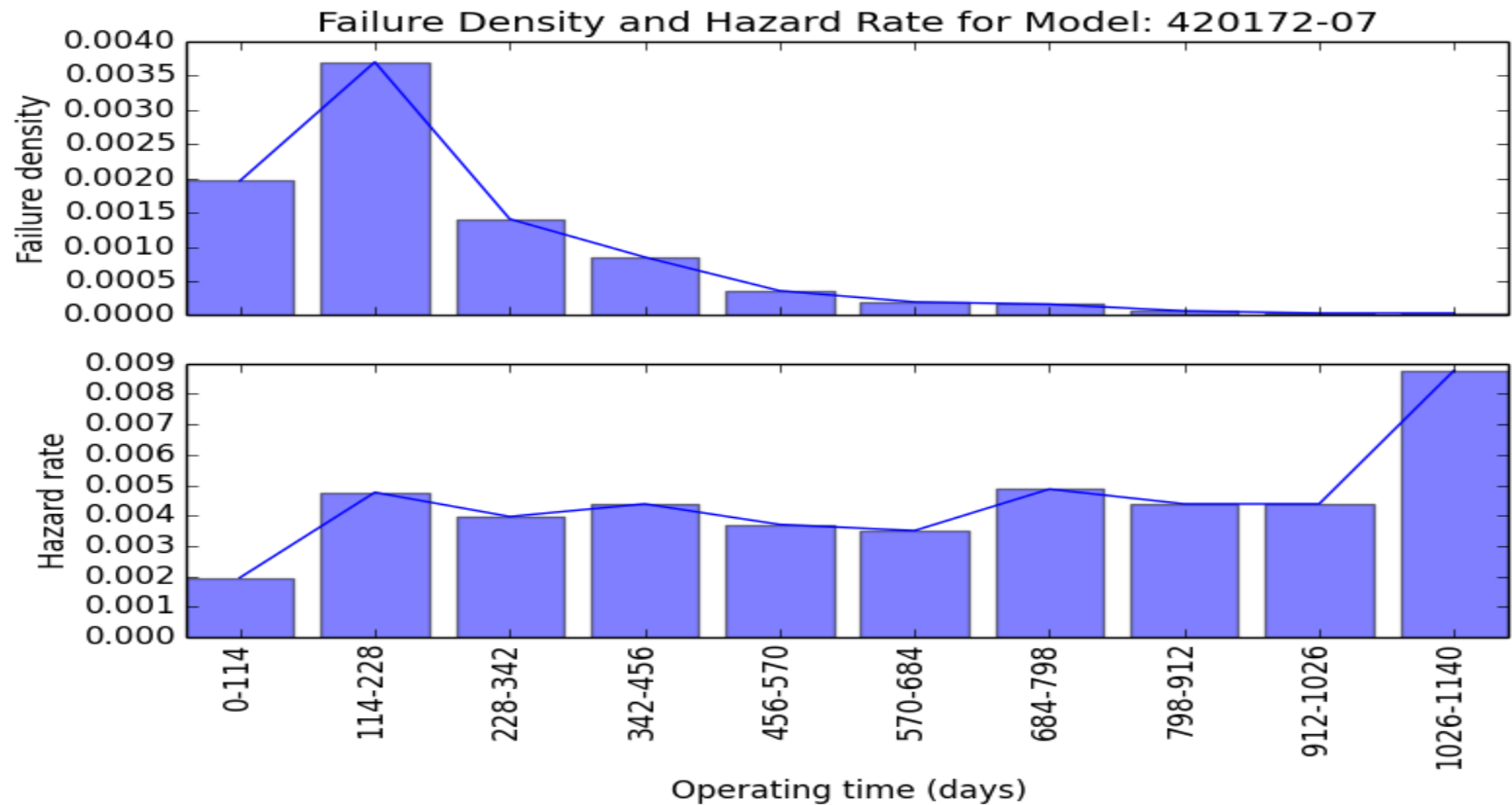
Failure Density and Hazard Rate for all devices

Interval	Number of failures	Devices remaining	Failure Density	Hazard Rate
0-425	4815	6388	0.00177354598696	0.00177354598696
425-850	819	1573	0.000301668569745	0.00122508507535
850-1275	369	754	0.000135916608347	0.00115150569512
1275-1700	216	385	7.95609414711e-05	0.00132009167303
1700-2125	106	169	3.90437953516e-05	0.00147580925861
2125-2550	32	63	1.17868061439e-05	0.00119514472456
2550-2975	18	31	6.63007845593e-06	0.00136622390892
2975-3400	4	13	1.47335076798e-06	0.000723981900452
3400-3825	8	9	2.94670153597e-06	0.00209150326797
3825-4250	1	1	3.68337691996e-07	0.00235294117647

Failure Density and Hazard Rate for All devices
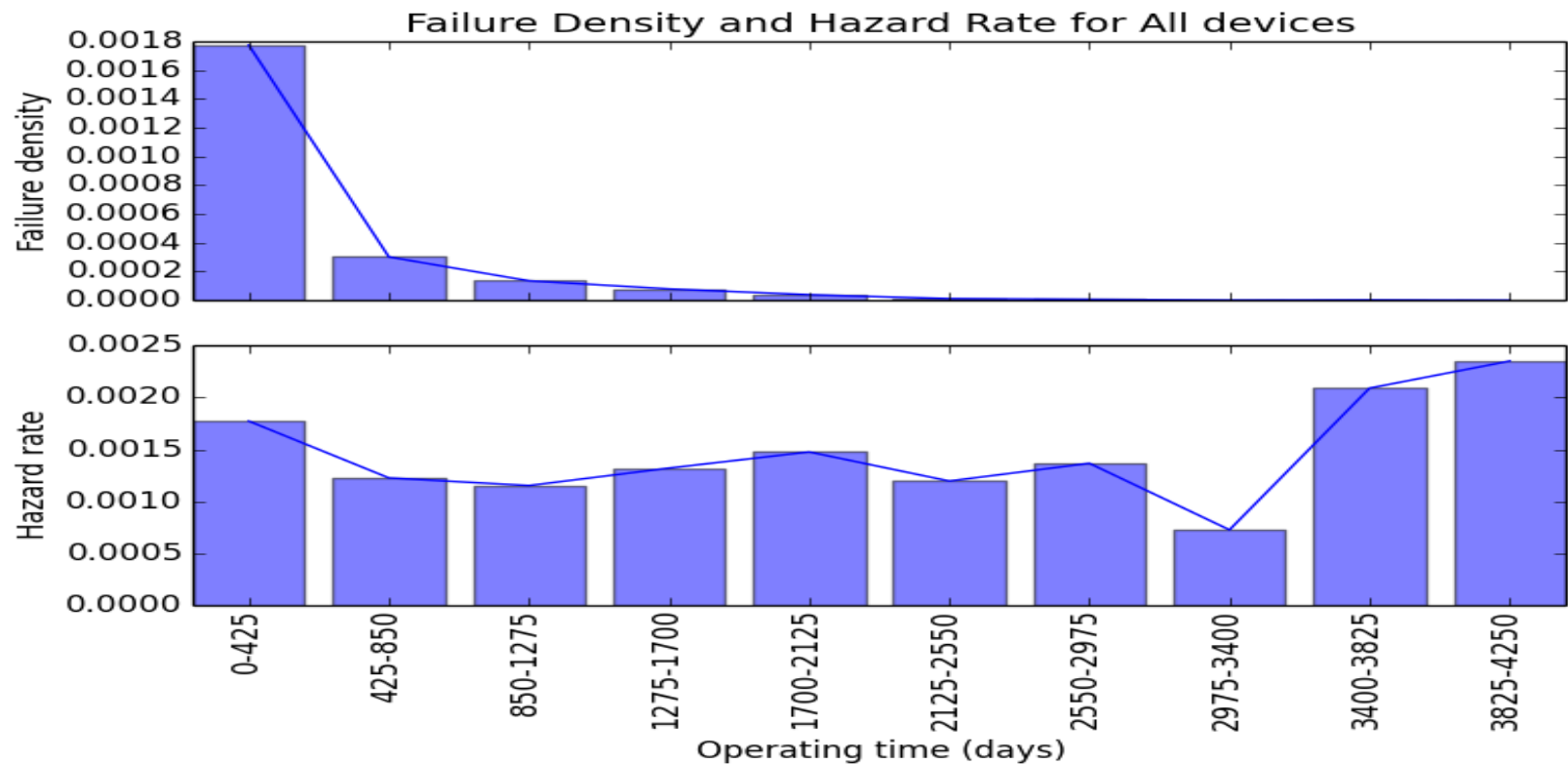
Hypothesis Testing
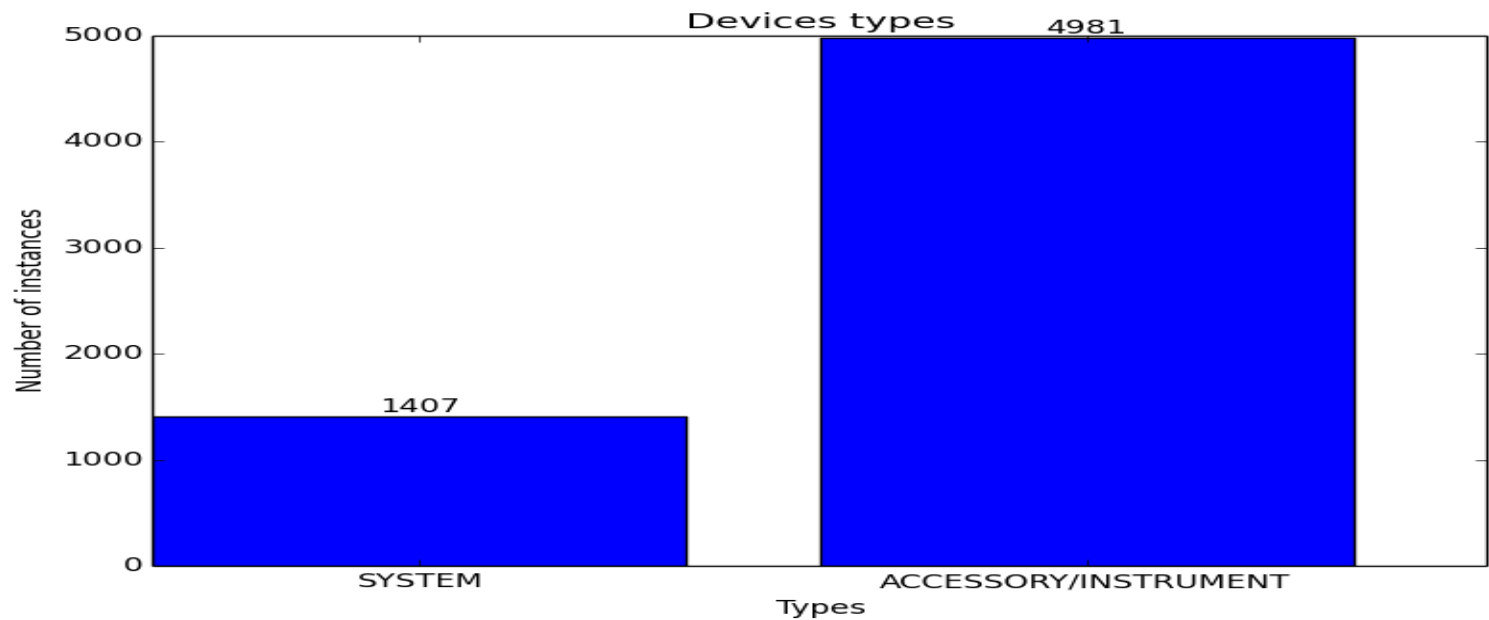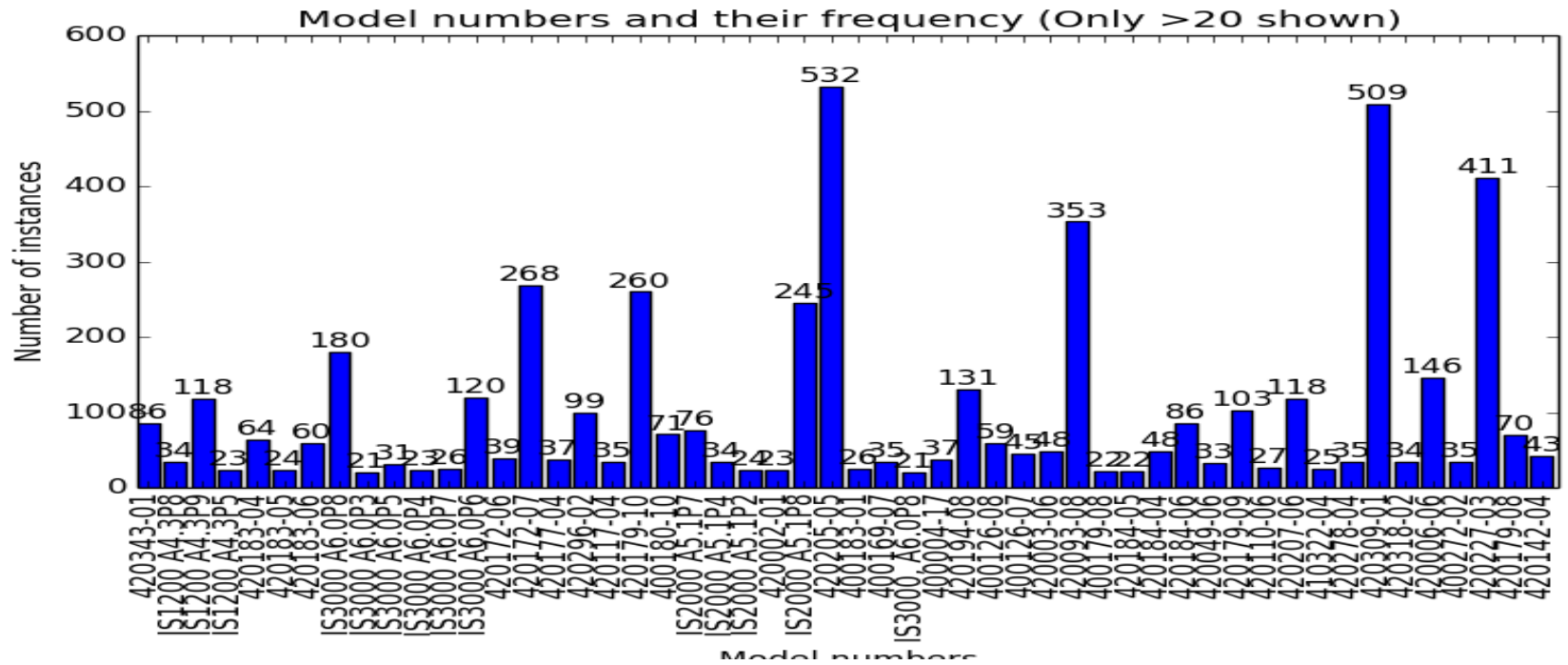
Model Number	SYSTEM	P(H0)	P(H1)
IS1200 A4.3P8	Y	1.0	0.0
IS1200 A4.3P8	N	1.0	0.0
IS1200 A4.3P9	Y	0.923728813559	0.0762711864407
IS1200 A4.3P9	N	0.0	0.0
420278-04	Y	0.0	0.0
420278-04	N	1.0	0.0
420194-08	Y	0.0	0.0
420194-08	N	0.984732824427	0.0152671755725
420177-04	Y	0.0	0.0
420177-04	N	1.0	0.0
IS1200 A4.3P5	Y	1.0	0.0
IS1200 A4.3P5	N	0.0	0.0
410322-04	Y	0.0	0.0
410322-04	N	0.92	0.08
400183-01	Y	0.0	0.0
400183-01	N	1.0	0.0
400004-17	Y	0.0	0.0
400004-17	N	1.0	0.0
420003-06	Y	0.0	0.0
420003-06	N	0.979166666667	0.0208333333333
420227-03	Y	1.0	0.0
420227-03	N	0.987804878049	0.0121951219512
420309-01	Y	0.0	0.0
420309-01	N	0.992141453831	0.00785854616896
IS3000 A6.0P8	Y	0.145251396648	0.854748603352
IS3000 A6.0P8	N	0.0	1.0
420207-06	Y	0.0	0.0
420207-06	N	1.0	0.0
420183-04	Y	0.0	0.0
420183-04	N	1.0	0.0
420183-05	Y	0.0	0.0
420183-05	N	0.916666666667	0.0833333333333
420183-06	Y	0.0	0.0

Probabilities of H0/H1 given the model number and device type
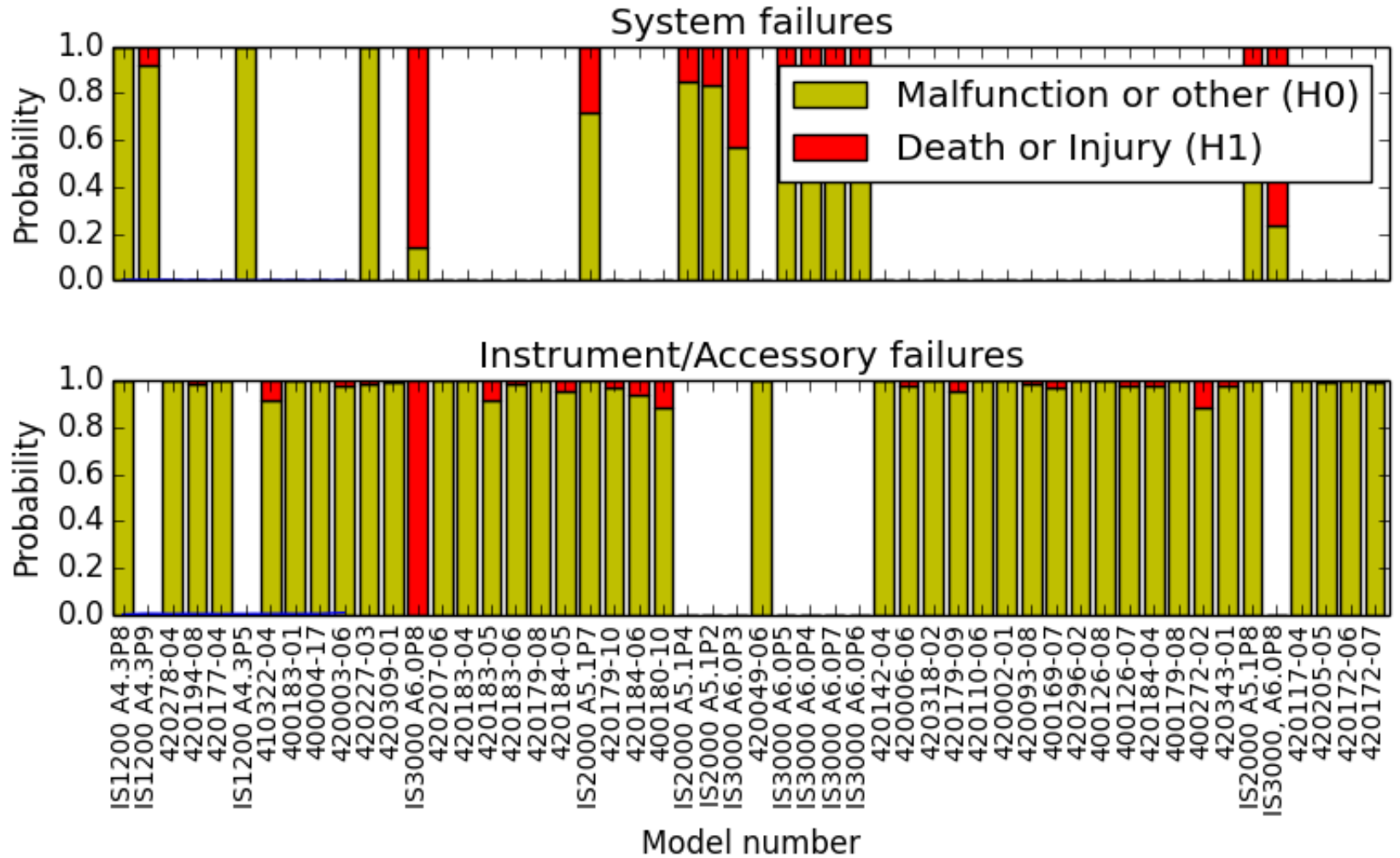
ML rule vector

Model Number	SYSTEM	Alarm
IS1200 A4.3P8	Y	0
IS1200 A4.3P8	N	0
IS1200 A4.3P9	Y	0
IS1200 A4.3P9	N	1
420278-04	Y	1
420278-04	N	0
420194-08	Y	1
420194-08	N	0
420177-04	Y	1
420177-04	N	0
IS1200 A4.3P5	Y	0
IS1200 A4.3P5	N	1
410322-04	Y	1
410322-04	N	0
400004-17	Y	1
400004-17	N	0
IS2000 A5.1P8	Y	0
IS2000 A5.1P8	N	0
IS3000 A6.0P8	Y	1
IS3000 A6.0P8	N	1
420207-06	Y	1
420207-06	N	0
420183-04	Y	1
420183-04	N	0
420183-05	Y	1
420183-05	N	0
420183-06	Y	1
420183-06	N	0
420184-05	Y	1
420184-05	N	0
IS2000 A5.1P7	Y	0
IS2000 A5.1P7	N	0

420179-10	Y	1
420179-10	N	0
420184-06	Y	1
420184-06	N	0
400180-10	Y	1
400180-10	N	0
IS2000 A5.1P4	Y	0
IS2000 A5.1P4	N	1
420343-01	Y	1
420343-01	N	0
420309-01	Y	1
420309-01	N	0
IS3000 A6.0P3	Y	0
IS3000 A6.0P3	N	1
420049-06	Y	1
420049-06	N	0
IS3000 A6.0P5	Y	0
IS3000 A6.0P5	N	1
IS3000 A6.0P4	Y	0
IS3000 A6.0P4	N	1
IS3000 A6.0P7	Y	1
IS3000 A6.0P7	N	1
IS3000 A6.0P6	Y	0
IS3000 A6.0P6	N	1
420117-04	Y	1
420117-04	N	0
420142-04	Y	1
420142-04	N	0
420006-06	Y	1
420006-06	N	0
420179-09	Y	1
420179-09	N	0
420110-06	Y	1
420110-06	N	0

400183-01	Y	1
400183-01	N	0
420093-08	Y	1
420093-08	N	0
420296-02	Y	1
420296-02	N	0
400169-07	Y	1
400169-07	N	0
400126-08	Y	1
400126-08	N	0
400126-07	Y	1
400126-07	N	0
420184-04	Y	1
420184-04	N	0
400179-08	Y	1
400179-08	N	0
IS3000, A6.0P8	Y	1
IS3000, A6.0P8	N	1
400272-02	Y	1
400272-02	N	0
IS2000 A5.1P2	Y	0
IS2000 A5.1P2	N	1
420002-01	Y	1
420002-01	N	0
420003-06	Y	1
420003-06	N	0
420227-03	Y	0
420227-03	N	0
420179-08	Y	1
420179-08	N	0
420205-05	Y	1
420205-05	N	0
420318-02	Y	1
420318-02	N	0

Some Observations:
- •Most of our failure density graphs were close to exponential, and hazard rates close to constant.
- •Deaths have occurred only due to System failures.

Concepts from class:
- Failure density
- Hazard rate
- •conditional probability
- hypothesis testing
- ML rule

Suggestions:
➢ The Final project should have a higher contribution to the final grade of the course.
➢The Final Project should be moved before the start of the final exam week.

Thank You! Questions?