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# COMPLAINT TRENDING ANALYSIS

## XXX DATE

Period: 1st Jan 2018 to 31st Jan 2019

Total # of Complaint Records in Scope: X\*

Strategy for reporting:

1. All Complaints in Scope (Overview)
2. Complaints per Product Range
3. Complaints per Individual Products

Reference Material:

- Post Marketing Surveillance Analysis 2019 – Data Protocol
- X Feb 2019 FINAL DATA SET.csv
- Not-Verified Complaints to Check.xls
- Install Base.csv

\* PENDING X, SUBMITTED X, REVIEW X, CLOSED X

V 2.1 updated EB X X 2019

NOTE: "Unknown" and "Empty" data has been removed from this analysis as it does not provide value in this instance

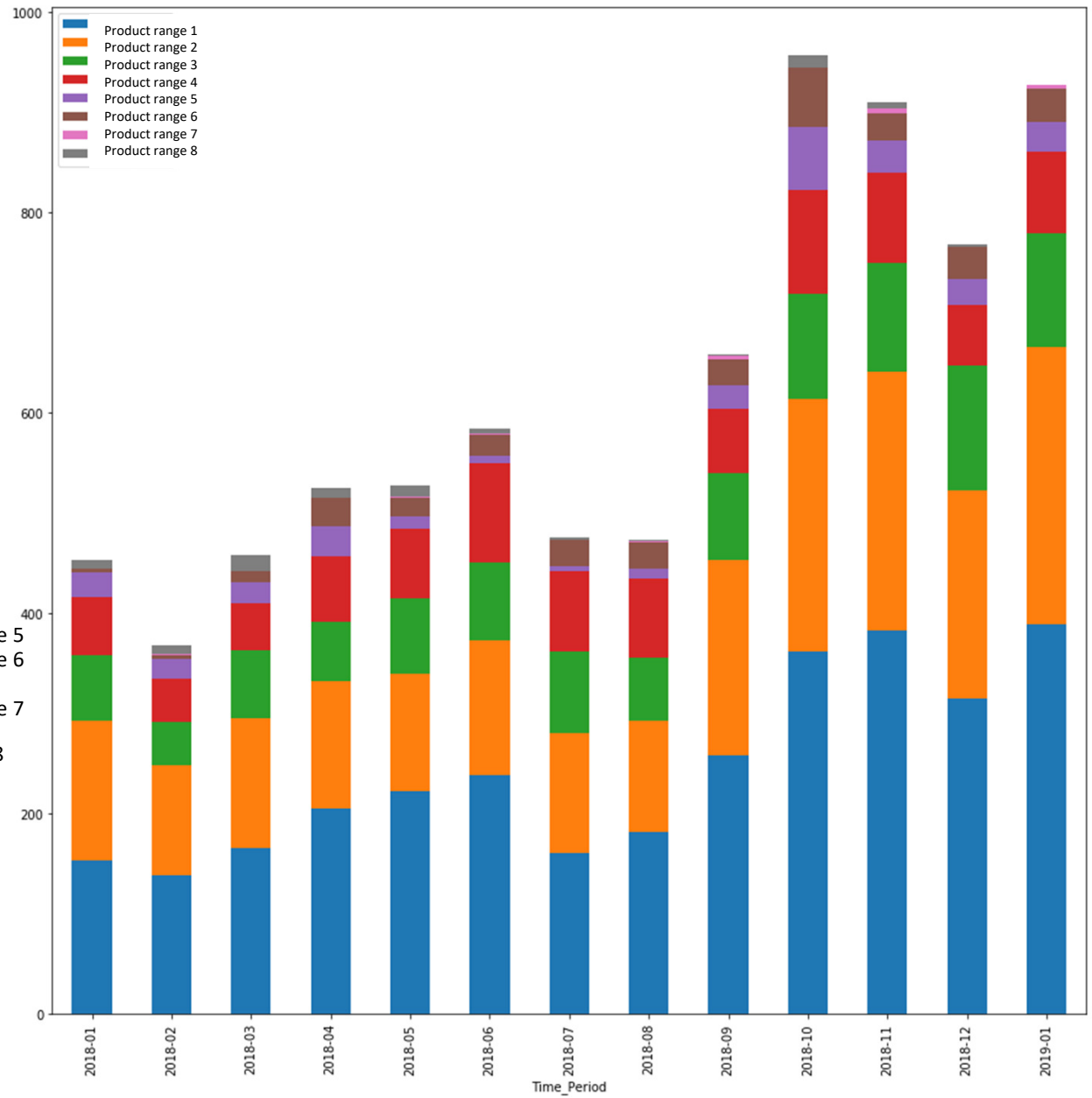
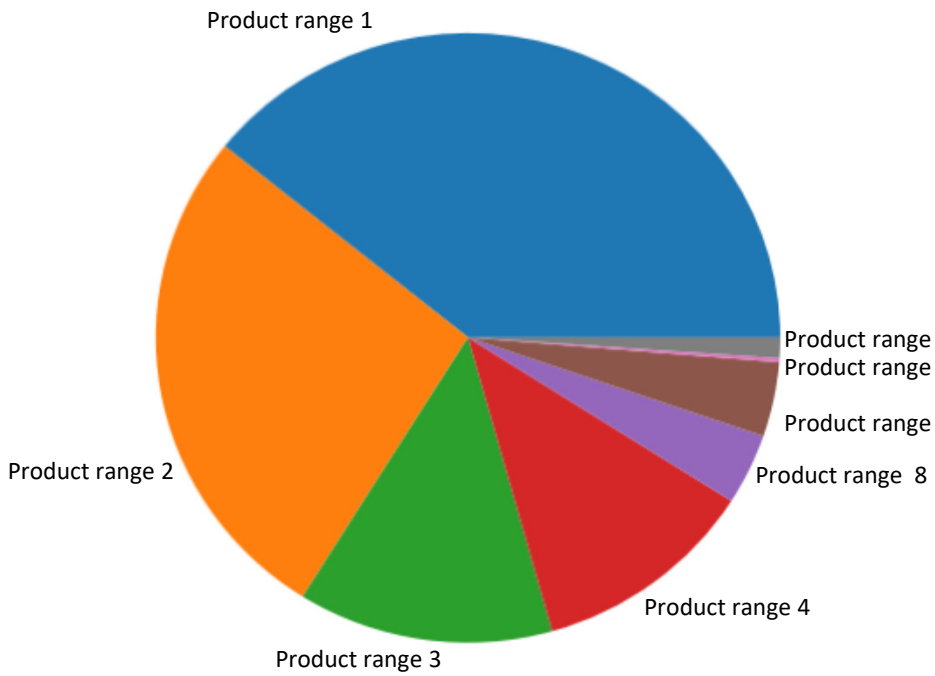
NOTE2: The customer Symptom Code has been determined to be the primary fault code in this analysis as the majority of complaints do not yet have fault codes in Agile. It is recommended that this data is reanalysed once the fault codes are available for this time period.

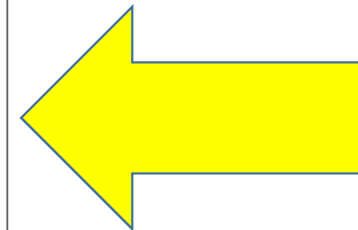
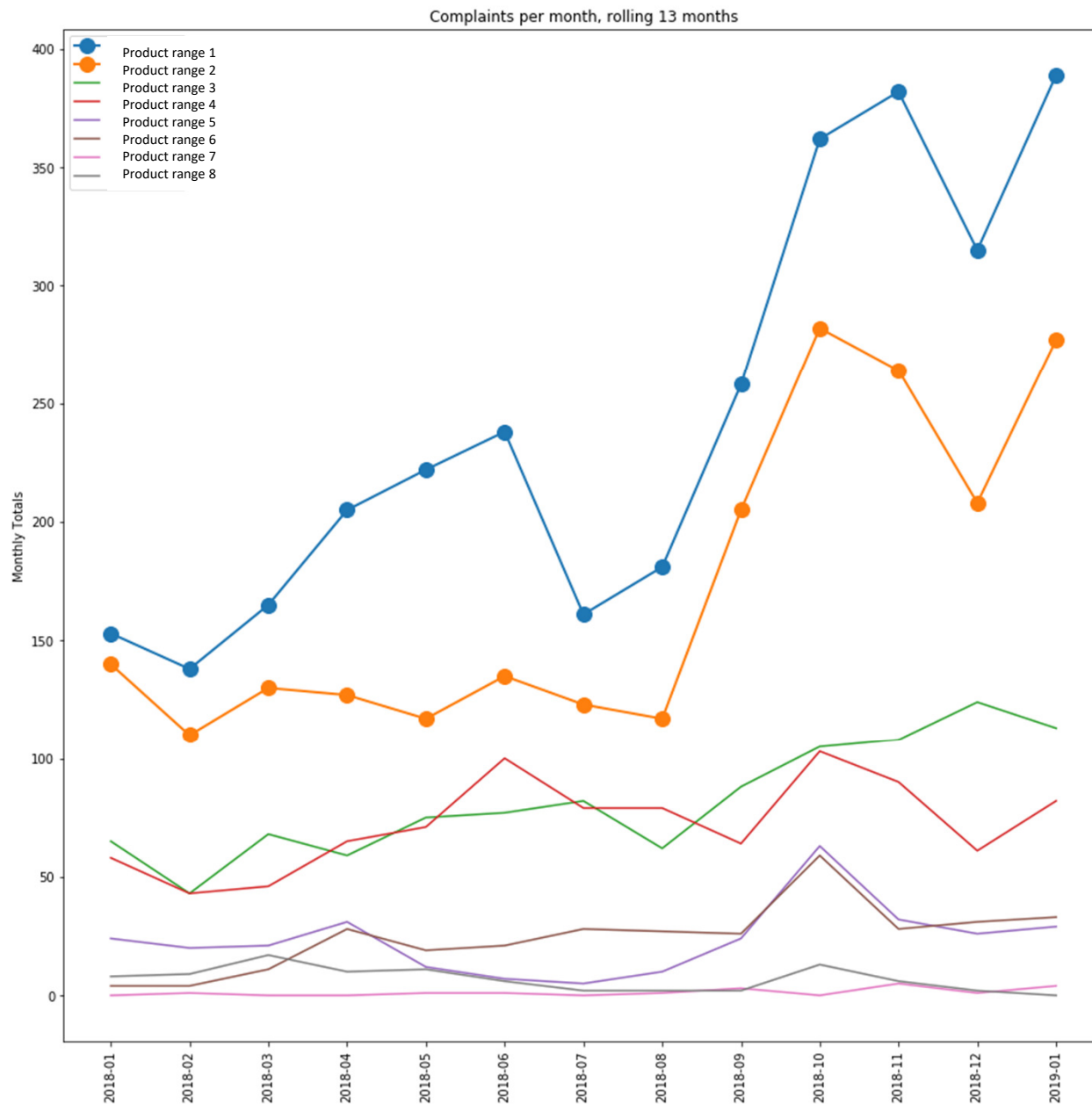
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# TOTAL Overview - All Complaints

# Total Complaints

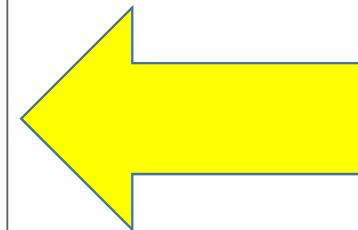
## 01 Jan 2018 – 31 Jan 2019





Increase driven by  
product ranges 1 & 2

other influences??



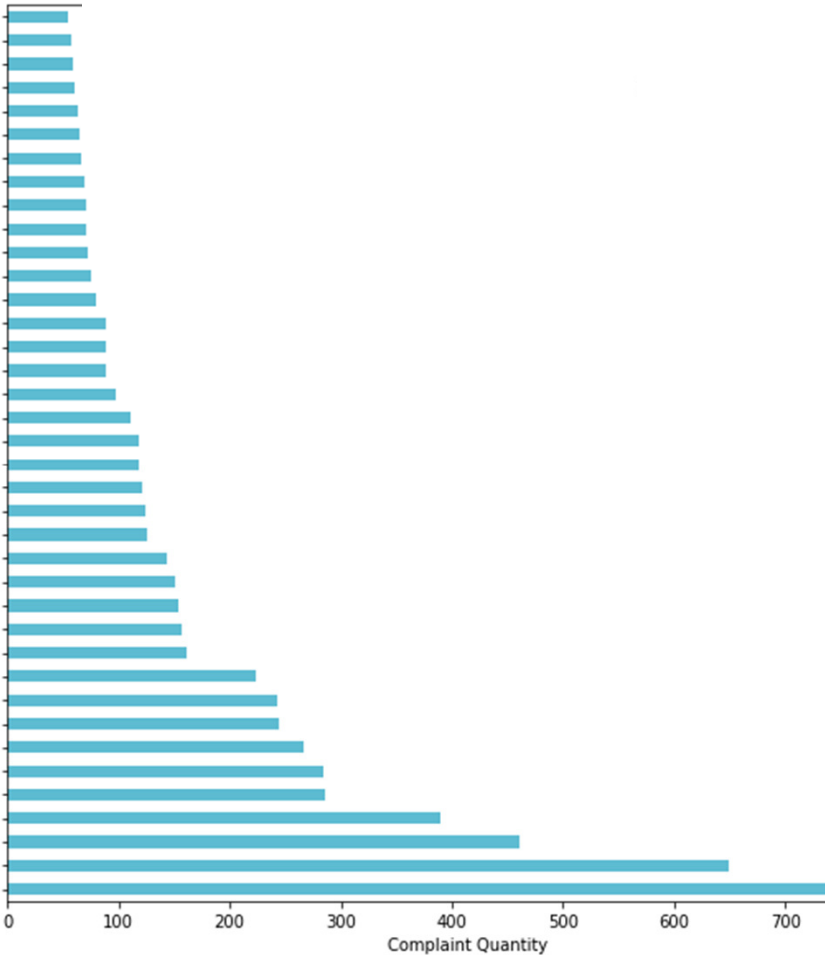
#### Agree Priorities

- 1)
- 2)
- 3)
- 4)

# Quantity Per Product

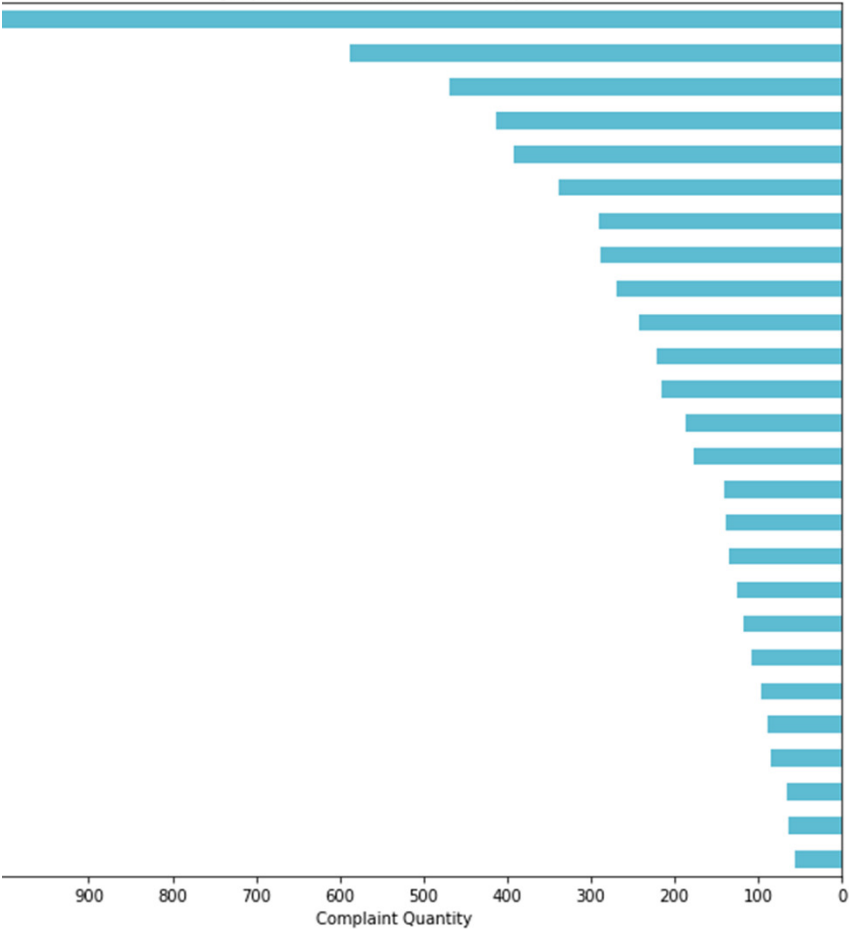
Products with > 50 complaints

Individual  
Product  
Names  
here

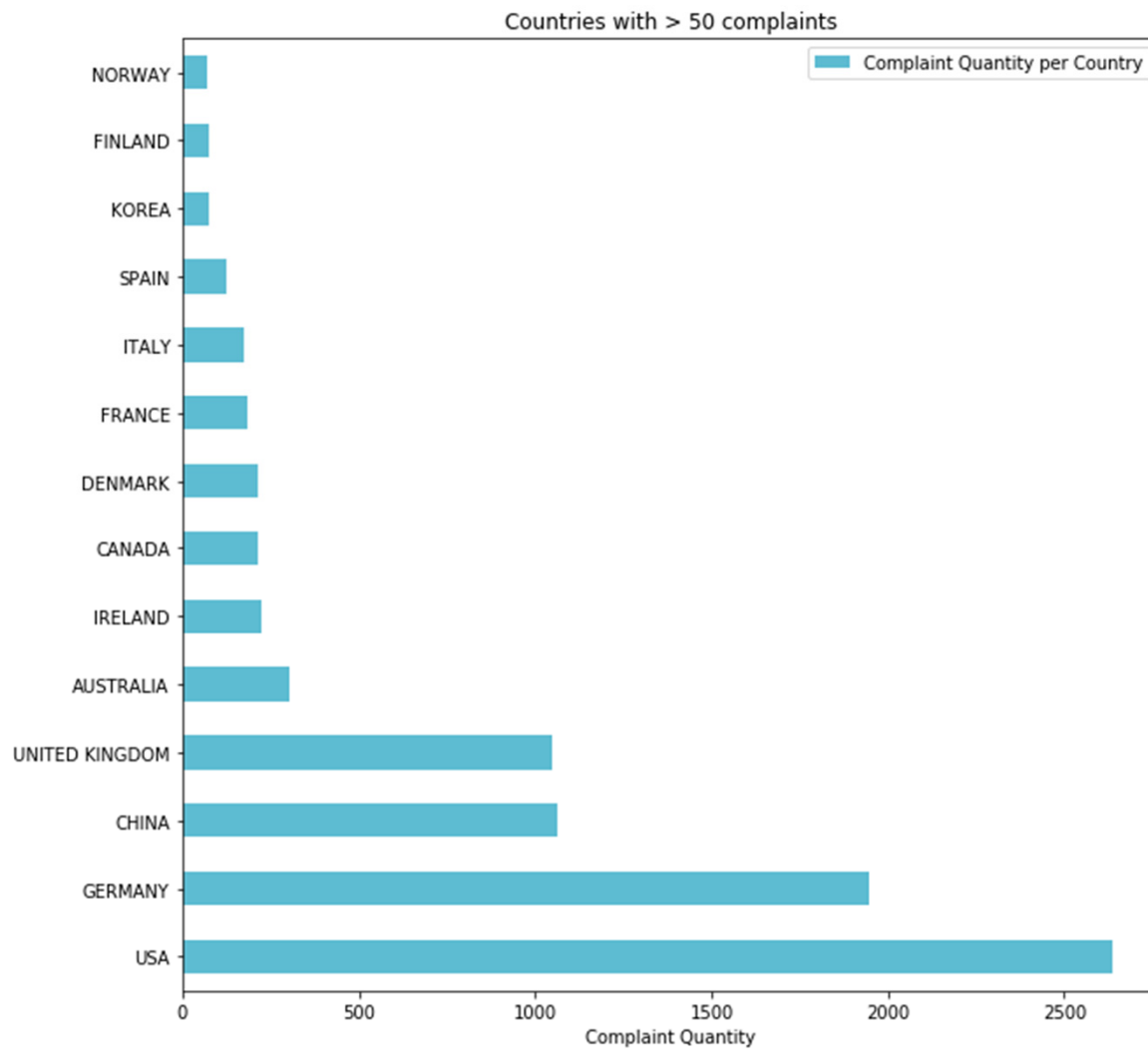


Symptom Codes with > 50 complaints

Individual  
Symptom  
Codes  
here



# Quantity Per Symptom Code



## Install Base

Country	
DENMARK	5620
USA	3917
CHINA	1754
SWITZERLAND	1410
SINGAPORE	1196
GERMANY	1158
AUSTRALIA	1028
NETHERLANDS	860
CANADA	655
INDIA	524
BRAZIL	461
JAPAN	425
NORWAY	417
POLAND	402
TURKEY	386
SWEDEN	349
IRAN (ISLAMIC REPUBLIC OF)	327
BELGIUM	321
ITALY	308
NEW ZEALAND	286
SPAIN	276
FRANCE	272
KOREA	269
ECUADOR	247
AUSTRIA	223

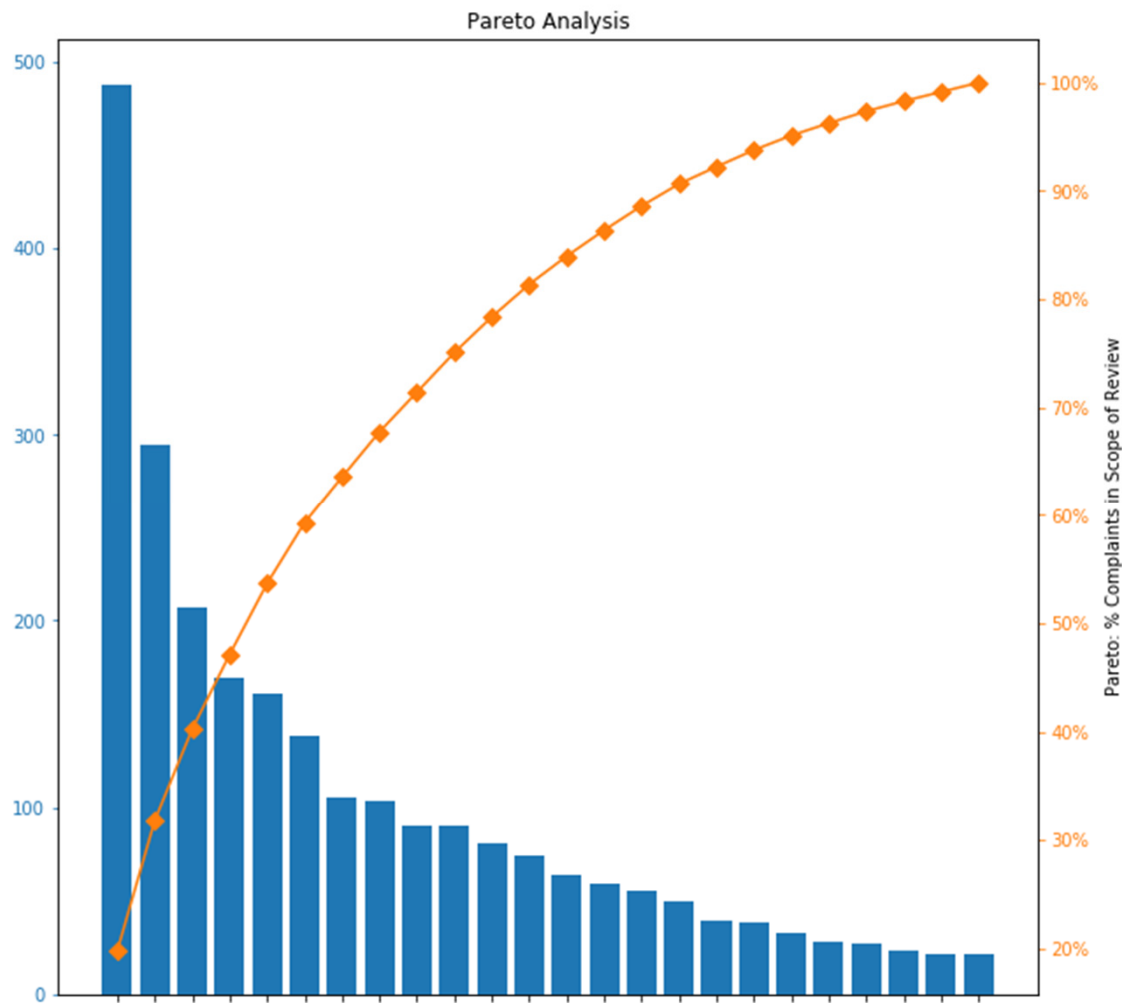
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## PRODUCT RANGE Overview

	Product Range 1	Product Range 2	Product Range 3	Product Range 4	Product Range 5	Product Range 6	Product Range 7	Product Range 8
Search Criteria								
Total #	3169	2180	1069	941	304	319	17	88



# Product Range 1



Top 5 Countries (Complaint Quantity)

Complaint Quantity	
USA	946
GERMANY	648
CHINA	541
UNITED KINGDOM	397
AUSTRALIA	86

Top 5 Customer Symptom Codes in Top 5 Countries

	Quantity	Pareto %
PROBE	349	13.33
PATIENT RESPONDER	273	23.76
HEADSET ISSUE	178	38.96
SOFTWARE ISSUE	156	44.92
MAIN/DIGITAL BOARD	133	50.00

**MATCH**

Top 10 largest Install Base in Country

	Quantity
GERMANY	575
USA	485
DENMARK	400
CHINA	394
POLAND	238
NORWAY	227
NETHERLANDS	226
AUSTRALIA	144
BRAZIL	136
ROMANIA	126

## CAPAs:

- P. Responder, CAPA XXX Owner: EB
- Probe, CAPA XXX Owner: EB

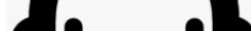
## Actions

- EB to ship back PR examples ASAP
- See separate slide RE: data investigation for headsets

## HeadSet Issue – (Quick) Breakdown of Data

Raw Data File: # Specifica

## # Specifically per model



	Symptom_Code
Repair	54
Faulty	24
Headband broken	17
Unknown	11
Headset broken	10
Headset issue	9
Headphones cable	7
Contra issue	6
Mic issue	6
Bone conductor	5
Broken	4
Right side issue	4
Contra Headphones	3
Headphones issue	3
Output issue	3
Unknown	3
Left side issue	3
Contra Headset	3
Headset	2
Headphones broken	2
Request	2
Talk forward issue	2
Headphone issue	2
Headban broken	2
Headset noise	2
Tone issue	2

[illegible]

## Cross Reference

3 headset types in use but  
root cause not clear

3 headset types in use but  
root cause not clear

Investigate further?  
Monitor closely thorough  
individula product PMS  
Process?

Monitor closely thorough  
individula product PMS  
Process?

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# Individual PRODUCT Overview

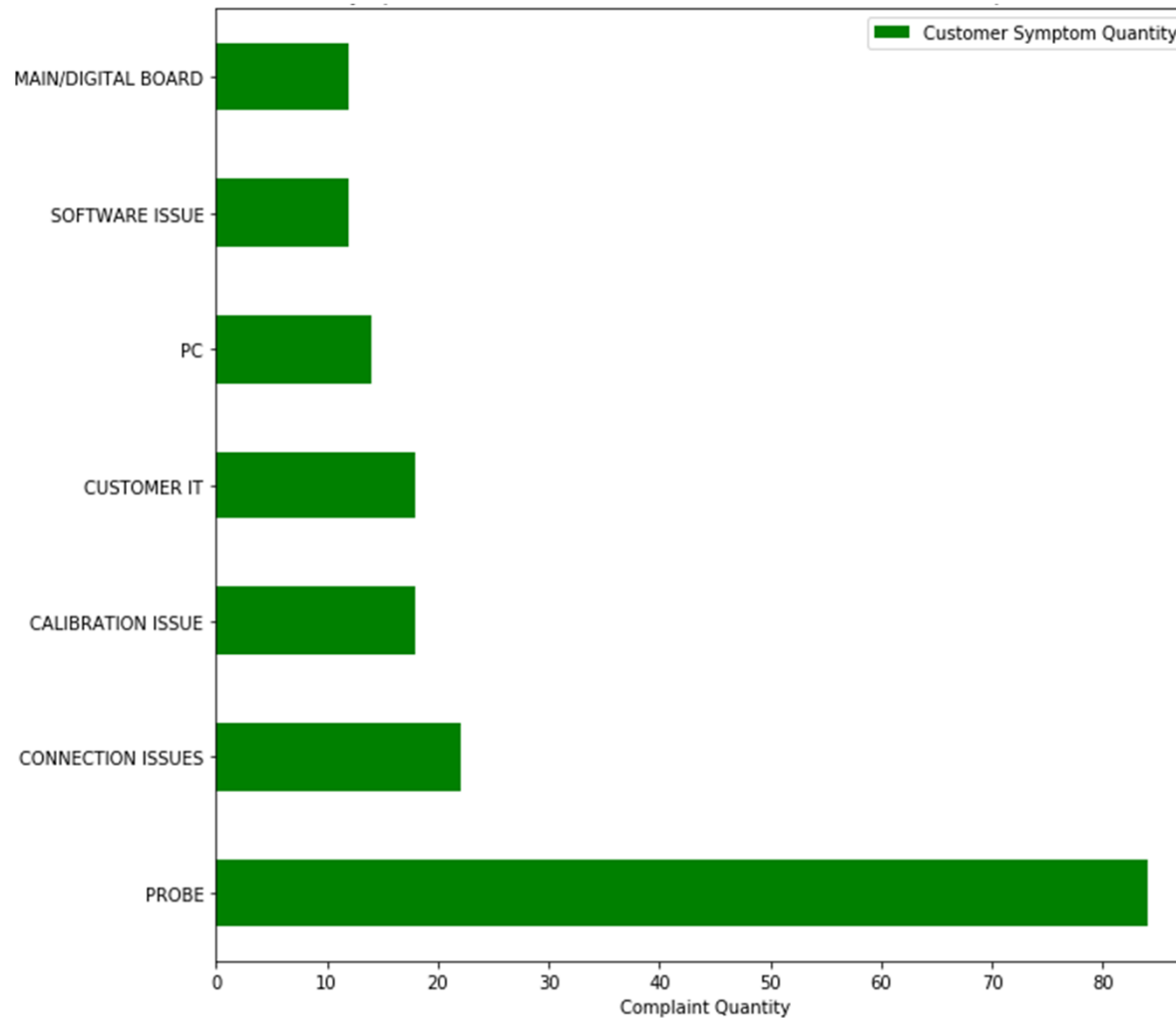
XXXX Product 1  
XXXX Product 2  
XXXX Product 3  
XXXX Product 4  
XXXX Product 5

XXXX Product 6  
XXXX Product 7  
XXXX Product 8  
XXXX Product 9  
XXXX Product 10

XXXX Product 11  
XXXX Product 12  
XXXX Product 13  
XXXX Product 14  
XXXX Product 15

XXXX Product 16  
XXXX Product 17

p\_XXX = ['Product Name', 'Product Number']



## Install Base

Country	
USA	880
NETHERLANDS	349
GERMANY	324
AUSTRALIA	274
CANADA	109
TURKEY	105
NEW ZEALAND	67
ITALY	65
FRANCE	65
SWEDEN	63

### Further Investigation

- CAPA opened for Probe specifically for this product,
- Investigate link between probe and connection issues, subset of data required...

# Potential Adverse Event Identified and Investigated

#	Date Received	Product	Description	Reportable?	Report Date	CAPA #
1						
2						
3						
4						
5						
6						
7						
8						

## Search for Complaints with potential Adverse Event and/or Patient Impact

### Key Words...

'BLOW'	'ACCIDENT'	'COMPLICATION'	'MISTAKE'	'CONCERN'	'INCORRECT'	'WRONG'	'NON-COMPLIANCE'
'SHOCK'	'SAFE'	'BLED'	'RASH'	'SMOKE'	'SKIN'	'HAZARD'	'NONCOMPLIANCE',
'FIRE'	'INJUR'	'BLEED'	'SKIN'	'BLOOD'	'DISTRESS'	'INFECTION'	'TOXIC'

### Results, continued...

- Search though closed, cancelled and "not verified" complaints produced no results.
- Search thorough all other complaints in this analysis produced a list of 299 to review.

## Results, continued...

Case 1 Called out to investigate further to see if linked to other issues...