

12 Feb 2019 | Analysis

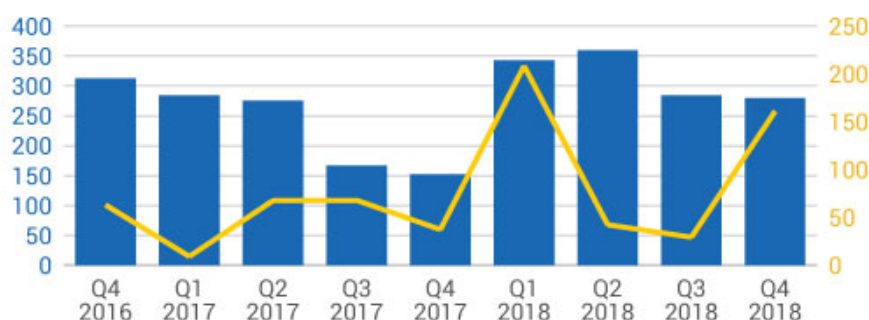
Q4 Recalls Snapshot: Recalled Device Units Soar 449%; Bad Software Leading Recall Cause For 11th Quarter In A Row

by [Shawn M. Schmitt](#)

While the number of recalled products fell 1% in the fourth quarter of 2018, the number of recalled device units spiked dramatically. Machine failure was the top recall cause based on units, while software was blamed for causing the most recalled products for the 11th consecutive quarter. Check out our Q4 recalls infographic.

The fourth quarter of 2018 was a mixed bag for the medical device industry when it came to corrections & removals. While on the one hand, the number of recalled products remained relatively flat at 280 in Q4 (down 1% from [Q3's 284 recalls](#)), on the other, the number of recalled device units spiked dramatically. There were 161 million units recalled in Q4, an increase of 449% when compared to Q3's 29.4 million, consulting firm Stericycle says in its most recent [recalls index](#). Machine failure was the top recall cause based on units – mostly due to one large recall – while software was blamed for causing the most recalled products for the 11th consecutive quarter. Meanwhile, five manufacturers initiated 10 or more recalls in Q4, the largest number of firms to do so since Q3 2016, and the second highest since Q3 2013.

SNAPSHOT: Device Recalls Q4 2018

MEDICAL DEVICE RECALLS & UNITS (in millions)


MACHINE MISFORTUNE CONTINUES

At 74%, machine failure was the top cause based on units, mainly due to one large recall. This is the second consecutive quarter machine failure was the top cause based on units.



**OF MEDICAL DEVICE
RECALLS WERE NATIONWIDE**

AVERAGE CLASS I UNITS RECALLED PER QUARTER

Q2 2018
599,165

Q3 2018
14,035,195

Q4 2018
1,380,706

CONNECTING THE DOTS

- The average recall size was 575,449 – the second highest quarter since Q3 2006.
- At 28%, software was the top cause based on recalls for the eleventh consecutive quarter. No other cause was responsible for more than 15% of recalls.
- Five companies reported 10 or more recalls in Q4 2018. This is the highest number since Q3 2016 and the second highest since Q3 2013.

TOP RECALL CAUSES BASED ON NUMBER OF EVENTS



Software Issue

79



Mislabeling Issue

43



Quality Issue

36



Sterility

27

Source: Stericycle ExpertSOLUTIONS Q4 2018 Recall Index

Get a PDF of this infographic [here](#).

From the editors of *The Gray Sheet*