MEDICAL INDICATORS

May 11, 2020

TempaDOT Non-Sterile Statement

The following Tempadot Catalog# are **not** sterile: 5124NS, 5122NS, 5532NS, 5192R, 5502R, 5557, 5147, 5001 and 5002 but they are manufactured in a control environment. "**Control environment**" means that we performed Microbial Environmental testing on a quarterly basis of the production floor and samples are collected as per TDQA-031 for air viable and machine surface viable from our contract laboratory. Then, those samples were analyzed for bacteria and mold as per our contract laboratory methods.

In addition, Bioburden Testing was also performed on samples back in 2019 from product catalog# 5124NS and 5122NS. The purpose of those testing were to determine pre-sterilization microbial count on Non-sterile samples. This was done using ANSI/AAMI Method 1.
The bioburden results for each of the two lots: 06981 (5124NS) and 06947(5122NS) showed no detectable bacterial or fungal bioburden on the tables below as per contract laboratory report# **R-562654-R0** and **R-538540-R0.**

Bioburden Test Results on Tempa Dot

Slash #	Sample Description	Lot No.	A	B	C	D	E	F	G	H	I	J	Avg	Adjusted Avg.
001-010	WA#1 (5124NS)	06981	0	0	0	0	0	0	0	0	0	0	<1	<1
011-020	WA#2(5124NS)	06981	0	0	0	0	0	0	0	0	0	0	<1	<1
021-030	WA#3(5124NS)	06981	0	0	0	0	0	0	0	0	0	0	<1	<1

The counts are inclusive of Bacteria, Yeasts and Molds. Samples were tested individually and the average is presented in the table.

Legend:

NA = Not applicable
cfu = Colony Forming Units
Avg = Average bioburden multiplied by the PF
Adjusted Avg = Avg multiplied by the EF
Plate Factor (PF) = 1
Efficiency Factor (EF) = 1.0 GBL# 329887 Ref# 32361-148-42085

Table 1(5124NS): No microbial count detected

Bioburden Test Results on Tempa Dot

Slash #	Sample Description	Lot No.	A	B	C	D	E	F	G	H	I	J	Avg	Adjusted Avg.
001-10	WA#1 (5122NS)	06947	0	0	0	0	0	0	0	0	0	0	<1	<1
011-20	WA#2(5122NS)	06947	0	0	0	0	0	0	0	0	0	0	<1	<1
021-30	WA#3(5122NS)	06947	0	0	0	0	0	0	0	0	0	0	<1	<1

Legend: The counts are inclusive of Bacteria, Yeasts and Molds. Samples were tested individually and the average is presented in the table.

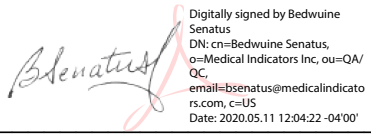
NA = Not applicable
Avg = Average bioburden multiplied by the PF
Adjusted Avg = Avg multiplied by the EF
EF = Efficiency Factor 1.0 GBL# 329887
Ref# 32361-148-42085
cfu = Colony Forming Units
PF = Plate Factor 1

Table 2 (5122NS): No microbial count detected

The samples tested harbored an adjusted average bioburden of <1 cfu/sample. What this test means is that Non-sterile TempaDOT thermometers do not inhibit the recovery of viable spores when they are inoculated with a known quality of viable organisms.

Note: 1 cfu is a measure of viable bacterial or fungal cells.

In summary, the reports showed that non-sterile Tempadot Thermometers have a very low bioburden and that the components used in those thermometers do not inhibit the viability of spores when inoculated into a medium. Therefore, 5124NS, 5122NS, 5532NS, 5192R, 5502R, 5557, 5147, 5001 and 5002 are safe to be used without being sterilized. I have also attached a 2019 Environmental Monitoring Summary report for the production floor.

X 

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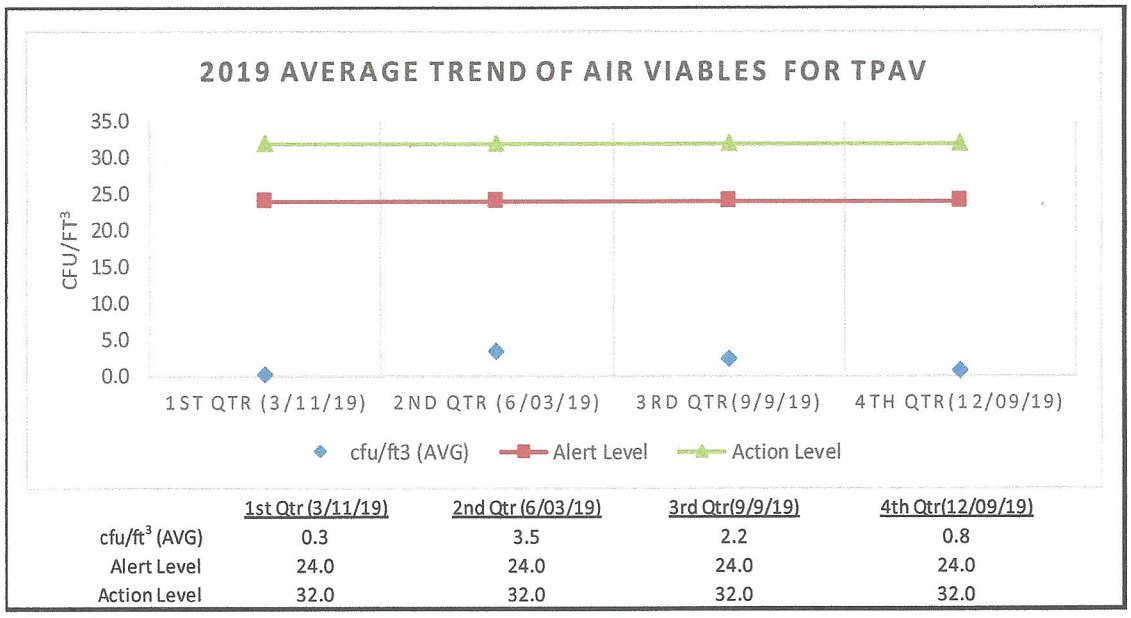
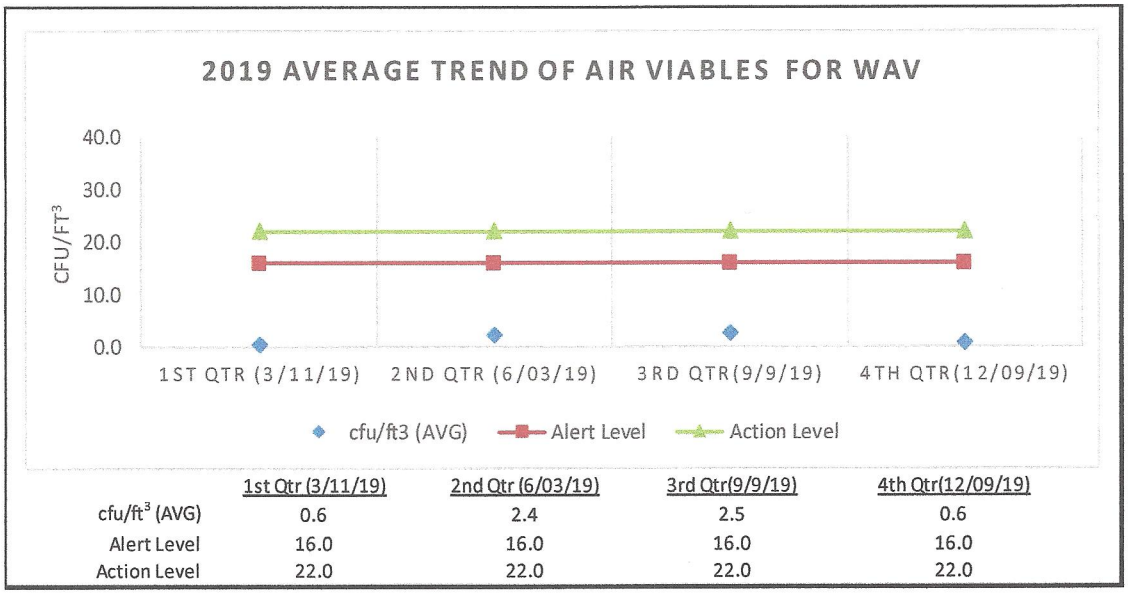
2019 Environmental Monitoring Trending Summary for Medical Indicators



	1st Qtr (3/11/19)	2nd Qtr (6/03/19)	3rd Qtr(9/9/19)	4th Qtr(12/09/19)
cfu/ft³ (AVG)	0.3	3.5	2.2	0.8
Alert Level	24.0	24.0	24.0	24.0
Action Level	32.0	32.0	32.0	32.0



	1st Qtr (3/11/19)	2nd Qtr (6/03/19)	3rd Qtr(9/9/19)	4th Qtr(12/09/19)
cfu/ft³ (AVG)	0.6	2.4	2.5	0.6
Alert Level	16.0	16.0	16.0	16.0
Action Level	22.0	22.0	22.0	22.0

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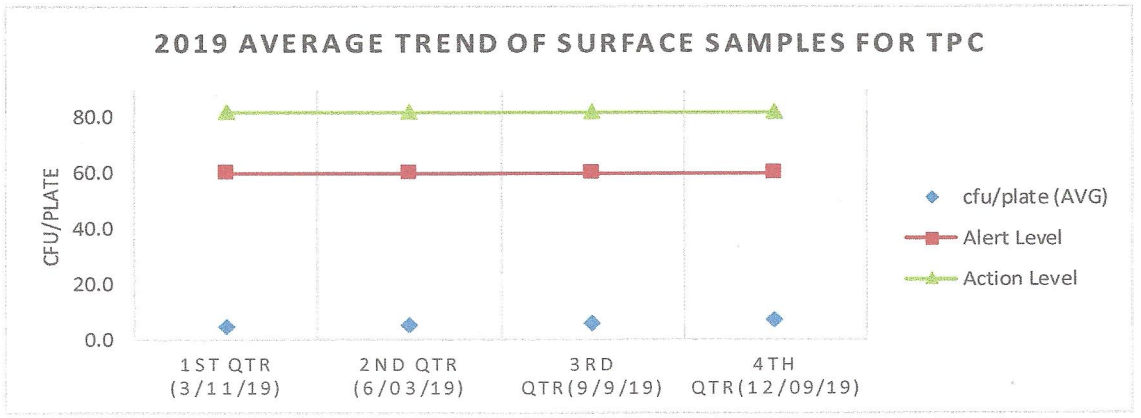
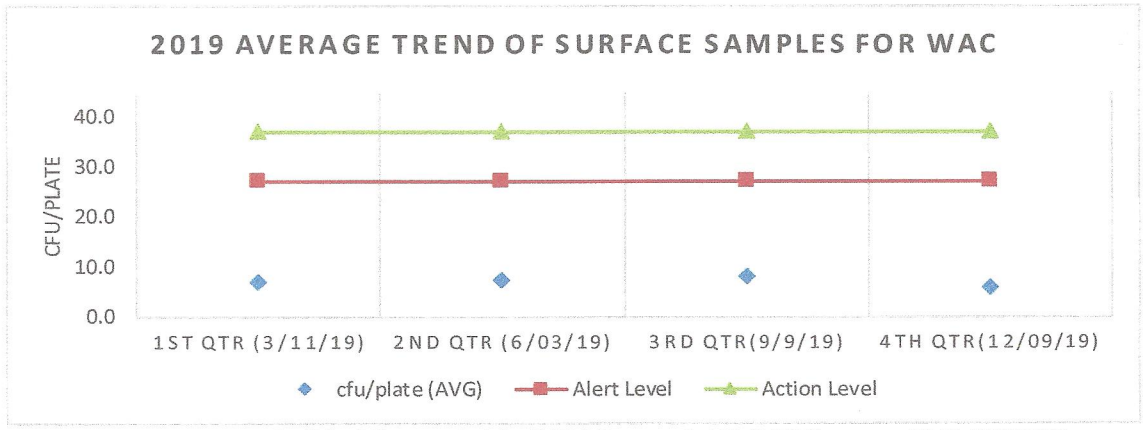


	1st Qtr (3/11/19)	2nd Qtr (6/03/19)	3rd Qtr(9/9/19)	4th Qtr(12/09/19)
cfu/plate (AVG)	4.2	5.0	6.1	7.2
Alert Level	60.0	60.0	60.0	60.0
Action Level	82.0	82.0	82.0	82.0



	1st Qtr (3/11/19)	2nd Qtr (6/03/19)	3rd Qtr(9/9/19)	4th Qtr(12/09/19)
cfu/plate (AVG)	6.9	7.2	8.1	5.7
Alert Level	27.0	27.0	27.0	27.0
Action Level	37.0	37.0	37.0	37.0

Conclusion: This final report summarizes the results obtained on surface samples and air viables for 2019 at Medical indicators Inc. The highest reading identified was during 3rd quarter on surface samples for WAC and during 2nd quarter on air viables for TPAV. Those readings did not exceed the alert or action level limit. However, any alert or action level detected will trigger an investigation on the specific area and additional testing of affected lot will be required for action level observed to ensure products manufactured are safe and can be sold.

Signature: _____ Digitally signed by Bedwuine Senatus DN: cn=Bedwuine Senatus, o=Medical Indicators Inc, ou=Quality department, email=bsenatus@medicalindicators.com, c=US Date: 2020.01.06 09:40:52 -05'00' Date: 1/6/2020

QA/RA Manager

01/06/2020