Product Feedback Negative

145929	Steve Hardaker	24/05/19	Derek Lamb	VM-2500-S not powering on

INFORMATION ONLY ISSUE **DO NOT** ADD NOTES!
I put a demo VM-2500-S out on SOR for trial with Embrace patient transport service, it was an older demo unit, s/n 60940145, which we received Jan 13 but was the only one left.

It failed immediately, failing to power up. It came back, we were unable to replicate the fault, it went back on trial and it failed again.

Video evidence was provided by customer so we can see they are trying to power it up correctly.

Looks like either and intermittent fault with the keypad, or something to do with the battery not being sufficient to power it up but no low battery warning was displayed.

Not too much of a concern as this is a very old unit but it also happened to a new unit in June 2018 (see issue 121610), so have added both incidents to an ongoing agenda to discuss with Bluepoint.

141784	Steve Hardaker	03/04/19	Derek Lamb	R-22AV customer moving to R-22AVG due to high failure rate

Added by Steve Hardaker sent to Steve Nixon
INFORMATION ONLY ISSUE **DO NOT** ADD NOTES!
Glenn at Cryptonfix reported problems with R-22AV sensors reading high. He has seen a lot of failures where a sensor will calibrate with a reading around 10 mV but a few weeks later the sensor is failing calibration on a Crypton machine. When he tests them, the sensors have drifted over 13 mV.

He is very unhappy with Teledyne sensors, I have offered to move him over to Viamed R-22AVG. He will order 50 right away and will be returning the failed Teledyne sensors for replacement with R-22AVG.

He is happy not to wait to see how the R-22AVG works out as, in his words: "they can`t possibly be any worse!"

139219	Steve	27/02/1	Steve	Automotive customer moving from R-22AV to

	Hardaker	9	Nixon	R-22AVG

Added by Steve Hardaker sent to Steve Nixon
INFORMATION ONLY ISSUE **DO NOT** ADD NOTES!
FYI - Gemco Service Ltd has reported customers having problems with a number of R-22AV sensors reading too high. Purchased 2nd Nov 18, date code H8 & I8.

He wanted to return 180 sensors for exchange but I suggested we can only replace the known faulty ones due to them being 4 months old, which he accepted.

Offered him the R-22AVG, he wants to try a small batch before committing fully so I offered him 10 at the 100-off price.

134229	Steve Hardaker	13/12/18	Derek Lamb	R-22AV failures - CARS automotive

Copy Issue Main Issue #134228
Added by Steve Hardaker sent to Steve Nixon
INFORMATION ONLY ISSUE **DO NOT** ADD NOTES!
Calibration and Repair Services (CARS), an automotive customer is having problems with the R-22AV reading high. Batch dated F8.

I have offered R-22AVG in replacement but this is obviously a quality issue as we have seen it now with a number of customers.

134205	Steve Hardaker	13/12/18	Ryan Swaine	R-17A-LV high failure rate

Added by Steve Hardaker sent to Steve Nixon
Celtech Engineering Services have raised concerns over the quality of the R-17A-LV sensor.

Joe recently returned 6 sensors with very high outputs, 2-3 mV over their QA values. See SRS66849. They were supplied on IN155798 - 19/3/18, date codes A8.

I`m not yet able to move them over to a Viamed alternative but as we currently sell over 400 pa of the R-17A-LV, I think we should get the first batch in. Steve, can you order some of the R-17A-LVG?

130178	Steve Hardaker	12/10/18	Derek Lamb	R-22AV failures - high output

Added by Steve Hardaker sent to Steve Nixon
INFORMATION ONLY ISSUE **DO NOT** ADD NOTES!
Just FYI - another automotive customer, Electronic Services, is reporting R-22AVs with high outputs.

A number of sensors from date codes C8 & D8 sold 06/18 are reading up to 16.5mV. Some went high and came back down but about 6 others have been open for 3 weeks and are still over 13mV. See SRS66782.

Incidentally, the barometric pressure at the customer location is below standard at 1009mB today, this is not pressure related.

127022	Steve Hardaker	30/08/18	Steve Nixon	Maxtec FloCap pricing feedback

Added by Steve Hardaker sent to Steve Nixon
INFORMATION ONLY ISSUE **DO NOT** ADD NOTES!
Followed up lead from Maxtec from Royal London Hospital for 4410100 FloCap.

Offered at the reduced price of £165.00+VAT for a box of 24, which is £6.875+VAT per unit. He said this is very expensive and they are currently buying the EasyCap II from NHS Supply Chain in packs of 6 at a price that equates to £5.33+VAT.

He asked about shelf life, I advised 3 years from new, but he says they would not get through 24 in 3 years as they only get used if absolutely necessary due to no waveform capnography being available.

He said the flow indicator is a bonus and he will ask the staff their opinion but he doesn`t think that they will go ahead due to the price.

Product Feedback Positive

149334	Steve Hardaker	11/07/19	Derek Lamb	R-17A-LVG feedback

INFORMATION ONLY ISSUE **DO NOT** ADD NOTES!
I have moved Celtech Engineering over from Teledyne R-17A-LV to Viamed R-17A-LVG for use on Bosch devices. He has tested some and found no problems so far.

132631	Steve Hardaker	21/11/18	Steve Nixon	Microstim DB3 airworthiness assessment

Over the last 7 months, I`ve been working with Leidos Supply Ltd (primary equipment supplier for the MOD) and RINA Consulting (testing house) to get the Microstim DB3 through the Special Purpose Aeromedical Equipment (SPAME) airworthiness assessment.

I`m pleased to report that the airworthiness process is now complete and the device has been declared to pose no serious risk to either the aircraft or patient. They do caution that there is still some work to do, and once this is complete, I will obtain something to substantiate the accreditation for the Technical Files.

One thing that has arisen is the requirement to only use batteries that are declared safe for air use. They are happy to use their own batteries and have requested a part number for a device that ships without a battery.

Can we do this, or would you rather cover this with stock and account memos?

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26 Nov 2018 Steve Hardaker
Provided part number 2510001 for a Microstim without a battery.

With regards to the standards, the customer advised the following:
"I should be able to share with you the defence standards which have been applied. I have been informed that these standards mirror civilian aviation standards but until the project is signed sealed and delivered I wouldnt want to share anything that has the slightest potential to change."

With regards to anticipated usage:
"I dont predict annual demand to be too high. There isnt scope to add further

users to the entitlement so new demands will probably come about when a device is damaged."

128745	Steve Hardaker	24/09/18	General	MD300-C2 customer feedback

INFORMATION ONLY ISSUE **DO NOT** ADD NOTES!
Just some feedback from a follow up I did with Solihull Hospital as to their experience with the MD300-C2 (2810011):

"Looks promising so far, out all the ones we trialled these came out on top from a combined score we based on price, performance and comfort.

I have made recommendations to procurement that we just purchase these in future to see how we get on with them."

124140	Ryan Swaine	17/07/18	Steve Nixon	Evaluation Sample of compatible Draeger Neonatal Flow Sensor Insert

Added by Ryan Swaine sent to Ryan Swaine
Evaluation Sample of compatible Draeger Neonatal Flow Sensor Insert:

17/07/2018

Georgi Boianov (ex Draeger Engineer) has run a provisional test on a Babylog 8000.

His initial assessment is that it fits, calibrates and works perfectly. The data is exactly what they would expect from an original Draeger.

Pictures attached.

The whole system is going to be run for 24 hours, Georgi will let us know if there are any problems during this period.

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20 Jul 2018 Ryan Swaine
Next Action Changed From Ryan Swaine To Steve Nixon

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20 Jul 2018 Ryan Swaine24 hour test completed and the sensor performed perfectly.

The only criticism is that the silicone band should be glued in place, as it can become dislodged when removed and inserted. The original Draeger is glued in place. Correspondence attached.

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20 Jul 2018 Steve Nixon
Thanks, great qualified feedback

Feedback - Product Innovation

134515	Ryan Swaine	18/12/18	Steve Nixon	VM-3160 - Inspiration Medical (Germany)

Added by Ryan Swaine sent to Steve Nixon
Christoph from Inspiration Medical in Germany has given me the following comments and information relating to the VM-3160:

There is a huge requirement for this type of device in Germany, there are currently thousands of Masimo RAD-8 and Nellcor PM100 sold per year.

Distributor pricing for both devices:-
Nellcor PM100 - supplied with DS100A sensor = EUR €650
Masimo Rad-8 - supplied with extension cable, but no sensor = EUR €490

Requirements for Homecare market, not currently listed on the provisional specifications of the VM-3160:

1) It will require a Nurse Call connection.
2) It will need adjustable Alarm volume.
3) The maximum alarm volume needs to be higher than that of the VM-2160 and VM-2500.

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19 Dec 2018 Steve Nixon
If for homecare, why nurse call?

Does Nellcor PM100 and Masimo Rad-8 have 1,2,3?

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19 Dec 2018 Steve Nixon
1) Yes we plan to add nurse call (same as Nellcor/Masimo), may not be on the initial release. Currently working with the notified bodies to get approvals prior to MDR time frames. After on-going discussions with notified bodies, we should be able to provide a time frame for implementation of nurse call function.

2) Yes alarm volume will be adjustable.

3) Yes the alarm will be louder than the current units (buzzer). The standards

now require a back-up alarm sounder, so the unit will have active speaker (louder) with a conventional buzzer as back-up.

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21 Dec 2018 Ryan Swaine
Thanks Steve. apparently the Nurse call is a prerequisite for their homecare market and I am lead to believe that both the PM100 and RAD-8 have them.

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05 Feb 2019 Ryan Swaine

125055	Ryan Swaine	31/07/18	Steve Nixon	Solid State O2 sensor for use inside ventilators

Feedback from Benno Bieri @ IMT Information Management Technology AG

The project they had in mind for this technology has been cancelled, but it may pop up again in the future.

With regards to the standards and requirements:

Q1) What is the measuring range you require?

A1) Roughly 21% to 26%

Q2) What is the maximum O2% allowed to be present in the ventilator?

A2) The standard requires the concentration to stay below 25% when no additional fire protection measures are foreseen

Q3) I understand that there are standards that require the O2 monitoring in certain ventilator designs, please can you give me the details of the standards, so we can research it?

A3) IEC 60601-2-12 particular standard for ventilators:

In order to reduce the risk to PATIENTS, to other persons or to the surroundings due to fire, ignitable material, under NORMAL and SINGLE FAULT CONDITIONS, shall not at the same time be subjected to conditions in which:

• the temperature of the material is raised to its minimum ignition temperature,

and• an oxidant is present.

NOTE Air mixtures with a volume fraction of less than 25 % oxygen are not considered to be an oxidant.

Q4) Environmental conditions within the ventilator; temperatures, pressure and humidity range?

A4) Typically 15 to 45..50 degree Celsius inside the housing (with ambient temperature typical spec 15 - 40 C (sometimes down to 10C)

Pressure is normal ambient air pressure from elevation of 100m to 3000m, sometimes up to 4000m (typical spec: 950 to 1069 mbar)
Humidity typical 20 to 95% without condensation

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24 Aug 2018 Steve Nixon

Priority Changed From 5 To 1 Thanks for the information.

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16 Oct 2018 Steve Nixon

As previously discussed have you explored other ventilator manufacturers, such as SLE, Acutronic...

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06 Feb 2019 Ryan Swaine

SLE are now aware of the sensor and will keep it in mind if required for any future developments.