

1st June 2020

T-7 medical oxygen sensor
Part number 0110057

Rationale for significant increase in price

The T-7 oxygen sensor was originally developed for the Teledyne TED range of oxygen analyzers and monitors, which were phased out in 2004. We have maintained the supply of this sensor in accordance with the requirements of the original PPQs (maintain accessories/parts >7 years). Compatible sensors have been produced by other manufacturers and the compatible sensors are used in other equipment such as ventilators and anaesthesia systems.

Besides the general increases (inflation/personnel/freight), the main reason for the increase is the large increases in manufacturing costs, mainly due to the cost of a specific specialist part (thermistor). The increase in manufacturing costs were effective in March, but we did not plan to apply any increase to the list price until we had exhausted existing stocks.

Going forward the T-7 may become prove to be commercially unviable if the pricing is too high for the market and sales decrease. We could look to second source an alternative thermistor, but as this is a significant component the sensor would need to be resubmitted for trials and third-party assessments, in order to meet the requirements of the EU MDD (Medical Device Directive) and then the (Medical Device Regulation). The extra costs incurred to meet the EU standards and directives would make this legacy sensor commercially unviable. Notified Body assessment may also deem it not possible to recertify, as the original associated oxygen analyzers and monitors have already been phased out.

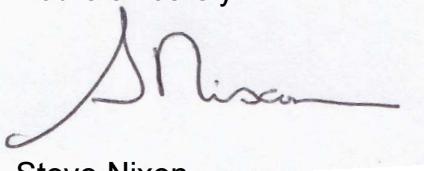
Unfortunately, the increased costs of maintaining the technical files, quality management systems and cost of increased number of audits for legacy products may well result in more and more products being prematurely phased out across the medical sector.

Further to requests from Cabinet Office and hospitals across the UK, over the last two months we have supplied T-7 sensors for use in ventilators in reaction to the COVID19 pandemic emergency. This was necessary as some OEM companies did not have sufficient stocks of compatible sensors, thankfully we had existing stocks and the production resources and capacity to assist.

Please note that we do also offer the T-7V (part number 0110058) which is a more competitively priced equivalent to the T-7.

Should you have any queries or require further information, please do not hesitate to contact me.

Yours sincerely



Steve Nixon
Director – Viamed Ltd.