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CC JSV
SW

FAX TRANSMISSION

Date : 14th April, 1999

From : Robert Hilman

To : Mr John Lamb
VIAMED Ltd.
15 Station Road
Cross Hills Keighly
West Yorkshire BD20 7DT
U.K.

Subject: Fax Hard silicon rubber pad

Dear Mr. Lamb,

With reference to your fax describing your findings concerning the difference in appearance of the material used in the hard finger pad, I am herewith bringing to your attention the following comments as forwarded by UDT to Medical Cables.

UDT has made no change in material, or in the tooling, and they have not changed vendors for the silicone rubber pads used in the finger clip pulse ox probes. Any difference noticed can only be attributed to lot variations. Liquid silicone rubber color may vary slightly from lot to lot due to molding and / or base material mixing. Many different suppliers such as Dow Chemical, Meghan, Nusil and Applied Silicone, produce this material. This is medical implant grade material of the highest quality. Should you need additional information, please feel free to contact me at 714 545 3469

Thanking you for your kind attention, I remain

Yours truly

Robert Hilman

cc: Chris Fontana VP.

FAX REF. :

15/04/99

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Robert Hillamn

MCI. 1340 Logan. Costa Mesa. CA 92626

Fax 001 714 545 7212

Dear Robert

Silcon Pads

Thanks for you quick reply. Unfortunately this may not answer the problem.

The variation in colour affects the transmission properties and therefore the response of the pulse oximeter.

We would expect this to be queried by our MDA.

Can you please obtain from UDT the part numbers and descriptions of the materials supplied by the different manufacturers.

If UDT cannot supply the tolerances we will need to contact the manufacturers direct from here.

I cannot stress too strongly how important this information is.

Kind regards

John S. Lamb