

Areas to be addressed

Medical Cables

Total QA ISO900/EN4600

FDA 510K

CE Mark & EMC

Documentation : Design Files: Manufacturing Files: Serial Numbers: Lot Numbers

Leaflets USA,

Labeling: Containers: Probe identification (e.g. Use only on Nellcor)

Manufacturers Product Liability

Probe Testing & QA

It is assumed that every probe leaving UDT will have been tested and the results logged and preferably a copy included with the probe.

This probably means original manufacturers equipment is required for the final tests.

I assume it will be the responsibility of UDT to acquire this equipment locally. Used equipment is available locally in the USA.

Viamed

Leaflets: Local languages

Local standards: World-Wide standards ex USA

Clinical Trials

Pricing

Need to establish pricing from UDT to Medical Cables on finished product and parts.

Pricing to Viamed on finished products and parts

Pricing to Master Distributors

Master Distributors need 15% off International Price List

Pricing to Sub distributors at International List

Pricing to customers

Need one International Distributors Price list

Target for Distributors to be able to sell at 30% less than OEM (Nellcor, Ohmeda etc. and make 25-30% GP. We will price to Distributors at Epic prices less 5% conditional on 30-45 day payment.

Warranty

There will be failures during the warranty period. Currently 12 months. I estimate this to be a maximum of 10%.

Most warranty failures will be traced back to user mistreatment but as a sales policy will still be repaired or replaced free of charge.

We would expect our distributors to keep the customer happy by giving an immediate exchange. The failed probe would then be repaired either locally or in the UK. I do not envisage return to the USA.

Do you have this factor built into your pricing or do you want it to be our total responsibility

Warranty from UDT

Warranty repairs carried out at local service centers at whose costs
Warranty products to be returned to Viamed or Medical Cables at whose cost
% of the pricing to include warranty costs
Third world No returns to USA or EEC
Testing of Probes by distributors

Payments

UDT 58 days
Master Distributors 30 days LC
Sub Distributors 30 days
Viamed and MC flexible by agreement
Packaging
Viamed was planning to receive the product in plastic bags and re-package in UK.
The preferred choice was a polypropylene plastic box:
This reduces freight and costs of packing are comparable to UDT cardboard boxes.
Drop shipping packaging
Product and packaging are subject to EEC legislation on labels
Also subject to re-cycling and re-usable legislation coming into effect soon (2000AD))

Inserts & Instructions

Viamed planning to print inserts in local languages.
Label product with Distributor labels
Drop shipments would place this burden on Master distributors
Drop shipments
Could be better to ship direct from USA to Master distributors the large quantities and small quantities from UK.
Invoicing from UK but copies need to be included in Packing for customs. Possible modem link to UK to print dispatch notes with pricing
Grey Imports Product can be purchased in the USA and shipped to other countries or purchased in Europe and shipped to the USA.
When it appears it causes problems.
Distribution contracts between Viamed and Distributors stipulate regions of sales responsibility
Viamed draft is available

OEMs

Manufacturers of Equipment: Low selling price
Joint venture decision Medical Cables & Viamed
Suggest Local Distributor is paid a nominal sum to look after our interests.
O.E.M's Re-labeling of the product range : very low selling price

Future Products

How do we finance future moulds : wrap round

Disposables

Disposables: Aristo cannot meet nellcor prices

Component prices

Need prices for all the components. including Flexible probe components, & wrap round. Repair of probes is a valuable and essential feature of the programme.

Extension Cables

Which types of cables will be available

Which samples to you have to reproduce.?

Need prices of the extension cables and the quantities to be ordered.

It is possible that this part of the range could be manufactured to order in the UK. This would reduce substantially the inventory costs.

Clip tool

Is the clip still required on extension cables using DB9 connectors. How far have we progressed

Need prices and quantities for this item. Is it universal and able to fit on all our cables.

Repairs

Our existing repair facility is purchasing components from Epic and it is essential that we second source all components prior to our product launch. We believe we have just been cut off.

The Nellcor 1 metre cable with integral DB9 and resistor is available I require prices for 100/250/500/and 1000 off. If the prices are right I probably have a market with other repair facilities throughout the world.

SpO2 Printed Circuit Boards

There is a need, presently satisfied by Nellcor and BCI, in certain countries to establish home produced monitors. Nellcor will only supply one probe per PCB so although the module is inexpensive the manufacturer only gets one probe. BCI are making a big impression into this market

Lead times

How long do you estimate it will take from the placing of a order to dispatch of product..

Some like Ohmeda/Nellcor/and Datex will be on monthly call off orders but most types will be either regular small orders or larger orders placed sporadically.

Lead time for small quantities?.

Generic probes without connectors available for both Finger and Flexible

It is important that we offer as many different types as possible at all times. Some of these can be prefabricated in the UK by using a generic probe and adding a connector.

Need a price for the Generic Probes

Complete Finger probes 4mtrs (13 ft) of cable no connector

Flexible Probes 4mtrs (13ft) of cable no connector

LED's

How many different types will there be

How long will it take to produce a new version from an original sample.

Packaging

We will be prepared to box the product in the UK and only require that you ship them in transparent bags with a label denoting Type and serial number.

Generic type probes should also have a serial number and some method of identifying the type of LED used

Clinical Trials

We have begun the process of locating in the UK a centre to carry out clinical trials