

Hi Tim,

Responses to Mortara UTK issues:

1. All documents have been uploaded to site.
2. The submitted User's Manual is the entire User's Manual for the UTK device.
3. Revised test report uploaded to site.
4. The UTK is used as a data transfer device, hooked up directly to an electrocardiograph machine. It is not intended to be a computer peripheral, however, in the future, this may be a possibility, but the computer would be a part of medical device system.
5. Per test engineer, this is in v3 of test report, and was in v2 as well.
6. Section eliminated. Report revised.

Thanks.

Regards,

Teresa White