

M2D2 Participation Application

Name: Christopher G. LaFarge

Organization: MedicaMetrix, Inc.

Address: 1 Old Sudbury Road, Wayland, MA 01778

Contact Information: e-mail: clafarge@mdmtx.com

Phone: 617-694-1713

I. Overview of Product

Product Name: ProstaGlove™, US Pat. 7,309,319

Medical Issue Addressed:

MedicaMetrix's *ProstaGlove*™ will permit acquisition of a *quantitative* measurement of prostate volume allowing more effective diagnosis and treatment of acute urinary retention, bladder outlet obstruction, prostate cancer, and problems of the prostate. By enabling this measurement at the point of care in the Urologist's office at a cost that is a fraction of the current 'gold standard', the trans-rectal ultrasound, *ProstaGlove*™ will re-define prostate examination and become the new standard for measuring prostate volume and growth.

Today, the digital rectal examination (DRE) of the prostate is the common method for determining its volume and growth. This examination is dependant upon palpation through the rectal wall with the forefinger and provides a subjective impression. DRE estimates of volume have been shown to be highly inaccurate when compared to direct measurement of the prostate (see figure at right).

Technical Description of Device:

The design of the *ProstaGlove*™ includes a disposable procedure glove with an embedded sensor which substitutes for an exam glove without changing the DRE exam procedure.

The glove includes a double-membraned index finger, a mechanism to inflate the outer membrane, a calibrated grid imprinted on the outer membrane, and a light emitter and encoder; and the hardware and software to scale, interpret and display the measurement, and infer appropriate volumetric measurements for the urologist.

The underlying technology used in the device is well known and understood, one which has been used for decades in optical mice, servo motors, and bar code readers among other applications. The device provides a reproducible and very accurate measurement of the distance the finger traveled from one anatomical landmark (lateral margin) to the other. This distance between lateral margins is strongly correlated to the overall prostate volume

Current Stage of Product Development:

We have developed a working prototype which has been tested on the lab bench with excellent results. Lab bench measurements of the 'palpable surface' of a Merck prostate model with a 2.8% error, of which 1.5% was inherent in the selection of 1 line/mm grid size for testing. The next step is to refine the prototype and create a manufacturing specification that will allow manufacturing of enough units for testing in human subjects to obtain data for regulatory approval.

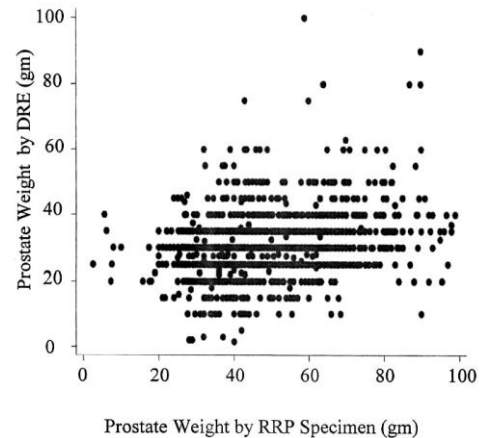
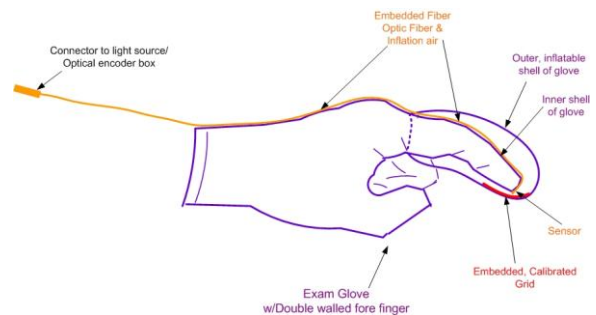


Figure: No correlation between DRE and Actual volume of the prostate. (*J. Urology*, Jan 2005).



II. Medical Significance

1. Describe the health issue or medical problem that the device intends to address and its hoped-for benefit.

Bladder Outlet Obstruction, BOO (a.k.a. “BPH”), is a multi-organ disease involving co-morbidities among the prostate, bladder, urethra, ureters and kidneys. As the prostate increases in volume it constricts the urethra which runs through its middle reducing the flow of urine, increase chronic retention. This in turn causes a number of complications throughout the urinary tract. There are also a number of reproductive system problems associated with this growth including epididymitis, prostatitis, and prostate cancer. Prostate volume is strongly correlated with severity of symptoms and disease onset, severity, and progression. The ProstaGlove™, will permit acquisition of *quantitative* measurement of prostate volume allowing more effective diagnosis and treatment of bladder outlet obstruction, acute urinary retention, prostate cancer, and other problems of the urinary tract and prostate. Individual patient time-series data will provide significant improvement in the objective tracking of changes in a patient's physical findings. Diagnosis and *early intervention* are significantly enhanced by knowing prostate volume and growth rate since the bladder obstruction due to prostatic enlargement is the root cause of all of these complications.

2. Describe the device's current status and potential effectiveness in addressing this medical problem. Please attach any supporting work, preliminary data or testing that is relevant in an appendix.

The *ProstaGlove*™ device is currently still in development. Lab bench testing has demonstrated a level of accuracy well above the design specifications, e.g., a 2.8% error (of which 1.5% was inherent in the selection of 1 line/mm grid size) compared with actual size. There is a large body of published literature supporting the importance of knowing prostate volume and growth rate in the diagnosis, monitoring, and treatment of prostate disease (a summary of a number of key articles may be found in Appendix 2).

3. Describe the potential advantages and disadvantages of this product over any existing or emerging products.

There are two key advantages that the ProstaGlove™ offers over existing procedures such as trans-rectal ultrasound and trans-rectal MRI. First, it is significantly less expensive (~\$15 vs. \$200-\$400+), and second, and most importantly, it is an in office-based procedure performed by the urologist that does not require a separate appointment with an imaging center, nor does it need to be performed by a technician, and it is within the bounds of today's credentialing requirements and stipulations.