

CDP

Cancer Diagnostic Probe



Fighting cancer with electronics,
form discovery to product



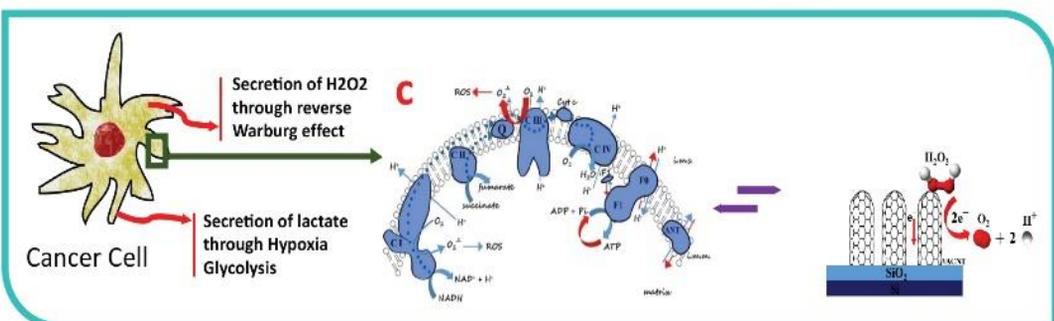
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Introduction

A novel label free device has been designed and developed to diagnose the presence of cancer in suspicious regions, based on determination of the hypoxia glycolysis in quantitative manner. Electrochemical signals produced due to cancer cell metabolism is the basis of our diagnostic procedure.

Importantly, integrated biosensor on the needles, named Cancer Diagnostic Probe (CDP), is fabricated and tested in real-time manner on the suspicious cancerous regions before and during surgery in mice species as well as human patients with breast cancer tumors (in vivo). The domain of suspicious margins with a resolution of 3mm was detected. It can be applied as an alternative method for frozen section pathology during the surgery with faster and more precise efficiency.





Introduction





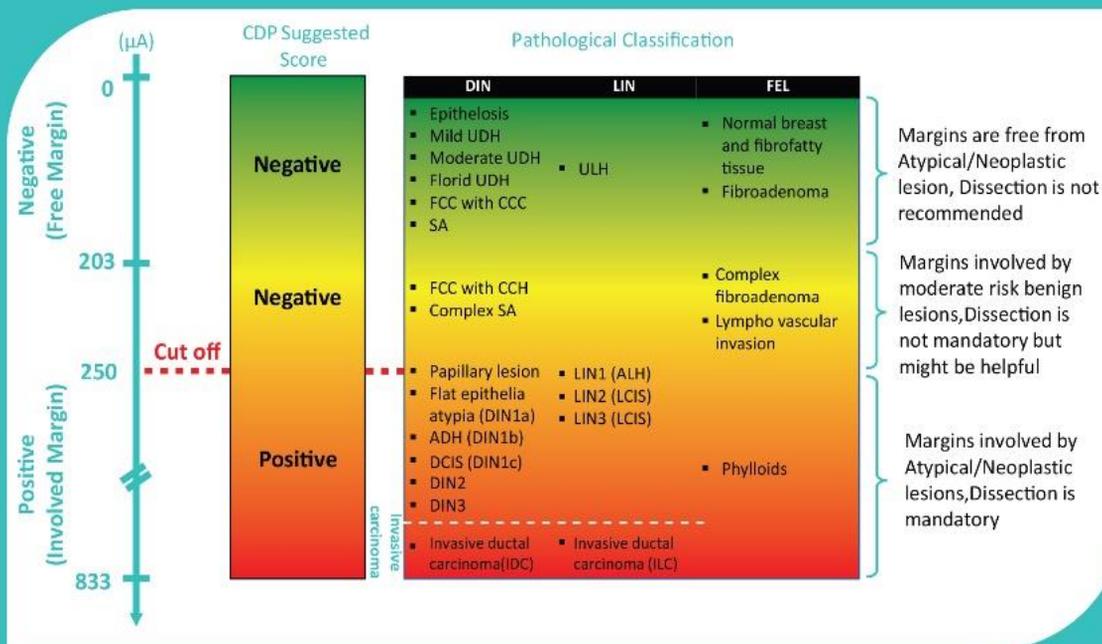
CDP Specifications

- Unique ability in intra-operative checking of internal margins (in-vivo)
- Real-time
- Disposable head probe to prevent disease transmission
- more than 97% sensitivity (correct positive scores on involved margins)
- more than 94% selectivity (correct positive scores on involved margins and correct negative scores on free margins)
- Integrated portable automatic electrochemical system
- Distinguished vocal and visual alarms
- Precise with declaration of Positive/Negative recommendation for dissection
- Ergonomic design
- Increased prognostic factor and survival rate of the patients





CDP Peak Responses Calibration Table Based on Pathobiological Classification(LIN,DIN,FEL)



DIN: Ductal Intraepithelial Neoplasia,
 LIN: Lobular Intraepithelial Neoplasia,
 FEL: Fibroepithelial lesion





Standards

IEC 60601-1: General requirements for basic safety and essential performance for medical equipment

IEC 60601-1-2: Medical electrical equipment – Part1-2: General Requirement for basic safety and essential performance- Electromagnetic disturbance.

ISO 62304: Medical device software life cycle process

ISO 10993-5,10: Biological evaluation of medical devices; tests for irritation, delayed type hypersensitivity and in-vitro cytotoxicity.

ISO 13485: Medical devices-Quality Management System-Requirements for regulatory purposes



Specification	Model: SG1
Classification	Medical Device Class C 
Power supply	220 V AC/ 50 Hz ~
Power consumption	25 watts
Maximum current (while charging)	150mA
Minimum measurable current – resolution (with Probe connection)	1nA ±5%
Isolation class (when used with AC / DC adapter included)	Class II 
Readability peak indicator	0uA-300uA
Functioning	60 min ON
Battery type	Godox VB18 II-IV 2200~AH
Battery life	12000 fully charge/discharge
Battery charging time	60min
Charger Type	Godox vc18 12-8v 2500
Charger pin model	3 pin
Connection device	Bluetooth module
Connection specification	Maximum 12m connection length



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