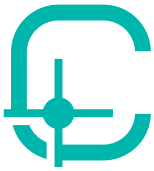


User's Manual

Cancer Diagnostic Probe

CDP instruction manual
version v. En5.0
June 06, 2019
Serial Number: CDP10003A
Model: SG3

Table of Contents

1 - GENERAL INFORMATION 5

1.1 - Aim. 5

1.2 - Symbols used 6

1.3 - Signal words 7

1.4 - Servicing request 8

1.5 - Demolition. 8

1.6 - Disposal Of Waste Batteris. 8

1.7 - Guaranty and Warranty 9

1.8 - Labelling 9

2 - WARNINGS 9

2.1 - General warnings 9

2.2 - Specific warnings 11

2.3 - Contraindications and side effects 14

2.4 - Battery Warnings 14

2.5 - Environmental conditions 15

3 - PRODUCT DESCRIPTION 15

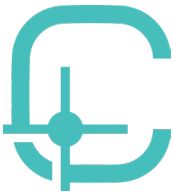
3.1 - Intended use 15

3.2 - Main components. 16

3.3 - Model 20

3.4 - Technical information. 20

4 - INSTRUCTIONS 21
4.1 - Transport and storage 21
4.2 - Preparation 21
4.3 - Functioning 23
4.4 - Importance of cleaning 24
5 - Alarms Interpretation 24
6 - Operating Guideline 29



CDP
CANCER
DIAGNOSTIC PROBE

1 - GENERAL INFORMATION

Content

✱ This instruction manual contains essential information about Cancer Diagnosing Probe functioning

✱ Before use, this manual should be thoroughly reviewed for the necessary information and precautions.

✱ Keep this manual in a safe and accessible location (e.g., in its own original packaging), away from any substances or liquids which could compromise its perfect legibility.

✱ This manual contains the cleaning methods recommended by Nano Hesgarsazan Salamat Arya for CDP probe.

✱ If you have any questions or comments about any information in this manual, please contact Nano Hesgarsazan Salamat Arya Co.

1.1 - Aim

The aim of this manual is to supply all the necessary information so that the client, will not only attains adequate use of the appliance; he/she will also be capable of using the instrument in the most autonomous and secure way possible. This includes information regarding technical aspects, functioning, maintenance, spare parts and safety.

1.2 - Symbols used

Symbol Meaning

Symbol	Meaning
	General or specific warning
	See instructions for use
	Serial number
	Indicates the manufacturer's batch code or lot
	Catalogue number
	Instrument isolation class II (only when connected with cable car cigarette lighter, for models where it is expected)
	Type B instrument
	Applied Part type BF
	Do not reuse
	Do not use if the package is damaged
	Do not re-sterilize
	Alternating current (where applicable)
	Direct current (where applicable)
	Earth (Ground)
	Store in a cool, dry place
	range of humidity to which the medical device can be safely exposed
	Storage temperature
	should not be disposed of in a landfill

Symbol	Meaning
	Do not put Li-Ion battery on trash box
	Li-Ion Battery recycling
	OFF Power
	ON Power
	In-vitro diagnosis device
	Sterilized using plasma Hydrogen peroxide
	manufacturer
	Date of manufacture
	Indicates the date after which the medical device is not to be used
	Refer to the instruction manual

1.3 - Signal words

The following signal words are used throughout this manual:

⚠ Warning:

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

ⓘ Caution:

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

Note:

Indicates additional helpful information.

1.4 - Servicing request

For any information regarding the correct interpretation of the instruction manual, use, maintenance, installation, and restoration of the product, please contact Nano Hesgar Sazan Salamat Arya, Unit 1, No. 9, E 21st St, Azadegan Boulevard, North Amirabad, Tehran, Iran.
Tel: +98 21 88335197, Fax: +98 21 88335197
Info@NanoElecHealth.com .

In order to facilitate the assistance service, please always indicate the serial number (SN) and Lot number (LOT) shown on the label applied on the box or the device.

1.5 - Demolition

The crossed dustbin symbol applied on the product or on its packaging indicates that the item should be disposed of separately. The correct disposal of the item when use has terminated, is defined and organized by the manufacturer.

The end user, who has to proceed with disposal, must therefore contact the manufacturer and follow the system and procedures the manufacturer has organized for the separate collection, treatment and disposal at end-of-life. The correct separate collection of the out of use device which will permit recycling, treatment and destruction in an ecologically friendly manner and will contribute to avoid possible negative effects on the environment and for health while privileging the reuse and/or recycling of the collected waste components. Please note that the owner will be subject to administrative sanctions in case of unauthorized disposal of the item.

1.6 - Disposal Of Waste Batteris

This symbol on the battery or on the packaging indicates that the battery provided with this product shall not be treated as household waste. By ensuring these batteries are disposed of correctly, you will

prevent potentially negative consequences for the environment and human health which could otherwise be caused by inappropriate waste handling of the battery. The recycling of the materials will help to conserve natural resources. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, your household waste disposal service or the shop where you purchased the product.

1.7 - Guaranty and Warranty

RDSS products have one year of unconditional warranty and 10 years of after-sales services.

1.8 - Labelling

Each device has got an identifying label, positioned on the device itself and/or on the box. This label includes information about the manufacturer, the product, the CE mark, the serial number (SN) or lot number (LOT). It must never be removed or covered.

2 - WARNINGS

2.1 - General warnings

⚠ The product must be used by trained personnel only, having attended specific training for this device and not for similar products.

⚠ Before carrying out any kind of operation on the appliance (training, installation, use), the operator must carefully read the enclosed instructions, paying particular attention to the procedures to be followed for installation and for correct use.

⚠ In the case of any doubts in correct interpretation of the

instructions, please contact Nano Hesgarsazan Salamat Arya Co. for any necessary clarifications.

⚠ Check the appliance regularly, carry out the prescribed maintenance, as indicated by the manufacturer in this user's manual.

⚠ If any failure or incorrect functioning of the device is detected, it must be immediately substituted with a similar item so that the rescue procedures are guaranteed without any interruption.

⚠ Do not alter or modify the appliance in any way; any such interference could cause malfunctions and injury to the patient and/or rescuer.

⚠ The appliance must not be tampered in any way with (modification, adjustment, addition, replacement). In such cases, all responsibility for any malfunctions or injuries caused by the appliance will be denied.

⚠ Register and store with these instructions: lot number, place and date of purchase, first date of use, date of checks, name of users, any comments.

⚠ ***Attention:*** laboratory testing, post production tests, instruction manuals cannot always consider every possible scenario for use. This means that in some cases the performance of the product could be notable different from results to date obtained. Instructions are continually being updated and are under tight surveillance of fully qualified staff with adequate technical formation.

⚠ The best instructions are the continuous use under the supervision of trained and competent personnel.

⚠ Ensure that all the necessary precautions are taken in order to avoid the hazards that can arise as a result of contact with blood or body fluids.

⚠ Using device in anyway other than described in this manual is forbidden.

⚠ There is a LED on the charger which indicate whether the probe properly connected to the charger or not. The red color means the probe correctly connected to charger and charging process continues until the LED color turns in to blue which means charging is completed. When no color has been shown means probe is not correctly placed on charger. Make sure that the probe is correctly installed on its charger

⚠ The maximum distant between probe and computer in an operating room should be less than 12 meter and surgeon needs to check the results on computer regularly in order to avoid probe misconnection to the computer.

⚠ Handle with care.

2.2 - Specific warnings

⚠ Training routines must be registered on a special registry in which the names of those trained, of the trainers, date and place are indicated. This register which will certify the eligibility of the operators to use the CDP probe has to be kept for a period of 10 years after the disposal of the device itself. This register will be made available to the competent authorities and/or manufacturer if requested.

⚠ Before using the device, the perfect operating state of the device must be checked as specified in the Instruction manual. If any damage or abnormalities which could influence the correct functioning and the safety of the device, the patient and or the user are detected, the device must be immediately removed from service and the Manufacturer must be contacted.

⚠ Before connecting the appliance, always ensure that the electrical outlet indicated on the device labeling and the type of plug used, correspond to those of the power network to which you want to connect it.

⚠ If the plug supplied with the unit is incompatible with the

electrical outlet, contact a qualified technician to replace the plug with a suitable type. In general, it is unwise to use adapters, multiple sockets and/or extensions. Whenever their use was indispensable, you must use accessories in compliance with safety regulations, although care should be taken not to exceed the maximum power incurred, which are indicated on the adapters and extensions.

⚠ The device can't be used for external margins.

⚠ When the device is being used, the assistance of qualified staff must be guaranteed.

⚠ The device should not be exposed to or come into contact with any source of combustion or inflammable agents.

⚠ Store in a cool, dry, dark place and do not expose to direct sun.

⚠ Do not store the device underneath any heavy objects which could cause structural damage.

⚠ Store and transport the device in its original packaging.

⚠ Never dismantle the appliance. For any kind of intervention, contact Nano Hesgarsazan Salamat Arya technical service. Any intervention, even minimum, on the device voids the warranty, and in any case does not guarantee the fulfillment of the technical requirements.

⚠ Use only original accessories.

⚠ Do not leave the device connected to the power outlet when it's fully charged.

⚠ Do not pull cable to remove plug from the socket; to disconnect hold plug with fingers.

⚠ Use and keep the instrument in a safe environment, protected from bad weather condition and keep off excessive heating.

⚠ Never immerse the appliance in water.

⚠ Wait for the connection sound after pressing the Connect key. If the CDP probe is on, after about 2 seconds, the sound of the connection is heard. Avoid repeatedly pressing the Connect key.

⚠ This appliance must be used exclusively for which it was designed and as described in this manual. Any other use is considered improper and therefore dangerous and the manufacturer cannot be held responsible for damage caused by improper, incorrect and/or unreasonable use.

⚠ No electrical and/or mechanical part contained in the CDP is designed to be repaired by the customer and/or user. Do not open the device; do not touch the electrical and/or mechanical properties. Always contact Nano Hesgarsazan Salamat Arya technical service.

⚠ The lead battery contained within the medical device should not be treated as household waste. Dispose of this component at a designated collection point for recycling.

⚠ Never use CDP HeadProbe when the package is open or scratched. Always make sure the HeadProbes are sterile.

⚠ CDP probe heads are intended to be in contact with patient's tissue during operating procedure. Make sure the proper contact to the tissue in order to avoid any noise due to inappropriate contact.

⚠ As probe heads are disposable, after surgical procedure ended they should be removed immediately in to the safety box

⚠ CDP probe should be utilized with specific and sterile cover which should be removed immediately in to infectious bag after surgical procedure terminated. Also the probe itself can be sterile by using standard sterilization methods including ethylene oxide and formalin pills.

⚠ During the time that probe reads data from the live tissue environment, the indicator embedded on it is red. After reading signal has been completed, the red indicator light is off and the

surgeon can remove the probe from the desired location. It is highly recommended that the probe remains in the environment as long as the indicator light is on, this does not last more than 10 seconds.

⚠ Never try to re-sterilize the CDP HeadProbes. The HeadProbe are single used only.

2.3 - Contraindications and side effects

The use of this device, if used as described in this manual, does not present any contraindications or collateral effects.

2.4 - Battery Warnings

⚠ IMPORTANT SAFETY INSTRUCTIONS-SAVE THESE INSTRUCTIONS. DANGER-TO REDUCE THE RISK OF FIRE OR ELECTRIC SHOCK, CAREFULLY FOLLOW THESE INSTRUCTIONS.

⚠ GHS classification: Not available (This product is outside the scope of GHS system since it's considered as an "article")

⚠ Inhalation: The steam of the electrolyte has an anesthesia action and stimulates a respiratory tract.

⚠ Skin contact: The steam of the electrolyte stimulates a skin. The electrolyte skin contact causes a sore and stimulation on the skin.

⚠ Eye contact: The steam of the electrolyte stimulates eyes. The electrolyte eye contact causes a sore and stimulation on the eye.

⚠ Especially, substance that causes a strong inflammation of the eyes is contained.

⚠ Environmental effects: Since a battery cell remains in the environment, do not throw out it into the environment.

⚠ Specific hazards: If the electrolyte contacts with water, it will generate detrimental hydrogen fluoride. Since the leaked electrolyte is inflammable liquid, do not bring close to fire.

2.5 - Environmental conditions

CDP unit:

Storage humidity: from 0 to 93%
Functioning temperature: from +5 to +60 °C
Functioning humidity: from 10 to 93%
Storage temperature: from -25 to +70 °C
Minimum battery charge level for accurate working: 15%

HeadProbe:

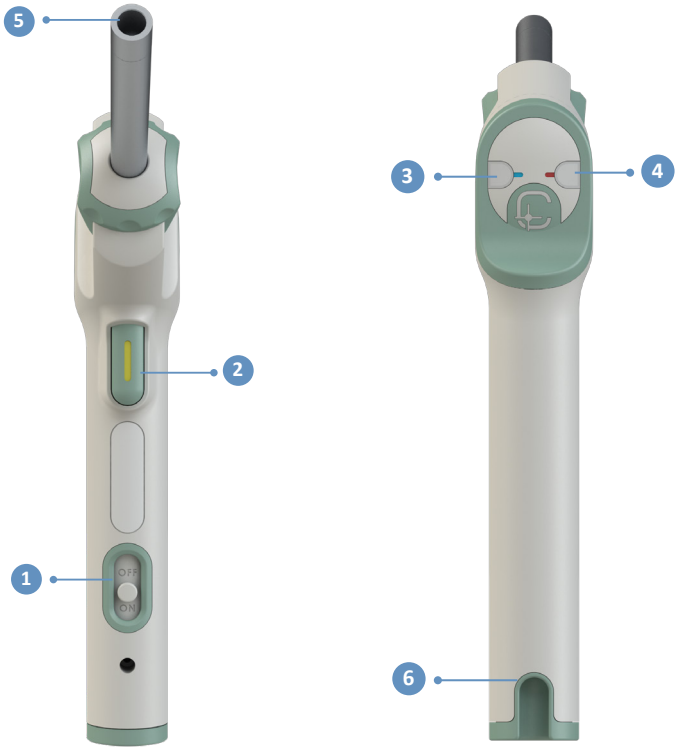
Functioning temperature: from -10 to +70 °C
Functioning humidity: from 0 to 80%
Storage temperature: room temerature
Storage humidity: from 0 to 80 %

3 - PRODUCT DESCRIPTION

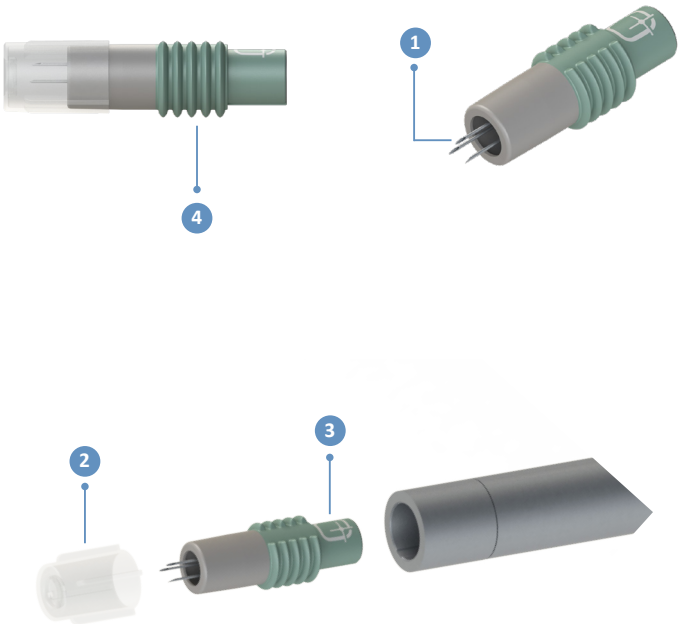
3.1 - Intended use

Cancer Diagnostic Probe's (CDP) aim is to diagnose the presence of neoplastic cells in internal boundaries (Cavity side margins) of patients under gone breast cancer surgery. The system determines the hypoxia assisted glycolysis metabolism associated with cancer cells in a real time quantitative electrochemical manner. This probe is calibrated based on World Health Organization (WHO) ductal intraepithelial neoplasia (DIN) classification system.

3.2 - Main components

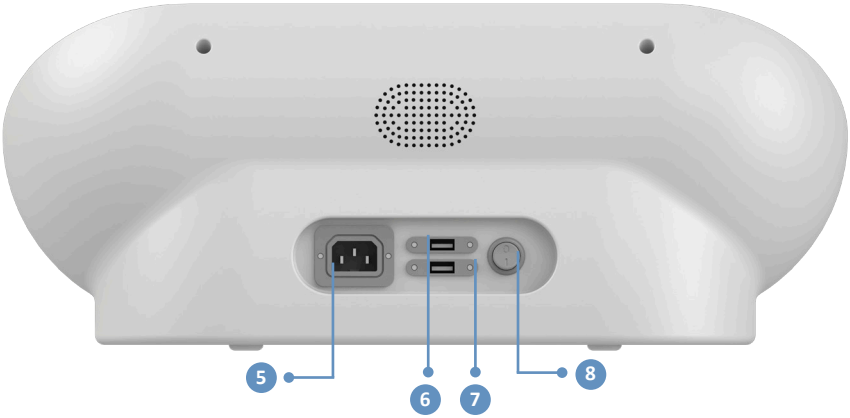


1	Power Key
2	Test key
3	Busy LED place
4	Ready LED place
5	HeadProbe entrance
6	Charger internal pin



1	HeadProbe needles
2	HeadProbe Cap
3	HeadProbe connector
4	Needles plastic holder


2
3
1
4
Cancer Diagnosis Probe Breast
Connected
Negative
Delta1
Delta2
Neoadjuvant
Adjuvant
Lymph node


5
6
7
8

1	AC Power connection
2	Up
3	Down
4	Charging station
5	Power Input
6	USB1
7	USB2
8	On-Off Button
9	Connection button on software
10	Test key on software
11	Diagnosis results
12	Connection status
13	Lesion suspicious to surgeon button
14	Battery percentage

3.3 - Model

Model: SG3

REF CDP10003A Nano Hesgarsazan Salamat Arya (NHSA) – Portable Cancer Diagnostic Probe 11.1 V, with battery & Bluetooth

3.4 - Technical information

Specification	CDP10003A
Classification	Medical Device Class II a
Power supply	8.3V-0.58A DC ⎓
Power consumption	0.7VA
Maximum current (with Probe connection)	1mA ±5%
Minimum measurable current – resolution (with Probe connection)	1nA ±5%
Isolation class (when used with AC / DC adapter included)	Class II
Compliance potential	±5V
Weight	0.285Kg
Dimensions	50 x 160 x 40 mm
Readability pick indicator	0uA-300uA
Functioning	60 min ON
Battery type	Godox VB18 II-IV 2200~AH
Battery Charge	7.4v, 860mAh
Battery life	12000 fully charge/discharge
Battery charging time	40min
Charger Type	Godox vc18 12-8v 2500 2500~ah
Charger Input	220 V ~/ 50 Hz ~

Specification	CDP10003A
Charger Output	8.3V-0.58A DC
Connection device	Bluetooth module
Connection specification	Maximum 12m connection length

4 - INSTRUCTIONS

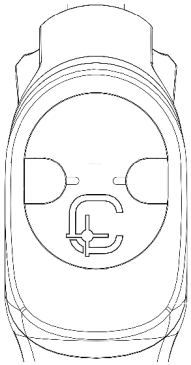
4.1 - Transport and storage

Before transporting the appliance, make sure that it is correctly packed also assure that there are no risks of shocks, bumps or falls during the transportation.

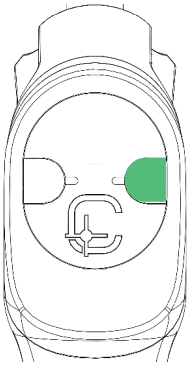
Keep the original package in case of any further transport and for storage. Any damage occurred to the appliance during transport and handling is not covered by the guarantee and the client is responsible for repairs or replacement of the damaged parts. The device must be stored in a dry, cool area away from direct sunlight. It must not be in contact with any substances or chemical agents which could cause damage and reduce safety characteristics.

4.2 - Preparation

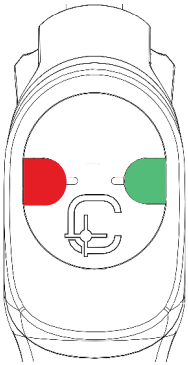
The appliance must be checked before every use so as to reveal any working abnormalities and/or damage caused by transport and/or storage. CDP probe status can be determined with green and red LEDs placed on top of the device. The below table shows CDP Probe working status and corresponding LED configuration.



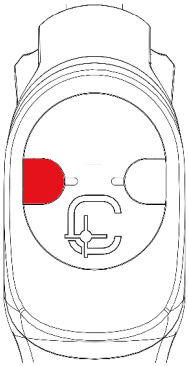
CDP Probe is OFF



CDP Probe is ON and ready to use



CDP Probe is under test process and busy



CDP Probe has technical problem at the moment

⚠ **On opening the packaging and before each use, check the integrity of the device, paying particular attention to the presence of damages to the HeadProbe connector, which could make accessible internal parts under tension, and cause breakage and/or peeling of power cable. In such cases do not connect the plug to the power outlet.**

4.3 - Functioning

✱ Turn on the CDP Unit.

✱ Turn on the probe; when the green LED turns on, Touch the connect icon on the software.

✱ After 2 seconds you can hear connection sound status from device.

✱ Place the HeadProbe on CDP, put the HeadProbe's needles into the margin and push Test key on probe.

✱ When you push the test key, red (busy) LED turns on; wait for 7 seconds while red LED turns off.

✱ Test result will appear on the monitor.

✱ Replace HeadProbe with a new one and repeat above steps.

⚠ Ⓧ Do not reuse HeadProbes, HeadProbes are disposable.

Use only the original disposable HeadProbes provided by the manufacturer.

Li-ion Before using the device, check the charge state of the battery. Before each use, proceed with the charging of the battery. To maintain a good state of the device, recharge the battery every 1-hour use.

4.4 - Importance of cleaning

The medical literature reports incidents of cross-contamination resulting from improper cleaning, or disinfection. It is strongly recommended that after using CDP, clean its surface with Alcohol-based rapid disinfectant.

⚠ Do not spray disinfectant directly at connector.

When selecting appropriate methods and conditions for cleaning, disinfection, and sterilization, follow the policies at your institution, applicable national laws and standards, and professional society guidelines and recommended practices, in addition to the instructions given in this manual.

5 - Alarms Interpretation

The response of CDP was categorized to four main zones include: dark Green, light green, yellow and Red through DIN classification based on 2013 WHO edition. These alarms were calibrated for both IMs and "suspicious to surgeon regions".

In this regard,

✱ Dark green zone named as "Free" region contains: benign breast tissues (e.g. normal breast tissue, glandular and lobular usual hyperplasia, fibrosis, simple cysts,);

► CDP recommends no dissection of "free" lesion.

✱ Light green zone named "low suspicious" lesion contains: SA, fibrocystic changes (FCC) with columnar cell changes (CCC), florid hyperplasia;

► CDP suggests that it is better to dissect the low suspicious lesion.

✱ Yellow zone named "High suspicious" lesion contains: foci of ADH, LDH, and FCC with a foci of Florid DH;

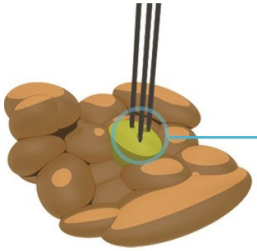
► Total removing the margin contain one high suspicious lesion is preferred.

► If the surgeon hesitates to remove total margin the lesion with the distance of 0.5 cm from each side must be dissected.

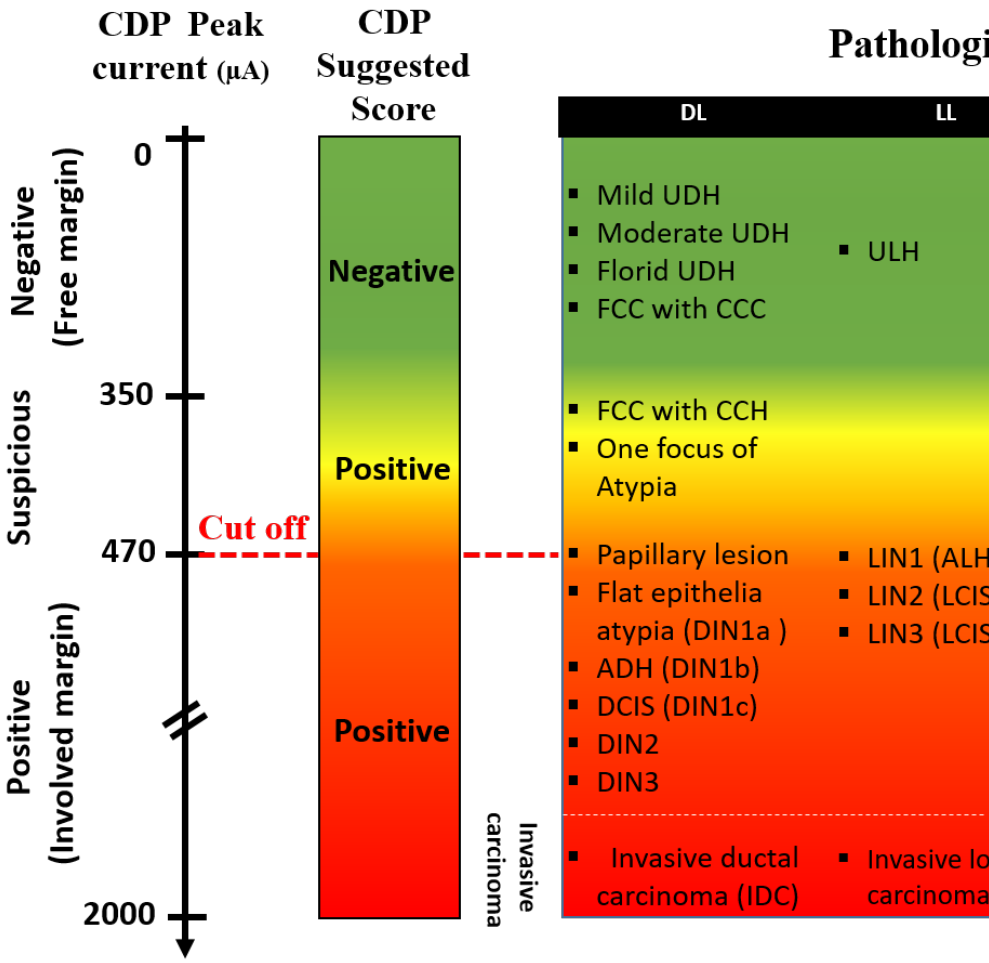
► If one of neighboring lesions were also "High suspicious", the recommendation for margin dissection would become crucial.

✱ Red zone named "positive" lesion contains: ADH, IDC, DCIS, Phyllodes sarcoma;

► according to CDP, dissection of the margin contained at least one positive lesion is mandatory.

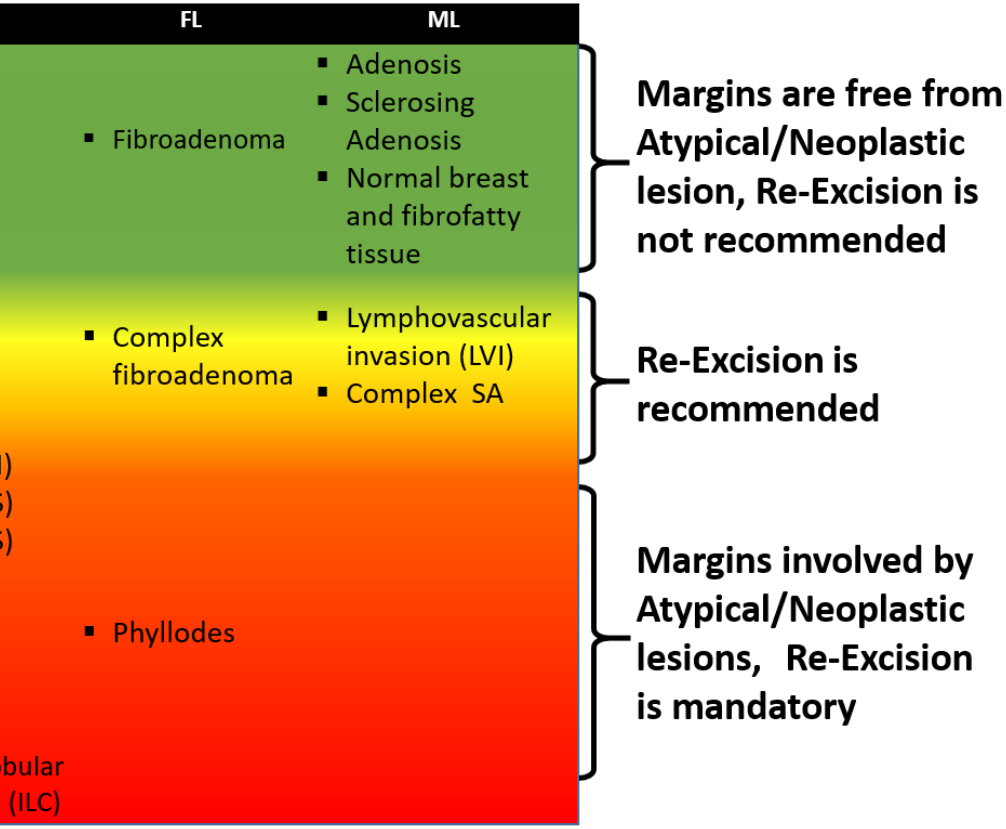


CDP suggestion for low suspicious regions is to dissect targeted area with a diameter of 5mm .



DL: Ductal Lesion, **LN**: Lobular Lesion, **FL**: Fibroepit

ical Classification



helial lesion, **ML:** Miscellaneous Lesion

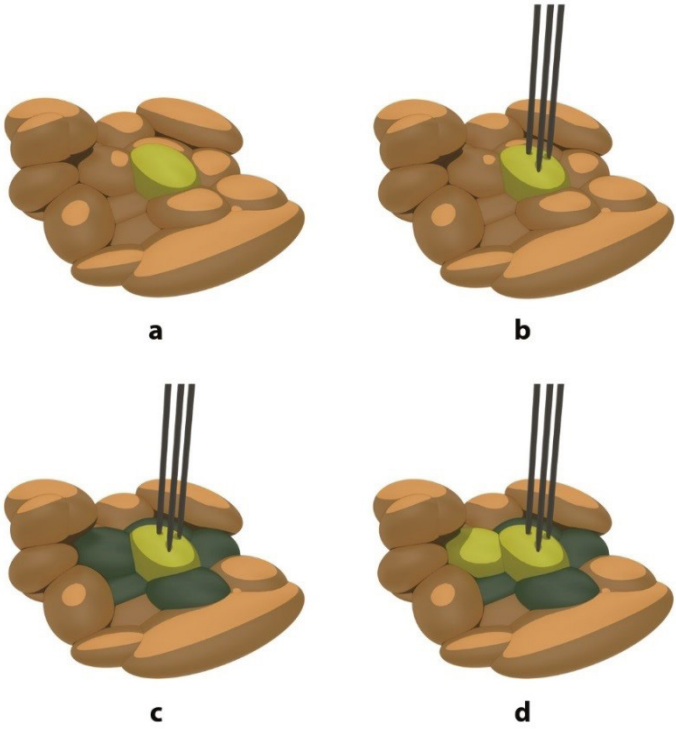


Image1. a) High suspicious area; b) the area around the suspicious region should be checked. c) If the neighboring regions around the “high suspicious” area (In the distance of 0.5 cm) were in green or low suspicious zones, dissection of the suspicious region is sufficient and there is no need to remove a layer of the margin, otherwise, in case of d) existence of other high suspicious regions around the first one, dissection of a layer is obligatory.

6 - Operating Guideline

There are three protocols to check Internal Margins (IMs) of the patients:

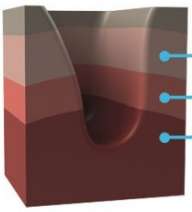
Full Scan:

* In each patient, all IM surfaces (posterior, anterior, superior, inferior, medial and lateral) must be checked with the distance of 3cm.

* Note: One individual HeadProbe must be used for each test.

Checking suspicious region to surgeon: When a lesion is suspicious to the surgeon due to his/her physical touching or the historical radiology images of the patient, Adenosis of the cells might be found. In this case, one should click the "*suspicious regions to surgeon*" icon and check the suspicious region. If the result was positive whole of the margin must be dissected. Otherwise CDP doesn't recommend dissecting the lesion.

Closest margins to the tumor: In the margins with the closest distance to the tumor, the operator should divide the margin into three regions include: upside, middle-side and downside, then, check each margin separately.



In the margins with the closest distance to the tumor, one should divide the margin into three regions include; upside, middle-side and Downside and check each region separately.

ATTACHMENT A – TRAINING REGISTER

⚠ The product must be used only by trained personnel who have attended specific training for the use of this device and just for products with similar characteristics

⚠ Keep this document at least 10 years after the end of life of the device.

Operator's name	Training date		Training method (user›s manual, during service, former class, etc.)	Trainer
	Basic Trainig	Advanced Training		

ATTACHMENT B – MAINTENANCE REGISTER

⚠ Perform the required maintenance and to respect the life span of the device, as indicated by the Manufacturer in the User's Manual.

Service Date	Kind of service (maintenance/ chek/extension of span)	Operation made on the Device	Result	Person in change of service (operator/ Authorized centre/ manufacturer)

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