



USER INSTRUCTIONS

ISSUE J



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|---------------------------|--|
| 1. PRO neck | Sensor pushes onto this location : see section 2 |
| 2. Red LED | Illuminates when Operative Care is Advised (OCA) : see section 4 |
| 3. Yellow LEDs | Illuminates when Preventive Care is Advised (PCA) : see section 4 |
| 4. Green LED | Illuminates when no treatment is required : see section 4 |
| 5. Blue LED | Illuminated:
constantly = battery charging,
intermittent = measurement in progress |
| 6. Tooth icons | Sensor is attached and indicates which surfaces can be measured |
| 7. Low battery symbol | Battery charge has only 90 minutes remaining |
| 8. Busy symbol | Shows during measurement and during system test |
| 9. DOWN key | Scroll down through menu items |
| 10. ENTER key | Confirm next action |
| 11. Lip hook cable socket | Lip hook cable plug (18) connects to this |
| 12. Charging contacts | At rear and bottom of PRO, used to connect to the charging cradle |
| 13. CANCEL (on / off) key | Cancel task or longer press to switch on / off |
| 14. UP key | Scroll up through menu items |
| 15. Bluetooth icon | Bluetooth enabled |
| 16. Alphanumeric display | Shows both results (digital) and scrolling messages |
| 17. Lip hook cable | Connects the lip hook or test adaptor to the PRO |
| 18. Lip hook cable plug | Connects to the lip hook cable socket on the PRO (11) |
| 19. Lip hook socket | Connects to lip hook connection pin (21) |
| 20. Lip hook | Placed on patient's lower lip |
| 21. Lip hook pin | Connects to lip hook socket on cable (19) |
| 22. Sensor | Connects to PRO neck (1) : see section 2 |
| 23. Sensor tuft | Contact point for measurement, placed on tooth site to be measured |

Congratulations on your purchase of this CarieScan PRO.

This leading edge product identifies dental caries earlier and more accurately than any other product on the market. Used in accordance with these directions the CarieScan PRO will give years of reliable accurate detection readings. Monitoring is simplified with clear numeric information showing disease progression or improvement on the integrated screen. Internal menu functions allow you to customise the product including enabling LED and system prompts.

The PRO should be used to assess the occlusal and free smooth surfaces on teeth.

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1. Box Contents

Order codes	Item	Quantity
CP-SYS-01	CarieScan PRO system:	
	PRO	1
	Display Stand	1
	Charging Cradle	1
CP-STC-01	Lip Hook Cable	1
CP-PSU-01	Power Supply Unit	1
CP-TSN-01	Cable Test Adaptor	1


2. Other Accessories

Order codes	Item	Quantity
CP-PRF-01	CarieScan Patient Record Forms	50
CP-LHK-01	Lip Hook	1
CS-OCC-50	CarieScan Sensor Pack	50

3. Charging the CarieScan PRO

Before using the PRO for the first time, charge the battery for a minimum of 8 hours (overnight).

The mains plug from the Power Supply Unit (PSU) should be plugged into an ac mains socket. The dc jack from the PSU must be inserted into the power socket at the rear of the Charging Cradle. To charge the CarieScan PRO, place it into the Charging Cradle. The blue LED on the CarieScan PRO will illuminate until the PRO is fully charged or until it is removed from the cradle. The product is disabled from use during charging.

The Low Battery status indicator  will show when the PRO has less than about 90 minutes of charge remaining.

The CarieScan PRO has been certified for use via the charging cradle with only the supplied power charger. Any attempt to charge or power the CarieScan PRO from any other source will render the product warranty permanently invalid.

4. Getting Started

How to Use the PRO

1. Ensure the PRO is charged.
2. Before first use each day, test the PRO as per section 6.
3. Ensure the PRO, cable and stand have been cleaned with alcohol based wipes.
4. Place the PRO in the stand with the cable inside the patient area.
5. Place a new sensor and lip hook into the patient area.
6. Clean the teeth and remove any intra-oral appliances.
7. Ensure there is no sensor on the PRO.
8. Connect the Lip hook connector cable to the PRO by pushing the plug fully into the socket on the side of the PRO.
9. If your cross infection methods require the use of a protective sheath apply this now by sliding the PRO inside the sheath with the tip of the PRO projecting out of the top of the sheath. We recommend *Pinnacle Syringe Sleeve with Opening*.
10. Turn the PRO on by pressing and briefly holding the 'CANCEL' key.
11. The display will show all segments and run a self test. Satisfactory completion of the self test is indicated by 'OK' being shown on the display followed by 'ATTACH SENSOR'.
12. Use cotton wool rolls to isolate the quadrant to be measured to prevent moisture from affecting readings.
13. Connect the Lip Hook to the connector cable, and place the hook over the patients lower lip.
14. Attach the sensor to the PRO. With the display of the PRO facing you, the tuft on the sensor should be facing away from you. Push the sensor onto the neck of the PRO until it 'clicks'.
15. If the 'Air Dry' prompt is enabled the PRO will beep and flash the LEDs while the display reads 'AIR DRY TOOTH'. This is to remind you to ensure that the tooth to be measured must be air dried for 5 seconds using a 3-in-1 syringe*. This prompt can be disabled via the menu.
16. Press the 'ENTER' key to acknowledge this prompt. The PRO will beep and the display will read 'PRESS ENTER TO START'
17. Press the 'ENTER' key again. The PRO will beep and the blue LED will flash.

18. Place the sensor on the tooth site to be measured. As soon as the sensor is placed on the tooth, the measurement cycle begins. Progress is indicated by four beeps after which the reading is displayed numerically on the display. An average measurement takes approximately 4 seconds. The measurement cycle will be interrupted if you remove the sensor from the tooth before a new result is displayed.










Measurement of occlusal surface

19. On completion of a successful measurement, record the value and site. We recommend the use of a CarieScan patient record form.
20. To continue measuring on additional tooth sites, place the sensor on another tooth site (ensuring the site is dry), the PRO will automatically start another measurement cycle.
21. When you have completed all the measurements you wish to take:
 - Switch the PRO off by pressing and holding the CANCEL key until the display shows “BYE”
 - Remove the hook from the patients lip and dispose of as sharp contaminated waste.
 - Remove the sensor from the CarieScan PRO by squeezing the sensor on the side grips to release the catch. All sensors must be disposed of as sharp contaminated waste.
 - Remove the sheath and dispose of as contaminated waste.
 - The CarieScan PRO, Connector Cable and stand should be cleaned with alcohol-based wipes.
 - Return the PRO to either the stand or the charging unit as necessary.

**Note: Drying time is based on standard air pressure of 40psi.*

5. What the Readings Mean

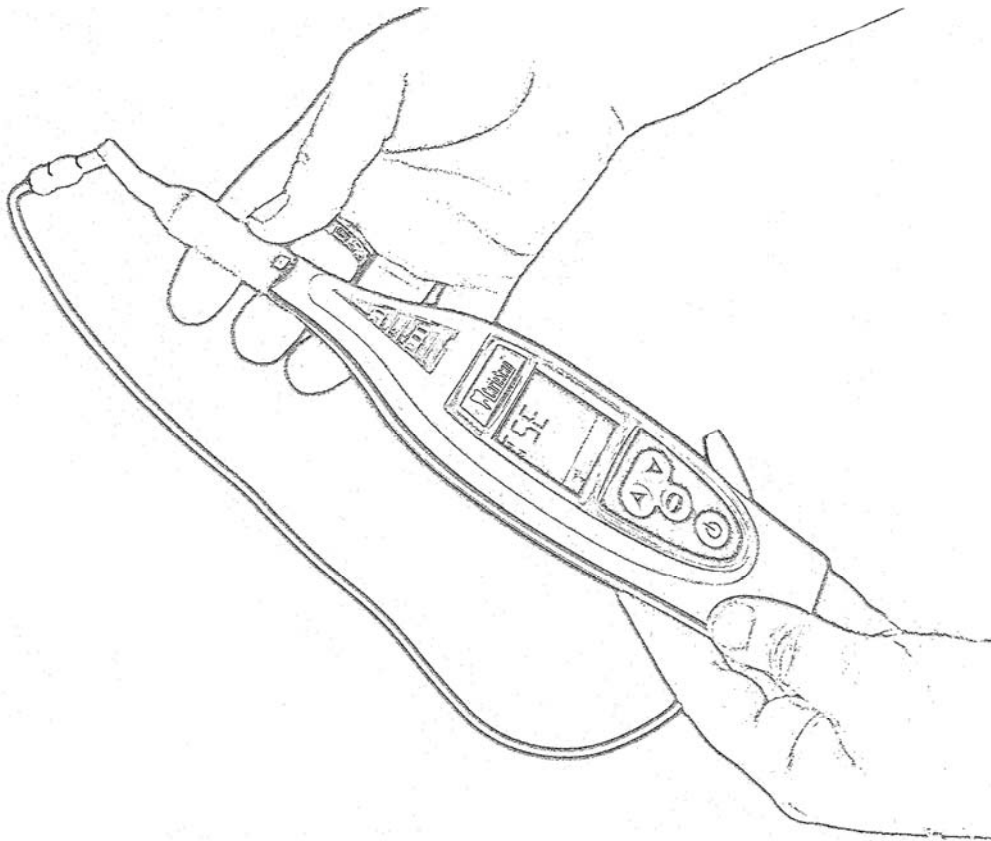
	<p>0</p>	<p>OBSERVATION: Sound tooth surface</p> <p>ADVICE: No treatment required beyond continuing surveillance, with Reassessment and Review at intervals appropriate to the particular caries risk characteristics of the patient.</p>
	<p>1 - 20</p>	<p>OBSERVATION: Possibility of first indications of initial carious change beneath the enamel surface.</p> <p>ADVICE: Preventive Care Advised (PCA) Consider localised oral hygiene advice with use of fluoride toothpaste and review with monitoring over time.</p>
	<p>21 - 30</p>	<p>OBSERVATION: Probability of first indications of initial carious change beneath the enamel surface.</p> <p>ADVICE: Preventive Care Advised (PCA) Consider localised oral hygiene advice, diet advice, with use of fluoride toothpaste and review with monitoring over time.</p>
	<p>31 - 50</p>	<p>OBSERVATION: Possibility of significant carious change beneath the enamel surface warranting specific preventive care.</p> <p>ADVICE: Preventive Care Advised (PCA) Consider fluoride varnish or (on pit & fissure sites) pit & fissure sealants, with localised oral hygiene, diet advice and personalised review with monitoring over time.</p>
	<p>51 - 90</p>	<p>OBSERVATION: Probability of significant carious change beneath the enamel surface warranting specific preventive care.</p> <p>ADVICE: Preventive Care Advised (PCA) Strongly consider fluoride varnish or (on pit & fissure sites) pit & fissure sealants, with localised oral hygiene, diet advice and personalised review with monitoring at shorter intervals.</p>
	<p>91 - 99</p>	<p>OBSERVATION: Possibility of established decay equating to carious change extending through the enamel and into superficial dentine warranting specific preventive, or possibly operative, care.</p> <p>ADVICE: Preventive Care Advised (PCA) Strongly consider either fluoride varnish or (on pit & fissure sites) pit & fissure sealants, with or without a sealant restoration technique. In addition, localised oral hygiene and diet advice should be given with personalised review and monitoring over short intervals. Operative intervention may be appropriate for the high caries risk patient.</p>
	<p>100</p>	<p>OBSERVATION: Established caries. The likelihood that significant dentine caries involvement is present indicates that, subject to patient profile, Operative Care is Advised for this lesion.</p> <p>ADVICE: Operative Care Advised (OCA) Minimally Invasive Dentistry means that the restoration should be as small as possible. (examples: amalgam, composite, glass ionomer).</p>

*Note: Green and yellow LEDs will only be available if enabled from the menu

6. System Test

We recommend that a daily test of the system is performed.

1. Turn the PRO 'ON' by pressing and briefly holding the 'CANCEL' key.
2. With the display facing you connect the Cable Test Adaptor to the PRO neck with the pin facing away from you, locating it with a click.
3. 'SYSTEM TEST' is shown on the display indicating the device has detected the adaptor.
4. Connect the Lip hook connector cable to the PRO by pushing the plug fully into the socket on the side of the PRO.
5. Connect the Lip Hook connector cable socket onto the pin of the adaptor.
6. Press 'ENTER' to start the test.
7. 'Ok' indicates a pass.
8. 'CFL' may indicate the lip hook connector cable is damaged. In this case replace the cable or contact your supplier for advice.
9. The PRO will return to the 'SYSTEM TEST' state until the Cable Test Adaptor is removed.



Checking the system with the Test Adaptor

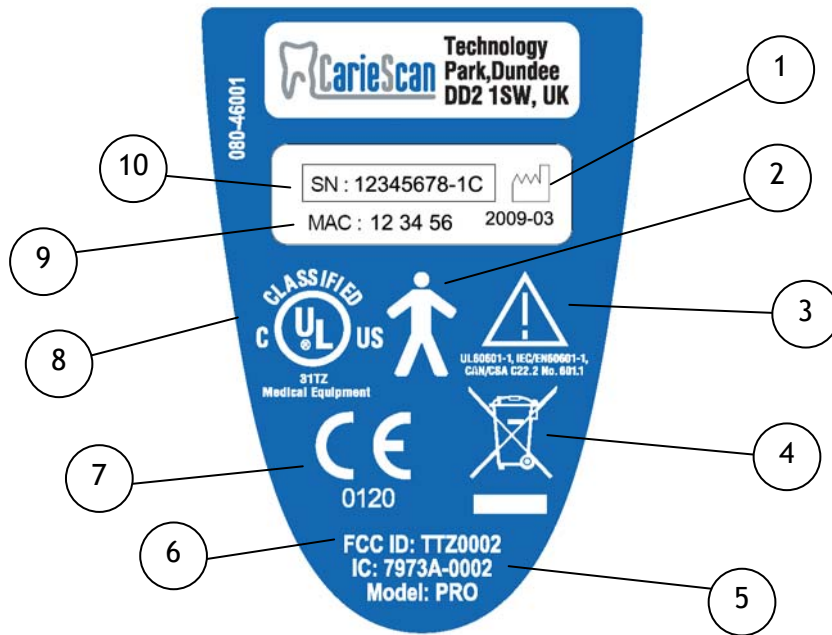
7. System Messages

Message	Meaning
OK	Self test (at startup) and system test passed
MENU	Browse menu items
ATTACH SENSOR	Sensor is not attached
PRESS ENTER TO START	Device is ready to start
CHECK SENSOR NOW	Sensor has detached during measurement
BYE	Powering off
SYSTEM TEST	Test Adaptor has been attached
CFL	System Test failure

8. Menu items

Message	Meaning
DEMO	Enters demonstration mode
ENABLE / DISABLE COMMS	Enables / Disables Bluetooth communications
ENABLE / DISABLE PROMPT	Enable / Disable AIR DRY TOOTH prompt
ENABLE / DISABLE LED	Enable / Disable green & yellow LEDs for results
FIRMWARE REV	Display current firmware revision
SERVICE	Enter Service menu (for Service personnel only)
EXIT MENU	Exit Menu

9. Label Glossary



1. Year and month of manufacture.
2. Type B applied part
May be connected to earth and can be immediately released from the patient
3. See Accompanying Documents for further information (this User Manual)
Electrical Device certified to comply with the stated Medical Device Directives
4. Waste Electrical and Electronic Equipment (WEEE) Directive
This product cannot be discarded as unsorted municipal waste. Separate collection of such waste is necessary.
5. IC: 7973A-0002; This device complies with Industry Canada RSS210.
6. FCC ID: TTZ0002; This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
 - i. this device does not cause harmful interference, and
 - ii. this device accepts any interference received, including interference that may cause undesired operation.
7. Meets the provisions of the EU Council Directive 93/42/EEC
8. MEDICAL EQUIPMENT
WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1, CAN/ CSA C22.2 No. 601.1.
Control Number 31TZ.
9. Unique identifier from the last 6 digits of the Bluetooth MAC address.
10. Serial number + hardware issue and revision.

10. Important Information

Intended Use

The CarieScan PRO is intended for use by dental professionals as an aid in the diagnosis and monitoring of dental caries.

The PRO is indicated for the detection and monitoring of primary coronal dental caries.

Note: When using the device on teeth up to 3 years after eruption - you should not rely solely on a single CarieScan PRO measurement result for making a treatment decision on a tooth surface on such teeth. Use the device to monitor the tooth surface over time to help determine the treatment decision.

With deciduous teeth care should be taken to cross-reference CarieScan PRO readings with the results of conventional clinical examinations and the clinician's judgement.

Note: The CarieScan PRO has been optimised for in-vivo use only.

Restrictions on Use

The CarieScan PRO is a prescription only device.

If using on patients with a fixed orthodontic appliance avoid contacting any metal parts of the appliance to ensure reliable measurement.

Contraindications

The CarieScan PRO should not be used on patients with cardiac pacemakers fitted. The CarieScan PRO cannot be used to assess:

- Secondary caries
- The integrity of a restoration
- Dental root caries
- The depth of an excavation within a cavity preparation

The CarieScan PRO should not be used when tooth surfaces are covered with an excess of plaque and / or other debris. Ensure the teeth are cleaned and excess plaque removed.

Cleaning and Infection control

As with all dental procedures, universal cross-infection precautions should be observed. Please visit www.cariescan.com for recommended infection control barriers.

The PRO and accessories must not be autoclaved. Cleaning should be carried out by using alcohol based wipes. Sensors are single use; a new sensor pack must be used for each patient at each new visit. Use only the separately available CarieScan sensor packs with the CarieScan PRO.

IMPORTANT: Used sensors must be disposed of as sharp contaminated waste. All such waste must be placed in a suitable receptacle marked as biohazard, conforming to the required regulations.

Warnings

It is the responsibility of the Dental Healthcare Professional to understand:

- the appropriate use of this product
- the health of each patient
- the dental procedures being undertaken
- industry and governmental agency recommendations, requirements, and regulations for the safe practice of dentistry.

Service

CarieScan PRO contains no user serviceable parts. If any problems arise, please contact your supplier.

Temperature Range

Storage conditions: -20°C to $+60^{\circ}\text{C}$.

Normal operating temperature range of the PRO is 0°C to $+50^{\circ}\text{C}$ at non-condensing relative humidity of 10% to 90% RH.

Charger Unit

Input: 100V-240V ac, 47Hz-63Hz

Output: 6V dc, 0A - 1.7A

Classification

- Internally powered equipment
- Type B applied part
- Not intended to be sterilised.
- Not suitable for use in the presence of flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- Intended for continuous operation

General

- The Charging cradle must remain outside the patient area, defined as a radius of 2 metres from the patient.
- The CarieScan PRO must be kept dry.
- The Cable Test Adaptor is for system checks only and must not be used in a patient's mouth.

Quality and Safety Certifications

The product is manufactured by CarieScan Ltd in accordance with ISO 13485:2003.
The product is CE marked in accordance with Medical Device Directive 93/42/EEC.

This product is certified to comply with:
IEC60601-1, UL 60601-1, CSA 22.2 No.601-1, EN60601-1-2, FCC 47CFR Part 15

Guidance and manufacturer's declaration - electromagnetic emissions		
The CarieScan PRO is intended for use in the electromagnetic environment specified below. The customer or the user of the CarieScan PRO should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The CarieScan PRO uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The CarieScan PRO is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

These limits are designed to provide reasonable protection against harmful interference in a typical dental installation. This equipment generates, uses and may radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- i. Reorient or relocate the receiving device.
- ii. Increase the separation between the equipment.
- iii. Connect the equipment into an outlet on a circuit different from that to which the other devices are connected.
- iv. Consult the manufacturer or field service technician for help.

We hereby declare the product CarieScan PRO FCC ID:TTZ0002 is a class 2 BT device (max 1mW Transmit power) and for typical product usage the antenna distance from a person is 15cm. The product is not subject to the routine RF exposure evaluation as per Section 2.1093 of the FCC rules.

11. Declaration of Conformity

We herewith declare that the generic family of devices, Hand Held Caries Detection Devices, meet the provisions of the Council Directive 93/42/EEC for medical devices and the UK Medical Devices Regulations SI 1994/3017.

The Technical File is retained in the premises of the manufacturer.

Primary Product Safety Standards Fulfilled

IEC / UL 60601-1 General Requirements for Safety
CSA-C22.2 No.601.1-M90 Part 1 General Requirements for Safety

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