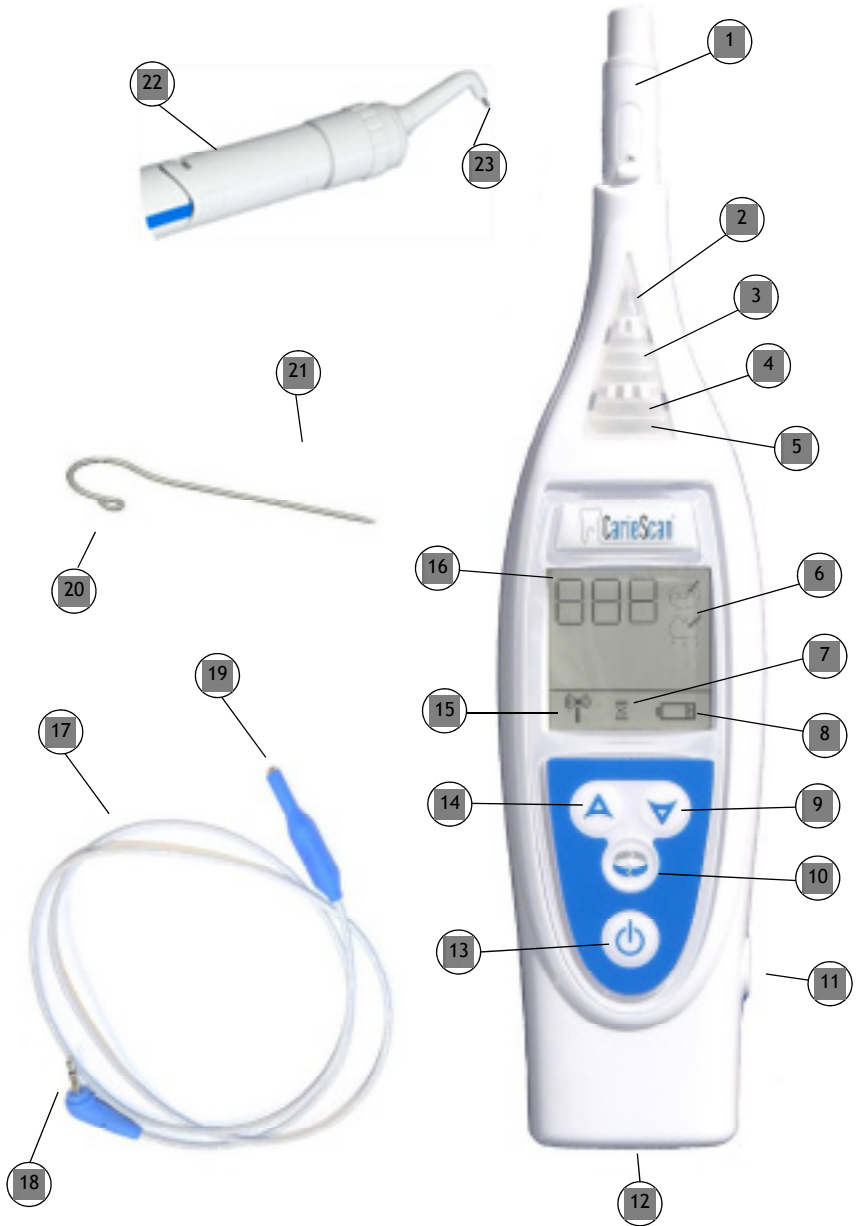




# USER INSTRUCTIONS

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- |                           |   |
|---------------------------|---|
| 1. PRO neck               | Collar pushes onto this location: see Section 4   |
| 2. Red LED                | Illuminates when measurement value is 100: see Section 5                                |
| 3. Yellow LEDs            | Illuminates when measurement value is between 1 and 99: see Section 5                   |
| 4. Green LED              | Illuminates when measurement value is 0: see Section 5                                  |
| 5. Blue LED               | Illuminated:<br>constantly = battery charging<br>intermittent = measurement in progress |
| 6. Tooth surface icons    | Sensor is attached and indicates which surfaces can be measured                         |
| 7. Busy symbol            | Shows during measurement and during system test   |
| 8. Low battery symbol     | Indicates battery requires recharging   |
| 9. DOWN key               | Scroll down through menu items  |
| 10. ENTER key             | Confirm 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. POWER (on / off) key  | To switch on / off  |
| 14. UP key                | Scroll up through menu items  |
| 15. Bluetooth icon        | Bluetooth enabled   |
| 16. Alphanumeric display  | Shows digital results and user 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. Collar                | Connects to PRO neck (1) : see Section 4  |
| 23. Sensor head           | Contact point for measurement, placed on tooth site to be measured                      |

Congratulations on your purchase of this CarieScan PRO.

This leading edge product helps identify dental caries early. Used in accordance with these directions the CarieScan PRO will give years of reliable service. Monitoring is simplified with clear numeric information aiding assessment of disease progression or improvement on the integrated screen.

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

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## 1. Box Contents

Re-order codes	Item	Quantity
CP-SYS-10	CarieScan PRO system:	
	PRO	1
	Charging Cradle	1
	Lip Hook Cable	1
	Collar	2
	Power Supply Unit	1
	Cable Test Adaptor	1
	Tray of 20 sensors	1
	Lip hooks (in the slot in back of the tray)	2
	PRO Sleeves	20
	Instructional Literature	1


## 2. Accessories

Re-order codes	Item	Quantity
CP-LHK-10	Lip Hook	10
CP-STH-01	PRO Sleeves	200
CS-OCC-40	2 trays of 20 sensors	40
CP-TSN-01	Cable Test Adaptor	1
CS-CLR-01	Collar	1
CP-STC-01	Lip Hook Cable	1
CP-PSU-01	Power Supply Unit	1

## 3. Charging the CarieScan PRO

Before using the PRO for the first time, charge the battery for a minimum of 4 hours.

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 first show when the PRO has less than about 90 minutes of charge remaining. The PRO should be recharged as soon as possible to ensure uninterrupted use.

The CarieScan PRO has been certified for use with only the supplied charging cradle and power supply unit. 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 and cable as per section 6.
3. Ensure the PRO and cable have been cleaned with alcohol based wipes.
4. Place the Collar onto the neck of the PRO.
5. Attach a sensor. Remove a paper tab from the sensor tray (start at rear left corner). With the PRO upright to the tray, press down firmly to click a sensor onto the collar.
6. Connect the Lip hook connector cable to the PRO by pushing the plug fully into the socket on the side of the PRO.
7. To minimise the risk of cross infection, a protective sleeve must be used (CarieScan PRO Sleeves, CP-STH-01). Apply the sleeve by sliding the PRO inside with the sensor tip protruding through the hole at the top of the sleeve. Remove the top covering by peeling the blue layer and remove the paper backing.
8. Remove any intra-oral appliances and clean the teeth (removal of plaque is adequate).
9. Use cotton rolls to isolate the quadrant to be measured to ensure the site remains dry.
10. Connect the Lip Hook to the connector cable, and place the hook over the patient's lower lip.
11. Turn the PRO on by pressing and briefly holding the POWER key.
12. 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.
13. 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 using a 3-in-1 syringe\*. This prompt can be disabled via the menu.
14. Air dry the tooth surface to remove any pooled saliva\*.  
**This is an important step that must not be missed.**
15. Press the 'ENTER' key to start. The blue LED will flash.
16. Place the sensor on the tooth site to be measured. As soon as the sensor is placed on the tooth, the measurement cycle begins. An average measurement takes approximately 2 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*

17. On completion of a measurement, record the value and site (this may be via manual recording of site and values in the patient record, using the available CarieScan record form or automatically via CarieScan RemoteView software, available at no charge from the CarieScan website).
18. To continue measuring on additional tooth sites, place the sensor on another tooth site. The PRO will automatically start another measurement. The tooth may require air drying again (after about 2 mins).
19. When you have completed all the measurements you wish to take:
  - Switch the PRO off by pressing and holding the POWER key until the display shows “BYE”
  - Remove the hook from the patients lip and sterilize as per your cross-infection control policy (see Section 10).
  - Remove the sleeve and dispose of as contaminated waste.
  - Eject the sensor from the CarieScan PRO by rotating the cuff on the collar in the direction of the arrow (counter-clockwise) then releasing. All sensors must be disposed of as sharp contaminated waste.
  - The CarieScan PRO, cable and collar should be cleaned with alcohol-based wipes.
  - Return the PRO to either the sensor tray or the charging cradle as necessary.

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

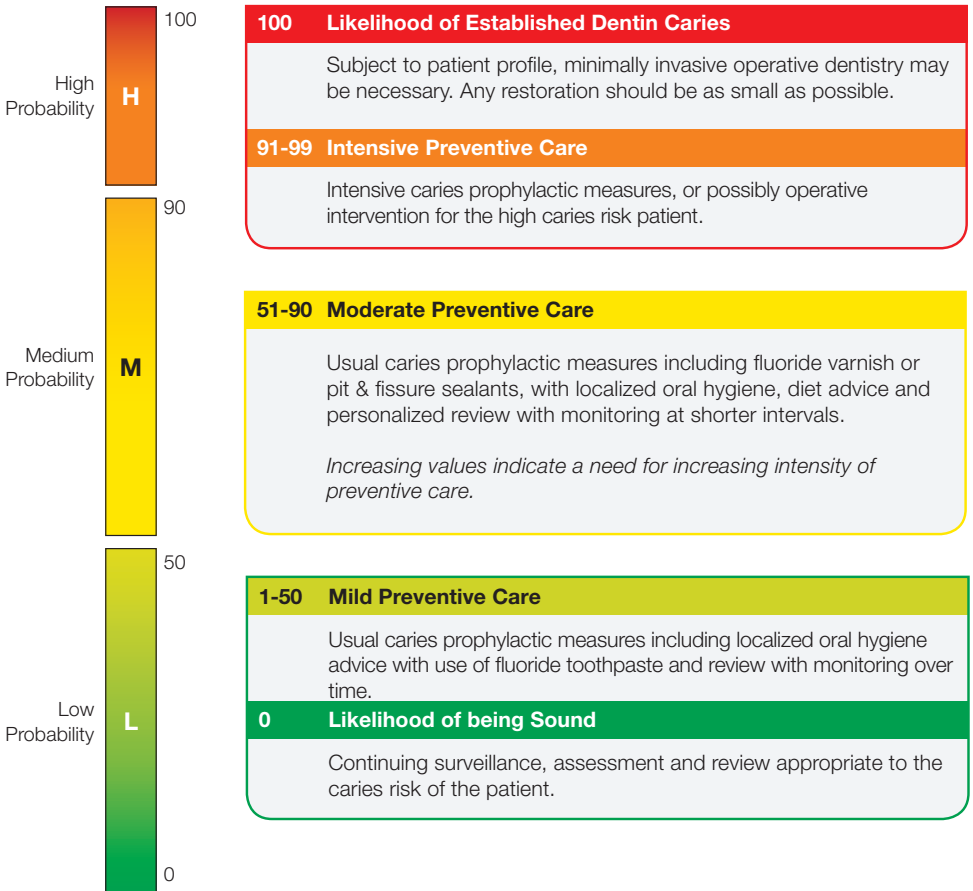
### 5. Using the results

**Note: All CarieScan PRO readings are only a guide to lesion detection and assessment. Any final diagnosis and treatment decision is the responsibility of the Dentist who should be integrating all the information available, including that from clinical visual and radiographic caries examinations, as well as patient risk factors.**

This table shows the results which will appear on the CarieScan PRO. It describes what that result is likely to mean in terms of caries extent and some possible types of treatment options advocated by cariologists (Pitts N B, Longbottom C. Preventive Care Advised (PCA) / Operative Care Advised (OCA) - categorising caries by the management option. Community Dentistry and Oral Epidemiology 1995; 23: 55-59).

#### Caries Probability

#### Possible Treatment Options



## 6. System Test

Damage to the cable is always possible. We recommend that a daily test of the system is performed.

1. Remove the collar if present (squeeze the textured side grips to release the catch, then remove from the PRO).
2. Turn the PRO on by pressing and briefly holding the POWER key.
3. 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.
4. "SYSTEM TEST" is shown on the display indicating the device has detected the adaptor.
5. Connect the Lip hook connector cable to the PRO by pushing the plug fully into the socket on the side of the PRO.
6. Connect the Lip Hook connector cable socket onto the pin of the adaptor.
7. Press 'ENTER' to start the test.
8. "OK" indicates a pass.
9. "FAIL" may indicate that the lip hook cable is either not properly connected to the PRO or is damaged. In this case replace the cable or contact your supplier for advice.
10. The PRO will return to "SYSTEM TEST" until the Cable Test Adaptor is removed.

*Checking the system with the Test Adaptor*



## 7. Menu items

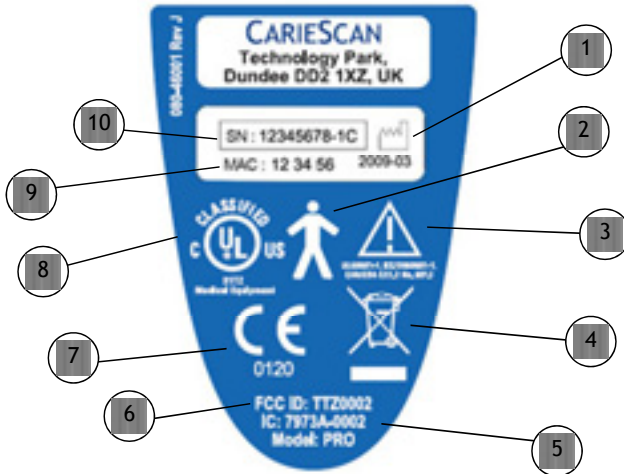
### MENU

Demo	Result demo
Comms	Bluetooth on/off
Warning	'Air dry tooth' on/off
LEDs	Only red LED on/off
Firmware rev	Show firmware version
Language	Set display languages
Service	
Exit menu	

## 8. 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	Press ENTER to start measuring mode
CHECK SENSOR NOW	Sensor has detached during measurement
BYE	Powering off
SYSTEM TEST	Cable Test Adaptor has been attached
FAIL	System Test failure

## 9. Label Glossary



1. Year and month of hardware 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).
4. Electrical Device certified to comply with the stated Medical Device Directives 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. It should be used as an adjunct to clinical decision making, supporting preventive treatment planning in conjunction with caries risk assessment, but not justifying premature restorative intervention.

*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.*

### Restrictions on Use

The CarieScan PRO is a prescription only device. US Federal law restricts this device to sale by or on the order of a qualified dental professional.

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:

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

**USA only: The CarieScan PRO should not be used on primary teeth.**

The CarieScan PRO should not be used when tooth surfaces are covered with an excess of plaque and / or other debris. Removal of excess plaque with a toothbrush is adequate.

### Cleaning and Infection control

As with all dental procedures, universal cross-infection precautions should be observed.

The CarieScan PRO sleeve (CP-STH-01) must be used to ensure that cross infection prevention requirements are met. See Section 4, item 7 for instructions on applying the sleeve.

**Only** use alcohol based wipes to clean the CarieScan PRO, collar and cable. No parts or accessories may be autoclaved other than the lip hook. The lip hooks supplied should be re-used, they should be cleaned and disinfected / sterilized according to your cross-infection procedures.

Sensors are single use; a new sensor must be used for each patient at each visit. Only CarieScan sensors (CS-OCC-40) may be used 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:  $-20^{\circ}\text{C}$  to  $+60^{\circ}\text{C}$ .

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

### Power Supply 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 CarieScan PRO system complies with the Code of Federal Regulations Title 21 Part 872 Subpart B. 510(k) numbers: K090598 and K111321.

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.

<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment – guidance</b>
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 Code of Federal Regulations Title 21 Part 872 Subpart B in the USA. 510(k) numbers: K090598 and K111321, the Council Directive 93/42/EEC for medical devices in the EU 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

CarieScan PRO and the CarieScan logo are trademarks of CarieScan Ltd and are not to be copied or reproduced in any format. The CarieScan PRO is protected by UK Patent 2385136B and Registered Community Designs EC000680467-0002. Equivalent patent and design applications are pending in other countries.

We have a policy of continual improvements, so specifications and literature may change from time to time. Please see our website <http://www.cariescan.com> for the most up-to-date revisions.



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