

ZedScan™ I

Instructions for use

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This document forms the Instructions for Use and technical description of the Zilico **ZedScan I** system

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This manual applies to the **ZedScan I** system, which includes the following components:



- **ZedScan I** handset
- Docking Station
- Single-use EIS sensor (Supplied separately)



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Contents

1 Introduction	3	4 Taking Measurements — Scanning Mode	20
1.1 Indications for Use	3	4.1 Preparing the Patient for Colposcopy	20
1.2 Contraindications and Precautions	3	4.2 Fitting a Single-Use EIS Sensor	20
1.3 System Overview	3	4.3 Confirming Patient Details	20
1.4 Principle of Operation	4	4.4 Selecting the Referral Cytology	21
1.5 Performance Data	5	4.5 Calibration Check	21
1.6 Warnings and Cautions	6	4.6 Taking Measurements in Scanning Mode	22
1.6.1 Warnings	6	4.6.1 QA Checks	23
1.6.2 Cautions	7	4.6.2 Measurement Procedure	24
1.7 Symbols	8	4.6.3 Failed Readings	24
		4.6.4 Skipping a Measurement Point	25
2 Components	10	4.7 Completing Scanning Mode	25
2.1 Handset and Docking Station	10	4.8 Is the Colposcopic Impression	25
2.1.1 Unpacking and Installation	10	Consistent with HG-CIN?	
2.1.2 Charging	10	5 Analysis	26
2.2 Software	11	5.1 HG-CIN detected by the ZedScan™ I	26
2.2.1 Software Requirements	11	5.1.1 Colposcopic Impression of HG-CIN	26
2.2.2 Software Installation	11	— Possibility of See & Treat	
2.2.3 Starting the PC Application	11	5.1.2 Colposcopic Impression of HG-CIN	28
2.3 Software Configuration	11	— Diagnostic Biopsies	
2.4 Handset — Overview of the Main Parts	14	5.1.3 Colposcopic Impression NOT	30
2.5 Handset Screen Display — General Layout	15	Consistent with HG-CIN	
2.5.1 Main Screen Area	15	5.2 No HG-CIN detected by the ZedScan™ I	31
2.5.2 Menu Area	15	5.2.1 Colposcopic Impression of HG-CIN	31
2.5.3 Keypad	15	5.2.2 Colposcopic Impression NOT	31
2.5.4 Status Bar	16	Consistent with HG-CIN	
2.6 Power Saving	16	6 Taking Measurements — Single Point Mode	32
3 Preparing the Handset for Use	17	7 Completing an Examination	34
3.1 Switching on the Handset	17	7.1 Switching the Handset Off	34
3.2 Entering Session Information into the	18		
PC Application			
3.2.1 Entering Patient Details	18		
3.2.2 Downloading Session Information	19		
to the Handset			

8 Reviewing Session Information	35	12 Specifications	44
8.1 Displaying the Results of a Previous Session	35	12.1 Handset	44
8.2 Printing Session Information	36	12.2 Docking Station	45
9 Errors and Warnings	37	12.3 Agency Approvals	45
9.1 QA Errors	37	12.4 Emissions and Immunity Information	45
9.2 Warnings	37	12.5 Accessories	50
9.2.1 Warning: Low Battery	37	12.6 Warranty	50
9.2.2 System Alarm	38	12.7 Life of Product	50
9.2.3 Warning: Wrong Referral Cytology	39	12.8 Disposal	51
9.2.4 Warning: Fit Sensor!	39	Appendix 1: Referral Cytology Reporting Systems	52
9.2.5 Warning: Reading Failed!	39	Modified BSCC 2008 (UK)	52
9.2.6 Warning: Remove Sensor!	39	TBS 2001 (US and other countries)	53
9.2.7 Connected to Host: Active Link	40	ECTP Terminology	54
9.2.8 Warning: Data Will Be Lost!	40	AMBS 2004 (Australia)	55
10 Troubleshooting and Fault Finding	41		
11 Cleaning and Maintenance	43		
11.1 General Cleaning Guidelines	43		
11.2 Preventative Maintenance	43		
11.2.1 General	43		
11.2.2 Battery	43		
11.3 Calibrations and Adjustments	43		
11.4 Storage and Care	43		

1 | Introduction

1.1 Indications for Use

The **ZedScan™I** is intended to be used as an adjunct to colposcopy in women suspected of having cervical neoplasia and will improve the accuracy of colposcopy for the detection of High-Grade Cervical Intraepithelial Neoplasia (HG-CIN; CIN2+).

The **ZedScan™I** is only appropriate for testing of the cervical epithelium and cannot be used for examination of any other epithelial tissue.

1.2 Contraindications and Precautions

The **ZedScan™I** should not be used on women who are actively menstruating at the time of examination as this may compromise the ability to take valid measurements on the cervix.

Caution should be exercised when using the **ZedScan™I** in the follow scenarios:

- i. The squamo-columnar junction is not entirely visible (also known as type three cervix).
The **ZedScan™I** can be used on cervixes of this type to determine if HG-CIN is present even if there is no evidence of a colposcopic abnormality. However, the presence of HG-CIN cannot be excluded solely on the basis of the **ZedScan™I** results because HG-CIN may be present around the squamo-columnar junction that has not been examined.
- ii. There are limited data on the ability of **ZedScan™I** to detect high-grade cervical glandular intra-epithelial neoplasia (HG-CGIN). In cases where the women have been referred with a cytological abnormality of the glandular cells then **ZedScan™I** should only be used to detect any co-existing HG-CIN.

It is paramount that the colposcopist manages the above scenarios in keeping with good colposcopic practice.

1.3 System Overview

The **ZedScan™I** system consists of:

- A portable hand-held device.
- A single-use Electrical Impedance Spectroscopy (EIS) sensor.
- A docking station.
- Software — for installation onto a suitable PC.

The handset takes EIS readings and the on-board user interface guides the operator and displays the results to assist in the clinical management of the patient.

1.4 Principle of Operation

The **ZedScan™ I** uses EIS to provide an objective assessment of cervical epithelial tissue that can be seamlessly combined with colposcopic examination to improve the accuracy of the procedure.

EIS measures the electrical properties of the cervical epithelium which are determined by the size and shape of the epithelial cells and their arrangement into stratified layers. These properties are known to change during the development of neoplasia.

The **ZedScan™ I** is an adjunct to colposcopy and is used, after the application of acetic acid (3–5%), to take a series of 10 to 12 readings from the Transformation Zone (TZ). The device provides an assessment of neoplasia which, coupled with the colposcopic impression, helps to decide if and where a biopsy/biopsies should be taken or if treatment could be offered at the time of the examination ('See & Treat'). The **ZedScan™ I** can also be used in 'Single Point Mode' where the result is delivered while the device is in contact with the cervix; this mode enables the user to position the biopsy forceps accurately before taking a biopsy.

The **ZedScan™ I** uses a proprietary algorithm to process the EIS data into a measure of the likelihood that HG-CIN is present. Those sites where the likelihood of HG-CIN is above a minimum threshold are indicated on the handset screen and the user may consider taking a diagnostic biopsy to confirm the presence of disease; selecting the precise site using the 'Single Point Mode'. If the likelihood that HG-CIN is present is above a higher threshold then it will be suggested that 'See & Treat' could be considered.

Using **ZedScan™ I** as an adjunct provides a more accurate assessment of the patient and identification of biopsy sites than colposcopic impression alone.

1.5 Performance Data

The **ZedScan™ I** was used in a multi-centre clinical study of the impact of using EIS as an adjunct to colposcopy. Table 1 below shows the results obtained.

Table 1 The performance of colposcopy was assessed based on all biopsies taken and is expressed on a per woman basis. If multiple biopsies were taken, then the worst result obtained determines diagnosis. The Colposcopy + **ZedScan™ I** results were determined based on a single biopsy taken at the site with the greatest likelihood of HG-CIN. The threshold was chosen so that the sensitivity of Colposcopy + **ZedScan™ I** was equal to Colposcopy Alone.

N=196	COLPOSCOPY ALONE	COLPOSCOPY + ZedScan™ I	STATISTICAL SIGNIFICANCE
Sensitivity	88.5% (95%CI 79.9-94.4%)	88.5%	NS
Specificity	38.5% (95%CI 29.4-48.3%)	65.1%	p<0.0001
PPV	53.5% (95%CI 45.0-61.8%)	67.0%	p=0.0006
NPV	80.8% (95% CI 67.5-90.4%)	87.7%	NS
Accuracy	63.5% (95% CI 59.2-67.5%)	75.5%	p<0.001
Positive Likelihood Ratio	1.43 (95%CI 1.24-1.69)	2.53	p<0.0001

Data from: Tidy JA, et al. Accuracy of detection of high-grade cervical intraepithelial neoplasia using electrical impedance spectroscopy with colposcopy. Br J Obstet Gynaecol (2013) 120:400-11 DOI: 10.1111/1471-0528.12096.

1.6 Warnings and Cautions

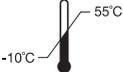
1.6.1 Warnings

- Users of this device should be medically-qualified practitioners with experience in performing colposcopy. All users should take the time to read and understand these instructions before performing any procedure.
- This device is intended only as an adjunct in patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- The handset uses a single-use EIS sensor for patient examinations. Do not re-use, or sterilise and re-use this sensor as this will compromise the performance of the **ZedScan™ I** and invalidate the warranty.
- Always inspect the device and sensor, particularly the electrodes, before use. Do not use a damaged device and replace a damaged sensor with a new one.
- Do not touch the electrodes on the handset.
- Protect the device from exposure to water or any other liquids except for wipes approved for cleaning clinical equipment.
- Always ensure that the battery indicator on the device shows at least 50% charge before use. The handset can be fully-charged from fully-discharged in around 2h 40m.
- If this device is used adjacent to, or stacked with other equipment, the device should be observed carefully to verify normal operation.
- Do not attempt to open the case or repair the electronics. Opening the case may damage the device and will void the warranty. There are no user serviceable parts in this unit or in its accessories.
- While the device is in contact with the patient, do not defibrillate.
- No modification of this equipment is allowed.
- Do not use in an oxygen-rich environment or in the presence of flammable agents.
- Do not touch the PC, laptop or docking station at the same time as touching the patient.

1.6.2 Cautions

- The device should never be stored or operated in areas where it could get wet or could be exposed to any environmental conditions like extreme temperature or humidity, direct sunlight, dust, etc.
- Do not autoclave, sterilise, or immerse this device in liquid or use caustic or abrasive cleaning agents.
- This device includes audible alarms and visual warnings which assure the correct operation of the device.
- If this device fails to respond as described or indicates that it is not functioning correctly, discontinue use and contact the supplier of the device.
- All service to the device must be performed by a Zilico-authorized service centre or by Zilico. Replacement of the battery is not permitted.
- This equipment complies with IEC 60601-1-2:2001 for Electromagnetic Compatibility (EMC) for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in these Instructions for Use.
- Follow local, state and national recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials; please contact Zilico regarding take-back or recycling of the device.
- Dispose of used battery promptly. Keep away from unsupervised children. Do not disassemble and do not dispose of in fire.
- The **ZedScan™ I** system does not have a physiological effect.
- The battery used in this device may present a risk of fire or chemical burn if mistreated. Do not disassemble, heat above 100°C (212°F), or incinerate. Do not replace battery. Use of another battery may present a risk of fire or explosion.

1.7 Symbols

Symbol	Definition of Symbol		
	Consult Instructions for Use.		Prefixes the serial number of the device.
	Indicates separate collection for electrical and electronic equipment (WEEE), and that it contains a battery which falls within the scope of the battery directive.		Prefixes the date of manufacture of the device.
	Type BF Applied Part (patient isolation from electrical shock). The snout of the handset is a Type BF Applied Part.		Indicates the name address of the legal manufacturer of the device.
	CE marking indicating conformance to EC directive No 93/42/EEC concerning medical devices. This marking is applied to the handset, docking station and single-use EIS sensor to indicate compliance with Annex VII of the directive.		The EIS Sensor is Single Use. Do Not Reuse.
	Warning. Pay particular attention to items marked with this symbol in these Instructions for Use. This symbol is solely to inform.		Denotes the expiry date of the single use EIS sensor. Do not use the sensor after the expiry date has passed.
			Keep the system dry when packaged for storage and transportation.
			Store and transport the system at a temperature between -10°C and 55°C.
			DC Power

2 | Components

ZedScan™I comprises a handset which is used to examine the patient, a docking station used to charge and connect the handset to a PC, a single-use EIS sensor and a software application that manages the creation and storage of session information.

2.1 Handset and Docking Station

2.1.1 Unpacking and Installation

- Unpack the handset and docking station. If any component is damaged or missing, contact the supplier for assistance.
- Place the docking station on a level surface in close proximity to the PC or laptop that is to be used to create, download and store session information.
- Place the handset on the docking station. Ensure that it is correctly seated on the four-pin connector on the docking station.
- Ensure the PC or laptop is switched on.
- Connect the USB connector from the docking station to a free USB port on the PC or laptop. If you intend to disconnect the docking station from time to time, it is preferable but not essential to always connect using the same USB port.

The PC or laptop will install the required hardware drivers automatically. If this does not occur, the CD provided includes copies of the required drivers.



It is likely that the PC or laptop is not certified to be used within the patient environment.

2.1.2 Charging

The handset will charge whenever it is seated on the docking station. Ideally the handset should be fully charged before use and an examination should not be started if the battery indicator shows less than 50%. The latter recommendation is to ensure that, even if the handset is not returned to the docking station for an extended period, the device will retain sufficient charge to maintain the data collected during the examination. The handset will go into a power saving mode after a period of inactivity. In power saving mode the green LED in the snout will flash every 10 seconds. Depressing any key on the keypad will restore the handset to full power.

Prior to storage, ensure the handset is powered down after use to avoid depletion of the battery.

2.2 Software

ZedScan™I uses a PC Application which creates session information and downloads this to the handset ready for the examination. Once the examination is complete, the PC Application downloads the data from the handset so that it can be printed and/or exported for future reference.

All of the software elements within the system display their unique version number at start-up. If you are unsure about the software version you are using, contact Zilico technical support.

2.2.1 Software Requirements

The software is designed for use with Windows XP Professional, Windows Vista, Windows 7 and Windows 8.

The .NET framework is also required. If this is not installed on the PC or laptop, you will be prompted to install it when you first try to run the application; the CD provided with the **ZedScan™I** system includes a copy of the .NET framework installer.

2.2.2 Software Installation

The PC Application does not need to be installed. Simply copy the application from the CD provided onto the PC or laptop's desktop.

2.2.3 Starting the PC Application

To run the PC Application:



- Double-click on the Zilico PC Application icon on the computer's desktop.

2.3 Software Configuration

The software provided with the **ZedScan™I** can be configured to local requirements by selecting the following:

- The operating language of the PC Application and the handset.
- The cytology reporting terminology (Appendix 1).
- The location of the patient database file.
- The details of the clinic/institution where the testing takes place.

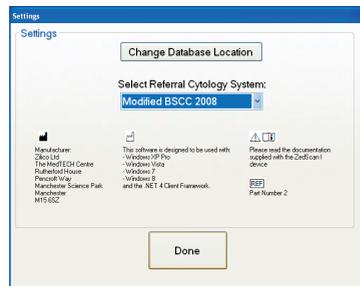
To configure the PC Application on first use:

- Run the PC Application.
- On first use the following screen will appear.



Accept the End User License by clicking “Accept” as indicated

- In the settings start-up screen, select the appropriate referral cytology reporting system from the drop-down menu (see Appendix 1). You can change the location of the patient database if required. The default location of the database is in the ProgramData folder on the main drive of the PC but this can be changed to a location specified by the user by clicking on “Change Database Location”. If the preference is to maintain the patient database on a networked drive location then this may need to be agreed by arrangement with the IT Systems Administration depending upon local policies and practices. Click **Done** to save your information.

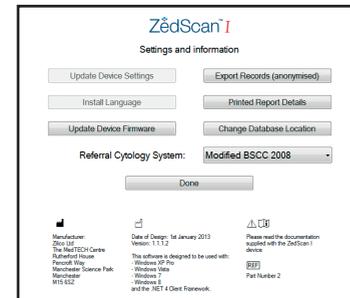


- The Start Screen will then appear.



To reconfigure the PC Application:

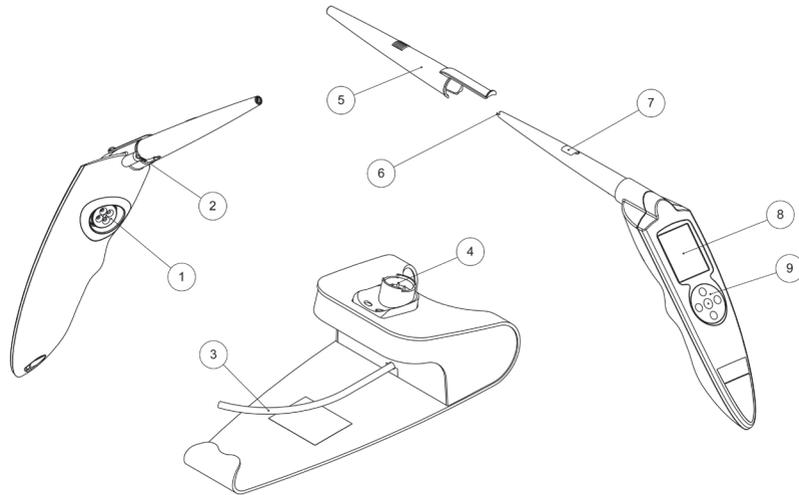
- There may be situations where the configuration of the device may need to be changed; for example the user wishes to operate in a different language or the device is moved to a new location. Click the **Settings and Information** icon (in the top right of the PC Application screen) to open the Settings and Information page.



- Click the **Update Device Settings** button and enter the required details on the screen that appears. Click **OK** to save your information.
- To display the user interface in another language, click the **Install Language** button and choose the language that you require.
- The handset firmware can be updated by clicking on the **Update Device Firmware** button. Navigate to and then select the required file.
- To specify or change information that you want to appear on printed reports, click the **Printed Report Details** button, enter the required information and click the **OK** button.
- To change the location of the database containing previous session records, click the **Change Database Location** button, navigate to the required location and click the **OK** button.
- Choose the cytology system that is to be used for referrals from the drop-down list.
- Click the **Done** button to return to the main screen.

2.4 Handset – Overview of the Main Parts

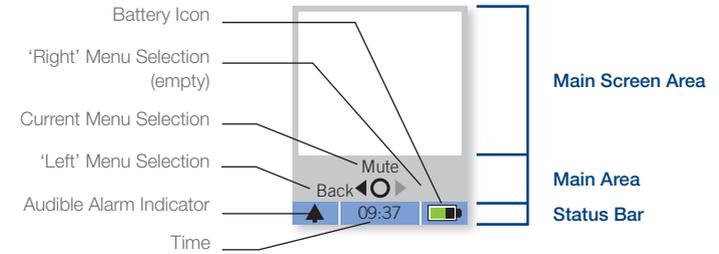
The main parts of the handset are shown in the following illustration. Familiarise yourself with the locations of the controls and the display screen.



- 1 Docking station connector** — connects the handset to the docking station.
- 2 Micro switch** — this pin registers that an EIS sensor has been attached.
- 3 USB cable** — connects the docking station to a PC or laptop. The cable includes an isolation unit to protect the user and patient from any hazard associated with connecting the device to a non-ISO 60601-certified PC.
- 4 Four-pin connector** — receives the handset to facilitate transfer of session information and to charge the handset battery.
- 5 Single-use EIS sensor** — replaced for each patient.
- 6 Gold electrodes (pins)** — to take EIS measurements.
- 7 Snout LEDs** — visual indication of device status or analysis results in Single-Point Mode.
- 8 On-board user interface** — displays information to guide an operator when taking readings and shows the results of these readings.
- 9 Keypad** — to make menu selections and move between screens.

2.5 Handset Screen Display – General Layout

User-interface screens are shown on a colour graphic LCD. The general layout of the display is as follows:



2.5.1 Main Screen Area

The Main Screen Area displays real-time information when performing an examination, displays results and warnings should they occur.

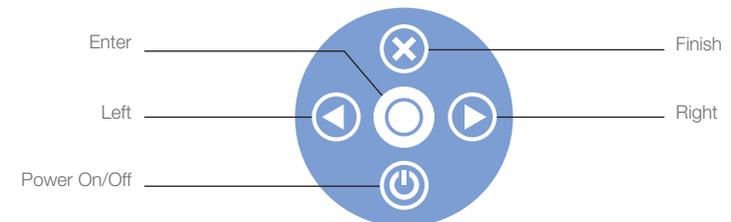
2.5.2 Menu Area

A simple menu system is displayed at the bottom of the handset's LCD screen, above the Status Bar. The menu system provides a flexible, general-purpose selection mechanism. Menu selections are made using the keypad from a list of options, which can be different for each screen. Every menu option is associated with text for display.

- The 'left' ('◀') and 'right' ('▶') arrows on the keypad are used to change between the options.
- The circle under Mute represents the 'Enter' ('⊙') key on the keypad which selects the current option. In some instances, the circle is replaced with X.
- The ⊗ key on the keypad completes a set of readings.

2.5.3 Keypad

The handset's keypad is used to make menu selections and move between screens.



3 | Preparing the Handset for Use

The information contained in this section relates to frequently used functions of the system.

2.5.4 Status Bar

The lowest part of the display shows general status information for the system.

Audible Alarm Indicator	<ul style="list-style-type: none">  A 'bell' symbol is shown in the bottom left of the screen while an alarm or warning is on-going.  The bell symbol is shown crossed out with a dashed white line if the audible indication has been muted.  The bell symbol is crossed out with a solid white line if the warning has no associated audible alarm.
Time	<p>The handset's internal clock is updated from the PC Application, together with session information. The internal clock is not maintained while the handset is switched off.</p> <p>The time is displayed in the centre of the Status Bar with a flashing colon between hours and minutes if the internal clock date and time are valid – i.e. they have been updated from the PC Application.</p> <p>No time is shown if the internal clock is not valid.</p>
Battery	<p>If the handset is running on its internal battery, the approximate charge level is shown as a green bar with an icon in the bottom right of the Status Bar.</p> <p>It is recommended that the battery display shows at least 50% of charge remaining before starting an examination.</p> <p>This icon will flash if the charge is below the 'low battery' warning threshold.</p> <p>A charging symbol is displayed if an external supply is charging the battery.</p>

2.6 Power Saving

- To save power, the display backlight dims after a pre-set period (20 seconds) of inactivity. If the backlight is dimmed, press any key to brighten the display.

After a further period of inactivity, the display turns off and the snout LED will flash green once every 10 seconds to indicate the device is in power saving mode.

If the handset continues to be inactive for a period of 1 hour, the handset will automatically switch off, provided there is no patient data waiting to be transferred to the PC.

- If the display is turned off, press the **On/Off** key to turn on the display.

3.1 Switching on the Handset

Before you can use the handset to take measurements, it must be switched on. A Self-Test programme is run to make sure that the handset is operating correctly.



- Press the handset's **Power On/Off** button.
 - The handset displays the Zilico logo and runs a Self-Test programme.
 - The Self-Test includes an activation of the green and orange LEDs located on the snout, and the audible indicator. It is necessary to observe these during Self-Test to ensure that they are functioning correctly.
- If the test fails, a SYSTEM ALARM Code: 0002 screen is displayed indicating that the Self-Test has failed. Refer to System Alarm in Section 9.2.2.



The device must not be used if it fails the Self-Test and should be returned for servicing.



- Confirm that the colours shown on the display are correct, as shown in the following screenshot. If they are not, return the device for servicing.
- To proceed, select **Next** and press **Enter**.

3.2 Entering Session Information into the PC Application

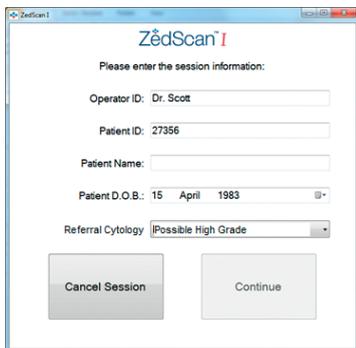
To prepare the handset for use in an examination, you must first create a new session and download details of the session to the handset using the PC Application.

3.2.1 Entering Patient Details

- Ensure the handset is attached to the docking station.
- Start the PC Application.

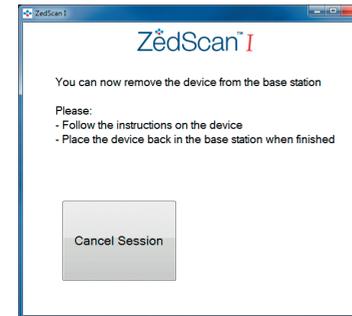


- Click the **Start New Session** button.
- Enter your **Operator ID**.
- Enter the **Patient ID** (maximum 16 characters).
- Enter the **Patient Name**.
- Enter the patient's date of birth (**Patient D.O.B.**).
- Select the **Referral Cytology** from the drop-down list.



3.2.2 Downloading Session Information to the Handset

- Click the **Continue** button.



- Remove the handset from the docking station.
Place the handset in a convenient place ready for use in the examination.



Do not attempt to use the handset to examine the patient when it is still connected to the docking station.

4 | Taking Measurements – Scanning Mode

4.1 Preparing the Patient for Colposcopy

The patient should be prepared for colposcopy as per local guidelines and practice.

4.2 Fitting a Single-Use EIS Sensor

A single-use EIS sensor must be fitted over the snout of the handset before commencing the examination.



Check the expiry date on the EIS sensor before use and do not use if it has exceeded this date.

Do not use an EIS sensor if its packaging is damaged or broken as this may affect the cleanliness of the electrodes and the accuracy of the measurement.

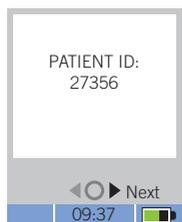
Do not reuse an EIS sensor.

- Pick up the handset.
- Unwrap a single-use EIS sensor and slide it over the snout of the handset until the EIS sensor clicks into position.
The sleeve can only be fitted to the handset in one orientation.



Do not attempt to use the device to examine the patient if an EIS sensor has not been fitted.

4.3 Confirming Patient Details



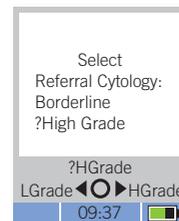
Confirm the Patient ID displayed on the screen is correct.

To do this:

- Select **Next** and press **Enter** to move to the next screen.
- If the Patient ID is not correct then the handset should be returned to the docking station and the patient details re-entered.

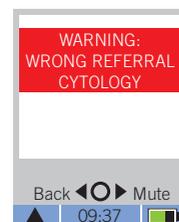
4.4 Selecting the Referral Cytology

Select the Referral Cytology. This must match the cytology defined for the session.



To do this:

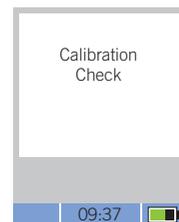
- Press **▶** or **◀** until the correct cytology is displayed on the screen.
- Press **Enter** to move to the next screen.



- If your selection differs from that entered on the PC (Section 3.2.1), a warning screen is displayed.

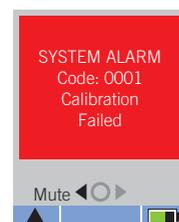
Return the handset to the docking station and re-start the session.

4.5 Calibration Check



An internal calibration check is performed once the referral cytology has been correctly entered to ensure the handset is calibrated and ready for use in an examination.

- If the check passes, the Scanning Mode screen is displayed.



- If the check fails, a Warning screen is displayed. Refer to System Alarm in Section 9.2.2.



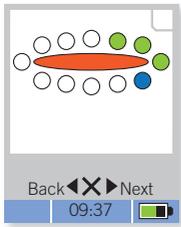
If the handset fails the calibration check, it must not be used to examine the patient.

4.6 Taking Measurements in Scanning Mode

In this mode it is intended that the Transformation Zone (TZ) should be surveyed using a series of EIS readings, as far as possible, evenly spaced around the TZ. The purpose of this is to ensure that readings are taken on both acetowhite and non-acetowhite regions because it is known that HG-CIN can be found in non-acetowhite areas of the cervix¹.

Between 10-12 measurements should be taken around the TZ; the exact number will depend upon the size of the TZ but the minimum number is 10 to ensure adequate coverage.

To assist in taking measurements from the correct places, the Scanning Mode screen displays a diagrammatic representation of the measurement zone using coloured dots to indicate the location and status of each measurement point.

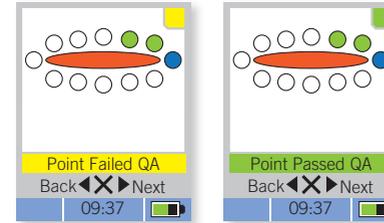


The following screen shows the situation after four readings have been taken:

- White points – where a reading has not yet been taken, or reading has been skipped.
- Green points – where a reading has been successfully taken.
- The current point is shown in blue if a reading is not in progress or yellow if a reading is in progress.

4.6.1 QA Checks

The system makes continuous QA checks between measurements to ensure that the tip of the handset is positioned in good contact with the cervix and that the homogeneity of the underlying epithelial tissue is sufficient to take a valid reading. The results of these checks are shown immediately as follows:



On the square at the top right of the display:

- Amber = QA check failed.
- Green = QA check passed.

On the snout LED:

- Off = QA check failed.
- Green = QA check passed.

As text at the top of the menu area:

- “Point Failed QA” on an amber background = condition check failed.
- “Point Passed QA” on a green background = condition check passed.



A reading can only be taken if the point passes QA.

¹ Jeronimo J, et al. Visual appearance of the uterine cervix: correlation with human papillomavirus detection and type. Am J Obstet Gynecol 47:e1-8.

4.6.2 Measurement Procedure

- Under colposcopic guidance, place the tip of the handset's snout in contact with the cervix using light but firm pressure to stabilize the tip of the single-use EIS sensor on the surface of the cervix and to ensure good contact. Excessive pressure should be avoided to prevent damage to the cervical epithelium.
- Hold the handset steady until "Point Passed QA" is shown on the handset screen and the snout LED is green. If the QA checks are not passed after about 10-15 seconds, it may be that either the tip of the sensor is not making good contact or the site is not suitable for taking an EIS reading. In this circumstance the tip of the sensor should be lifted off the cervix and repositioned to either improve contact or take the reading at a site close by.
- Press **Enter** (⊙) to take a reading. A reading takes between two and 10 seconds.
While the reading is being taken the snout LED will change to continuous orange, the QA check information will disappear from the Scanning Mode screen and the measurement point will change to yellow.
If the reading is successful, there will be a double beep sound, the snout LED will turn off and the measurement point returns to blue on the Scanning Mode screen.
- Lift the tip of the sensor off the cervix and move to the next site. **DO NOT** drag the tip across the cervix as this may cause damage and lead to bleeding.
- Press **Enter** to select the new site. The Scanning Mode screen shows the new site in blue and the previous, successful reading site is shown in green. The QA checks start and, when the checks are passed as shown by the green snout LED or the other indicators described above, press **Enter** again to take a reading.
- Repeat this process to take readings at a total of 10-12 points around the cervix.
- Once 12 readings have been taken the green snout LED will no longer come on; see section 4.7 Completing Scanning Mode.

4.6.3 Failed Readings

The **ZedScan™ I** carries out QA checks during data collection to ensure that the device remains in good contact with the cervix and that the measurements are of sufficient quality to be analysed. All QA checks have to be passed or the reading will fail.



If a reading fails, the green and orange LEDs will flash alternately and a Warning screen is displayed:

- Select **Back** and then press **Enter** on the Warning screen and repeat the reading.

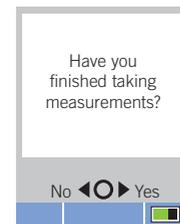
4.6.4 Skipping a Measurement Point

If you are unable to obtain a reading at a particular point, and want to move on to the next point, you can skip a point and then come back to it later.

- Press ◀ or ▶ to move around the measurement points on the Scanning Mode screen.

4.7 Completing Scanning Mode

A complete survey in Scanning Mode requires 10-12 readings depending upon the size of the TZ. When you have taken the required number of measurements:



- Press ⊙ if you have taken 10 or 11 measurements and want to complete the examination.
Note that if you have taken 12 measurements, the following screen is displayed automatically.
- Select **Back** and press **Enter** to return to the Scanning Mode screen to take any measurements that have been skipped.
- Select **Yes** and press **Enter** to complete measurements.

4.8 Is the Colposcopic Impression Consistent with HG-CIN?

You will then be asked to give your opinion on whether you think HG-CIN is present, based on your examination of the cervix.

The answer to this question is used in the Analysis phase.



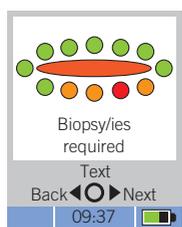
- Select **Back** and press **Enter** if you wish to return to the previous screen.
- Select **Yes** (press '▶') and press **Enter** if you believe that HG-CIN is present.
- Select **No** (press '▶' twice) and press **Enter** if you believe HG-CIN is not present.

5 | Analysis

Data collected during the colposcopic examination is processed using a proprietary algorithm to produce a Results screen.

This algorithm takes as its inputs the referral cytology, the colposcopic impression of HG-CIN and the measurements taken in Scanning Mode — see Principle of Operation in Section 1.4. The results are displayed on the handset screen in the form of a “clock face” representation of the cervix, similar to the Scanning Mode screen, as shown below.

The central ellipse represents the os. The sample points are shown around the os in their nominal positions. Each point is coloured to indicate its analysis result.



- Clear/white – no reading.
- Green – analysis indicates that HG-CIN is unlikely to be present.
- Amber – analysis indicates that HG-CIN is likely to be present.
- Red – the point with the highest likelihood that HG-CIN is present.

The following sections describe the Results screens from the analysis.

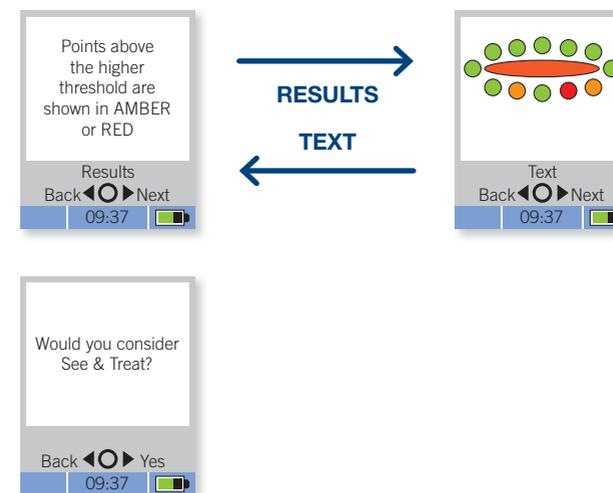
5.1 HG-CIN detected by the ZedScan™ I

If analysis of the EIS data indicates that HG-CIN is present, the sites are shown in either red or amber on the handset screen; see examples below. The possible actions that can be taken will depend upon the result of the colposcopic examination and the referral cytology result.

5.1.1 Colposcopic Impression of HG-CIN – Possibility of See & Treat

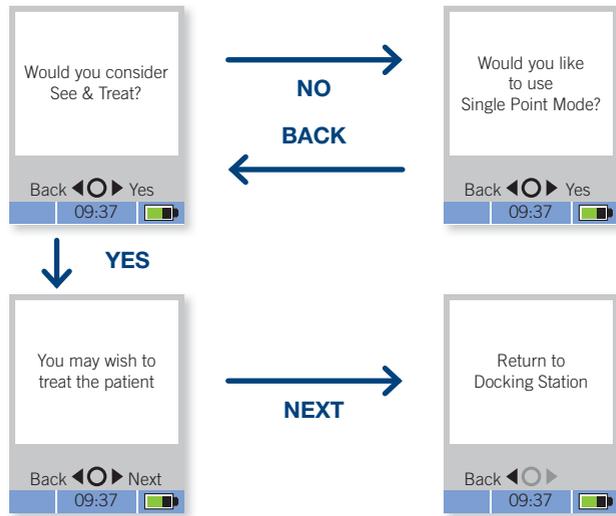
If HG-CIN has been identified during colposcopic examination and the likelihood of HG-CIN calculated by the ZedScan™ I is above the higher threshold, then the screens suggesting See & Treat will be displayed (see below).

- Select **Next** and press **Enter** to reach the next screen.



If the sites indicated by the ZedScan™ I correspond to an area of HG-CIN identified during the examination then See & Treat should be considered, but the decision to carry out a loop-excision (LLETZ or LEEP) should also be based on clinical judgement and local practice and guidance. If the decision is to carry out a loop-excision then the use of the ZedScan™ I is complete.

- Select **Yes** (press '▶') and press **Enter**.
- Then select **Next** (press '▶') and press **Enter**.
Select **Back** (press '◀') and press **Enter** to return to the results screen.



If the decision is not to carry out a loop-excision but to take a diagnostic biopsy(ies) then the option will be offered to use the **ZedScan™ I** in Single Point mode to better identify the most appropriate site(s) for biopsy – see Taking Measurements – Single Point Mode in Section 6.

- Select No (press '▶' twice) and press **Enter**.

5.1.2 Colposcopic Impression of HG-CIN – Diagnostic Biopsies

If the likelihood of HG-CIN calculated by the **ZedScan™ I** is above the lower threshold value then the screens suggesting taking a diagnostic biopsy will be displayed.

If the sites indicated on the screen correspond to areas of HG-CIN identified during the examination then a single diagnostic biopsy may be taken at one of these sites.

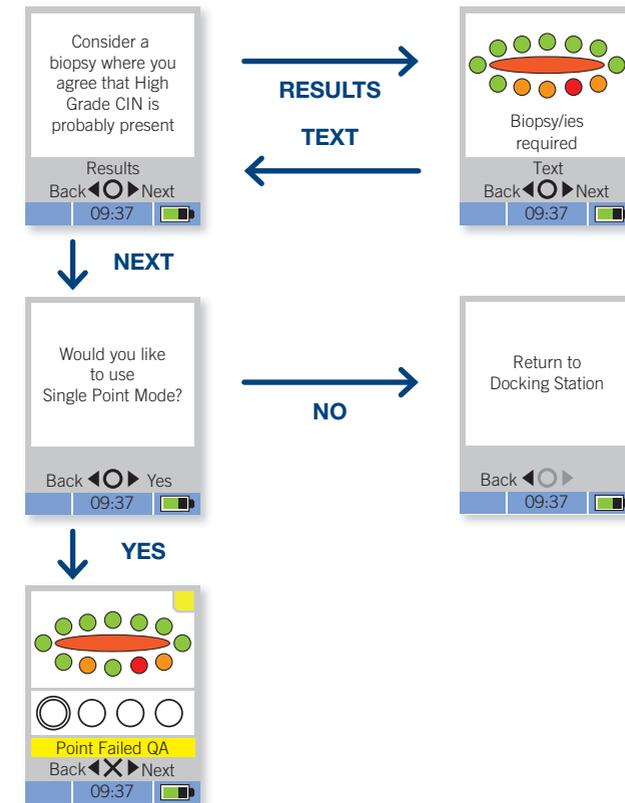
Alternatively, there may be disagreement between the examination and the **ZedScan™ I** as to the location of HG-CIN. In this case it is recommended that a single biopsy is taken at the site indicated in red because this has the greatest likelihood that HG-CIN is present; additional colposcopic biopsies may be taken based upon clinical judgement and local practice and guidance.

The **ZedScan™ I** has the option of Single Point Mode which provides a method of identifying the presence of HG-CIN prior to taking a biopsy – see Taking Measurements – Single Point Mode in Section 6.

- Select **Next** (press '▶') and press **Enter** to access the option for Single Point Mode.
- Then select **Yes** (press '▶') and press **Enter** to start Single Point Mode.

OR

- Select **No** (press '▶' twice) and press **Enter** to return the **ZedScan™ I** to the docking station.



5.1.3 Colposcopic Impression NOT Consistent with HG-CIN

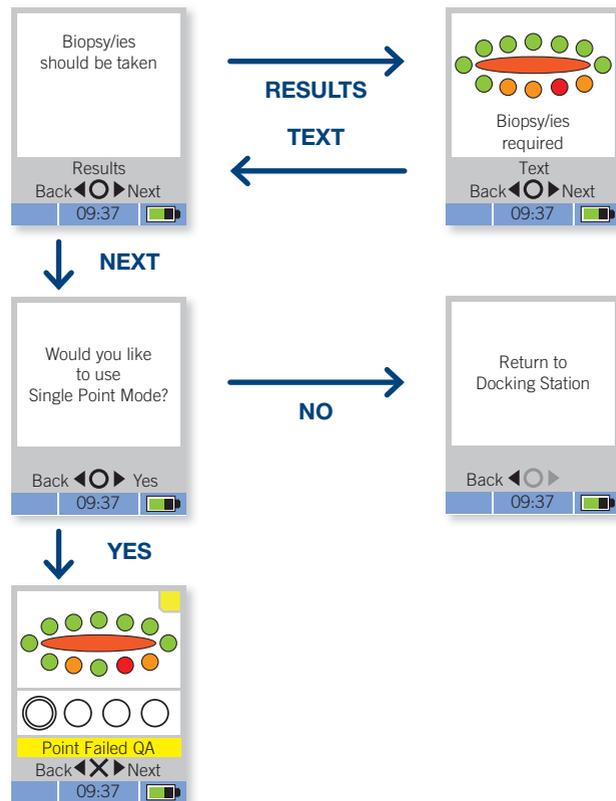
Even if HG-CIN has not been identified during the examination, the EIS data collected and analysed by the **ZedScan™ I** may identify sites that are above the lower threshold value and these are indicated on the Results screen.

The cervix can be re-examined at the sites indicated by the **ZedScan™ I** and it is suggested that a single biopsy be taken at the site indicated in red as this has the greatest likelihood that HG-CIN is present. You can elect to use Single Point Mode to identify the best site, see Taking Measurements – Single Point Mode In Section 6

- Select **Next** (press '▶') and press **Enter** to access the option for Single Point Mode.
- Then select **Yes** (press '▶') and press Enter to start Single Point Mode.

OR

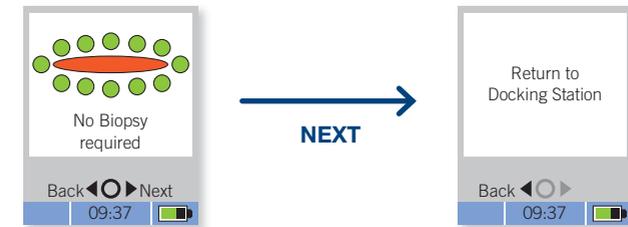
- Select **No** (press '▶' twice) and press **Enter** to return the **ZedScan™ I** to the docking station.



5.2 No HG-CIN detected by the ZedScan

Analysis of the EIS data does not indicate that HG-CIN is present at any of the sites tested; all sites are indicated in green on the handset screen.

- Select **Next** (press '▶') and press **Enter** to return to the docking station.



Management of the patient will depend upon the result of the colposcopic examination and the referral cytology result, taking in to account that the **ZedScan™ I** did not detect HG-CIN.

5.2.1 Colposcopic Impression of HG-CIN

If HG-CIN has been identified during the examination then a diagnostic biopsy(ies) may be taken based upon clinical judgement and local practice and guidance.

5.2.2 Colposcopic Impression NOT Consistent with HG-CIN

If HG-CIN has not been identified during the examination then there is no requirement to take a diagnostic biopsy(ies). The fact that the **ZedScan™ I** also did not detect HG-CIN means that it is highly unlikely that disease is present.

6 | Taking Measurements — Single Point Mode

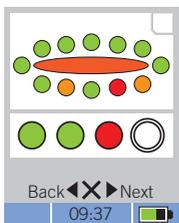


If, following the use of the **ZedScan™I** in Scanning Mode to carry out an assessment around the TZ, you intend to take one or more diagnostic biopsies, the option to use Single Point Mode is offered; this mode is designed to help identify the best site(s) for biopsy.

In this mode the **ZedScan™I** is operated exactly as previously except that data analysis is immediate and the result is presented while the tip is still in position on the site. The result is presented both on the handset screen and using the snout LEDs.

In Single Point Mode the EIS data is analysed in exactly the same way as in Scanning Mode, but the threshold value is based upon the results of the Scanning Mode on this patient. This optimises the process so that the most likely sites of HG-CIN will be identified.

Single Point Mode allows you to take and record up to four single-point readings to define the best location to take biopsies.



The example screen opposite has the Scanning Mode results shown in the top part of the screen for reference and three readings that were taken in Single Point Mode shown in the lower part of the screen. In this example the first two Single Point Mode readings were below the threshold for HG-CIN whereas the third was above the threshold. As well as being displayed on the handset screen the result for each site is indicated using the snout LEDs.

- Once the Single Point Mode has been selected place the tip of the sensor on the cervix at a point where you would consider taking a biopsy. This selection may be based on either colposcopic examination or the **ZedScan™I** results or both.
- Hold the handset steady until "Point Passed QA" is shown on the handset screen and the snout LED is green. If the QA checks are not passed after about 10-15 seconds, it may be that either the tip of the sensor is not making good contact or the site is not suitable for taking an EIS reading. In this circumstance the tip of the sensor should be lifted off the cervix and repositioned to either improve contact or take the reading at a site close by.

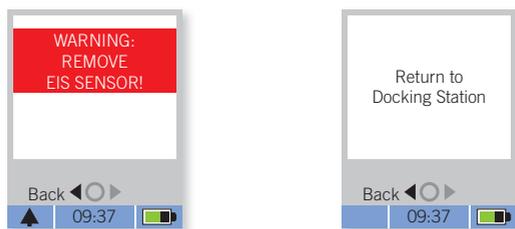
- Press **Enter** to take a reading. A reading takes between two and 10 seconds. While the reading is being taken the snout LED will change to continuous orange and the first Single Point Reading indicator will change to yellow.
- If the reading is successful, there will be a double beep sound and the result of the data analysis will be immediately displayed on the snout LEDs and the screen on the handset. If the likelihood of HG-CIN is above the threshold set from the Scanning Mode results then the orange LED will flash and the first Single Point Mode site will be shown in red on the handset screen. Alternatively, if the result is below that threshold then the green LED will flash and the site will be shown as green on the handset screen.
- If the result is below the threshold at the first site (as shown in the example above) then the tip of the sensor should be lifted off the cervix and re-positioned to take another reading. When positioned appropriately, press Enter, wait until the QA checks are passed and then press Enter to take another reading.
- When the orange LED flashes, indicating that it is likely that HG-CIN is present at that site, the **ZedScan™I** can be held in position on the cervix while biopsy forceps are brought into position; the **ZedScan™I** is then moved away as the forceps are positioned exactly on the reading site, greatly increasing the likelihood that the biopsy will confirm the presence of HG-CIN.
- When the required number of readings has been taken, press ⊗ to complete the examination.

The following precautions are relevant to the use of the Single Point Mode:

- The **ZedScan™I** is designed to take readings on the cervix and cannot be used to take measurements on excised tissue such as a biopsy.
- If the intention is to take more than one biopsy then care has to be exercised when using the **ZedScan™I** following the first biopsy as the device cannot take accurate readings if blood is present on the surface of the cervix. Either stop the bleeding at the first site before continuing or take a biopsy at the more posterior site first.

7 | Completing an Examination

Once you have completed an examination, the following screens are displayed:



When the EIS sensor has been discarded to clinical waste, the handset can be returned to the docking station. The results of the examination will then be uploaded automatically from the handset by the PC Application and the report screen will be displayed – see Reviewing Session Information in Section 8.



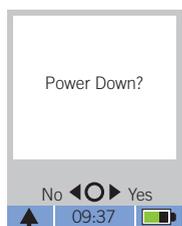
Ensure you remove and discard the EIS sensor before placing the handset on the docking station.

DO NOT leave the EIS sensor inside the patient.

After a set period of inactivity, the display screen will turn off and the handset will go into a power saving mode, indicated by a flashing green light on the snout LED, once every 10 seconds. Depressing any key on the keypad will restore the handset to full power.

7.1 Switching the Handset Off

To avoid discharge and depletion of the battery, the device must be switched off after use.



To switch the handset off:

- Press the **On/Off** button. The following screen is displayed:
- Select **Yes** and press **Enter** to switch off the handset.

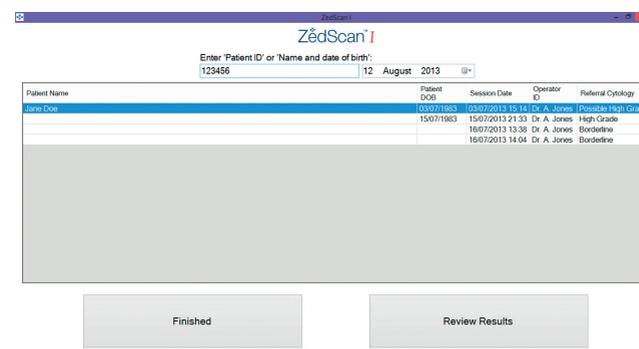
8 | Reviewing Session Information

The PC Application can be used to review session information which has been collected from the handset. The information relating to the current patient is displayed for review immediately after the handset has been docked; there is the option to enter comments into the report which can then be printed for inclusion in the patient file.

Alternatively information for patients examined previously can be recovered using the 'Review Old Session' facility. In this case it is not possible to edit any existing comments nor to add additional comments but it is possible to print out the report.

8.1 Displaying the Results of a Previous Session

- Start the PC Application.
- Click the **Review Old Session** button.
- Enter a search term such as the **Patient ID** or **Surname plus Date of Birth**. When using Patient ID as the search term, the information must be entered in full. If searching by Surname, a minimum of the first 4 characters of the Surname in addition to the Date of Birth are required.
 - A list of previous sessions for the chosen patient is displayed.
- Select the session that you want to review.

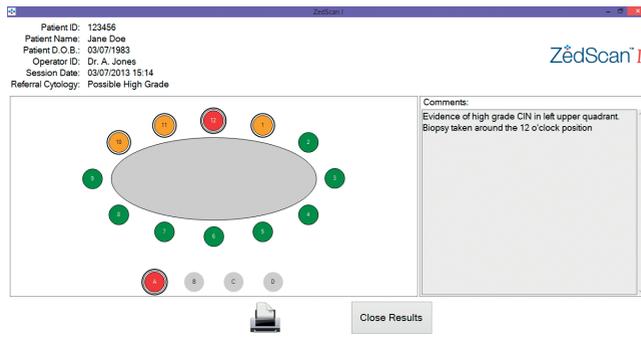


You can sort the sessions by Session Date, Operator ID or Referral Cytology by clicking on a column heading.

- Click the **Review Results** button.

9 | Errors and Warnings

The Scanning and Single Point results for the selected patient are displayed.



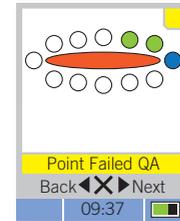
8.2 Printing Session Information

- Display the results of the session that you want to print.
- Click the **Print** button.

You can print to colour or black and white depending on your printer's settings.

In-built diagnostics and monitoring capabilities ensure that the device cannot be used to take readings if it is not functioning correctly or a step in the workflow has not been satisfied.

9.1 QA Errors



The in-built QA checks are designed to ensure that EIS sensor is in correct contact with the cervix and that the homogeneity of the underlying tissue is sufficient to provide usable EIS data. The tip of the handset must be correctly positioned against the cervix to obtain a reading. If the position fails QA checks, then it will not be possible to take a reading. The snout LED will not be illuminated and 'Point Failed QA' is displayed on the screen.

Adjust the placement of the tip of the handset by lifting it off the cervix, repositioning it and then repeating the process. A green LED on the snout indicates correct positioning.

9.2 Warnings

Warnings are displayed in red on the handset screen and accompanied by an audible alarm. See Specifications in Section 12 for details of the audible alarms.

- Select **Mute** and press **Enter** to turn off the audible alarm for two minutes.

9.2.1 Warning: Low Battery



This screen appears when the battery charge level falls below the 'low battery' warning threshold.

The handset should be returned to the docking station to charge as soon as the current examination is completed. An examination should **not** be started if this warning is already apparent.

9.2.2 System Alarm

A System Alarm screen is displayed if there is a problem with the device.

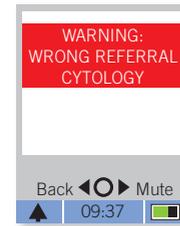


Do not attempt to use the device if a System Alarm has occurred. Turn the device off and contact the supplier for advice quoting the Alarm Code that has appeared.

The following alarms may occur:

ALARM	CAUSE	ACTION
Code 0000: Unknown.	The cause of the alarm cannot be determined.	Return for service
Code 0001: Calibration Failed	The device has failed to calibrate successfully.	Return for service
Code 0002: Self-Test Failed	The device has not completed its self-test successfully and may not have erased previous session information.	Return for service
Code 0003: Default Configuration Loaded	No configuration is loaded onto the handset.	Return for service
Code 0004: Update failed	A software update for the handset was not received correctly.	Turn off then try again

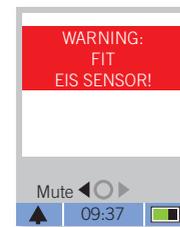
9.2.3 Warning: Wrong Referral Cytology



This screen appears when an operator has selected a different referral cytology result to the one downloaded to the handset from the PC Application as part of the session information.

- The handset should be returned to the docking station and session information re-entered ensuring that the referral cytology is correctly entered.

9.2.4 Warning: Fit Sensor!



This screen indicates that the handset has not been fitted with a single-use EIS sensor. Both LEDs on the snout will also flash.

- Fit an EIS sensor onto the handset and ensure that it is pushed fully home.

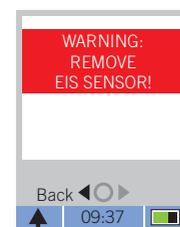
9.2.5 Warning: Reading Failed!



This screen appears when a reading has failed.

- Select **Back** and press **Enter** and re-take the reading.

9.2.6 Warning: Remove Sensor!

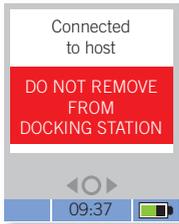


This screen appears when the handset has been returned to the docking station with the EIS sensor still attached.

- Remove the EIS sensor and return the handset to the docking station.

10 | Troubleshooting and Fault Finding

9.2.7 Connected to Host: Active Link



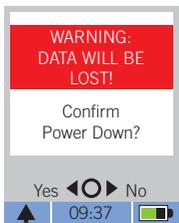
This screen indicates that the PC Application is downloading a software update to the handset. No action is required by the operator.



Do not remove the handset from the docking station when a software update is in progress.

9.2.8 Warning: Data Will Be Lost!

This screen indicates that the 'Power Down' function has been requested but the operator has not downloaded data from the handset.



- Select **Yes** and press **Enter** to turn the handset off and lose session information.
- Select **No** and press **Enter** to return to the previous screen.

To retain measurements collected from the current session, return the handset to the docking station and download the data using the PC Application.

POSSIBLE	POSSIBLE CAUSE	POSSIBLE SOLUTION
Handset not charging when placed onto docking station.	Docking station not plugged into a PC or the PC is turned off.	Ensure the docking station is connected to a PC using the USB cable and that the PC is switched on. The isolation unit on the USB cable should have the green LED lit when the USB cable is plugged in and the handset is docked. A red light shows when the handset is removed. Ensure PC Application is running and recognises when the handset has been connected.
Failing QA on readings.	EIS sensor not correctly fitted.	Remove the EIS sensor and re-fit it, taking care that the sensor is properly positioned to contact the locating pin on the underside of the snout. The sensor can be removed from the handset even during a set of readings without losing the data.
'Patient ID: None' is displayed on the handset screen at the start of the examination.	The handset was not properly connected to the PC so that the patient data could be downloaded.	Check that the handset is correctly located on the docking station – 'Connected to host' should be shown on the handset screen. Check that the docking station is connected to a working USB port on the PC. Try an alternative USB port if there is any doubt. The green LED on the isolation unit on the USB cable should be lit when the handset is docked.
The 'Connect Device' warning is displayed on the data entry screen even though the device is connected.	The device driver for the USB connection is either not installed or has ceased to operate properly.	The CD that comes with the ZedScan™ I contains the device drivers for the USB connection. The driver can be re-installed.

11 | Cleaning and Maintenance

POSSIBLE	POSSIBLE CAUSE	POSSIBLE SOLUTION
EIS sensor fails to engage on the handset.	The sensor may not be positioned correctly.	Ensure that the sensor is placed on to the snout of the handset so that the locating feature on the bottom of the sleeve engages with the locating pin on the snout of the handset.
Handset Interface freezes. Cannot operate any of the key functions.	The handset may have suffered a software problem.	Power down the handset and then turn it on again. Any data collected by the handset will have been lost but you can either start again or chose to carry out a colposcopic examination without the ZedScan™ I . If this problem repeats itself then return the device to the supplier. If the handset does not respond to the power button, return the device to the supplier.
Handset will not switch on.	The battery may not be sufficiently charged. The handset may have been stored in power saving mode, causing the battery to deplete.	Connect the handset to the docking station and allow it to charge for 2-3 hours prior to use. Ensure the handset is powered down and switched off after use to prevent depletion of the battery.
The handset does not fully charge after 2-3 hours.	The USB port may not be supplying sufficient current to the device.	The USB port should supply a current of 500mA. Check the available current supplied via the USB port. If the USB port is not capable of supplying 500mA, a powered USB hub can be used to boost the available current. (See Section 12.2).



For further advice and assistance on troubleshooting or to report a fault with your ZedScan system, please contact your local supplier or e-mail Zilico on: support@zilico.co.uk



This device is a precision electronic instrument and must be repaired by qualified technical professionals. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.

11.1 General Cleaning Guidelines

Wipe the handset and base unit with a wipe approved for the cleaning and decontamination of medical equipment. Do not use undiluted bleach, detergent or any other cleaning solution, as permanent damage could result. Dry with a soft cloth or allow to air dry.

The device does not require sterilisation and should not be immersed in liquid. Do not autoclave.

Prevention of cross contamination between patients is achieved by use of the single-use EIS sensor.



The handset and docking station have no level of protection against the ingress of fluids.

11.2 Preventative Maintenance

11.2.1 General

Do not drop the device or use it for purposes other than its intended use.

11.2.2 Battery

The battery has a life of 3 years.

The battery in the handset must only be changed by Zilico-authorized service personnel.

11.3 Calibrations and Adjustments

The device has a built in quality assurance test to ensure that the internal circuits are functioning correctly. No further routine maintenance or calibration or adjustment is needed.

If the device has not been used for a prolonged period of time, allow it to sit on the docking station, connected to a PC for one to two hours to fully re-charge.

11.4 Storage and Care

The handset should be connected to the docking station when not in use. Ensure the handset is powered down and switched off prior to storage to avoid depletion of the battery.

When handling the handset, avoid contact with the four pins at the end of the snout. Damage to these pins may affect the correct operation of the device.

12 | Specifications

12.1 Handset

ITEM	TECHNICAL SPECIFICATION
Operating Voltage	4.75V to 5.25V dc at 500mA (max) from the docking station only. Otherwise internally powered.
Operating temperature range	5°C–35°C
Storage temperature range	-10°C–55°C
Operating and storage humidity	0–90% The device does not contain parts which are likely to be sensitive to humidity.
Operating and storage pressure	900–1100 mbar The device does not contain parts which are likely to be sensitive to atmospheric pressure.
Level of ingress protection	IPX0
Operating range	
76Hz – 20kHz	0–1500Ω
20kHz – 100kHz	0–500Ω
100kHz – 625kHz	0–250Ω
Accuracy	
305Hz – 20kHz	100–250Ω ±2%+5Ω
50Hz – 20kHz	250–1500Ω ±5%
20kHz – 100kHz	100–500Ω ±5%
100kHz – 156.25kHz	100–250Ω ±5%
156.25kHz – 625kHz	100–250Ω ±10%
All frequencies	<100Ω ±5%+5Ω
Audible tones	'High' tone = 988Hz ±1% (B5), 'Mid' tone = 880Hz ±1% (A5), 'Low' tone = 784Hz ±1% (G5).
Tone 1	200ms high, 50ms gap, 200ms low. Used for a successful self-test on power-up.
Tone 2	200ms mid, 200ms gap, 200ms mid; pair repeated every 5s. Used for warnings.
Tone 3	200ms high, 200ms gap; repeated indefinitely. Used for alarms.

Note that the results of the measurements made by the handset are not directly available to the operator as impedances as they are converted into a measurement of the likelihood that HG-CIN is present. The accuracies given here are provided as a statement of the measurement limits of the device.

12.2 Docking Station

ITEM	TECHNICAL SPECIFICATION
Operating Voltage	4.75V to 5.25V dc at 500mA (max) from a USB type A host or USB charger only.
Operating temperature range	5°C–35°C
Storage temperature range	-10°C–55°C
Operating and storage humidity	0–90% The device does not contain parts which are likely to be sensitive to humidity.
Operating and storage pressure	900–1100 mbar The device does not contain parts which are likely to be sensitive to atmospheric pressure.
Level of ingress protection	IPX0

Connection to a USB type A host port capable of supplying a current of 500mA.

Some PCs or laptops may have USB ports capable of supplying 100mA. If this is the case, the handset will not charge effectively. A powered USB hub can be used in this case to boost the available current. Contact the supplier for further details.

12.3 Agency Approvals

Approved to EN60601-1 and EN60601-1-2. The handset is Internally Powered when used with the patient. It is a Type BF applied Part. The docking station is suitable for connection to EN60601-1 or EN60950 ITE equipment.

A process which follows the requirements of ISO13485:2012, ISO14971:2012, EN62304:2006 and EN62366:2008 was used in design of this device.

Designed and manufactured following a process certified against ISO13485:2012 and 93/42/EEC Annex II.

12.4 Emissions and Immunity Information

This device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided within this document. Portable and mobile RF communications equipment can affect the readings made by this device.



This equipment is intended for use by healthcare professionals only.

Do not use additional cables with this system. The cable attached to the docking station is intended to plug directly into a USB Type A port on a desktop PC or laptop.

The handset must be used with a single-use EIS sensor when making measurements on patients. Failure to do so could affect the accuracy of the measurement.

Use of this device with other cables or accessories could increase the EMC emissions or decrease the EMC immunity of the system.

GUIDANCE AND MANUFACTURER'S DECLARATION — ELECTROMAGNETIC EMISSIONS

The **ZedScan™ I** is intended for use in the electromagnetic environment specified below. The customer or user of the **ZedScan™ I** should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The ZedScan™ I uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF CISPR 11	Class B	The ZedScan™ I is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	The ZedScan™ I is not intended to be connected to ITE equipment which is connected to the public low-voltage supply network that supplies buildings used for domestic purposes.

If the **ZedScan™ I** is stacked or used adjacent to other equipment, observe the **ZedScan™ I** and other equipment to verify normal operation before use.

GUIDANCE AND MANUFACTURER'S DECLARATION — ELECTROMAGNETIC IMMUNITY

The **ZedScan™ I** is intended for use in the electromagnetic environment specified below. The customer or user of the **ZedScan™ I** should assure that it is used in such an environment.

Immunity test	IEC 60601 – test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% Note 2 Note 3
Electrical fast transient/burst IEC 61000-4-4	±2kV	±2kV on USB connection between stand and ITE equipment	Mains power quality to ITE equipment should be that of a typical commercial or hospital environment. Note 3
Surge IEC 61000-4-5	Not applicable	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power input lines IEC 61000-4-11	Not applicable	Not applicable	Not applicable
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Note 1: The **ZedScan™ I** does not directly connect to the supply mains.

Note 2: Operation and accuracy of handset tested whilst handheld, without resetting, false alarms or change of operating mode and able to make readings, this is considered essential performance.

Note 3: Ability for battery to charge, and for data communications to be achieved tested whilst handset docked to stand and connected to ITE equipment, this is considered essential performance.

GUIDANCE AND MANUFACTURER'S DECLARATION — ELECTROMAGNETIC IMMUNITY

The **ZedScan™ I** is intended for use in the electromagnetic environment specified below. The customer or user of the **ZedScan™ I** should assure that it is used in such an environment.

Immunity test	IEC 60601 – test level	Compliance level	Electromagnetic environment – guidance
Conducted Immunity IEC 61000-4-6	3Vrms 150kHz to 80MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the ZedScan™ I when connected together; including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	$d = 1.2 \sqrt{P}$ 80MHz to 800MHz $d = 2.3 \sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m) : Note b. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey : Note c, should be less than the compliance level in each frequency range : Note d. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note a: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

Note b: The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

Note c: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **ZedScan™ I** is used exceeds the applicable RF compliance level above, the **ZedScan™ I** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **ZedScan™ I**.

Note d: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

GUIDANCE AND MANUFACTURER'S DECLARATION — ELECTROMAGNETIC IMMUNITY

The **ZedScan™ I** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **ZedScan™ I** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **ZedScan™ I** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitted W	Separation distance according to frequency of transmitted m		
	150kHz to 80MHz $d = 1.2 \sqrt{P}$	80MHz to 800MHz $d = 1.2 \sqrt{P}$	800MHz to 2.5GHz $d = 2.3 \sqrt{P}$
Conducted Immunity IEC 61000-4-6			
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

12.5 Accessories

The handset is supplied with a docking station and PC Application. Single-use EIS sensors are sold separately.

Note: Examination by EIS requires the use of standard colposcopy instruments and consumables. These will not be supplied by Zilico.

12.6 Warranty

Zilico warrants **ZedScan™ I**, when new, to be free of defects in material and workmanship and to perform in accordance with manufacturer's specifications for a period of one year from the date of purchase from Zilico or its authorised distributors or agents.

Zilico will either repair or replace any components found to be defective or at variance from manufacturer's specifications within this time at no cost to the customer. It shall be the purchaser's responsibility to return **ZedScan™ I** to Zilico or an authorised distributor, agent, or service representative. This warranty does not include breakage or failure due to tampering, misuse, neglect, accidents, modification, or shipping.

This warranty is also void if the instrument is not used in accordance with manufacturer's recommendations or if repaired by other than Zilico or an authorised agent. Purchase date determines warranty requirements. No other express warranty is given.

Further technical information is available from the manufacturer.

12.7 Life of Product

The product has a service life of three to five years. It is able to detect an internal fault which leads to its loss of operation. In the event of a technical alarm condition being indicated by the device, return for service.

12.8 Disposal

This product is required to comply with the European Union's Waste Electrical and Electronic Equipment (WEEE) Directive 2002/96/EC. It is marked with the following symbol:



This symbol indicates that this product is not to be disposed of with household waste, according to the WEEE Directive (2002/96/EC) and your national law.

This product should be handed over to a designated collection point, e.g., on an authorised one-for-one basis when you buy a new similar product or to an authorised collection site for recycling waste Electrical and Electronic Equipment (EEE).

Improper handling of this type of waste could have a possible negative impact on the environment and human health due to potentially hazardous substance that are generally associated with EEE and products of this type. At the same time, your cooperation in the correct disposal of this product will contribute to the effective usage of natural resources.

For more information about recycling this product, please contact Zilico.

Caution:

- Dispose of used battery promptly. Keep away from unsupervised children. Do not disassemble and do not dispose of in fire.
- The battery used in this device may present a risk of fire or chemical burn if mistreated. Do not disassemble, heat above 100°C (212°F), or incinerate. Do not replace battery. Use of another battery may present a risk of fire or explosion.

Appendix 1 | Referral Cytology Reporting Systems

Modified BSCC 2008 (UK)

(Effective April 2013)

SQUAMOUS ABNORMALITIES	
ZedScan™ I Screen Display	Definitions
Borderline/Border	Borderline change in squamous cells, not otherwise specified
Low-grade/LGrade	Low-grade dyskaryosis (includes all cases of koilocytosis provided that no high-grade dyskaryosis is present)
?High-grade/?HGrade*	Borderline change, high-grade dyskaryosis not excluded*
High-grade/HGrade	High-grade dyskaryosis (moderate)
High-grade /HGrade	High-grade dyskaryosis (severe)
?invasive /?inv	High-grade dyskaryosis ?invasive squamous carcinoma

GLANDULAR ABNORMALITIES	
ZedScan™ I Screen Display	Definitions
Borderline glandular/BGlan	Borderline glandular
Glandular neoplasia/GNeo	Glandular neoplasia of endocervical type
Glandular neoplasia/GNeo	Glandular neoplasia of non-cervical type

* borderline/?High grade may be used in cervical screening programmes that do not employ high risk HPV testing to triage borderline or low grade dyskaryosis.

TBS 2001 (US and other countries)

(The Bethesda System)

SQUAMOUS ABNORMALITIES	
ZedScan™ I Screen Display	Definitions
ASC-US	Atypical squamous cells of undetermined significance
LSIL	Low-grade squamous intraepithelial lesion
ASC-H	Atypical squamous cells cannot exclude HSIL
HSIL	High-grade squamous intraepithelial lesion, favour moderate dysplasia
HSIL	High-grade squamous intraepithelial lesion, favour severe dysplasia
Squamous carcinoma/SqCar	Squamous cell carcinoma
GLANDULAR ABNORMALITIES	
ZedScan™ I Screen Display	Definitions
AGC	Atypical glandular cells, endocervical type
AIS	Endocervical adenocarcinoma in situ Endocervical adenocarcinoma Atypical endocervical cells, favour neoplastic
AIS	Adenocarcinoma: Endometrial Extrauterine NOS (specify in free text)

ECTP Terminology

(European Commission Training Programme)

SQUAMOUS ABNORMALITIES	
ZedScan™ I Screen Display	Definitions
Koilocytes/Koil	Koilocytes (without changes suggestive of intraepithelial neoplasia) Squamous cell changes (not definitely neoplastic but merit early repeat)
CIN 1	Mild dysplasia
CIN 2	Moderate dysplasia
CIN 3	Severe dysplasia Carcinoma in situ
?invasive/?inv	Severe dysplasia ?invasive Invasive squamous cell carcinoma
GLANDULAR ABNORMALITIES	
ZedScan™ I Screen Display	Definitions
Atypical glandular/AtypG	Atypical glandular cells (qualify)
AIS	AIS Endocervical adenocarcinoma
AIS	Adenocarcinoma: Endometrial Extrauterine NOS

AMBS 2004 (Australia)

(Australian Modified Bethesda System)

SQUAMOUS ABNORMALITIES	
ZedScan™ I Screen Display	Definitions
?LSIL	Possible low-grade squamous intraepithelial lesion
LSIL	Low-grade squamous intraepithelial lesion
?HSIL	Possible high-grade squamous intraepithelial lesion
HSIL	High-grade squamous intraepithelial lesion
Squamous carcinoma/SqCar	Squamous cell carcinoma
GLANDULAR ABNORMALITIES	
ZedScan™ I Screen Display	Definitions
AGCUS	Atypical endocervical cells of undetermined significance
AIS	Endocervical adenocarcinoma in situ Endocervical adenocarcinoma
AIS	Adenocarcinoma

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