# ZedScan™

*a new standard in colposcopy*

- Seamless integration into colposcopic practice
- Non-visual diagnosis
- Rapid real-time results
- Improved accuracy
- Better patient management
- Simple, easy to use system

# ZedScan™

*an objective approach to colposcopy*

## Challenges of Colposcopy

Colposcopy plays a significant role in the management of women with abnormal cervical cytology. The performance of colposcopy can however vary widely with reported sensitivity and specificity for the detection of HG-CIN ranging from 30–99% and 39–92% respectively.

Colposcopy is a subjective procedure with clinical decisions on whether to offer treatment, return to routine surveillance or retain the patient for follow up formed on the ability to assess the extent of disease based on visual colposcopic indicators. However, as not all HG-CIN exhibits aceto-whitening and changes in aceto-whiteness and vascularity are not specific to HG-CIN, inaccurate colposcopy can lead to inappropriate or over-treatment, diagnostic delays pending histological confirmation, or repeated colposcopic examination to avoid a missed diagnosis.

## **ZedScan**™: A quantitative assessment of the cervix

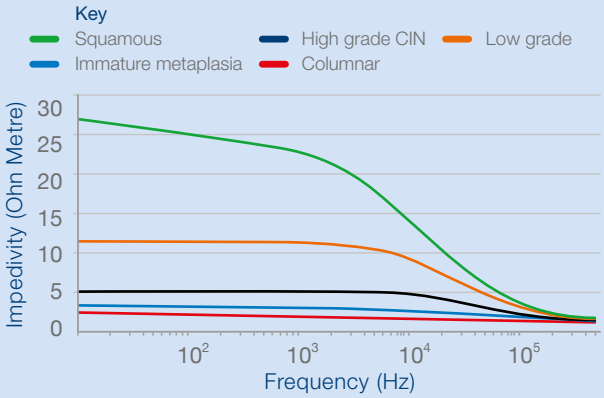
**ZedScan**™ is a multi-component system comprising a portable handset, docking station, single use EIS sensor and analysis software.

**ZedScan**™ is used as an adjunct to colposcopy, providing an objective assessment of cervical epithelial tissue and supporting better patient management by enabling clinicians to make a more informed decision at first visit.

## Mode of Action EIS

**ZedScan**™ uses Electrical Impedence Spectroscopy (EIS) to identify and differentiate cervical tissue types according to their electrical properties. These properties are known to change during the development of neoplasia, with more dysplastic cells exhibiting a reduced resistance to the flow of current as a result of structural changes.

### EIS spectra




## Objective assessment

**ZedScan**™ surveys the cervix by taking EIS readings at multiple points around the transformation zone. Each reading is given a nominal value and characterized by comparison with a reference, providing a non-visual semi-quantitative, reproducible assessment of the epithelial tissue.

## **ZedScan**™ Components

**ZedScan**™ consists of a portable hand-held device, docking station, single use sensor and analysis software. The docking station connects to a laptop or PC via a USB port enabling rapid data transfer when the handset is docked. Versatile, easy to use software allows the clinician to add comments to the results with the option to print for inclusion into the patient file, as required.

• Ergonomic wireless handset

• Single use sensor

• Easy-to-use software for analysis

• Requires minimal space

# ZedScan™

*increasing accuracy, informing decisions*

## Supplements colposcopy

- **ZedScan**™ incorporates seamlessly into existing colposcopic practice with EIS readings taken following colposcopic impression on application of 3–5% acetic acid
- Referral cytology and colposcopic impression are incorporated into the analysis for increased accuracy
- Increased sensitivity and specificity relative to colposcopy alone
- Locates the highest likelihood of HG-CIN when identifying the most appropriate biopsy site

## Non-visual diagnostic

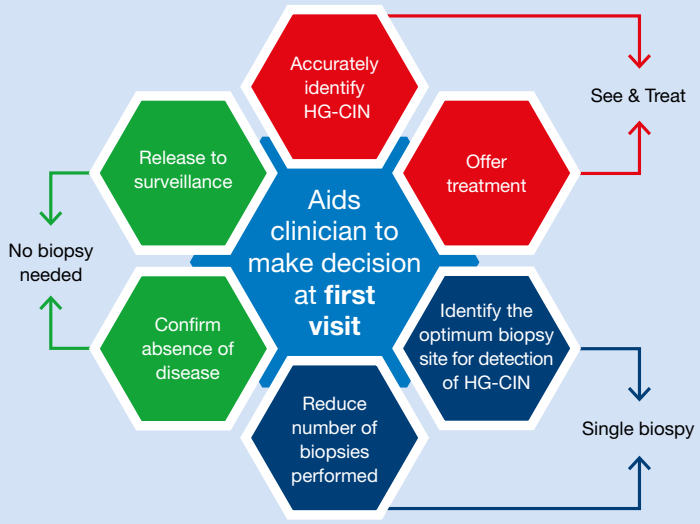
- Reduces subjectivity by generating a nominal value for each reading by EIS
- Quantifies the degree of dysplasia by comparing the reading at each point with a reference value
- Can detect and identify CIN status in non-aceto-white areas of the cervix, increasing accuracy of detection

## Increased accuracy in detecting HG-CIN when used as an adjunct to colposcopy

Clinical trials using **ZedScan**™ to supplement colposcopy have shown a significant increase in sensitivity, specificity and PPV relative to colposcopy alone.* *(See **ZedScan**™ Data Sheet for details.)*

The ZedScan algorithm utilises variable thresholds with cut-off values aimed at increasing specificity. As a result clinicians have greater confidence in making treatment decisions at first visit. *(Refer to See & Treat flier for details.)*

- Reduction in false positives and over-treatment
- Reduced risk of missed disease
- Better patient management




* Tidy J, Brown B, Healey T, Daayana S, Martin M, Prendiville W, Kitchener H. (2013), *Accuracy of detection of high-grade cervical intraepithelial neoplasia using electrical impedance spectroscopy with colposcopy.* BJOG 120 (4), pp 400-411

# ZedScan™

*confidence to treat: reassurance to release*

## Rapid, reliable, real-time results

- Surveys the cervix by taking 10–12 readings from around the transformation zone
- Scan of the cervix completed within 2–3 minutes
- Identification of optimum biopsy site in real-time using Single Point Mode
- Convenient single use sensor prevents cross contamination
- Integrated QA testing prior to each reading confirms integrity of the device
- Built-in checks ensure correct patient identification and cytology
- Full audit trail with patient ID, operator ID and cytology referral automatically integrated into each patient report

## Better patient management

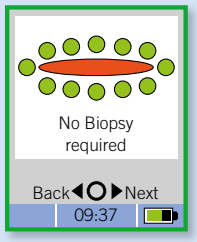
- 95% specificity, 97% PPV for HG-CIN gives clinicians confidence to offer See & Treat when appropriate
- High specificity ensures only those patients who qualify are identified for treatment, reducing the incidence of over-treatment
- Confirmation of normal colposcopy provides reassurance to release the patient back to routine surveillance, removing the need for confirmatory biopsy
- In patients selected for biopsy, the use of Single Point Mode identifies the most appropriate location for biopsy, eliminating the need to take multiple samples for histological analysis and minimising any associated patient discomfort

## HPV Positive, Low Grade Smear Referral

If HG CIN has not been detected at colposcopy and **ZedScan**™ also indicates the tissue is normal, it is highly unlikely that disease is present. A corresponding negative result from both **ZedScan**™ and colposcopy provides the necessary reassurance to release HPV positive low grade referral patients back to routine surveillance (according to local guidelines), without the need for a confirmatory biopsy.

Furthermore discharge of disease free patients releases clinic time for new appointments.

• Model of disease free cervix




• Negative ZedScan™ result

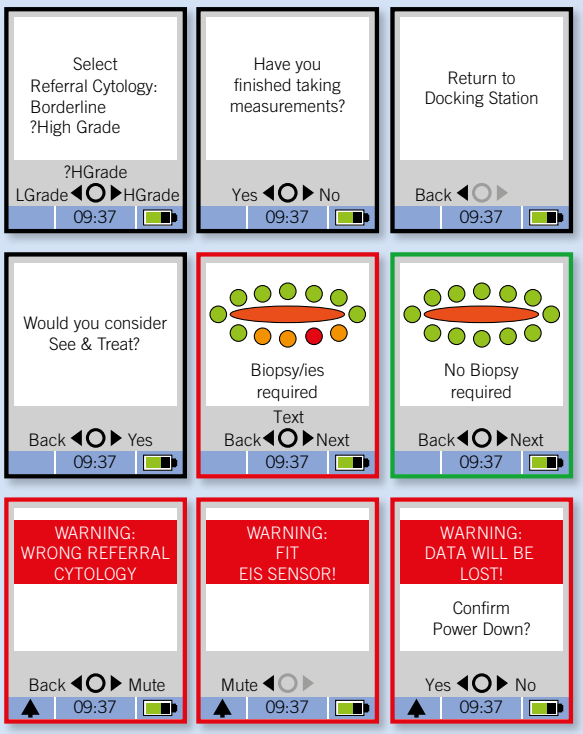
# ZedScan™

*when less means more*

## Easy-to-use

- Portable hand-held device and docking station can be easily transported between colposcopy suites
- Simple keypad and graphical display guide the user through the process in a stepwise manner
- Audible alerts and visible indicator on the snout and display show the status of each reading as it is being taken, enabling the user to track progress
- Automatic upload of results to database via the docking station
- Simple reporting software allows clinicians to add comments
- Results can be saved electronically or printed out for inclusion in patient files


## Graphical colour LCD interface displays results and directs the user through the process




The LCD screen provides real-time information during the examination with simple instructions indicating the next action.

Screenshots enable the user to track progress and reveal results, aiding decisions on treatment.

Warnings are displayed on screen alerting the user to issues as they occur and prompting corrective action.

# ZedScan™

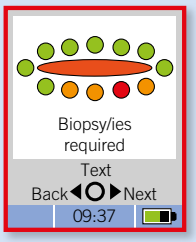
*when less means more*

## Positive economic impact

- Cost savings associated with a 40% reduction in treatment-only appointments as more patients are treated at first visit
- Up to 62% reduction in biopsies performed generating a significant decrease in histology costs**
- Release of clinic hours for new patient referrals, increases patient throughput and reduces waiting times

** Whyte, S., Bessey, A., Chilcott, J. (2013) *Economic Evaluation of the ZedScan electrical spectroscopy device used as an adjunct to colposcopy*, ScHARR report

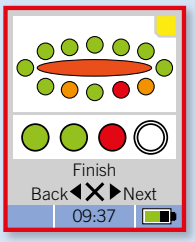

## Single Point mode identifies the optimum location to biopsy, avoiding the need to take multiple samples




- Red spot indicates highest likelihood of HG CIN

Colposcopists will often take multiple biopsies from around the transformation zone as a means of confirming HG-CIN.

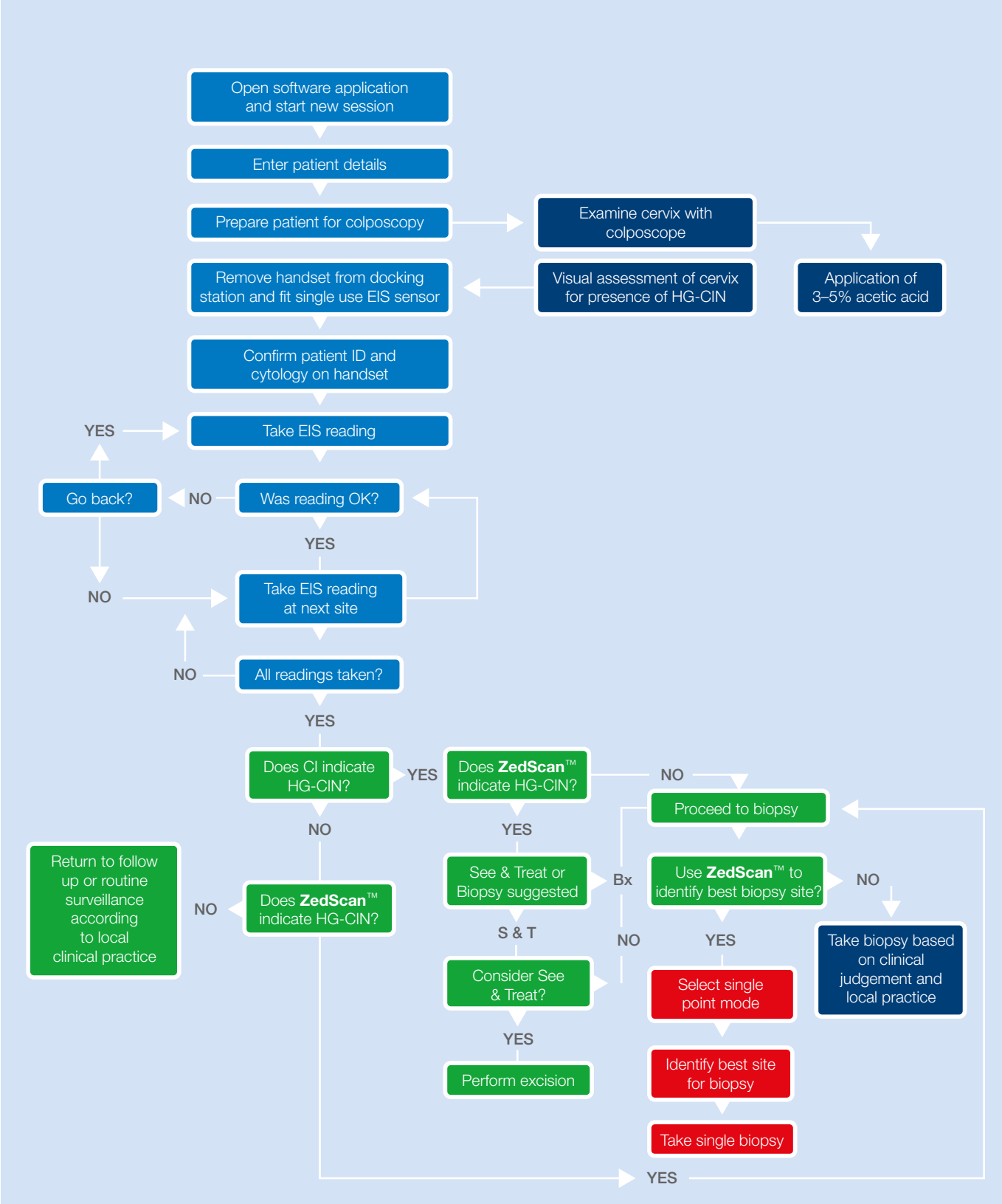
After completing a scan of the cervix, **ZedScan™** will identify the location of the points which indicate the highest likelihood of HG-CIN, denoted as red and orange dots on the graphical representation.




- Users can take up to 4 additional readings to locate the best biopsy site around the area originally identified as HG CIN, enabling the biopsy forceps to be brought into position

Switching to single point mode, users can then focus in on the most dysplastic tissue indicated by the red dot and in real-time, pinpoint the precise location at which to biopsy, whilst still in contact with the cervix.

# ZedScan™
## process flow chart



# ZedScan™

## Technical Specifications

| Handset | Technical Specification |
|---|---|
| Dimensions (D x W X H) | 49mm x 323mm x 157mm |
| Operating Voltage | 4.75V to 5.25V dc at 500mA (max) from the docking station only. |
| Operating temperature range | 5°C–35°C |
| Storage temperature range | -10°C–55°C |
| Operating and storage humidity | 0–90%<br>The device does not contain parts which are likely to be sensitive to humidity. |
| Operating and storage pressure | 900–1100 mbar<br>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 |
| **Docking Station** | **Technical Specification** |
| Dimensions (D x W x H) | 125mm x 276mm x 76mm<br>125mm x 276mm x 117mm (with docked handset) |
| 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%<br>The device does not contain parts which are likely to be sensitive to humidity. |
| Operating and storage pressure | 900–1100 mbar<br>The device does not contain parts which are likely to be sensitive to atmospheric pressure. |
| Level of ingress protection | IPX0 |

## Ordering Information

| Product Code | Description | Pack size |
|---|---|---|
| ZS1UK01C | **ZedScan**™ system<br>Includes 1 x handset, 1 x docking station,<br>1 CD containing software application with 1 user licence,<br>Instructions for use. | 1 System |
| ZS-CX120S | Single use EIS sensor | 1 x 120 individually wrapped sensors |

## Supplied and manufactured by

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