

In relation to electrical impedance imaging generally they conclude that:

EIT is a relatively new imaging method... evolved over the last 20 years. It has the potential to be of great value in clinical diagnosis; however, EIT is a technically difficult problem to solve in terms of developing hardware for data capture and the algorithms to reconstruct the images. EIT (offers) low cost, but low resolution, images. Inaccurate modelling... and poor signal-to-noise ratio causes its main limitation.

Mammography is recognised as the only diagnostic tool which has had a significant impact on screening (and diagnosis/staging). Further study, comparing EIT with mammography geometry is recommended.

(ix) Technology review: the use of electrical impedance scanning in the detection of breast cancer³²

Commencing with a review of the technology involved in EIS, the article then covers the research regarding the TransScan TS2000 in some depth – including studies comparing this device with mammogram and other modalities such as ultrasound and Tc-sestamibi scintimammography.

With regard to the device under assessment, the existence of the MEIK device and Cherepenin's work is noted but there is no discussion of the device's clinical relevance. The only comment made is that robust data for the MEIK is limited and the clinical application of these algorithms has yet to be demonstrated.

(x) Electrical impedance scanning for early detection of breast cancer in young women: preliminary results of a multicenter prospective clinical trial³³

A prospective, multicentre clinical trial assessing the device TS2000ED; subjects were recruited from 3 US and 3 Israeli sites – asymptomatic women presented at these clinics for breast screening; a smaller sub-set presented for breast biopsy. This preliminary study was designed to assess the sensitivity and specificity for the use of this device for routine screening of women aged 30-39 years. The inclusion and exclusion criteria are stated:

- aged 30-39 inclusive; not pregnant; no previous cosmetic breast operation, breast biopsy or operation within 90 days of the exam, or fine needle aspiration (FNA) within 30 days of exam;
- not lactated in within the previous 3 months; no exposure to chemotherapeutic agents; no known breast cancer; no implanted electrical device; no palpable breast abnormality.

A total of 1,103 subjects were eligible and all women underwent CBE (clinical breast examination) and EIS (electrical impedance scanning); EIS was undertaken prior to any additional management and the EIS researcher was blinded to results of other investigations (including biopsies).

Sensitivity was calculated on data obtained from patients with subsequently histologically proven malignancy. Specificity was calculated on the sub-population of all women who had negative assessment with all other screening and diagnostic modalities or who were independently clinically assessed (CBE) as not requiring any further screening assessment.

³² Hope, TA, Iles, SE: Technology review: the use of electrical impedance scanning in the detection of breast cancer; *Breast Cancer Res* 2004, 6: 69-74

³³ Stojadinovic, A, Nissan, A, Gallimidi, Z et al: Electrical impedance scanning for early detection of breast cancer in young women: preliminary results of a multicenter prospective clinical trial; *Journal of Clinical Oncology*; 23: 12: 2703-2715; April 20, 2005

The algorithm (P) for this study was developed on a learning data set of 43 cancer and 335 non-cancer patients aged ≤ 50 years. Sensitivity and specificity for this learning group was 37% and 91% respectively. The authors note that as EIS is strongly influenced by hormonal factors, and electrical impedance reduces with age, so differing algorithms need to be employed for different aged populations.

This study calculated the absolute breast cancer risk of T-Scan positive women at 1:147, as compared to 1:1,186 for T-Scan negative women.

On analysis the sample size of carcinomas was considered insufficient to examine sensitivity, however specificity was assessed. The results of this study are presented in the tables below.

Table 3: CBE, US and MMG findings in women with positive and negative EIS examinations

	EIS negative			EIS positive		
	n:patients	n:biopsies	n:cancers	n:patients	n:biopsies	n:cancers
CBE normal	790	98	17	99	9	2
CBE abnormal	198	66	7	16	6	3
MMG: 0	9	8	1	1	0	0
MMG: 1	235	17	2	22	4	0
MMG: 2	127	12	1	16	1	1
MMG: 3	35	16	0	3	1	0
MMG: 4	76	72	12	5	3	1
MMG: 5	10	10	7	2	2	2
US: no finding	102	18	4	16	5	0
US: simple cyst	59	9	0	10	0	0
US: solid lesion	120	91	15	14	6	3
US: mixed solid/cystic	7	5	0	1	1	0

Table 4: Specificity, sensitivity, and 95% CIs in patient cases recorded at all six sites

Variable	All cases: %	95%CI	Age in years			
			<40: % (n)	40-49:(n)	≥ 50 : %(n)	
Specificity						
Screening	89	87% to 91%	90 (467)	91 (320)	81 (32)	
Benign/no biopsy	88	82% to 94%	87 (52)	89 (53)	no observations	
Benign/biopsy	93	89% to 97%	91 (55)	97 (67)	89 (28)	
Total non-cancer	90	88% to 92%	89 (574)	91 (440)	85 (60)	
Sensitivity						
All cancers	17	4% to 30%	50 (6)	10 (10)	8 (13)	
Invasive cancers	17	2% to 32%	75 (4)	0 (8)	9 (11)	
NPV	Total	98	97% to 99%	99 (516)	98 (409)	81 (63)
PPV	Total	4	0% to 8%	5 (64)	2 (41)	10 (10)

Table 6: Probability of breast cancer for an EIS-positive woman relative to that of a woman randomly selected from the population according to age

Age in years	Sensitivity	Specificity	Rate of carcinoma	Increased relative likelihood
All ages	17	89	6 of 1,000	1.53
<50	25	90	3 of 1,000	2.48
<40	50	89	1.5 of 1,000	4.52

The authors noted that the study is limited: the sample population may be skewed as the subjects were drawn from breast care clinics; there was no longer term follow-up and the small sample size for cancers. They conclude that:

Sensitivity and specificity in the intended use population (younger than age 40) for the modified EIS breast algorithm was 50% and 90% respectively; however, sample size for detected cancers in this population is limited and continued follow-up and study are necessary.

And that:

Given the preliminary findings in this study, however, larger population-based studies centred on average-risk women younger than age 40 are needed to explore this issue further.

(xi) Prospective study of electrical impedance scanning for identifying young women at risk of breast cancer³⁴

This report is the first report from a clinical trial undertaken in the US and Israel; the study protocol was designed with FDA input. It was considered a pivotal study for assessment of this device for breast cancer risk assessment in young women.

A two-arm (specificity and sensitivity cohorts), prospective, observational, multicentre clinical trial assessing the device TS2000ED for sensitivity and specificity for routine screening women of asymptomatic aged 30-39; subjects were recruited from 24 sites, including gynaecology clinics with no primary patent presentations for breast disease. There was only partial overlap (2 sites) between the two arms of the study. The inclusion and exclusion criteria are stated:

(women) aged 30-39 inclusive; not pregnant; no previous cosmetic breast operation, breast biopsy or operation within 90 days of the exam, or fine needle aspiration (FNA) within 30 days of exam; not lactated in within the previous 3 months; no exposure to chemotherapeutic agents; no known breast cancer; no implanted electrical device; no palpable breast abnormality.

The EISYS algorithm for this study was refined on an independent data set of 700 patients with verified breast cancer. The previous algorithm(P) was refined to maximise specificity (minimise false negatives) while maintaining a reasonable sensitivity.

EIS examiners underwent standardised training; the EIS examiner was blinded as to the clinical status of the patients.

The authors state that there were no adverse effects from the use of this device, nor reports of patient discomfort; results from a post-procedure questionnaire have been included.

Specificity arm: A total of 1,361 asymptomatic women between the ages of 30-39 were enrolled consecutively from 13 sites (11 US and 2 Israeli); subjects were recruited from women who attended for a routine well-woman examination. The inclusion and exclusion criteria are stated.

All women underwent CBE and EIS; the EIS results were recorded and the woman was advised of the result, but there was no study protocol for further investigation of

³⁴ Stojadinovic, A, Moskovitz, O, Gallimidi, Z et al: Prospective study of electrical impedance scanning for identifying young women at risk of breast cancer; *Breast Cancer Research and Treatment* (2006) 97: 179-189

those women who were EIS positive (further investigation was left at the discretion of the attending doctor); the authors state:

Hence, in this study it was assumed that all participating women (in this arm of the study) were negative for breast cancer.

The overall EIS positive rate was 4.9%; hence the specificity was 95.1% (95% CI = 94.0 to 96.2%). We do not have adequate follow up to account for possible cancers that may have been detected in this population but the correction, if any, is minimal at best.

Sensitivity arm: A total of 189 women who had been referred for a breast biopsy and aged 30-45 years were enrolled consecutively from 13 sites (7 US and 6 Israeli); the inclusion and exclusion criteria are stated. The inclusion of women up to the age of 45 (rather than the initial protocol age of 39) was done to expedite the accrual of women while maintaining pre-menopausal breast tissue characteristics; the change in the protocol was approved by the FDA. All women underwent conventional investigations plus EIS immediately prior to biopsy.

50/189 (26.5%) of the women were found to have malignancies; with statistical analysis the authors concludes that the average sensitivity was 38% (95% confidence interval = 25-49%).

Additional analysis of the population variables showed that increasing brassiere cup size, a positive family history and age were significantly correlated with positive EIS results ($p < 0.05$). The use of EIS to assess the relative risk was also statistically determined:

Combining the results from the two studies, the average relative risk of a woman with a positive EIS examination was 7.68 (95% CI= 4.06 to 11.3).

This study calculated the absolute breast cancer risk of T-Scan positive women at 1:108, as compared to 1:918 for T-Scan negative women.

Table 5: Relative probability of having breast cancer if EIS positive relative to lifetime risk of cancer according to established risk factors:

Class	Condition	Relative risk
EIS screening	EIS positive	7.7
Family history:	One 1 st degree relative	1.2
	Two 1 st degree relatives	2.9
	Three or more 1 st degree relatives	3.9
Genetic factors	BRCA mutation	5.7
Histopathology	Atypical hyperplasia	4.0
	LCIS	6.0 to 12.0

There are flaws in the study protocol as described, specifically with the assumption that all women in the specificity arm were malignancy free; the authors considered that the approach was reasonable given the low disease prevalence in the intended use population. It should be noted that however, that with statistical analysis this assumption would bias any results *against* the T-Scan device.

The study protocol did not include any follow-up of EIS positive women in the specificity arm of the study: further investigation is stated to have been left to the discretion of the attending physician and is not recorded in the study. An ethical issue is raised, whether, given the study aim (and subsequent findings), the women with a

positive EIS should have routinely been offered further investigation as per the proposed screening use of this device. The study authors do not comment on this ethical issue in this journal article.

The authors conclude that:

at its current level of performance EIS should only be used to 'rule in' (identify) women who should be followed up rather than 'rule out' women who have known abnormalities from being recommended for a follow-up because of a negative EIS examination.

And that:

further large-scale, long-term follow-up studies are required and (are) underway in the intended use population.

(xii) Electrical impedance scanning as a new breast cancer risk stratification tool for young women³⁵

This study is of the final results from the multi-centre clinical trial undertaken in the US and Israel described above. The study protocol was designed with FDA input and as this is a continuation of the same trial the protocol is the same as that previously described above. In this journal article the authors address the potential flaws and ethical concerns raised in the review (above) of the article based on the preliminary findings.

Specificity arm: A total of 1,751 asymptomatic women between the ages of 30-39 were enrolled consecutively from 17 sites (15 US and 2 Israeli). Subjects were recruited from women who attended for a routine well-woman examination; all women underwent CBE and EIS. 93 women in this cohort were T-Scan positive; the specificity was calculated at 94.7% (95% CI = 93.7 to 95.7%).

Sensitivity arm: A total of 390 women who had been referred for a breast biopsy and aged 30-45 years were enrolled consecutively from 18 sites (12 US and 6 Israeli). All women underwent conventional investigations plus EIS immediately prior to biopsy. In this cohort, 87 histopathologically confirmed malignancies were found; sensitivity was calculated at 26.4% (95% confidence interval = 17.4 to 35.4%).

The results from the two study arms...were combined to estimate the relative probability that a T-Scan positive woman has breast cancer relative to that of a randomly selected woman from the population at large.

The table is reproduced below; the authors note that:

A T-Scan positive woman was almost five times as likely as the average woman in the 30-39 years old population to have breast cancer *at the time of the examination*.

Table 5: Estimated relative and absolute risks of breast cancer in different groups of women:

Female population	Relative risk (95%CI)	Absolute risk
Average risk, age 30-39 years	-	1:667 0.0015
Average risk, age 40-49 years	-	1:340* 0.0029
1 st degree relative with breast cancer	2.0 (1.7 to 3.9)	1:333 0.0030
T-Scan screen positive	4.95 (3.16 to 7.14)	1:136 0.0074

*Absolute risk = (1cancer/400 mammograms)/85% for assumed mammographic sensitivity in women age 40-49

Second to last column is number of cancers/mammogram performed and last column is absolute risk of cancer.

³⁵ Stojadinovic, A, Nissan, A, Shriver, GD et al: Electrical impedance scanning as a new breast cancer risk stratification tool for young women; *Journal of Surgical Oncology*; 2008; 97: 112-120

The authors have specifically commented about the concerns raised with the previous article reporting the preliminary results of this study. Firstly, the assumption made regarding the specificity cohort, that all women in this cohort were assumed not to have breast cancer. They state:

Hence, all T-Scan positive results in this arm were considered false positives. It should be noted that this assumption biases estimates of specificity against the T-Scan device.

And:

This study did not include long-term follow-up of T-Scan positive patients. Accordingly, the study does not provide significant insight regarding the extent to which women who are positive on a current T-Scan examination carry a higher future or lifetime risk for breast cancer.

Secondly, they address the ethical concerns raised by the study protocol: that the protocol did not stipulate follow-up of EIS positive women in the specificity arm of the study and that further investigation was left to the discretion of the attending physician and is not recorded in the study. They state that conventional, currently recognised management was undertaken and that:

Importantly, the assumption that all T-Scan negative patients were breast cancer-free did not affect patient care.

In addition they state that:

Negative T-Scan results were not taken into consideration in the clinical management of women in either cohort.

They conclude that:

The targeted use of this non-invasive and low cost, low risk stratification tool and the paradigm tested in this study may...provide an opportunity to identify women who otherwise would be excluded from further testing and suffer the consequences of delayed diagnosis of breast cancer.

Importantly, the data assembled to date determines the risk at time of examination and suggests risk for developing breast cancer at a later time; however continued surveillance in T-Scan positive patients is warranted as lifetime risk in this patient cohort is unknown and remains the focus of on-going multi-year trials.

(xiii) Expert Report: assessment of breast cancer risk in asymptomatic women age 30-39 using electrical impedance³⁶

This report reviews the pivotal study of the T-Scan 2000ED conducted under the auspices of the FDA. The reports preliminary and final results were published and the two relevant papers have been reviewed above.

Background is given, including that breast cancer is the leading cause of cancer death for women aged 15 to 54; in absolute numbers in the USA, about 12,000 new cases of breast cancer are diagnosed each year in women under age 40 (approximately 9,000 new cervical cancer cases are diagnosed each year among all women). Most women under 40 present having self-detected their cancer, and as a result the cancers are more advanced, with a greater morbidity and mortality.

The report notes that prior to the initiation of the study, the clinically relevant threshold for success for this device was determined by the FDA as a relative probability for breast cancer that is equal to or greater than two times the average risk in the target population, which is similar to the risk of developing breast cancer for women with a first degree relative with breast cancer. Women in this latter category are routinely offered regular screening.

³⁶ Akin, MD, Colton, TC et al: Expert Report: assessment of breast cancer risk in asymptomatic women age 30-39 using electrical impedance; FDA Expert Committee; downloaded 24/6/2010

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The authors of this report conclude that:

Because all candidates for the T-Scan ED exam are asymptomatic, under the age of 40, and have no known risk factors, it is imperative to recognize that these women would not be identified as having increased risk without the availability of the T-Scan ED exam, and typically would not be referred to a radiologist until the age of 40 or the detection of a palpable mass.

Given that the T-Scan ED exam provides useful information, does not entail risk to the patient and fills an important clinical void for both patients and physicians, we fully expect that as the T-Scan ED comes to market it will occupy an important place in the Ob/Gyn risk assessment armamentarium and drive further development in an area that is very much in need of technological improvement.

We believe that sufficient data has been presented to conclude the T-Scan ED device is both safe and effective, and can be used as a complement to CBE in asymptomatic women ages 30-39. The pivotal trial data strongly support the conclusion that the T-Scan ED exam can successfully partition women into two groups: one that has an elevated risk for cancer and would benefit from additional surveillance and one that has an average (or lower) risk who would follow the current Standard of Care.

The T-Scan 2000 ED system addresses an unmet clinical and public health need, and presents no notable risks to the patient. We believe this PMA meets the standard for establishing safety and effectiveness, and therefore support approval of this technology for the proposed indications as labeled (*sic*).

It is noted that subsequent consideration by the FDA *Obstetrics and Gynecology Devices Panel*³⁷ resulted in the advice that this device be found "not approvable"; the documentation³⁸ of this decision was not available for this report.

(xiv) New and emerging technologies for breast cancer detection³⁹

The *Horizons* publication assesses and dismisses all EI devices as, although safe, ineffective for breast cancer diagnosis.

There are three misconceptions in the *Horizons* report:

- a) Although all of these devices use electrical signals, not all EI devices use the same technological process and not all EI devices are designed for stand-alone diagnosis. The assessment undertaken by the *Horizons* reviewer does not appear to have taken these differences into account.
- b) Only one of the studies that have been reviewed had breast cancer diagnosis as an endpoint; the other two identified risk stratification as the primary endpoint. The review appears to be solely an assessment of these types of device for breast cancer diagnosis and not of the differing types of device in relation to the differing therapeutic indications proposed: risk assessment and adjunct to mammogram.

³⁷<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/ucm125145.htm> (accessed 24 June 2010)

³⁸ Panel discussion transcript available for purchase from the FDA under FOI; this document was not accessed for this report.

³⁹ Australia and New Zealand Horizon Scanning Network: National Horizon Scanning Unit: Emerging Technology Bulletin: New and emerging technologies for breast cancer detection; *Department of Health and Aging; Australian Government*, February 2009

- c) The *Horizons* publication states that the Stojadinovic journal articles are of the same group of women with incremental recruitment. These studies have been reviewed in some detail in this report for comparison; it is clear that there are two separate studies, one is published in toto; the second study has followed an academic convention, with publication of preliminary results and subsequent publication of the final study results.

The question is raised regarding missed or delayed diagnosis if these devices are used. Despite the flaws identified in this report, this concern remains a significant one, particularly with the misrepresentation in the marketing of the one device currently on the ARTG (MEIK, the device under assessment).

6. Efficacy and Performance

EI is relatively new technology, with ongoing development since the late 1970's. In considering the potential clinical application of this technology there is some confusion as, although this group of devices all assess variations in electrical impedance, the means to do so varies, the operator technique varies and the information obtained is computer-manipulated and presented in differing ways.

MEIK, the device under assessment, provides a tomographic 3D image which then requires interpretation. There is limited research available on this device and the studies themselves are small and methodologically flawed. The studies presented by the sponsor and the one further study found during the literature search conclude that more research is required to establish if there is any clinically useful role for this device. At this stage there is no clinical evidence that this device is able to perform in either a screening, risk assessment or diagnostic role.

The clinical data available regarding the efficacy of other EI devices (T-Scan) is however substantial and credible. Given that T-Scan 2000 device operates in a different manner, the information regarding this device cannot be applied generally to all EI devices. The use of the T-Scan 2000 *as an adjunct to mammography, and for use and interpretation by radiologists*, is supported by the data available; the use of this device as a generic, direct to public, screening tool is not supported by the data available.

From the literature reviewed for this report, there is sufficient evidence to support the use of the T-Scan 2000ED device for routine screening *risk assessment of asymptomatic women aged 30-39 years*. Risk assessment is not diagnostic, nor a 'screening' test in the conventional sense; this assessment is akin to the non-diagnostic first trimester screening for Down's syndrome undertaken as part of the current Standard of Care (ultrasound and serum testing of the mother to obtain a risk evaluation, which then informs the need for further investigation). The use of this device as a generic, direct to public, screening tool is not supported by the data available. Any screening program would need to incorporate careful, conventional and appropriate assessment as follow-up for those women with a positive result, similar to the current Standard of Care for women with 1st degree relatives diagnosed with breast cancer.

7. Safety/Adverse events

From the literature reviewed, all forms of EI devices appear to be safe, without any adverse events reported by patients.

The main concern regarding this device, and this type of device generally, is misuse. In particular, the misapprehension by individual women that they have been appropriately screened and do not seek further assessment; the use of this device by non-medical personnel (the MEIK requires clinical interpretation of the images obtained as does the T-Scan 2000) and the persuasion of women away from acknowledged screening and investigative modalities with the false belief that this device offers a similar (or better) screening and assessment function.

Specifically regarding the device under assessment, this device is misrepresented in the information available from the websites. In particular the [redacted] site repeatedly mentions cancer, and cancer screening; the site does also state that [redacted] supports and recommends mammograms to those who are eligible... (but qualifies the advice by stating that)...Mammograms are suitable if you are postmenopausal, are not on HRT, and do not have dense breast tissue.' (folio, p111) The site advocates the use of this device for follow-up screening for women who have already had breast cancer (folio, p114). This advice is not consistent with the current Standard of Care and is not supported by any of the literature reviewed. These are serious misrepresentations of the capabilities of the MEIK device and EI technology in general.

Although not part of this review it is also noted that the [redacted] site recommends the use of both 'thermal radiometry' and 'infrared thermography' for breast cancer assessment. (folio, p 112)

8. Summary of comments and rationale:

EI is relatively new technology, with ongoing development since the late 1970's. In considering the potential clinical application of this technology there is some confusion as, although this group of devices all assess variations in electrical impedance, the means to do so varies, the operator technique varies and the information obtained is computer-manipulated and presented in differing ways.

MEIK, the device under assessment, provides a tomographic 3D image which then requires interpretation. There is limited research available on this device and the studies themselves are small and methodologically flawed. At this stage there is no clinical evidence that this device is able to perform in either a screening/risk assessment or diagnostic role.

The clinical data available regarding the efficacy of other EI devices (T-Scan) is however substantial and credible; however, the information regarding this device cannot be applied generally to all EI devices. The use of the T-Scan 2000 *as an adjunct to mammography, and for use and interpretation by radiologists*, is supported

by the data available; the use of this device as a generic, direct to public, screening tool is not supported by the data available.

From the literature reviewed for this report, there is sufficient evidence to support the use of the T-Scan 2000ED device for routine screening *risk assessment of asymptomatic women aged 30-39 years* (which then informs the need for further investigation). The use of this device as a generic, direct to public, screening tool is not supported by the data available. Any screening program would need to incorporate careful, conventional and appropriate assessment as follow-up for those women with a positive result, similar to the process currently undertaken with mammography by [REDACTED]

Although none of the EI devices have had any adverse events reported, the main concern regarding this type of device is misuse.

Unfortunately the flagrant and serious misuse of the MEIK device in this way in Australia is already apparent in the information available for assessment. Specifically, the misapprehension by individual women that they have been appropriately screened and do not seek further assessment; the use of this device by non-medical personnel (the MEIK requires clinical interpretation of the images obtained as does the T-Scan 2000); and the persuasion of women away from acknowledged screening and investigative modalities with the false belief that this device offers a similar (or better) screening and assessment function. An additional concern regarding the device under assessment is the serious misrepresentations of the capabilities of the MEIK device, and EI technology in general, on the sponsor and manufacturers websites.

9. Conclusion(s)

MEIK, the device under assessment, provides a tomographic 3D image which then requires interpretation. There is limited research available on this device and the studies themselves are small and methodologically flawed. At this stage there is no clinical evidence that this device is able to perform in either a screening/risk assessment or diagnostic role.

The clinical data available regarding the efficacy of other EI devices (T-Scan) is however substantial and credible; however, the information regarding this device cannot be applied generally to all EI devices. The use of the T-Scan 2000 *as an adjunct to mammography, and for use and interpretation by radiologists*, is supported by the data available. In addition, there is sufficient evidence to support the use of the T-Scan 2000ED device for routine screening *risk assessment of asymptomatic women aged 30-39 years* (which then informs the need for further investigation). The use of either the T-Scan 2000 or 2000ED devices as a generic, direct to public, screening tool is not supported by the data available.

Although none of the EI devices have had any adverse events reported, the main concern regarding this type of device is misuse and the impact on the health of individual patients as a result. Unfortunately the flagrant misuse of this device in this way is already apparent in the information submitted for assessment.

10. Recommendation(s):

The submitted clinical data and the clinical data provided by the literature search undertaken, does not meet the requirements of Schedule 3, Part 8 of the *Therapeutic Goods (Medical Devices) Regulations 2002* for the device under assessment ([REDACTED])
[REDACTED] – *Electrical impedance scanner*, (MEIK)
manufactured by [REDACTED]

In addition, there are substantial concerns regarding the current marketing of this device in Australia, the potential for misuse of this device, the impact on the health of individual patients as a result as well as regarding the implications for the health of the Australia public. Unfortunately the flagrant misuse of this device is already apparent in the information submitted for assessment.

Given the degree of foreseeable misuse (and the misuse to which this device has apparently already succumbed) the device does not have a favourable risk/benefit profile. In addition, with the known potential for a very serious medical condition and the lack of any supportive clinical evidence, the risk of an adverse outcome is extremely high.

Although there is clinical evidence available for other forms of EI technology, for other clinical indications, this cannot be extrapolated to the device under assessment. Based on the data available for assessment for this report, the [REDACTED]
[REDACTED] – *Electrical impedance scanner*, manufactured by [REDACTED]
[REDACTED] does not have a place in the market in Australia.

Name & dated signature of Clinical Assessor:

Name:	[REDACTED]	Date:	6 August 2010
Signature:	[REDACTED]		

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Appendix 1:

Bi-RADS Classification

The Breast Imaging Reporting and Data System (BI-RADS) has been developed by The American College of Radiology (ACR) in conjunction with other committees. The BI-RADS Assessment Categories have been used to develop clinical management strategies at each classification. The categories are:

- 0: Incomplete
- 1: Negative
- 2: Benign finding(s)
- 3: Probably benign (malignancy rate <2%)
- 4: Suspicious abnormality (up to 95% chance of malignancy)
- 5: Highly suggestive of malignancy (over 95% chance of malignancy)
- 6: Known biopsy – proven malignancy