BREAST-Q Version 2.0[©]

A Guide for Researchers and Clinicians

USER'S GUIDE VERSION 2.0 November 2017

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Table of Contents

1.	Wh	at is the BREAST-Q©?	3
2.	Hov	w was the BREAST-Q© Developed?	4
3.	BRI	EAST-Q© Scales	4
	3.1.	Augmentation Module	7
	3.2.	Reduction/Mastopexy Module	8
	3.3.	Mastectomy Module	9
	3.4.	Reconstruction Module	9
	3.5.	Breast Reconstruction Expectations Module	11
	3.6.	Breast Conserving Therapy Module	11
4.	Adı	ministration of the BREAST-Q©	12
5.	Sco	ring the BREAST-Q©	13
6.	Inte	erpretation of the BREAST-Q©	13
7.	Cor	nditions of Use of the BREAST-Q©	13
8.	Fre	quently Asked Questions	14
9.	BRI	EAST-Q© Publications	16
Αŗ	pend	ix 1: Modifications to BREAST-Q to create Version 2.0	16
Αŗ	pend	ix 2: QScore	21

1. What is the BREAST-Q©?

The BREAST-Q© is a rigorously developed patient-reported outcome (PRO) measure designed to evaluate outcomes among women undergoing different types of breast surgery. BREAST-Q Version 1.0 was published in 2009 and Version 2.0 was published in 2017. **Appendix 1** shows the minor modifications made to improve wording. Version 2.0 was tested in a much larger sample and the scores derived for the two versions is equivalent.

There are currently 6 BREAST-Q© modules. The Breast Cancer module (comprised of 4 of the 6 modules) is designed to provide clinicians and researchers the ability to tailor their own version of the questionnaire to suit their needs. Each module is divided into multiple scales that can be used independently. The scales are psychometrically linked across the various modules and patient treatment groups, and can thus be used for comparison between different patient groups.

- 1) Augmentation Module
- 2) Reduction/Mastopexy Module
- 3) Breast Cancer
 - a. Mastectomy Module
 - b. Reconstruction Module
 - c. Breast Reconstruction Expectations Module
 - d. Breast Conserving Therapy (BCT) Module

All BREAST-Q© modules are based on an underlying conceptual framework developed from extensive qualitative research with breast surgery patients, close examination of the research literature and engagement of healthcare professionals who work with breast surgery patients. The conceptual framework of the BREAST-Q© modules is comprised of the following two overarching themes (or domains): 1) Health-Related Quality of Life (QOL) and 2) Patient Satisfaction. Under each of these domains, there are six subthemes; QOL: 1) Psychosocial, 2) Physical and 3) Sexual well-being; and Patient Satisfaction: 4) Satisfaction with Breasts, 5) Satisfaction with Outcome and 6) Satisfaction with Care. Body image is an important concept for breast surgery patients. This concept is measured by several of our BREAST-Q© scales within each module.



2. How was the BREAST-Q© Developed?

A description of the development and validation of the BREAST-Q©, as well as many publications for further reading, is available in Section 9 - BREAST-Q© Publications.

3. BREAST-Q© Scales

The table below shows BREAST-Q© modules and scales, including the number of items, response options, time frame and the Flesch-Kincaid grade level (FK).

NOTE: The following BREAST-Q© scales in the Mastectomy, Breast Conserving Therapy and Reconstruction modules are exactly the same for <u>all breast cancer patients</u>.

- Preoperative scales: Satisfaction with Breasts, Psychosocial, Sexual and Physical Well-being Chest
- Postoperative scales: Satisfaction with Doctor, Medical Team and Office Staff

Name of Module	Name of Scale	Items	Response Options	Recall period	FK
Augmentation	Psychosocial Well-Being	9	none of the time / all of the time	past week	7.6
(Preoperative)	Sexual Well-Being	5	none of the time / all of the time	past week	9.4
(i resperante)	Physical Well-Being: Chest	5	none of the time / all of the time	past week	9.8
Satisfaction with Breasts		6	dissatisfied / satisfied	past week	0.6
	Psychosocial Well-Being	9	none of the time / all of the time	past week	7.6
Augmentation	Sexual Well-Being	5	none of the time / all of the time	past week	9.4
(Postoperative)	Physical Well-Being: Chest	7	none of the time / all of the time	past week	10.5
	Satisfaction with Breasts	15	dissatisfied / satisfied	past week	2.3
	Satisfaction with Implants	2	dissatisfied / satisfied	past week	4.8
	Satisfaction with Outcome	8	disagree / agree	n/a	4.7
	Satisfaction with Information	16	dissatisfied / satisfied	n/a	5.5
	Satisfaction with Surgeon	12	disagree / agree	n/a	5.7
	Satisfaction with Medical Team	7	disagree / agree	n/a	5.1
	Satisfaction with Office Staff	7	disagree / agree	n/a	5.1
Name of Module	Name of Scale	Items	Response Options	Recall period	FK
Reduction	Psychosocial Well-Being	9	none of the time / all of the time	past week	6.2
(Preoperative)	Sexual Well-Being	5	none of the time / all of the time	past week	9.0
(**************************************	Physical Well-Being	14	none of the time / all of the time	past week	6.7
	Satisfaction with Breasts	11	dissatisfied / satisfied	past week	1.0
	Psychosocial Well-Being	9	none of the time / all of the time	past week	6.2
Reduction	Sexual Well-Being	5	none of the time / all of the time	past week	9.0
(Postoperative)	Physical Well-Being	14	none of the time / all of the time	past week	6.7
,	Satisfaction with Breasts	13	dissatisfied / satisfied	past week	0.9
	Satisfaction with Nipples	5	dissatisfied / satisfied	past week	4.5
	Satisfaction with Outcome	8	disagree / agree	n/a	6.4
	Satisfaction with Information	13	dissatisfied / satisfied	n/a	5.6
	Satisfaction with Surgeon	12	disagree / agree	n/a	5.7
	Satisfaction with Medical Team	7	disagree / agree	n/a	5.1
	Satisfaction with Office Staff	7	disagree / agree	n/a	5.1

Name of Module	Name of Scale	Items	Response Options	Recall period	FK
Mastectomy	Psychosocial Well-Being	10	none of the time / all of the time	past week	7.0
(Preoperative)	Sexual Well-Being	6	none of the time / all of the time	past week	10.0
	Physical Well-Being: Chest	10	none of the time / all of the time	past week	4.5
	Satisfaction with Breasts	4	dissatisfied / satisfied	past week	2.7
	Psychosocial Well-Being	10	none of the time / all of the time	past week	7.0
Mastectomy	Sexual Well-Being	6	none of the time / all of the time	past week	10.0
(Postoperative)	Physical Well-Being: Chest	11	none of the time / all of the time	past week	4.6
	Adverse Effects of Radiation	6	not at all / a lot	past week	7.9
	Satisfaction with Breasts	4	dissatisfied / satisfied	past week	2.7
	Satisfaction with Surgeon	12	disagree / agree	n/a	5.5
	Satisfaction with Medical Team	7	disagree / agree	n/a	5.1
	Satisfaction with Office Staff	7	disagree / agree	n/a	5.1
Name of Module	Name of Scale	Items	Response Options	Recall period	FK
	Psychosocial Well-Being	10	none of the time / all of the time	past week	7.0
Dogometwystica	Sexual Well-Being	6	none of the time / all of the time	past week	10.0
Reconstruction (Preoperative)	Physical Well-Being: Chest	10	none of the time / all of the time	past week	4.5
(Freoperative)	Physical Well-Being: Abdomen	4	none of the time / all of the time	past week	13.2
	Physical Well-Being: Shoulder and				
	Back	11	none of the time / all of the time	past week	7.2
	Satisfaction with Breasts	4	dissatisfied / satisfied	past week	2.7
	Satisfaction with Abdomen	1	dissatisfied / satisfied	past week	4.4
	Psychosocial Well-Being	10	none of the time / all of the time	past week	7.0
	Sexual Well-Being	6	none of the time / all of the time	past week	10.0
	Physical Well-Being: Chest	11	none of the time / all of the time	past week	4.6
	Physical Well-Being: Abdomen	7	none of the time / all of the time	past week	11.0
	Physical Well-Being: Shoulder and				
Reconstruction	Back	11	none of the time / all of the time	past week	7.2
(Postoperative)	Adverse Effects of Radiation	6	not at all / a lot	past week	7.9
	Satisfaction with Breasts	15	dissatisfied / satisfied	past week	4.6
	Satisfaction with Abdomen	3	dissatisfied / satisfied	past week	8.6
	Satisfaction with Nipple				
	Reconstruction	1	dissatisfied / satisfied	past week	10.3
	Satisfaction with Back	8	none of the time / all of the time	past week	1.2
	Satisfaction with Implants	2	dissatisfied / satisfied	past week	4.8
	Satisfaction with Information	15	dissatisfied / satisfied	n/a	7.7
	Satisfaction with Surgeon	12	disagree / agree	n/a	5.6
	Satisfaction with Medical Team	7	disagree / agree	n/a	5.1
	Satisfaction with Office Staff	7	disagree / agree	n/a	5.1

Name of Module	Name of Scale	Items	Response Options	Recall period	FK
	Information Needs	1	n/a	preoperative	6.5
	Making Decisions	1	n/a	preoperative	7.3
	Complications	1	n/a	postoperative	7.2
	Support from Medical Staff	5	unlikely/very likely	during process	5.4
Breast	Pain: Postoperative*	6	unlikely/very likely	first week postop	1.4
Reconstruction	Appearance: Chest	1	n/a	after expansion	2.2
Expectations (Preoperative)	Pain: Expander	1	n/a	after placement	3.8
Long Form	Pain: Expansions	1	n/a	after expansion	5.2
Long romm	Coping	5	unlikely/very likely	first year	4.0
Note: *indicates	Appearance: Clothed*	5	unlikely/very likely	after 1 year	3.0
the scales and	Appearance: Unclothed	1	n/a	after 1 year	3.3
items included in	Appearance: Breast Symmetry*	1	n/a	after 1 year	5.0
the Expectations	Appearance: Breast Scars	1	n/a	after 1 year	5.0
Short Form	Sensation: Breast*	1	n/a	after 1 year	4.9
	Appearance: Breast Size	1	n/a	after 1 year	5.9
	Appearance: Breast Shape	1	n/a	after 1 year	4.9
	Appearance: Breast Natural	1	n/a	after 1 year	4.2
	Movement: Breast	1	n/a	after 1 year	3.0
	Appearance: Chest Sides	1	n/a	after 1 year	5.8
	Sensation: Chest Sides	1	n/a	after 1 year	4.4
	Appearance: Nipples	1	n/a	after 1 year	6.1
	Sensation: Nipples	1	n/a	after 1 year	5.4
	Sensation: Breasts	5	unlikely/very likely	after 1 year	3.8
	Awareness: Implants	1	n/a	after 1 year	4.6
	Physical: Abdomen	4	unlikely/very likely	after 1 year	7.8
	Appearance: Breast Symmetry*	1	n/a	after 10 years	5.7
	Revision Surgery	1	n/a	after 10 years	5.0
Name of Module	Name of Scale	Items	Response Options	Recall period	FK
Breast	Psychosocial Well-Being	10	none of the time / all of the time	past week	7.0
Conserving	Sexual Well-Being	6	none of the time / all of the time	past week	10.0
Therapy	Physical Well-Being: Chest	10	none of the time / all of the time	past week	4.5
(Preoperative)	Satisfaction with Breasts	4	dissatisfied / satisfied	past week	2.7
	Psychosocial Well-Being	10	none of the time / all of the time	past week	7.0
Breast	Sexual Well-Being	6	none of the time / all of the time	past week	9.9
Conserving	Physical Well-Being: Chest	9	none of the time / all of the time	past week	5.7
Therapy	Adverse Effects of Radiation	6	not at all / a lot	past week	7.9
(Postoperative)	Satisfaction with Breasts	11	dissatisfied / satisfied	past week	5.0
•	Satisfaction with Information:			·	
	Breast Surgeon	12	dissatisfied / satisfied	n/a	8.4
	Satisfaction with Information:				
	Radiation Oncologist	11	dissatisfied / satisfied	n/a	6.9
	Satisfaction with Surgeon	12	disagree / agree	n/a	5.4
	Satisfaction with Medical Team	7	disagree / agree	n/a	5.1
	Satisfaction with Office Staff	1	disagree / agree	1	5.1

Augmentation Module

Quality of Life Domains

- 1. Psychosocial Well-Being: This scale measures psychosocial well-being with items that ask about body image (e.g., accepting of body, feeling attractive) and a woman's confidence in social settings. Other items cover emotional health and self-esteem.
- 2. Sexual Well-Being: This scale measures sexual well-being and body-image issues with items that ask about feelings of sexual attractiveness when clothed and unclothed, sexual confidence as it relates to one's breasts and how comfortable or at ease a woman feels during sexual activity.
- **3. Physical Well-Being Chest**: This scale captures negative physical sequelae of the chest and upper body. There are questions about symptoms of pain or tightness in the breast area, as well as difficulty with mobility (e.g., lifting arms) and doing activities (e.g., running, lifting).

Satisfaction Domains

- 1. Satisfaction with Breasts: This scale measures body image in terms of a woman's satisfaction with her breasts. Items cover breast appearance (e.g., size, symmetry, softness, implant placement, cleavage), and satisfaction with breasts in relation to how a bra fits and how the breasts look when clothed or unclothed. There are also items specific to implants (e.g., rippling) and postoperative issues (e.g., scars).
- **2. Satisfaction with Outcome**: This scale measures a woman's overall appraisal of the outcome of her breast surgery. Items cover whether the woman's expectations were met with respect to the aesthetic outcome, the impact surgery has had upon her life, as well as satisfaction with the decision to have surgery (e.g., "I would do it again").

3. Satisfaction with Care:

- a. Information: This scale measures satisfaction with information provided about breast augmentation surgery from the surgeon. Items cover complications and risks (e.g., implant leakage, loss of nipple sensation, capsular contracture, rippling), implications for future breast cancer screening and breast-feeding, healing and recovery time, how the surgery would be done and breast appearance (e.g., breast size, scars).
- **b. Surgeon:** This scale measures satisfaction with the surgeon. Items ask about the surgeon's manner (e.g., professional, reassuring, thorough, sensitive) and communication skills (e.g., easy to talk to). Items also cover the extent to which the patient was involved in the decision making and her understanding of the process.
- **c. Medical team:** This scale measures satisfaction with members of the medical team (other than the surgeon). Items ask whether the staff were professional, knowledgeable and friendly, as well as how comfortable the woman was made to feel and whether she felt she was treated in a respectful manner.
- **d. Office Staff:** This scale measures satisfaction with interactions with members of the office staff. Items ask whether staff were professional, knowledgeable and friendly, as well as how comfortable the woman was made to feel and whether she felt she was treated respectfully.

Reduction/Mastopexy Module

Quality of Life Domains

- 1. Psychosocial Well-Being: This scale measures psychosocial well-being with items that ask about body image (e.g., accepting of body, feeling attractive) and a woman's confidence in social settings. Other items cover emotional health and self-esteem.
- 2. Sexual Well-Being: This scale measures sexual well-being and body-image issues with items that ask about feelings of sexual attractiveness when clothed and unclothed, sexual confidence as it relates to one's breasts and how comfortable or at ease a woman feels during sexual activity.
- **3. Physical Well-Being Chest**: This scale captures physical problems caused by breast size, including pain (e.g., breast, shoulder, back, neck), energy level, rashes and sleeping problems. There are also questions asking about activity limitations and balance.

Satisfaction Domains

- 1. Satisfaction with Breasts: This scale measures body image in terms of a woman's satisfaction with her breasts. Items cover breast appearance (e.g., size, symmetry, softness, cleavage), and satisfaction with breasts in relation to how a bra fits and how the breasts look when clothed or unclothed. There are also postoperative only items (e.g., location and appearance of scars).
- **2. Satisfaction with Nipples:** This scale measures satisfaction with the appearance of the nipples and areola complexes. Items cover their location on the breast, symmetry, shape and nipple sensation.
- **3. Satisfaction with Outcome**: This scale measures a woman's overall appraisal of the outcome of her breast surgery. Items cover whether the woman's expectations were met with respect to the aesthetic outcome and the impact surgery has had upon her life, as well as satisfaction with the decision to have surgery (e.g., "I would do it again").

4. Satisfaction with Care:

- **a. Information:** This scale measures satisfaction with information provided about breast reduction surgery from the surgeon. Items cover complications and risks (e.g., loss of nipple sensation), implications for future breast cancer screening and breast-feeding, healing and recovery time, how the surgery would be done and breast appearance (e.g., breast size, scars).
- **b. Surgeon:** This scale measures satisfaction with the surgeon. Items ask about the surgeon's manner (e.g., professional, reassuring, thorough, sensitive) and communication skills (e.g., easy to talk to). Items also cover the extent to which the patient was involved in the decision making and understanding of the process.
- **c. Medical Team:** This scale measures satisfaction with members of the medical team (other than the surgeon). Items ask whether the staff were professional, knowledgeable and friendly, as well as how comfortable the woman was made to feel and whether she felt she was treated in a respectful manner.
- **d. Office Staff:** This scale measures satisfaction with interactions with members of the office staff. Items ask whether staff were professional, knowledgeable and friendly, as well as how comfortable the woman was made to feel and whether she felt she was treated in a respectful manner.

Mastectomy Module

Quality of Life Domains

- **1. Psychosocial Well-Being**: This scale measures psychosocial well-being with items that ask about body image (e.g., accepting of body, feeling attractive) and a woman's confidence in social settings. Other items cover emotional health and self-esteem.
- 2. Sexual Well-Being: This scale measures sexual well-being and body-image issues with items that ask about feelings of sexual attractiveness when clothed and unclothed, sexual confidence as it relates to one's breasts and how comfortable or at ease a woman feels during sexual activity.

3. Physical Well-Being:

- **a. Chest**: This scale captures negative physical sequelae of the chest. There are questions about chest muscle pain and breast area discomfort, such as tightness, pulling, nagging, tenderness, aching and throbbing. There are also questions asking about activity limitations.
- **b.** Adverse Effects of Radiation: This scales measures physical changes such as soreness and dryness of the skin due to radiation.

Satisfaction Domains

1. Satisfaction with Breasts: This scale measures body image in terms of a woman's satisfaction with the breast area and asks questions regarding how comfortably bras fit, and how satisfied a woman is with her breast area both clothed and unclothed.

2. Satisfaction with Care:

- **a. Surgeon:** This scale measures satisfaction with the surgeon. Items ask about the surgeon's manners (e.g., professional, reassuring, thorough, sensitive) and communication skills (e.g., easy to talk to). Items also cover the extent to which the patient was involved in the decision making and understanding of the process.
- **b. Medical team:** This scale measures satisfaction with members of the medical team (other than the surgeon). Items ask whether the staff were professional, knowledgeable and friendly, as well as how comfortable the woman was made to feel and whether she felt she was treated in a respectful manner.
- c. Office Staff: This scale measures satisfaction with interactions with members of the office staff. Items ask whether staff were professional, knowledgeable, friendly, as well as how comfortable the woman was made to feel and whether she felt she was treated in a respectful manner.

Reconstruction Module

Quality of Life Domains

1. Psychosocial Well-Being: This scale measures psychosocial well-being with items that ask about body image (e.g., accepting of body, feeling attractive) and a woman's confidence in social settings. Other items cover emotional health and self-esteem.

2. Sexual Well-Being: This scale measures sexual well-being and body-image issues with items that ask about feelings of sexual attractiveness when clothed and unclothed, sexual confidence as it relates to one's breasts and how comfortable or at ease a woman feels during sexual activity.

3. Physical Well-Being:

- **a. Chest**: This scale measures physical problems such as chest muscle pain and problems in the breast area (e.g., tightness, pulling, tenderness). Other items ask about activity limitations and sleep problems due to discomfort.
- **b.** Adverse Effects of Radiation: This scale measures physical changes such as soreness and dryness of the skin due to radiation.
- **c. Abdomen and Trunk**: This scale measures negative physical sequelae of the abdomen following autologous tissue reconstruction (TRAM or DIEP flap). Items cover abdominal discomfort, bloating, bulging and pain, as well as difficulty doing certain activities due to abdominal weakness.
- d. Back and Shoulder: This scale measures negative physical sequelae such as pain and scarring following latissimus dorsi flap reconstruction (LD flap). Items cover arm and shoulder limitations that lead to difficulty performing certain activities due to arm stiffness and weakness.

Satisfaction Domains

- 1. Satisfaction with Breasts: This scale measures body image in terms of a woman's satisfaction with her breasts and asks questions regarding how comfortably bras fit and how satisfied a woman is with her breast area both clothed and unclothed. Postoperative items ask about breast appearance (e.g., size, symmetry, softness) and clothing issues (e.g., how bras fit; being able to wear fitted clothes). There are also implant-specific items (e.g., amount of rippling that can be seen or felt).
- **2. Satisfaction with Nipples**: This scale measures satisfaction with the appearance of the reconstructed nipple(s) and areola complex(es).
- **3. Satisfaction with Abdomen**: This scale measures patient satisfaction with abdominal appearance following autologous tissue breast reconstruction (TRAM or DIEP flap). Items ask about overall appearance as well as position of navel (belly button) and scars.
- **4. Satisfaction with Back**: This scale measures patient satisfaction with back and back scar appearance following latissimus dorsi flap reconstruction (LD flap). Items ask about overall back and scar appearance, as well as location of scar.

5. Satisfaction with Care:

- **a. Information:** This scale measures satisfaction with information provided about breast reconstruction surgery from the surgeon. Items cover types of breast reconstruction, complications and risks, healing and recovery time, how the breast(s) would look, implications for future breast cancer screening, how the surgery would be done and breast appearance (e.g., breast size, scars).
- **b. Surgeon:** This scale measures satisfaction with the surgeon. Items ask about the surgeon's manners (e.g., professional, reassuring, thorough, sensitive) and communication skills (e.g.,

- easy to talk to). Items also cover the extent to which the patient was involved in the decision making and understanding of the process.
- **c. Medical team:** This scale measures satisfaction with members of the medical team (other than the surgeon). Items ask whether the staff were professional, knowledgeable and friendly, as well as how comfortable the woman was made to feel and whether she felt she was treated in a respectful manner.
- **d. Office Staff:** This scale measures satisfaction with interactions with members of the office staff. Items ask whether staff were professional, knowledgeable and friendly, as well as how comfortable the woman was made to feel and whether she felt she was treated in a respectful manner.

Breast Reconstruction Expectations Module

These scales are designed to be administered preoperatively and assess patient expectations for the process and outcome of surgery. The expectations scales compliment the satisfaction and quality-of-life domains of the postoperative reconstruction module. Multi-item and categorical scale structures are used. Five scales provide a 0-100 score:

- 1. Expectations for Support from Medical Staff: This scale measures how much time and emotional support the patient is expecting to receive from the medical team and surgeon during the breast reconstruction process.
- **2. Expectations for Pain:** This scale measures the magnitude of pain the patient is expecting to experience in the first week after reconstruction surgery (e.g., soreness, amount of pain).
- **3. Expectations for Coping:** This scale measures how a patient is anticipating she will cope with the process of breast reconstruction during the first year after surgery (e.g., will get back to her normal life).
- **4. Expectations for Breast Appearance when Clothed:** This scale measures how a patient expects her breasts to look one year after surgery when she is clothed (e.g., look good in a bra, clothes will hang well).
- **5. Expectations for Breast Sensation:** This scale measures how a patient expects her breasts to feel when she touches them one year after breast reconstruction (e.g., harder than a natural breast, rippling).

Breast Conserving Therapy Module

Quality of Life Domains

- 1. Psychosocial Well-Being: This scale measures psychosocial well-being with items that ask about body image (e.g., accepting of body, feeling attractive) and a woman's confidence in social settings. Other items cover emotional health and self-esteem.
- 2. Sexual Well-Being: This scale measures sexual well-being and body-image issues with items that ask about feelings of sexual attractiveness when clothed and unclothed, sexual confidence as it relates to one's breasts and how comfortable or at ease a woman feels during sexual activity.

3. Physical Well-Being:

- a. **Chest**: This scale measures problems in the breast area (e.g., tightness, pulling, tenderness, pain). Other items ask about activity limitations and sleep problems due to discomfort.
- b. **Adverse Effects of Radiation**: This scale measures physical changes, such as soreness and dryness of the skin due to radiation.

Satisfaction Domains

1. **Satisfaction with Breasts:** This scale measures body image in terms of a woman's satisfaction with her breasts and asks questions regarding how comfortably bras fit and how satisfied a woman is with her breast area both clothed and unclothed. Postoperative items ask about breast appearance (e.g., size, symmetry, softness) and clothing issues (e.g., how bras fit, being able to wear fitted clothes).

2. Satisfaction with Care:

- **a. Information: Surgery:** This scale measures satisfaction with information provided about breast surgery from the surgeon. Items cover types of breast surgery, complications and risks, healing and recovery time, how the breast(s) would look, implications for future breast cancer screening, how the surgery would be done and breast appearance (e.g., breast size, scars).
- **b. Information:** Radiation: This scale measures satisfaction with information provided about radiation treatment from the radiation oncologist. Items cover why you need radiation, how the beam will feel, how the radiation might change your skin overtime and potential problems.
- **c. Surgeon:** This scale measures satisfaction with the surgeon. Items ask about the surgeon's manners (e.g., professional, reassuring, thorough, sensitive) and communication skills (e.g., easy to talk to). Items also cover the extent to which the patient was involved in the decision making and understanding of the process.
- **d. Medical team:** This scale measures satisfaction with members of the medical team (other than the surgeon). Items ask whether the staff were professional, knowledgeable and friendly, as well as how comfortable the woman was made to feel and whether she felt she was treated in a respectful manner.
- **e. Office Staff:** This scale measures satisfaction with interactions with members of the office staff. Items ask whether staff were professional, knowledgeable and friendly, as well as how comfortable the woman was made to feel and whether she felt she was treated in a respectful manner.

4. Administration of the BREAST-Q©

The BREAST-Q© is a self-administered questionnaire. Each scale takes 1-4 minutes to complete and an entire BREAST-Q© module can be completed in about 10-15 minutes.

Each module has preoperative and postoperative scales. The postoperative scales include the preoperative items in addition to items that address unique postoperative issues (e.g., scars). The preoperative and postoperative scales are linked psychometrically to measure change. Women may

complete the preoperative scales at any time prior to surgery (baseline assessment) and the postoperative scales at any time point after surgery (follow-up data). The BREAST-Q© may also be administered at a single time point as in a cross-sectional survey. Each researcher or clinician may decide the time points at which they would like to administer the scales. Of note, the BREAST-Q© Reconstruction Expectations Module scales differ in that they are designed for preoperative administration only.

It is important to note that patients do not need to complete all of the BREAST-Q© scales in any given study or clinical encounter. Each scale can be used independently of the other scales. Patients are given brief instructions at the beginning of each scale. You may use the paper and pencil format or create your own online version of the BREAST-Q© for ease of administration.

5. Scoring the BREAST-Q©

There is <u>no overall or total</u> BREAST-Q© score, only scores for each independent scale. All BREAST-Q© scales are transformed into scores that range from 0-100. The scores are computed by adding the response items together and then converting the raw sum scale score to a score from 0-100. For all BREAST-Q© scales, a higher score means greater satisfaction or better QOL (depending on the scale). If missing data is less than 50% of the scale's items, insert the mean of the completed items.

Use the Conversion Tables available from the authors to convert the raw summed scale score into a score from 0 (worst) to 100 (best).

See **Appendix 2** for instructions on how to score BREAST-Q Version 1.0 using QScore and look-up tables.

6. Interpretation of the BREAST-Q©

Interpretative data on individual patients' scores is not available, but longitudinal assessment at multiple time points should establish a personal norm for each individual patient. It is also expected that as measurement of QOL and satisfaction becomes more common in clinical settings, intuitive familiarity will develop both through individual and collective experience, as has occurred for more established measures of disease activity and severity. For more information about the BREAST-Q© we direct the reader to Section 9 showing BREAST-Q© publications.

7. Conditions of Use of the BREAST-Q©

Memorial Sloan Kettering Cancer Center and the University of British Columbia hold the copyright of the BREAST-Q© and all of its translations (past, on-going and future). To avoid any copyright infringement, a copyright notice shall be included on the original questionnaire and all its derivatives (including but not limited to translations) as follows:

"Memorial Sloan Kettering Cancer Center and The University of British Columbia © 2006, All rights reserved"

"BREAST-Q" VERSION 2.0 © Memorial Sloan Kettering Cancer Center and The University of British Columbia, 2017, All rights reserved"

The use of the BREAST-Q™ and its modules in non-profit academic research and in clinical care is <u>free</u> of charge.

Non-profit users can access and license the BREAST-Q© Version 2.0 using the following links:

Augmentation Module: https://fhspeds.mcmaster.ca/pedsCapOne/surveys/?s=3XDRF9MAWR

Breast Cancer Module: https://fhspeds.mcmaster.ca/pedsCapOne/surveys/?s=EC49T8JMDJ

Reduction / Mastopexy Module: https://fhspeds.mcmaster.ca/pedsCapOne/surveys/?s=EW9EJKK7RL

The use of the BREAST-Q© Version 2.0 by 'for-profit' organizations is subject to a <u>licensing fee</u>. For questions regarding fees to be paid by 'for-profit organizations', please contact:

Alexandra Buga, MS, MBA
Licensing Associate
Office of Technology Development
Memorial Sloan Kettering Cancer Center
1275 York Ave, New York, NY 10065
bugaa@mskcc.org

For questions regarding study design and optimal use of BREAST-Q© scales, please contact:

Andrea Pusic, MD, MHS, FACS, FRCSC Brigham and Women's Hospital 75 Francis St. Boston, MA 02115 apusic@bwh.harvard.edu

8. Frequently Asked Questions

What is the difference between BREAST-Q Version 1.0 and 2.0?

BREAST-Q Version 1.0 was published in 2009 and Version 2.0 was published in 2017. **Appendix 1** shows the minor modifications made to improve wording. Version 2.0 was tested in a much larger sample and the scores derived for the two versions is equivalent.

Do I need local ethics board (IRB) approval?

If your intent is to collect BREAST-Q© data for research purposes, a local ethics board must review your methods, patient recruitment, consent and privacy. If you are administering the BREAST-Q© for clinical care, ethics board approval is generally not required. If in doubt, contact your local ethics board.

Do I have to use all of the BREAST-Q© scales?

No, you do not have to use all of the scales. Each scale functions independently, therefore patients can be asked to complete <u>some or all</u> of a module's BREAST-Q© scales. It is not necessary for a patient to complete all of the scales within a module as there is <u>no overall or total</u> BREAST-Q© score. A researcher or clinician may therefore select a subset of scales depending on the particular purpose of the study or use.

Can I delete, add or change any items or response options in the BREAST-Q@?

No, you cannot delete or make any changes to the wording of any items or response options in a BREAST-Q© scale. Any modification to the content of the BREAST-Q© by deleting an item within a scale is <u>not acceptable</u>. There are three main reasons why deleting or adding items is not allowed. The first is that deleting or adding items would nullify the psychometric properties of BREAST-Q© scales. The second reason is that by deleting or adding items, it would then not be possible to score the BREAST-Q© and you would not be able to compare findings with those of other BREAST-Q© studies. Finally, deleting or adding items is prohibited under copyright laws.

Which module do I use for oncoplastic procedures?

For oncoplastic surgery procedures, the BREAST-Q© Reduction/Mastopexy module and the BCT module are recommended, depending on the exact nature of the procedure (i.e., for oncoplastic breast reduction, use Reduction module; for oncoplastic lumpectomy/glandular remodelling, use BCT module).

Which module do I use for fat grafting procedures?

For patients undergoing fat grafting procedures, either the BREAST-Q© Reconstruction or Augmentation modules may be used depending on the indications for the procedure (i.e., correction of defect following oncologic resection or cosmetic augmentation).

Can I translate the BREAST-Q© into a new language?

Yes, you can translate the BREAST-Q© into different languages. Check our table of translations available in REDCap to see if there is a translation in the language you need.

Augmentation Module: https://fhspeds.mcmaster.ca/pedsCapOne/surveys/?s=3XDRF9MAWR

Breast Cancer Module: https://fhspeds.mcmaster.ca/pedsCapOne/surveys/?s=EC49T8JMDJ

Reduction / Mastopexy Module: https://fhspeds.mcmaster.ca/pedsCapOne/surveys/?s=EW9EJKK7RL

If there is not a translation in the language you need, you will need to sign a licensing agreement prior to translating the BREAST-Q©. Please note that the developers of the BREAST-Q© own the copyright of all translation of the BREAST-Q©.

Who helps patients to complete the questionnaire in clinic?

The BREAST-Q© scales were designed for self-completion.

Are there specific time points when patients complete the scales?

A researcher or clinician can decide the time points (pre- and postoperatively) they would like to administer the scales. Each module of the BREAST-Q© has a preoperative and postoperative version. The postoperative version includes the preoperative items in addition to items that address unique postoperative issues (e.g., scars).

Is there an electronic version I can use, or can I code a version for online administration with my patients?

You may code a version for online administration and data collection, but do not delete, add or change any items or response options.

What should I do if the patient refuses to fill out the BREAST-Q©?

For research purposes, patients have the right to refuse to participate in a study. If the BREAST-Q© is being used in clinical practice and the patient does not wish to complete the questionnaire, it is helpful to explain to the patient that BREAST-Q© data is being collected to provide their healthcare provider with a complete understanding of their health-related quality of life and satisfaction as it relates to breast surgery. You can emphasize that the BREAST-Q© is quick and simple to complete.

What should I do if the patient asks for clarification of a question?

While completing the BREAST-Q©, some patients may ask for clarification of a particular question so that they can better understand and respond to it. You can help by rereading the question verbatim, but do not try to explain what the question means, rather suggest that the patient uses her own

interpretation of the question. All patients should answer the questions based on their own understanding of the items.

What should I do if a patient asks why the BREAST-Q© has to be filled out on more than one occasion (if administering the BREAST-Q© prospectively)?

Explain that patients must complete the same BREAST-Q© at additional visits in order to see if their answers change with time. This will give a more complete picture of how her health-related quality of life and satisfaction changes overtime.

9. BREAST-Q© Publications

Psychometric Publications

- Kaur M, Pusic A, Gibbons C, Klassen AF. Implementing electronic patient-reported outcome measures in outpatient cosmetic surgery clinics: an exploratory qualitative study. Aesthet Surg J. 2018 Oct. [Epub ahead of print].
- 2. Voineskos SH, Nelson JA, Klassen AF, Pusic AL. Measuring patient-reported outcomes: key metric in reconstructive surgery. Annu Rev Med. 2018 Jan 29;68:467-79.
- 3. Fuzesi S, Cano SJ, Klassen AF, Atisha D, Pusic AL. Validation of the electronic version of the BREAST-Q in the Army of Women Study. Breast. 2017 Mar;6(33):44-9.
- 4. Cano SJ, Klassen AF, Scott A, Alderman A, Pusic AL. Interpreting Clinical Differences in BREAST-Q Scores: Minimal Important Difference. Plast Reconstr Surg. 2014 Jul;134(1): 173e-5e.
- 5. Cano SJ, Klassen AF, Scott AM, Pusic AL. A closer look at the BREAST-Q©. Clin Plast Surg. 2013 Apr;40(2):287-96.
- 6. McCarthy CM, Cano SJ, Klassen AF, Scott A, Van Laeken N, Lennox PA, Cordeiro PG, Pusic AL. The magnitude of effect of cosmetic breast augmentation on patient satisfaction and health-related quality of life. Plast Reconstr Surg. 2012 Jul;130(1):218-23.
- 7. Pusic AL, Klassen AF, Snell L, Cano SJ, McCarthy C, Scott A, Cemal Y, Rubin LR, Corderio PG. Measuring and managing patient expectations for breast reconstruction: impact on quality of life and patient satisfaction. Expert Rev Pharmacoecon Outcomes Res. 2012 Apr;12(2):149-58.
- 8. Cano SJ, Klassen AF, Scott AM, Cordeiro PG, Pusic AL. The BREAST-Q: Further Validation in Independent Clinical Samples. Plast Reconstr Surg. 2012 Feb;129(2):293-302.
- 9. Chen CM, Cano SJ, Klassen AF, King T, McCarthy C, Cordeiro PG, Morrow M, Pusic AL. Measuring quality of life in oncologic breast surgery: a systematic review of patient-reported outcome measures. Breast J. 2010 Nov-Dec;16(6):587-97.
- 10. Cano S, Klassen AF, Scott A, Thoma A, Feeny D, Pusic A. Health outcome and economic measurement in breast cancer surgery: challenges and opportunities. Expert Rev Pharmacoecon Outcomes Res. 2010 Oct;10(5):583-94.
- 11. Pusic AL, Klassen A, Scott A, Klok J, Cordeiro PG, Cano SJ. Development of a New Patient Reported Outcome Measure for Breast Surgery: The BREAST-Q©. Plast Reconstr Surg. 2009 Aug;124(2):345-53.

- 12. Klassen A, Pusic AL, Scott A, Klok J, Cano S. Satisfaction and quality of life in women who undergo breast surgery: A qualitative study. BMC Womens Health. 2009 May 1;9:11.
- 13. Pusic AL, Reavey PL, Klassen AF, Scott A, McCarthy C, Cano S. Measuring patient outcomes after breast augmentation: Introducing the BREAST-Q: Augmentation Module. Clin Plast Surg. 2009 Jan;36(1):23-32.
- 14. Pusic AL, Chen CM, Cano S, Klassen A, McCarthy C, Collins ED, Cordeiro PG. Measuring quality of life in cosmetic and reconstructive breast surgery: a systematic review of patient-reported outcomes instruments. Plast Reconstr Surg. 2007 Sep;120(4):823-37.

Normative Value Publications

- 15. Mundy LR, Homa K, Klassen AF, Pusic AL, Kerrigan CL. Breast cancer and reconstruction: normative data for interpreting the BREAST-Q. Plast Recon Surg. 2017 May;139(5):1046e-1055e.
- 16. Mundy LR, Homa K, Klassen AF, Pusic AL, Kerrigan CL. Normative data for interpreting the BREAST-Q augmentation module. Plast Reconstr Surg. 2017 Apr;139(4):846e-853e.
- 17. Mundy LR, Homa K Klassen AF, Pusic AL, Kerrigan CL. Understanding the health burden of macromastia: normative data for the BREAST-Q reduction module. Plast Reconstr Surg. 2017 Apr;139(4):846e-853e. Focus of video by PRS editor: http://journals.lww.com/plasreconsurg/Pages/videogallery.aspx?videoId=1085&autoPlay=true

APPENDIX 1: Modifications to BREAST-Q to create Version 2.0. NOTE: If a scale is not in the list it is because it has not been changed.

Modifications to pre-operative BREAST-Q scales					
	Version 1.0	Version 2.0			
Changed original stem for all modules	in the past 2 weeks	in the past week			
Augmentation	Version 1.0	Version 2.0			
Satisfaction w Breast	a. How bras fit?	a. How your bras fit?			
Sexual Well-Being	n/a option	removed			
Physical Well-Being: Chest	5 response options	3 response options			
Reduction	Version 1.0	Version 2.0			
Sexual Well-Being	n/a option	removed			
Physical Well-Being: Chest	5 response options	3 response options			
Mastectomy	Version 1.0	Version 2.0			
Sexual Well-Being	n/a option	removed			
Physical Well-Being: Chest	neck pain, upper back pain, shoulder pain, arm pain, rib pain, shooting pains	removed			
	5 response options	3 response options			
Reconstruction	Version 1.0	Version 2.0			
Satisfaction w Breast	stem - breasts in mind or if you have had a mastectomy with your breast area in mind	change stem to 'breast area in mind'			
Satisfaction w abdomen	a. How your abdomen looks?	a. How your abdomen looks when <u>unclothed</u> ?			
Sexual Well-Being	n/a option	removed			
Sexual Well Bellig	Confident sexually about how your breast(s) look when <u>unclothed</u> ?	Confident sexually about how your breast area looks when <u>unclothed</u> ?			
Psychosocial Well- being	stem - breasts in mind or if you have had a mastectomy with your breast area in mind	changed stem to 'breast area in mind'			
Physical Well-Being: Chest	neck pain, upper back pain, shoulder pain, arm pain, rib pain, shooting pains	removed			
	5 response options	3 response options			
Physical Well-Being: Abdomen	lower back pain	removed			
ВСТ	Version 1.0	Version 2.0			
	5 response options	2 rospanse entions			
Dhysical Well Daines	3 response options	3 response options			
Physical Well-Being: Chest	neck pain, upper back pain, shoulder pain, arm pain, shooting pains	removed			
	neck pain, upper back pain, shoulder pain,				
	neck pain, upper back pain, shoulder pain,	removed			
	neck pain, upper back pain, shoulder pain,	removed added 'Pain in the muscles of your chest?"			

Modifications to post-operative BREAST-Q scales					
	Version 1.0	Version 2.0			
Changed original stem					
for all modules	in the past 2 weeks	in the past week			
Augmentation	Version 1	Version 2			
	a. How bras fit?	a. How your bras fit?			
	o. The amount of rippling (wrinkling) of				
	your implant(s) that you can see?	moved to separate section			
Satisfaction w Breast	p. The amount of rippling (wrinkling) of				
Satisfaction w breast	your implant(s) that you can feel?	moved to separate section			
	q. How your scars look?	removed			
		added o. How closely matched (similar) your			
		breasts are to each other?			
Sexual Well-Being	n/a option	removed			
Physical Well-Being:					
Chest	5 response options	3 response options			
Reduction	Version 1	Version 2			
Sexual Well-Being	n/a option	removed			
Physical Well-Being:					
Chest	5 response options	3 response options			
Mastectomy	Version 1	Version 2			
Sexual Well-Being	n/a option	removed			
	5 response options	3 response options			
Physical Well-Being:		added k. Swelling of the arm (lymphedema) on			
Chest		the side(s) that you had your breast surgery?			
	neck pain, upper back pain, shoulder pain,				
	arm pain, rib pain, shooting pains	removed			
Adverse Effects of					
Radiation		Added			
Reconstruction	Version 1	Version 2			
Satisfaction w breasts		Instructions added: If you had a mastectomy			
		and reconstruction of both breasts, answer			
		these questions thinking of the breast you are			
		least satisfied with			
	n. How closely matched your breasts are	n. How closely matched (similar) your breasts			
	to each other?	are to each other?			
	o. How your reconstructed breast(s) look now compared to before you had any				
	breast surgery?	removed			
Satisfaction with	Jiedat surgery.	Temoved			
Abdomen					
		a. How your abdomen (tummy area) looks			
	a. How your abdomen looks?	when <u>unclothed</u> ?			
		Added instructions: If you had implants in both			
Satisfaction with		breasts, answer these questions thinking of the			
Implants		breast you are least satisfied with.			

Satisfaction with		
Outcome		Removed
Sexual Well-Being'	n/a option	removed
	5 response options	3 response options
Physical Well-Being: Chest		added k. Swelling of the arm (lymphedema) on the side(s) that you had your breast surgery?
	neck pain, upper back pain, shoulder pain, arm pain, rib pain, shooting pains	removed
Physical Well-Being: Abdomen	h. Lower back pain?	removed
	a. How your abdomen feels now compared to before your surgery?	removed
	b. How your abdomen looks now compared to before your surgery?	removed
Adverse Effects of Radiation		Added
Nipple Reconstruction	shape, look, color, height questions	removed
Satisfaction w Surgeon	word 'plastic' in the stem	removed
BCT	Version 1	Version 2
Satisfaction w breasts		Added to instructions: If you have had a lumpectomy and radiation of both breasts, answer these questions thinking of the breast you are least satisfied with.
	n/a option	removed
Sexual Well-Being	g. That you enjoy your lumpectomy breast being touched?	removed
J .	h. That you feel sexual pleasure when your lumpectomy breast is touched?	removed
Physical Well-Being: Chest	neck pain, upper back pain, shoulder pain, arm pain, shooting pains	removed
	Items with wording 'lumpectomy breast'	changed to 'breast area'
Adverse Effects of Radiation	b. Your radiated areola looking different (e.g. too dark or too light)?	removed
		Instructions: added 'If you have had radiation on both breasts, answer these questions thinking of the breast you are least satisfied with'. Also changed word 'lumpectomy' to 'radiated'.
	Response option: 'I don't have this problem' & 'I have this problem and it bothers me'	removed
		word 'skin' added to question b & f
Satisfaction with information from		·
Radiation Oncologist Satisfaction with Surgeon		removed added c. Involved you in the decision-making process?

Appendix 2: Instructions for Scoring BREAST-Q Version 1.0[©] data using QScoreTM

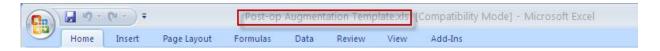
QScore is used to score BREAST-Q Version 1.0 for the Mastectomy and Reconstruction modules. You can access QScore on our website: www.qportfolio.org.

<u>NOTE</u>: The QScore program is <u>not</u> used to score the BREAST-Q Version 1.0 BCT module and Latissimus Dorsi (LD) scales. The BCT or LD scales are scored manually using scoring tables provided upon licensing. Contact <u>aklass@mcmaster.ca</u> if you require a copy of these look-up tables.

Q-Score, its accompanying manual and data entry templates are available to download from our website: www.qportfolio.org

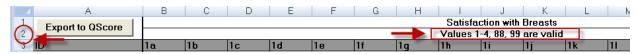
To score BREAST-Q data using QScore:

1. Select the appropriate QScore Excel template corresponding to the version of the BREAST-Q module you need scored. For example, if you've been administering the *BREAST-Q Postoperative Augmentation Module* choose the *Post-op Augmentation Template* for data entry.



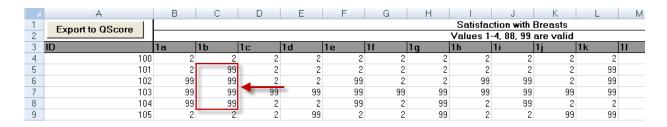
Post-op BREAST-Q Augmentation Template opened in Excel

2. The second row of each template indicates the valid numerical values allowed for each scale. A value of '88' should be entered if more than one answer choice was selected on the questionnaire, '66' if the non-applicable (N/A) option was selected and '99' for all missing information.

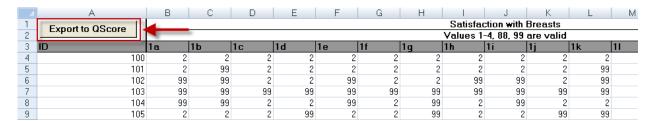


Important: Avoid making any changes to the first three rows of the template. Any change to this area will cause errors when the data is imported to QScore.

3. When entering your data, make sure there are no empty cells within the data template. Missing data or cells of unused scales should have a value of '99' entered.



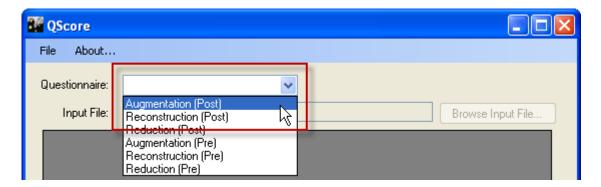
4. Once you have entered all your BREAST-Q data, press the 'Export to QScore' button in the upper left corner of the spread sheet. This process will save the data in a tab delimited text file, the required format for input to the QScore program.



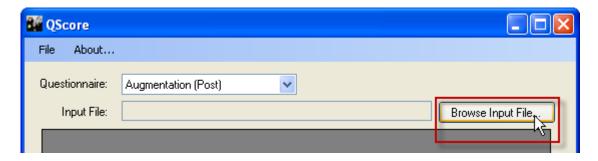
5. Name your file (1) and click 'Save' (2) to save it to your hard drive. A dialog box will appear with the following message: 'Data has been exported to [chosen directory]. This file will now close and you may now open the .txt file with the Scoring Utility.



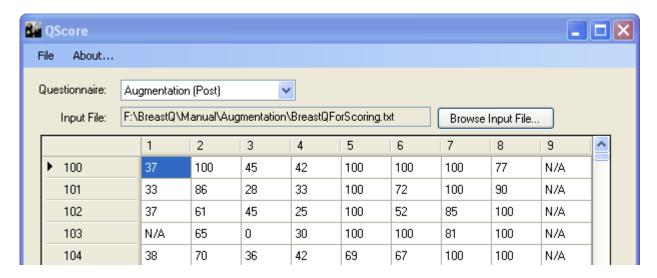
- 6. Start the QScore program.
- 7. Select the desired questionnaire version from the 'Questionnaire' drop down list.



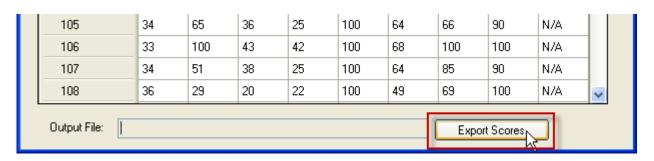
8. Next, click 'Browse Input File...' and locate the text file you would like to import.



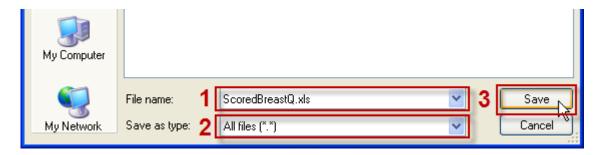
9. QScore will automatically score and display the results in an internal spread sheet.



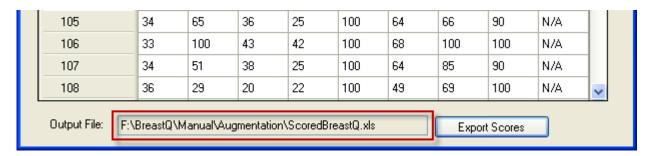
10. Select 'Export Scores' at the bottom of the program window.



- a. Name the file with the .xls extension (1) for example, ScoredBreastQ.xls
- b. select 'All files (*.*)' from the 'Save as type:' drop down list
- c. Click 'Save' to complete the export process



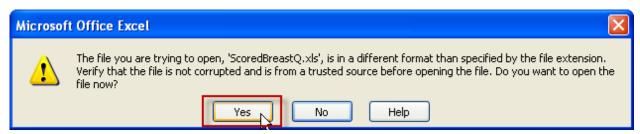
11. The 'Output File:' area in QScore now indicates the directory where the scored data has been saved.



12. Exit QScore.

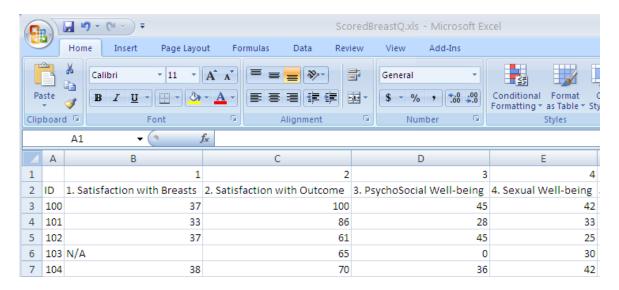
Opening QScore output in Excel:

1. Open the Excel spread sheet exported from QScore. A dialog box will appear with the following: 'The file you are trying to open, 'FILE NAME', is in a different format than specified by the file extension. Verify that the file is not corrupted and is from a trusted source before opening the file. Do you want to open the file now? Select 'yes'



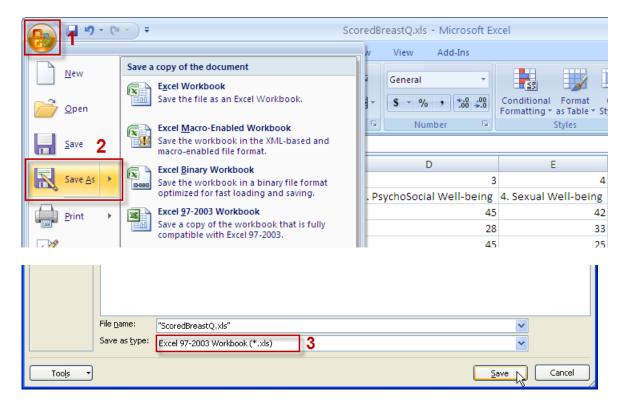
Note: This message appears because the file is still being read as a text file

2. The scored data is now opened and formatted for easy viewing in Excel.



Save the spread sheet in an Excel format.

- 1. Saving the spread sheet in an Excel format will prevent the '...different format...' message you received upon opening the file. To do this choose:
 - a. The office button in Microsoft Excel 2007 'File' in previous versions of Excel
 - b. Select 'Save As...'
 - c. And the Excel format you want from the 'Save as type:' drop down list.



Instructions for Scoring BREAST-Q Version[®] data using Scoring Tables

Data entry templates are available to download from: www.qporfolio.org.

- 1. Select the appropriate Excel template corresponding to the version of the BREAST-Q module you need scored. For example, if you've been administering the *BREAST-Q Postoperative Breast Conserving Therapy Module* choose the *Post-op BCT Template* for data entry.
- 2. The second row of each template indicates the valid numerical values allowed for each scale. A value of '88' should be entered if more than one answer choice was selected on the questionnaire, '66' if the non-applicable (N/A) option was selected and '99' for all missing information. When entering your data, make sure there are no empty cells within the data template.
- 3. Once all of your data has been entered into the template, sum the values within each scale and place that value in the last column of that row labeled 'Sum.' Do not include scores of '66', '88', and '99' in the sum (missing data).
- 4. For items missing data, add the mean of the completed items to the total sum score. If less than 50% of the questions have been answered, then the scale cannot be scored.
- 5. Using the scoring table provided, locate your sum score and insert the equivalent rasch transformed score.

Interpretation

All BREAST-Q scores range from 0-100. The scores are computed from the responses to the separate questions by adding them together and converting the score to a scale from 0 to 100 (similar to conversion into a percentage). A higher score means high satisfaction or better health-related quality of life.