

BREAST PHOTOGRAPHIC ASSESSMENT

1 Scope

This SOP describes the procedure for taking digital photographs of the breasts of REQUIRE breast cancer patients.

2 Purpose

To provide guidance for producing clinical images of breast cancer patients in the REQUIRE study to assess changes in breast appearance at two time points.

3 Process Owner (Responsibility)

The principal investigator of each study site is responsible for ensuring the implementation of this SOP and ensuring specific training is provided to all site staff who will be taking digital photos of the breasts.

4 Health and Safety

Not applicable.

5 References / Related Documents

- RQ11 Database Manual

All related documents will be available under www.REQUIRE.eu

6 Materials and Equipment

6.1 General / Inventory / Equipment

| Equipment | Recommended Manufacturer / Type | Product Code |
|---|---------------------------------|--------------|
| Digital camera (with fixed lens of 100 or 105 mm focal length, if available) | | |
| Adequate lighting | | |
| Device to transfer digital photos to computer | | |
| Measuring tape | | |
| Marking pen or round stickers | | |

6.2 Consumable Supplies

None.

6.3 Required Documents

- RQ1b Consent Form
- B4 Breast Photographic Assessment Form

All related documents will be available at www.REQUIRE.eu

7 Method

7.1 Requirements

- 7.1.1 Each breast cancer patient must consent to the photographic assessments on the REQUIRE consent form before any photographs are taken.
- 7.1.2 The photographs must be taken under standardized conditions, following the guidelines set out below, to ensure comparability of the serial photos taken at baseline and after two years and to reduce inter-site variation.

7.2 Time Points

The digital photographic assessment after breast conserving surgery will be taken at two time points:

- (1.) At baseline pre-radiotherapy
- (2.) 2 years after start of radiotherapy

7.3 Procedure

- 7.3.1 Camera specifications need to be kept constant throughout duration of the study to ensure comparability of serial photos.
- 7.3.2 All photographs must exclude the head (see **Figures**). Long hair should be pulled back.
- 7.3.3 There should be adequate lighting with no shadow on the patient or on the background.
- 7.3.4 The background should be unicoloured, e.g. grey.
- 7.3.5 Distance between lens and patient should be about 1 m.
- 7.3.6 Lens axis on level of the breast.
- 7.3.7 **Mark the patient's skin (a) at the suprasternal notch¹ and (b) 25 cm below point (a) in the midline (see Figure 1 and Figure 2). This is an essential requirement for BCCT.core image analysis. Reference marks must be clearly visible on the photos.**
- 7.3.8 Take two anterior views of the patient's chest - one with hands on the hips (**Figure 1**) and the other with hands above the head as far as possible (**Figure 2**).
- 7.3.9 One lateral view of the chest with hands above the head is also required (**Figure 3**).
- 7.3.10 Fill out B4 Breast Photographic Assessment Form in the REQUIRE database, indicating the time point and the distance between lens and breast.
- 7.3.11 Upload the photos directly to the electronic CRF B4 in the OpenClinica database.

¹ The V-shaped notch at the top of the breastbone (sternum).

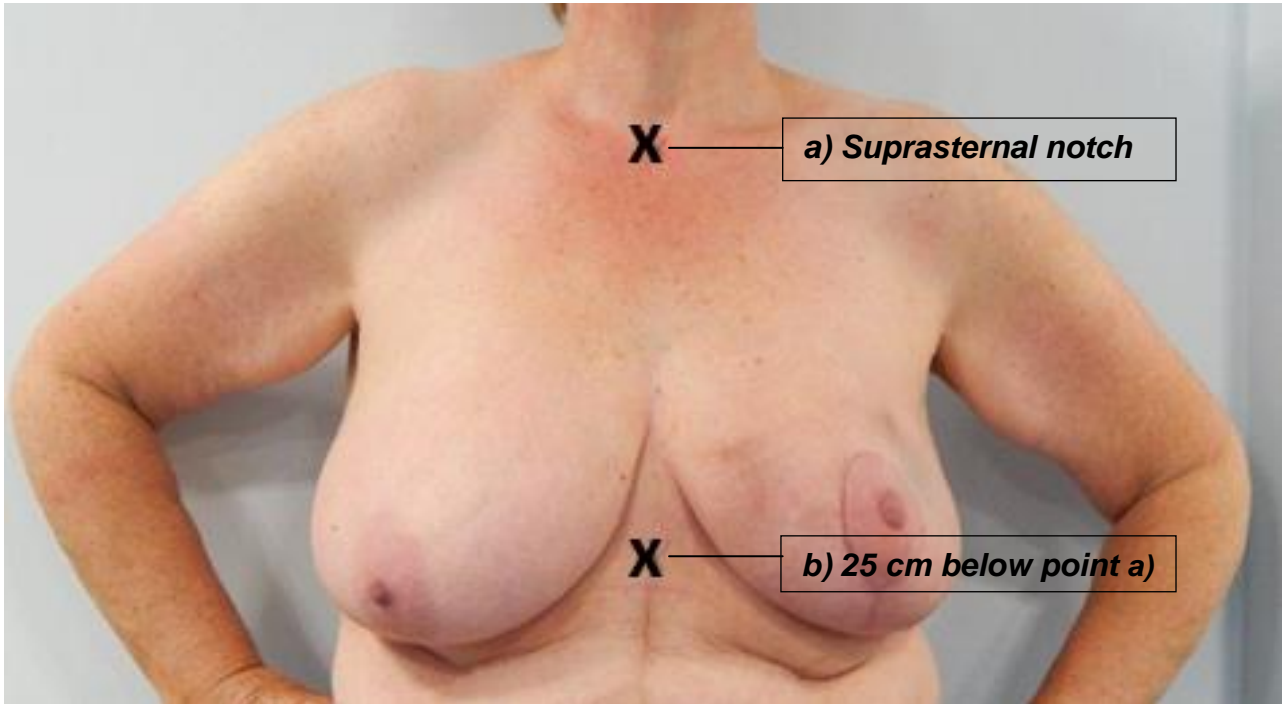


Figure 1: Anterior view, hands on hips

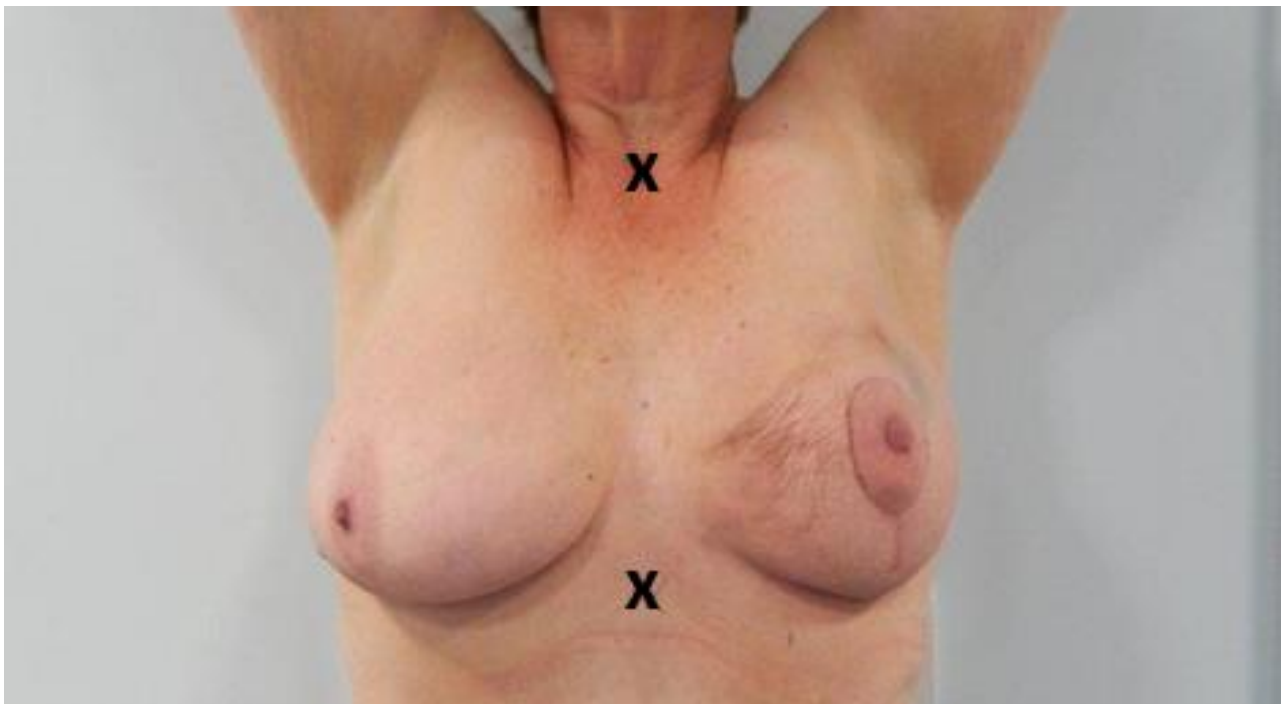


Figure 2: Anterior view, hands above head



Figure 3: Lateral view, hands above head

7.4 Storage of photos

- 7.4.1 Save as JPEG format
- 7.4.2 300 dpi (image width of 15 cm)
- 7.4.3 Working space – Adobe RGB (1998) or professional equivalent
- 7.4.4 DO NOT alter the image
- 7.4.5 Assign a file name as follows:
REQUIRE ID number and the date (dd-mmm-yy) the photo was taken
- 7.4.6 Please state the position of the patient when the photo is taken: UP for raised hands, HIP for hands positioned at the hips, and LAT for lateral view.
- 7.4.7 The last letter or number should represent the time point, e.g. B for baseline and 2 for year 2, e.g. RQ09999-9_05Jan14_UP_B; RQ09999-9_05Jan16_HIP_2, RQ09999-9_05Jan16_LAT_2

7.5 BCCT.core Image Analysis

REQUIRE recommends the use of free software (BCCT.core) to objectively assess change in breast appearance. Post-surgical baseline photographs will be compared with post-radiotherapy photographs at year 2 to assess factors considered to have an impact on the overall cosmetic result e.g. breast asymmetry, skin colour changes due to the radiotherapy and surgical scar visibility (Keshtgar et al. 2013 Breast Cancer Res Treat, Cardoso et al. 2007 Breast). This will be done centrally when all photos are available.

8 Document History

This is the version 1.2 of the SOP.