

Document information			
Author			
Reviewer		Date and signature	See electronic signature
Approver		Date and signature	See electronic signature

*Electronic signature and date on separate final page of this document. The date of the last signature shall be regarded as the release date for this usability evaluation plan.*

## Appendix B



**NILES**  
Non Invasive Lymph node Staging

## Appendix B1: Test instructions for participants – English

<b>ID (to be filled in by test leader)</b>	
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You will be asked to perform five scenarios, with five different patient cases. The cases are presented below. After calculating each case using NILS, fill in the appropriate clinical pathway based on the calculation and other available information in the table below. For each new case you have to clear the interface before entering the new information. It is possible that not all cases can be calculated in NILS. Make sure that you finish each case before you start the next case. If a case cannot be calculated, the column “NILS cannot assist in making the clinical decision” shall be marked in the result table below. You may not ask the test leader for assistance during the test, however you may ask organizational questions related to how the test session will be conducted. You have the instructions for use available during the whole session.

*Please note that we want to evaluate the usability of the calculator, not the clinical decision-making!*

Please fill in the information below.

<b>Initials:</b>	
<b>Date:</b>	
<b>Speciality:</b>	Surgeon  Oncologist  Experience as a specialist (years):
<b>Hospital you work at:</b>	SUS  Växjö  Kristianstad  Karlskrona  Other:
<b>Academic degree:</b>	MD  PhD
<b>Age:</b>	
<b>Gender:</b>	Female  Male

	<div>Other</div> <div>Do not want to say</div>
<div>Do you use any tool/system for prediction in your work today? If yes, which?</div>	<div>Yes</div> <div>No</div> <div>If yes, which:</div>

## Cases

### Case 1

A previously healthy 61-year-old woman with a screening detected lesion of one tumour in the left breast. The clinical mammography and ultrasound state a single 11 mm retromamillary tumour (approximately 1 cm from the mamilla) in the left breast. Ultrasonography revealed no suspicious findings in the axilla. Core needle biopsy results reported invasive NST; histologic grade 2; ER 98%; PgR 98%; HER2-negative and Ki67 77%. Vascular invasion was neither confirmed nor denied. Clinical examination of the left breast and axilla revealed no abnormalities.

Question	Your answer
What percentage did the calculation result in?	
How should the presented histogram be interpreted for Case 1?	

Please fill in the clinical pathway that you find most appropriate based on the information you have received and the NILS calculation. Note that several pathways can be appropriate.

	Consider omitting SLNB	Consider performing SLNB	Definitely perform SLNB	NILS cannot assist in making the clinical decision
Case 1				

## Case 2

An 83-year-old woman with no previous history of malignancy. Pharmacologically treated hypertension and hyperlipidemia. Presents with a self-detected palpable mass in the left breast. The clinical mammography and ultrasound state a single 18 mm tumour at 6 o'clock, 3 cm from the mamilla in the left breast. Ultrasonography revealed no suspicious findings in the axilla. Core needle biopsy results reported invasive mixed ductulobular; histologic grade 3; ER 78%; PgR 91%; HER2-negative and Ki67 18%. Vascular invasion was neither confirmed nor denied. The tumour was confirmed palpable upon clinical examination of the left breast and the examination of the axilla revealed no abnormalities.

Question	Your answer
What percentage did the calculation result in?	
How should the presented histogram be interpreted for Case 2?	

Please fill in the clinical pathway that you find most appropriate based on the information you have received and the Nils calculation. Note that several pathways can be appropriate.

	Consider omitting SLNB	Consider performing SLNB	Definitely perform SLNB	Nils cannot assist in making the clinical decision
Case 2				

### Case 3

A 22-year-old woman with a self-detected palpable mass in the right breast. The clinical mammography and ultrasound state a single 50 mm tumour at 6 o'clock, 4 cm from the mamilla in the right breast. Ultrasonography revealed no suspicious findings in the axilla. Core needle biopsy results reported invasive NST; histologic grade 3; ER <1%; PgR <1%; HER2-negative and Ki67 76%. Vascular invasion was neither confirmed nor denied. The tumour was confirmed palpable upon clinical examination of the right breast and the examination of the axilla revealed no abnormalities.

Question	Your answer
What percentage did the calculation result in?	
How should the presented histogram be interpreted for Case 3?	

Please fill in the clinical pathway that you find most appropriate based on the information you have received and the NILS calculation. Note that several pathways can be appropriate.

	Consider omitting SLNB	Consider performing SLNB	Definitely perform SLNB	NILS cannot assist in making the clinical decision
Case 3				

### Case 4

A previously healthy 68-year-old woman with screening detected findings in the left breast. The clinical mammography and ultrasound state a single 12 mm tumour at 9 o'clock, 5 cm from the mamilla in the left breast. Ultrasonography revealed no suspicious findings in the axilla. Core needle biopsy results reported invasive NST; histologic grade 3; ER 89%; PgR 91%; HER2-negative and Ki67 8%. Vascular invasion was neither confirmed nor denied. Clinical examination of the left breast and axilla revealed no abnormalities.

Question	Your answer
What percentage did the calculation result in?	
How should the presented histogram be interpreted for Case 4?	

Please fill in the clinical pathway that you find most appropriate based on the information you have received and the NILS calculation. Note that several pathways can be appropriate.

	Consider omitting SLNB	Consider performing SLNB	Definitely perform SLNB	NILS cannot assist in making the clinical decision
Case 4				

## Case 5

A 43-year-old woman with screening detected findings of bifocal breast tumour in the right breast. The clinical mammography and ultrasound states: 1) a 15 mm tumour at 10 o'clock, 4 cm from the mammilla in the right breast, and 2) 12 mm tumour at 7 o'clock, 3 cm from the mammilla in the right breast. Ultrasonography revealed no suspicious findings in the axilla. Core needle biopsy results reported: "Tumour 1." Invasive NST; histologic grade 2; ER 99%; PgR 99%; HER2-negative and Ki67 76%. Vascular invasion was neither confirmed nor denied. "Tumour 2." Invasive NST, histologic grade 2; ER 98%; PgR 98%; HER2-neg Ki67 71%. Vascular invasion was neither confirmed nor denied. Upon clinical examination, the physician found "tumour 1" palpable in the right breast. Clinical examination of the right axilla revealed no abnormalities.

Question	Your answer
What percentage did the calculation result in?	
How should the presented histogram be interpreted for Case 5?	

Please fill in the clinical pathway that you find most appropriate based on the information you have received and the NILS calculation. Note that several pathways can be appropriate.

	Consider omitting SLNB	Consider performing SLNB	Definitely perform SLNB	NILS cannot assist in making the clinical decision
Case 5				

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Please answer the questions in the table below.

This questionnaire gives you an opportunity to tell us your reactions to the system you used. Your responses will help us understand what aspects of the system you are particularly concerned about and the aspects that satisfy you. To as great a degree as possible, think about all the tasks that you have done with the system while you answer these questions. Please read each statement and indicate how strongly you agree or disagree with the statement by checking the box that corresponds best to how you feel. Thank you!

		<b>Strongly Disagree</b>						<b>Strongly Agree</b>
			<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	
1	I think that I would like to use this system frequently							
2	I found the system unnecessarily complex							
3	I thought the system was easy to use							
4	I think that I would need the support of a technical person to be able to use this system							
5	I found the various functions in this system were well integrated							
6	I thought there was too much inconsistency in this system							
7	I would imagine that most people would learn to use this system very quickly							
8	I found the system very awkward to use							
9	I felt very confident using the system							
10	I needed to learn a lot of things before I could get going with this system							



1. Overall, I am satisfied with the ease of completing the tasks in this scenario.

Strongly disagree ←————→ Strongly agree  
1 2 3 4 5 6 7

N/A

Comments:

2. Overall, I am satisfied with the amount of time it took to complete the tasks in this scenario.

Strongly disagree ←————→ Strongly agree  
1 2 3 4 5 6 7

N/A

Comments:

3. Overall, I am satisfied with the support information (on-line help, documentation) when completing the tasks.

Strongly disagree ←————→ Strongly agree  
1 2 3 4 5 6 7

N/A

Comments:

Do you have any other feedback?

**Thank you very much for taking the time to participate in this usability study of NILS!**