

CE Marking Study of the IlluminOss
Photodynamic Bone Stabilization System for
the Treatment of Humerus Fractures

NCT02394080

Statistical Analysis Plan (SAP)

October 31, 2016

STATISTICAL ANALYSIS PLAN

CE Marking Study of the IlluminOss® Photodynamic Bone Stabilization System for the Treatment of Humerus Fractures

Investigational Product: IlluminOss Photodynamic Bone Stabilization System (PBSS)
Protocol Number: 12-03-EUHUM-01
Sponsor: IlluminOss Medical, Inc.
993 Waterman Avenue
East Providence, RI 02914
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SIGNATURE PAGE

STUDY TITLE: CE MARKING STUDY OF THE ILLUMINOSS PHOTODYNAMIC BONE
STABILIZATION SYSTEM FOR THE TREATMENT OF HUMERUS FRACTURES

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REVISION HISTORY

Version	Date	Description of Changes
		Original signed SAP

LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

Abbreviation	Definition
AE	Adverse Event
CE	Conformité Européene
CI	Confidence Interval
CRF	Case Report Form
CSR	Clinical Study Report
DASH	Disability of the Arm, Shoulder and Hand
ICF	Informed Consent Form
IlluminOss	IlluminOss Medical, Inc.
ITT	Intent-to-Treat
MedDRA	Medical Dictionary for Regulatory Activities
PBSS	Photodynamic Bone Stabilization System
PD	Protocol Deviation
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SOC	System Organ Class
TEAE	Treatment-Emergent Adverse Event
VAS	Visual Analog Score
WHO	World Health Organization

1. INTRODUCTION

This Statistical Analysis Plan (SAP) is based on the IlluminOss Medical, Inc. (“IlluminOss”) Protocol Version NLD v3.0, (09 December 2015), GER v1.5.1 (25 June 2015). The SAP provides guidance for and description of the statistical methods and procedures to be implemented for the analysis and presentation of efficacy and safety data collected within the scope of IlluminOss Protocol 12-03-EUHUM-01.

Results obtained from the analysis outlined in this document will become the basis for the final Clinical Study Report (CSR) for this protocol. This SAP supersedes the statistical considerations identified in the protocol; where considerations are substantially different, they will be so identified. If additional analyses are required to supplement the planned analyses described in this SAP, they may be performed and will be identified in the CSR. Any substantial deviations from this SAP will be agreed upon between IlluminOss and Medpace and identified in the CSR. Any minor deviations from the tables/figures/listings (provided in a separate Programming Specifications document) may not be documented in the CSR, but will be noted within the Programming Specifications document.

2. STUDY OBJECTIVES

2.1.1 Primary Objective

The primary objective of this study is:

- To evaluate the normal radiographic fracture healing at the Day 180 visit.

2.1.2 Secondary Objectives

The secondary objectives of this study are:

- To evaluate the complete radiographic fracture healing at the Day 180 visit.
- To evaluate the normal radiographic healing, and complete radiographic healing at the Day 360 visit.
- To compare pain visual analog score (VAS), disability of the arm, shoulder and hand score (DASH), constant shoulder score from baseline to all follow up intervals.
- To assess no pain at palpation status, return to pre-fracture mobility status.
- To assess the range of motion, disability status, and return to work status.
- To assess the safety endpoints that include the incidence of adverse events, and the procedure- and device- related complication rate.

2.1.3 Other Objectives

In addition to the above study objectives, there are a few optional assessments about health economic data:

- Duration of physical therapy prescription.
- Use of supportive orthopedic devices post-surgery.
- Prescription and over-the-counter analgesic medication.

3. STUDY OVERVIEW

3.1 Overall Study Design and Treatment Assignment

This is a CE marking, prospective, multi-center, open-label clinical study to evaluate the performance of the PBSS in the treatment of acute fractures of the humerus. A maximum of 45 patients with fractures of the humerus are expected to be enrolled and will undergo IlluminOss device implant. Each patient enrolled in the study will be followed to 1 year post-index procedure. This study will include up to eight visits:

Visit 1: Screening and baseline procedures;

Visit 2: Surgery for device placement and post-index procedures and discharge;

and 6 Follow-up Visits:

Visit 3: 7-14 day follow-up (+3 days), At Germany sites, 7 day follow-up (± 4 days);

Visit 4: 30 day follow-up (± 14 days);

Visit 5: 60 day follow-up (± 14 days);

Visit 6: 90 day follow-up (± 14 days);

Visit 7: 180 day follow-up (± 30 days);

Visit 8: 360 day follow-up (± 60 days).

The scheduled activities performed for each visit are described in the following chart.

Schedule of Activities

	Visit 1	Visit 2	Visit 3 ⁴	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8
	Screening and Baseline	Surgery and Discharge	7-14 Day F/U (+ 3 days)	30 Day F/U (± 14 days)	60 Day F/U (± 14 days)	90 Day F/U (± 14 days)	180 Day F/U (± 30 days)	360 Day F/U (± 60 days)
Inclusion/Exclusion Review	X							
Informed Consent	X							
Patient Medical History	X							
Physical Exam	X							
Clinical Assessments ¹			X	X	X	X	X	X
Disability of the Arm, Shoulder and Hand (DASH) Score ³	X		X	X	X	X	X	X
Pain Visual Analog Scale (VAS)	X		X	X	X	X	X	X
Constant Shoulder Score ³	X		X	X	X	X	X	X
Total Active & Passive Range of Motion			X ²	X ²	X ²	X ²	X ²	X ²
Radiographs of Fracture	X		X			X	X	X
Adverse Events		X	X	X	X	X	X	X
Health Economic Assessment	X	X	X	X	X	X	X	X

¹ Clinical assessments include, but are not limited to, assessments for pain, return to pre-fracture mobility, return to work, disability status, use of pain medication and physical therapy prescription status.

² Assessment performed as tolerated.

³ The Disability of the Arm, Shoulder and Hand (DASH) Score and the Constant Shoulder Score are optional assessments at each follow-up visit. If the scores are taken at baseline, every effort should be made to take scores at the subsequent visits except Netherlands sites, at which it is optional.

⁴ At Germany sites, Visit 3 is scheduled as 7 day follow-up (± 4 days).

3.2 Study Assessments

3.2.1 Efficacy Assessments

Efficacy assessments include the proportions of patients who are confirmed to have achieved radiographic healing statuses, which are normal healing, and complete healing at the visits Day 180, Day 360. Normal radiographic healing is defined by two of four cortices or two of four views demonstrating bridging on standard radiographs. Complete radiographic healing is defined as three of four cortices or three of four views demonstrating bridging, with dissolution of the majority (> 75% on orthogonal views) of fracture lines.

Efficacy assessments also include the pain visual analog score (VAS), DASH, and Constant shoulder score. These scores are collected at the screening and baseline visit and each follow-up visit. The changes from baseline in the scores are also considered as efficacy variables.

Additional, efficacy assessments include pain at palpation status, return to pre-fracture mobility status, disability status, return to work status, range of motion.

As optional assessments, some health economic data will be analyzed: duration of physical therapy prescription, the use of supportive orthopedic devices post-surgery, and prescription and over-the-counter analgesic medication use.

Radiographs of fracture will be taken at the screening visit 1 and the post-surgery follow up visits: visit 3, visit 6, visit 7 and visit 8. Based on the radiographic results, the counts of cortices or views demonstrating bridging can be obtained for every patient. Then by the definition of normal radiographic healing and complete radiographic healing, the number and proportion of patients who are confirmed to have achieved normal healing as well as complete healing are calculated at each visit.

To measure the pain, a visual analog scale worksheet will be provided to a patient to mark the intensity of his/her pain during the last week. The pain VAS is collected at the screening and every follow-up visit. The baseline VAS will be defined as the measurement at screening visit.

Questionnaires are to be used for the assessment of DASH. A DASH score is calculated from the completed form. The form includes 30 questions about the activities or symptoms in the last week. Each of them has 5 selections (no difficulty, mild difficulty, moderate difficulty, severe difficulty, unable)/ (not at all, slightly, moderately, quite a bit, extremely)/(not limited at all, slightly limited, moderately limited, very limited, unable)/(none, mild, moderate, severe, extreme)/(no difficulty, mild difficulty, moderate difficulty, severe difficulty, so much difficulty that I am unable)/(strongly disagree, disagree, neither agree nor disagree, agree, strongly disagree). For each question, the response is converted to a number of 1, 2, 3, 4 or 5 accordingly. Over the answered questions, the DASH score can be calculated as:

$$\frac{[(\text{sum of } n \text{ responses}) - 1]}{n} \times 25, \text{ where } n \text{ is the \#number of completed responses.}$$

Note: A DASH score may not be calculated if there are greater than 3 missing items. That is, A DASH score will be missing if more than 3 questions are not answered. See Appendix A for more

details about the DASH questions and score calculation. Medpace will be responsible for the derivation of DASH score.

A constant shoulder score is calculated by adding up the 4 categories (Pain, Activities of daily living, Range of movement, and Power). See Appendix B for the questions, the conversion from responses to numbers and the calculation formula about Constant Shoulder Score. Medpace will be responsible for the derivation of constant shoulder score.

The scores are optional assessments at each follow-up visit. If the scores are taken at baseline (screening visit), every effort should be made to take scores at the subsequent visits except Netherlands sites, at which it is optional. The baseline DASH score and Constant shoulder score are the calculated values at screening visit.

3.2.2 Safety Assessments

Safety parameters include all treatment-emergent adverse events (AEs), adverse device effects (ADEs), serious adverse events (SAEs), and serious adverse effects (SADEs), procedure- and device-related complications.

Other safety assessments, procedure- and device-related complications may occur at any time during the surgery, indwelling period, or at the time of or following device removal, if performed.

4. STATISTICAL METHODOLOGY

4.1 Baseline, Endpoint, and Other Statistical Considerations

The statistical analyses will be performed by Medpace.

For both efficacy and safety assessments, the baseline values are defined as the measurements at the screening and baseline visit (Visit 1). Only scheduled visits will be used for analysis.

Descriptive summary statistics for continuous variables will include number (n), mean, standard deviation (SD), median and range (minimum, maximum) by visit. For categorical variables, frequency counts and percentages of each category will be presented. The corresponding confidence intervals (CI) will be calculated at 95%, 2-sided for the applicable analysis variables.

All data will be displayed in patient-level data listings which will be included as part of an appendix to the Clinical Study Report.

4.2 Analysis Population

The Intent-to-Treat (ITT) analysis population is defined as all patients who meet the study eligibility criteria, provide informed consent, undergo surgery, and have a successful implantation of the IlluminOss Photodynamic Bone Stabilization System into the intramedullary canal.

The modified Intent-to-Treat (mITT) analysis population is defined as all patients who provide informed consent, undergo surgery, and have a successful implantation of the IlluminOss Photodynamic Bone Stabilization System into the intramedullary canal.

Both efficacy and safety analyses will be performed on the ITT and mITT analysis populations.

4.3 Patient Disposition

Patients' disposition information will be summarized. Counts (frequency counts and percentage) of patients who sign the ICF, who undergo the implantation surgery, who complete the study, and who withdraw early from the study will be presented. The primary reasons for early withdrawals will also be tabulated. The total number of ITT patients will be used as the denominator for the percentage calculation.

4.4 Protocol Deviations

Clinical Data Management and the Clinical Project Manager will provide the clinical database generated protocol deviations and study monitor documented protocol deviations, and provide a list of all protocol deviations to the study team (categorized as Clinical Study Report (CSR) Reportable and CSR Non-reportable) prior to the database lock. The study team and the team physician will review the list and confirm the CSR reportable protocol deviations. The CSR reportable protocol deviations will be reviewed by the study team and Medical Monitor and finalized prior to database lock. This listing will include subject ID, study date when the deviation happened, and the specifics of the deviation.

According to the ICH E3, Structure and Content of Clinical Study Reports, a CSR reportable PD is related to inclusion/exclusion criteria, conduct of the trial, patient management or patient assessment that impact the safety of the jeopardize the quality of the study data. The following categories will be used for CSR reportable PDs:

- A subject that did not meet entry criteria,
- A subject that developed withdrawal criteria but were not withdrawn,
- A subject that received the wrong treatment or incorrect dose,

4.5 Demographics and Baseline Characteristics

Demographics and baseline characteristics will be summarized descriptively for the ITT and mITT analysis populations.

Demographic and baseline characteristics include, but are not limited to, age at informed consent, gender, pre-fracture work status, occupation, hand dominance, disability status, pre-fracture mobility, osteoporosis history, type I diabetes history, smoking status, fracture characteristics, duration of index procedure (hours), length of hospital stay (days), and fracture treatment. Continuous variables (e.g., age) will be summarized by descriptive statistics. Categorical variables (e.g., gender) will be summarized by the number and percentage of patients in corresponding categories.

4.6 Prior and Concomitant Medications

All medications administered during the study will be listed. Two separate listings of all prior medications and all concomitant medications including the reported term, start and stop dates, and other relevant data will be provided in subject-level. Concomitant medications include all medications taken on the surgery day or during the follow-up period. Prior medications include all medications taken before the surgery.

4.7 Medical History

All medical history records collected will be listed. A listing of all past and/or concomitant diseases or past surgeries subjects experienced including the reported term, onset/surgery and end dates, and other relevant data will be provided in subject-level.

4.8 Efficacy Analyses

Descriptive statistics for the baseline and post-surgery measurements at all applicable visits and the changes from baseline will be presented.

4.8.1 Primary Efficacy Analysis

The primary endpoint is the proportion of patients who are confirmed to have achieved normal radiographic healing (at least 2 of 4 cortices or at least 2 of 4 views demonstrating bridging on standard radiographs) by the Day 180 Visit.

The number and percentage of patients in the ITT and mITT populations achieving the primary endpoint will be presented along with the corresponding 95% binomial confidence interval. If the proportion of patients with normal fracture healing is at least 90% then the primary endpoint will be met.

4.8.2 Secondary Efficacy Analyses

- Similar to the primary efficacy endpoint, the proportion of patients who are confirmed to have achieved complete radiographic healing by the Day 180 visit, the proportion of patients who are confirmed to have achieved normal healing by the Day 360 visit, and the proportion of patients who are confirmed to have achieved complete healing by the Day 360 visit will be presented. The corresponding 95% binomial confidence intervals will also be calculated. Additionally and similarly, the fracture healing assessment at the Day 90 will also be analyzed as an endpoint.
- For the primary efficacy endpoint, the proportion of patients who are confirmed to have achieved normal radiographic healing by the Day 180 Visit, the comparison will be conducted between subgroups for fracture treatment: patients with IlluminOss alone or IlluminOss with screws versus patients with IlluminOss with plate and screws. A logistic regression model will be used to calculate the odds ratio, 95% confidence interval of odds ratio, and corresponding p-value will be calculated.
- Descriptive statistics for duration of index procedure and length of hospital stay will be presented.
- The pain VAS scores at baseline, each follow-up visit, change from baseline and percent change from baseline will be summarized descriptively along with the corresponding 95% confidence intervals.
- The DASH scores at baseline, each follow-up visit, change from baseline and percent change from baseline will be presented with summary statistics and 95% confidence.

- The number and percentage of patients in each Constant Shoulder Score category (Poor, Fair, Good, and Excellent) will be displayed for those patients on whom the score is available. A shift table will be used to summarize changes from baseline to all follow-up visits.
- The number and percentage of patients with no pain at palpation will be presented for each follow-up visit. Also, for the patients with pain on palpation, the counts and percentages of patients will be presented by severity (Mild, Moderate, Severe), clinical significance, and visit.
- The number and percentage of patients who returned to pre-fracture mobility will be presented for each follow-up visit.
- Range of motion will be assessed using ordinal variables reflecting the abduction, flexion, extension, and rotation of affected and unaffected arms. Summary statistics for range of motion will be presented at each follow-up visit. In addition, the number and percentage of patients for each level of those ordinal variables will be displayed.
- For disability status, the number and percentage of patients who are considered disabled, per Investigator assessment, will be presented for each follow-up visit.
- The number and percentage of patients who returned to work, and in what capacity (e.g., full-time, part-time, with limitations) will be presented for each follow-up visit.

4.9 Safety Analyses

Safety will be assessed using the incidence of treatment-emergent AEs and SAEs, complications associated with surgery and the use of anesthesia.

4.9.1 Adverse Events

All AEs from the time of signing the informed consent through study completion will be recorded on the Case Report Form (CRF). An AE is any untoward medical occurrence in a patient or a clinical investigation, when patient was administered a device without regard to the possibility of a causal relationship with use of this device. An AE can, therefore, be any unfavorable and unintended symptom, sign, disease or condition, or test abnormality whether or not considered related to the device. All AEs, including observed or voluntarily reported problems, complaints, or symptoms, are to be recorded on the Adverse Event CRF. Adverse events will be coded using the latest version of the Medical Dictionary for Regulatory Activities (MedDRA).

A treatment-emergent AE (TEAE) is any AE that starts during or after the implantation surgery through the end of the safety follow-up period. Device-related or procedure-related AEs will include those that are marked as ‘Definitely Related’, ‘Probably Related’ or ‘Possibly Related’ to the device/procedure.

Summarization of AEs will include patient and event incidence of the following:

- TEAEs
- SAEs
- Device-related TEAEs,
- Device-related SAEs
- Procedure-related TEAEs,
- Procedure-related SAEs,
- Death due to AEs,
- AEs leading to study termination

The numbers and percentages of patients with TEAEs and the frequencies of events will be summarized by MedDRA system organ class (SOC), preferred term, and severity. All TEAEs related to study device/procedure, SAEs, SAEs related to study device/procedure, and AEs leading to study discontinuation or withdrawal from the study will be summarized in the same manner. Summaries will be provided for the numbers and percentages of patients and numbers of events by system organ class, preferred term, for TEAEs (SAEs), device-related and procedure-related TEAEs (SAEs).

If a patient has more than 1 occurrence of the same AE, he/she will be counted only once within that preferred term in the summary tables. The most severe occurrence of an AE, as well as the most extreme relationship of the AE to the study devices or procedures will be indicated in case of multiple occurrences of the same AE.

All AEs will be included in by-patient listings. Specific by-patient listings of SAEs and TEAEs leading to discontinuation will be provided. The number of days between surgery and when the event occurred will be presented (i.e., relative start day), as will duration of AE.

4.9.2 Procedure- and Device-related Complication Rate

The proportion of patients who experience a procedure- or device-related complication at day 180 and day 360 will be presented along with the corresponding 95% binomial confidence intervals. Similarly, the proportion of patients with at least one procedure- or device-related complication at any follow-up visit and overall will be presented.

4.10 Additional Analysis

For the primary efficacy endpoint, the proportion of patients who are confirmed to have achieved normal radiographic healing by the Day 180 Visit, the comparison will be conducted between subgroups for fracture treatment: patients with IlluminOss alone or IlluminOss with screws versus patients with IlluminOss with plate and screws. A logistic regression model will be used to calculate the odds ratio, 95% confidence interval of odds ratio, and corresponding p-value will be calculated.

4.11 Optional Analyses

- Subgroup analyses: the efficacy and safety endpoints descriptive above may also be analyzed on subgroups. The subgroups would be defined by fracture location (proximal, diaphyseal, and distal fractures).
- Health economic data: Descriptive statistics for the duration of physical therapy prescription will be presented. The number and percentage of patients who used supportive orthopedic devices post-surgery, as well as by device category, and who used prescription and over-the-counter analgesic medication will be presented.

4.12 Interim Analyses

There will be an interim analysis conducted for this study when the last patient completes his/her Day 180 visit and the data for all patients through the Day 180 Visit are locked. The interim analyses will include the analyses of the primary endpoint, all secondary endpoints, and all health economic data using data collected by the Day 180 Visit. As the analyses are descriptive, no adjustments to the confidence intervals are deemed necessary as a result of the interim analyses for the single arm study.

5. SAMPLE SIZE DETERMINATION

Sample size for this post-marketing study was not statistically determined. The Sponsor decided that 30 subjects need to be enrolled and followed through 12 months to adequately describe the ability to implant the IlluminOss Photodynamic Bone Stabilization System and describe the safety and performance of the IlluminOss Photodynamic Bone Stabilization System. Due to potential enrollment failures and loss-to-follow-up, it was decided that 45 patients will be sufficient to ensure that at least 30 subjects are followed through 12 months.

6. PROGRAMMING SPECIFICATIONS

The programming specifications, including the mock-up analysis tables, figures, and data listings, as well as the derived database specifications, will be prepared in stand-alone documents. The programming specification documents will be finalized prior to database lock.

7. APPENDICES

7.1 Appendix A: Disabilities of the Arm, Shoulder

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Write.	1	2	3	4	5
3. Turn a key.	1	2	3	4	5
4. Prepare a meal.	1	2	3	4	5
5. Push open a heavy door.	1	2	3	4	5
6. Place an object on a shelf above your head.	1	2	3	4	5
7. Do heavy household chores (e.g., wash walls, wash floors).	1	2	3	4	5
8. Garden or do yard work.	1	2	3	4	5
9. Make a bed.	1	2	3	4	5
10. Carry a shopping bag or briefcase.	1	2	3	4	5
11. Carry a heavy object (over 10 lbs).	1	2	3	4	5
12. Change a lightbulb overhead.	1	2	3	4	5
13. Wash or blow dry your hair.	1	2	3	4	5
14. Wash your back.	1	2	3	4	5
15. Put on a pullover sweater.	1	2	3	4	5
16. Use a knife to cut food.	1	2	3	4	5
17. Recreational activities which require little effort (e.g., cardplaying, knitting, etc.).	1	2	3	4	5
18. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5
19. Recreational activities in which you move your arm freely (e.g., playing frisbee, badminton, etc.).	1	2	3	4	5
20. Manage transportation needs (getting from one place to another).	1	2	3	4	5
21. Sexual activities.	1	2	3	4	5

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
22. During the past week, to what extent has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups? (circle number)	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
23. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem? (circle number)	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. (circle number)

	NONE	MILD	MODERATE	SEVERE	EXTREME
24. Arm, shoulder or hand pain.	1	2	3	4	5
25. Arm, shoulder or hand pain when you performed any specific activity.	1	2	3	4	5
26. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5
27. Weakness in your arm, shoulder or hand.	1	2	3	4	5
28. Stiffness in your arm, shoulder or hand.	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
29. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? (circle number)	1	2	3	4	5

	STRONGLY DISAGREE	NEITHER AGREE NOR DISAGREE	DISAGREE	AGREE	STRONGLY AGREE
30. I feel less capable, less confident or less useful because of my arm, shoulder or hand problem. (circle number)	1	2	3	4	5

DASH DISABILITY/SYMPTOM SCORE = $\frac{[(\text{sum of } n \text{ responses}) - 1]}{n} \times 25$, where n is equal to the number of completed responses.

7.2 Appendix B: Constant Score

A.- Pain (/15): Average (1 + 2) A

1. Do you have pain in your shoulder (normal activities)?
No = 15 pts, Mild pain = 10 pts, Moderate = 5 pts, Severe or permanent = 0.

2. Linear scale:

If "0" means no pain and "15" is the maximum pain you can experience, please circle where is the level of pain of your shoulder. (Points given are inverse to the scale. E.g. level 5 in the scale means 10 points)

Level of pain:

Points:

0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15

15 14 13 12 11 10 9 8 7 6 5 4 3 2 1 0

B.- Activities of daily living (/20) Total (1 + 2 + 3 + 4) B

1. Is your occupation or daily living limited by your shoulder?
No = 4, Moderate limitation = 2, Severe limitation = 0
2. Are your leisure and recreational activities limited by your shoulder?
No = 4, Moderate limitation = 2, Severe limitation = 0
3. Is your night sleep disturbed by your shoulder?
No = 2, Sometimes = 1, Yes = 0
4. State to what level you can use your arm for painless, reasonably activities.
Waist = 2, Xiphoid (sternum) = 4, Neck = 6, Head = 8, Above head = 10

C.- Range of movement (leave this for the doctor or physiotherapist) **(/40):** **Total (1 + 2 + 3 + 4)** C

1.- FWD Flexion:	0 – 30	0 pts	2.- Abduction:	0 - 30
	31 -60	2 pts		31 - 60
	61 – 90	4 pts		61 - 90
	91 – 120	6 pts		91 - 120
	121- 150	8 pts		121 - 150
	> 150	10 pts		> 150

3.- External Rotation:		4.- Internal Rotation: (Dorsum hand to)	
Hand behind head & elbow forward	2	Thigh	
Hand behind head & elbow back	4	Buttock	
Hand above head & elbow forward	6	SI joint	
Hand above head & elbow back	8	Waist	
Full elevation of arm	10	T12	
		Between shoulder blades	10

D.- Power (/25): Points: average (kg) x 2 = D

First pull: Second pull: Third pull: Fourth pull: Fifth pull:
Average pulls:

TOTAL (/100): A + B + C + D

