442

CLINICAL STUDIES UNIT VISIT
MAYO CLINIC JACKSONVILLE

PATIENT NAME: REDACTED
(Please print) Last First M.I.

CLINIC NUMBE] REDACTED (N/A if non Mayo patient)

DATE OF BIRTH: REDACTED

TITLE OF PROTOCOL: The Benefits of "Ionized" Wrist Bracelets Study
IRB NUMBER: IRB # B-1086-99
PRINCIPAL INVESTIGATOR: Robert L. Bratton, M.D.

DATE: 12/20/00

The participant presented today for screening procedures for the above named study. The participant read the informed consent form. The Inclusion/Exclusion criteria was reviewed with the participant and they were given the opportunity to have their questions answered. The participant meets entry criteria, understands the study and agrees to enrollment. The informed consent was signed and a copy was given to the participant.

SIGNED, L Hall

Benefits of Ionized Wrist Bracelets
Investigator: R.L. Bratton, M.D.
Statisticians: P.C. O'Brien, Ph.D.
E.J. Atkinson

Day 0

Study number: 7-1089
IRB number: 1086-99 (J) 442
Revised: 10/25/2000 (M)

Name: REDACTED (Last) (First) (M.I.) DOB: REDACTED

Address: REDACTED

Phone: (Home) (Mobile)

1-4	442	Patient number
5-7	REDACTED	Patient initials
8-15		Mayo Clinic identification (leave blank if not a Mayo Clinic patient)
16-23	12-20-2000	Date of enrollment (MM-DD-YYYY)

Patient Eligibility Checklist (1→ 4 must be 'No' to enter)

	No	Yes	
24	0 ☒	1 ☐	1. Are you pregnant or suspect you are pregnant?
25	0 ☒	1 ☐	2. Are you currently breast feeding?
2	REDACTED		3. Are you under 18 years of age?
27	0 ☒	1 ☐	4. Do you have an implanted electrical device (i.e., pacemaker, electronic defibrillator, etc.)?
28	0 ☒	1 ☐	5. Are you taking any medication for joint or muscle pain (i.e., anti-inflammatories) on a regular basis?

Demographic Information

29-30 6. What is your age in years? REDACTED

31 7. What is your gender? 1 ☐ Male 2 ☑ Female

32 8. What best describes your ethnic background:

- 1 ☒ White
- 2 ☐ Black
- 3 ☐ Hispanic
- 4 ☐ Asian
- 5 ☐ American Indian
- 6 ☐ Alaskan Native
- 7 ☐ Other _____

33	0 ☐	1 ☒	9. Have you ever seen the 'ionized' wrist bracelet before?
34	0 ☒	1 ☐	10. Have you ever used the 'ionized' wrist bracelet before?
35	0 ☐	1 ☐	11. Do you believe these bracelets can help reduce joint/ muscle pain?

(?)

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September 2000

		Any current underlying joint/muscle pain	Any serious injury
36-37	Neck	1 ☒	1 ☐
38-39	Shoulders	1 ☐	1 ☐
40-41	Elbows	1 ☐	1 ☐
42-43	Wrists	1 ☐	1 ☐
44-45	Hands	1 ☐	1 ☐
46-47	Upper Back	1 ☒	1 ☐
48-49	Mid Back	1 ☒	1 ☐
50-51	Lower Back	1 ☐	1 ☐
52-53	Hips	1 ☐	1 ☐
54-55	Knees	1 ☒	1 ☐
56-57	Ankles	1 ☐	1 ☐
58-59	Feet	1 ☐	1 ☐

You must have current joint or muscle pain that affects at least one area mentioned above.

Name of person enrolling this subject: L Hall

442 h

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Survey Day 0

Study number: 7-1089
IRB number: 1086-99 (J)
September 2000

Name: REDACTED
(Last) (First) (M.I.)

Column	Item	
1-2	0 0	Survey day
3-6	_ _ _ _	Patient number

Please rate your pain involving the following body areas by checking the appropriate number on the scale. Zero being no pain and 10 being the most severe pain.

		No Pain ←									→ Pain as Bad as It Could Be
7-8	Neck	00☐	01☐	02☐	03☐	04☐	05☒	06☐	07☐	08☐	09☐ 10☐
9-10	Shoulders	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
11-12	Elbows	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
13-14	Wrists	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
15-16	Hands	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
17-18	Upper Back	00☐	01☐	02☐	03☐	04☐	05☐	06☒	07☐	08☐	09☐ 10☐
19-20	Mid Back	00☐	01☐	02☐	03☐	04☐	05☒	06☐	07☐	08☐	09☐ 10☐
21-22	Lower Back	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
23-24	Hips	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
25-26	Knees	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☒ 10☐
27-28	Ankles	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
29-30	Feet	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐

Reminder: "New" pain relievers or anti-inflammatory medications for joint or muscle pain are not allowed to be used during this study.

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Survey Day 1

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September 2000

Name: _____
(Last) (First) (M.I.)

Column	Item	
1-2	0 1	Survey day
3-6	_ _ _ _	Patient number

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		No Pain ←									→ Pain as Bad as It Could Be
7-8	Neck	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
9-10	Shoulders	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
11-12	Elbows	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
13-14	Wrists	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
15-16	Hands	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
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21-22	Lower Back	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
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25-26	Knees	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
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Survey Day 3

Study number: 7-1089
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September 2000

Name: _____
(Last) (First) (M.I.)

Column	Item	
1-2	0 3	Survey day
3-6	_ _ _ _	Patient number

Please rate your pain involving the following body areas by checking the appropriate number on the scale. Zero being no pain and 10 being the most severe pain.

		No Pain ←									→ Pain as Bad as It Could Be
7-8	Neck	00☐	01☐	02☐	03☐	04☐	05■	06☐	07☐	08☐	09☐ 10☐
9-10	Shoulders	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
11-12	Elbows	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
13-14	Wrists	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
15-16	Hands	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
17-18	Upper Back	00☐	01☐	02☐	03☐	04■	05☐	06☐	07☐	08☐	09☐ 10☐
19-20	Mid Back	00☐	01☐	02☐	03☐	04■	05☐	06☐	07☐	08☐	09☐ 10☐
21-22	Lower Back	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
23-24	Hips	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
25-26	Knees	00☐	01☐	02☐	03☐	04☐	05☐	06■	07☐	08☐	09☐ 10☐
27-28	Ankles	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐
29-30	Feet	00☐	01☐	02☐	03☐	04☐	05☐	06☐	07☐	08☐	09☐ 10☐

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