SPRING2

Clinical guidelines

TRANSCUTANEOUS PRF WITH THE SPRING2

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Mode of action

The mode of action of Pulsed Radiofrequency (PRF) has not been clear for quite a long time. But that has now changed: PRF has a beneficial effect on the redox status of cells that are subject to oxidative stress. Oxidative stress is the first stage of cell stress. The first measurable effect of this is an overproduction of free radicals by splitting molecules, resulting in radical pairs. If oxidative stress occurs intensively for a longer period of time, it causes inflammation.

When applying PRF, the very small magnetic component of the electromagnetic current causes a recombination of radical pairs, thus reducing the overproduction of radicals. This normalizes the reactivity of hyporeactive immune cells. The immune system then resumes its normal function, which causes a long-lasting anti-inflammatory phase.

Currents

During the active pulse there is no spread of the current outside the skin. For the extremities this means that if the direction of the current is longitudinal, the spread of the current is constrained by the anatomy. Treatment of extremities in a transverse direction are non-constrained and this affects the calculation of the proper current.

When the direction of the current is transverse, in case of knee pain or pain in de elbow for instance, the created electric fields are sensitive to the surface of the electrodes and to the distance between them. These are non-constrained currents and an exact calculation of the electric fields is close to impossible. Therefore, we have made an estimate by converting the current to a circular bundle that enters into a sphere.

Electrodes

For the Spring2 we have three sizes of (disposable) electrodes.:

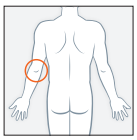
Small:	5.5 x 5.5 cm
Medium:	6 x 12 cm
Large	8 x 15 cm

The Spring2 recognizes the connected the electrodes and maximizes the output of the current, depending on the size of the connected electrodes. This way, the skin electrodes are always safe to use. The choice of size is depending on the area to be treated and/or on the distance between the electrodes. This distance can be calculated from the circumference of, for example, the knee or the elbow. The larger the area or the circumference, the larger the required electrode. The most used skin electrode size is Medium, although Large is being used increasingly. The minimum number of electrodes is two. However, it is also possible to work with 3 or 4 electrodes simultaneously.

Extremities

Mostly, extremities are being treated such as knees, elbows and shoulders. The Spring2 is CE-certified for use on the extremities only, as there were no clinical studies of application on the trunk at the time of CE-application. However, for research purposes application of PRF on the trunk is allowed provided there is approval of a Medical Ethical Committee.

How to treat?



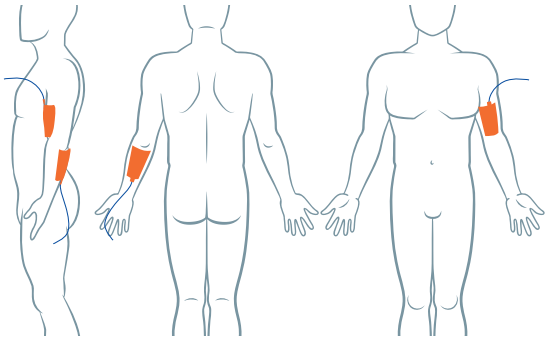
Elbow

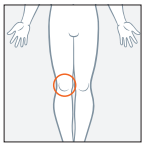
Electrode size:
Medium

Placement:
One skin electrode over the ulna and the other on the inside of the elbow

Treatment time:
15 minutes

Amplitude:
(see table I)





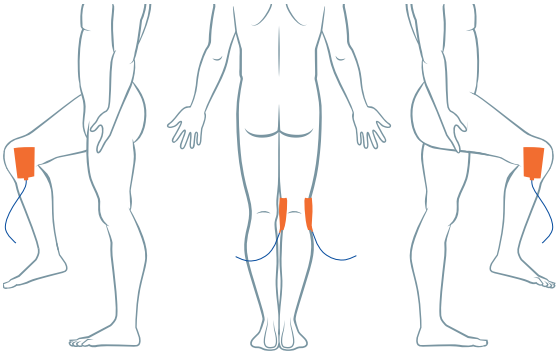
Knee / Ankle

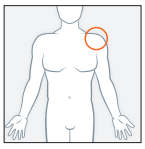
Electrode size:
Medium

Placement:
On either side of the knee / ankle: one skin electrode on the inside and one on the outside of the knee / ankle.

Treatment time:
15 minutes

Amplitude:
(see table I)





Shoulder

Electrode size:
Medium

Placement:
On either side of the shoulder: on the front side and one on the back side

Treatment time:
15 minutes

Amplitude:
(see table I)

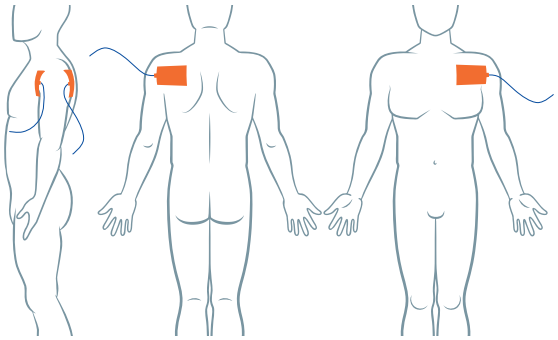


Table I

Circumference (cm)	Distance between Electrodes (cm)	Required Current(A)
20	12.7	0.7
22	14.0	0.8
24	15.3	0.8
26	16.6	0.9
28	17.8	1.0
30	19.1	1.0
32	20.4	1.2
34	21.6	1.2
36	22.9	1.4
38	24.2	1.4

Table I. Required currents for transverse current direction in the extremities

Hip

Electrode size:
Large

Placement:
Anteriorly and posteriorly over the hip joint

Treatment time:
15 minutes

Amplitude:
(see table II)

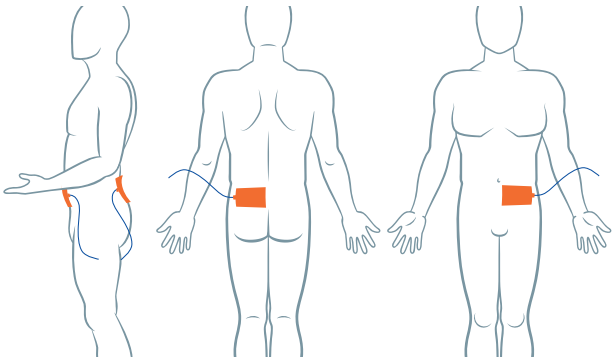
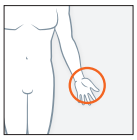


Table II

Circumference (cm)	Distance of Electrodes (cm)	Required Current(A)
79	20	1.4
86	22	1.6
94	24	1.6
102	26	1.8
110	28	1.8
118	30	2.0
126	32	2.2
134	34	2.4
142	36	2.4

Table II. The circumference is measured horizontally over the body at the level of the trochanter major



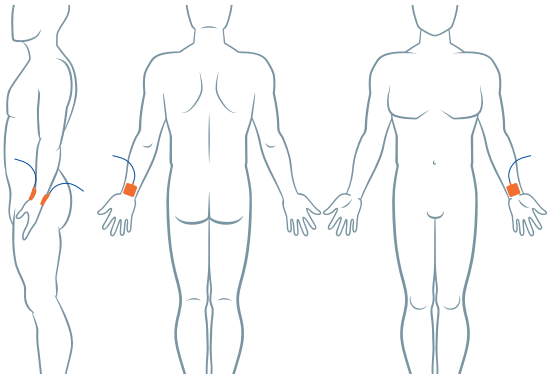
Wrist

Electrode size:
Small

Placement:
On either side of the wrist

Treatment time:
15 minutes

Amplitude:
0.3 – 0.4 Amps



Systemic PRF (RedoxPRF)

PRF is now known to have a specific effect on oxidative stress by reducing the overproduction of free radicals. Oxidative stress is the basic pathology of a long list of diseases and conditions. Many patients could therefore benefit from systemic application of PRF.

The intravascular immune cells are the target when they move through an activated tissue compartment as on as assembly line.

When applying RedoxPRF, the protocol would be the following:

- Electrode size: Medium
- Placement: One skin electrode on the inner surface of the upper arm high up in the axilla over the neurovascular bundle and the other electrode over the dorsal surface of the lower arm.
- Treatment time: 15 minutes
- Amplitude: (see table III)

Table III

Circumference (cm)	Required Current (A)
20	0.3
22	0.4
24	0.4
26	0.5
28	0.6
30	0.6
32	0.7
34	0.8
36	0.9
38	1.0
40	1.2
42	1.2
44	1.4
46	1.4

Table III. Required currents for 250V/m for longitudinal currents in the extremities

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ISO 13485 Medical Devices

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