PANDORASTAR
DEEP TRANCE MEDITATION MACHINE
www.pandorastar.co.uk

PandoraStar
"Risk Assessment & Informed Consent Form"
For Commercial Partners

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Introduction

This document provides details on the PandoraStar “Risk Assessment and Informed Consent Form”.

This form should be used by all commercial partners when providing sessions to clients. The latest form is included at the end of this document.

The following specific points should be noted:

- The lamp is not suitable for young children…
- The form must be completed in full by the client…
- The form must be reviewed and completed by the trained person supervising the session…
- At all times the client shall be monitored and not left unsupervised…
- As client details continually change it is a requirement to complete a new form for each session…
- In any situation where there is a client incident you should engage medical services as appropriate...

We want as many people as possible to have access to PandoraStar and its benefits and we take safety very seriously. Correct procedures will have been provided during your commercial training and are required at all times for commercial use.

Whilst we hope no one ever needs to complete an incident report you should compile an incident report file. Should an incident ever occur then you should notify us immediately providing a copy of the filed report to allow us to collectively deal with obtaining to best outcome.

Note: if you choose to give someone a session knowing that they have said yes to any of the questions on the consent form, then for your safety please seek medical permission and advice first. Also be fully aware that you are doing so <u>without</u> the consent or recommendation from Pandora Star LTD.

The “Risk Assessment & Informed Consent Form” is approached in two parts:

- Risk assessment
- Informed consent

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Risk Assessment

The risk assessment consists of a number of questions that aim to identify if a client is suitable for a session with the PandoraStar lamp. For each question the client is asked to truthfully circle YES or NO and if they answer YES to any question then they are NOT suitable for a session.

1) Have you ever personally suffered from epilepsy or had a seizure?

Seizures can be triggered by a number of situations in people with a history of them and or epilepsy.

Not all sufferers of seizures will be triggered by flickering light. In fact it's a relatively small proportion of them that are sensitive to light and contrasting patterns.

But flickering light is one of three main tests used by experts to see if someone suspected of being prone to seizures is in fact likely to have one and therefore requiring medication (the other two being hyperventilating or rapid breathing and sleep deprivation).

Even if the person has never been triggered to have a seizure by light before the risk is too high with a powerful device like PandoraStar.

2) Do you have any family history of epilepsy or seizures?

As with any condition, if there is a history in the family of seizures or epilepsy then there is a higher risk that it might happen with a family member.

3) Are you taking any medication for anxiety or depression?

Certain medications can make people more prone to having a seizure and certain medications can also increase levels of hormones like serotonin which PandoraStar use can also increase.

For example most antidepressants (SSRI's) work primarily by increasing the availability of serotonin. There is a very small chance that someone on SSRI's who gets an extra boost of serotonin from another source could get a toxic level of this in the system which can be dangerous to their health. It is very unlikely, but we still have to be aware that it may be possible.

According to epilepsy.com (a wealth of useful information) there is a rare but possible reduction in threshold to seizures that can occur with the use of:

- Anti-asthma drugs like Aminophylline and Theophylline
- Hormones like Insulin, Prednisone and Estrogen because of the way they affect blood sugar levels
- Antibiotics like Penicillin, Isoniazid, Lindane, Metronidazole and Nalidixic acid
- Neuroleptics like Clozapine, Phenothiazines and Butyrophenones
- Immunosuppressants like Chlorambucil and Cyclosporine A
- Antidepressants
- Local and general anesthetics like Lidocaine, Bupivicaine, Procaine and Enfluraneketamine
- ANY sort of recreational drug or alcohol
- And a few other again rare but possible effects by way water toxicity (see epilepsy.com website for full list)

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There are so many medications that we do not know the side effects of, that we have to decide based upon safety and not chance.

4) Do you have any psychological or psychiatric conditions?

PandoraStar is not a replacement for therapy nor does it claim to be. Yes many people do get almost miraculous healing benefits from PandoraStar.

Because of the types of states that people can go into while having a PandoraStar session.., it is possible that repressed, unconscious, and/or hidden memories can be brought to the surface and made conscious. This can be disturbing for people and they may not be ready to face such things. Again you cannot know in advance if this will happen and this is where training is invaluable.

But, if the person is already aware of or being treated for a psychological condition then the risk is higher that they may have an unpleasant experience.

5) Have you ever had any head or brain injuries, or had brain surgery?

Any sort of brain trauma or injury can increase the risk of seizures even after full recovery. Seizures are of course a result of out of control brain electrical activity and so it is not surprising that a shock to the brain physically can result in problems with this electrical activity.

6) Have you ever had a stroke?

People who have had a stroke (a temporary interruption of blood flow to the brain) are statistically more likely to be at risk from seizures afterwards even after a full recovery.

7) Are you taking any photosensitive medication?

This is more precautionary than dangerous in most cases but again it's possible that certain medications, even common ones, can increase the sensitivity to light. The usual risk is sunburn from UV light which PandoraStar has filtered out anyway but even blue light can have a slight effect on the skin.

PandoraStar is unlikely to cause any issues here at all but below is a list of possible medications that can increase sensitivity to light in case someone is concerned about that.

- Alpha-hydroxy acids in cosmetics
- Antibiotics (ciprofloxacin, doxycycline, levofloxacin, ofloxacin, tetracycline,
- trimethoprim)
- Antifungals (flucytosine, griseofulvin, voricanozole)
- Antihistamines (cetirizine, diphenhydramine, loratadine, promethazine,
- cyproheptadine)
- Cholesterol lowering drugs (simvastatin, atorvastatin, lovastatin, pravastatin)
- Diuretics (thiazide diuretics: hydrochlorothiazide, chlorthalidone, chlorothiazide.;
- other diuretics: furosemide and triamterene)
- Non-steroidal anti-inflammatory drugs (ibuprofen, naproxen, celecoxib, piroxicam,
- ketoprofen)
- Oral contraceptives and estrogens

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- Phenothiazines (tranquilizers, anti-emetics: examples, chlorpromazine, fluphenazine,
- promethazine, thioridazine, prochloroperazine)
- Psoralens (methoxsalen, trioxsalen)
- Retinoids (acitretin, isotretinoin)
- Sulfonamides (acetazolamide, sulfadiazine, sulfamethizole, sulfamethoxazole,
- sulfapyridine, sulfasalazine, sulfasoxazole)
- Sulfonylureas for type 2 diabetes (glipizide, glyburide)

8) Are you pregnant?

There is little to link pregancy with increased risk of a seizure other than altered hormone levels but the risk to an unborn baby from the mother possibly having a seizure is too great a risk to even consider.

9) Have you had laser treatment to your face within the last month?

As with question 7) this is about possible skin reactions. With laser treatment the skin will already be sensitive and so adding more light exposure may affect the healing process.

10) Are you under the influence of recreational or psychoactive drugs?

This is obvious. The body and brain is already in an altered state beyond being able to predict what affect stimulation might have. Recreational drugs alter brain chemistry. So does PandoraStar. Mixing the two could lead to a bad experience and can increase the risk of a seizure.

11) Are you under the influence of alcohol?

Same as with question 10) alcohol alters brain chemistry and we cannot predict what the effect might be. Judgement is also impaired which could lead to deciding to stay in a session even if normally the person would stop due to discomfort.

Informed Consent

The informed consent sets out the consensual terms of having a PandoraStar lamp session, capturing client details for record of the session and for informing the client of possible risks.

There will always be a small risk to using any type of technology that alters brainwave patterns. People will usually not know in advance if they are going to have a problem. We cannot predict all possible situations. What we can do is our best to minimise them and continue to learn.

12) I confirm that I have read the form carefully, understand the questions and have answered truthfully

Habit causes people to skim over questions and not really read them properly sometimes so be aware of this. It's not about scaring them off.., it's about safety first. People may also be so keen to try PandoraStar that they consider a question to not be important. We can't help this but make sure you re-assure them that you are happy to answer ANY questions.

You could of course have the person see the form before they come to see you so that they have plenty of time to read carefully and opt out if they choose to.

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Note: They MUST fill out the form and sign at the session and not bring it to the session pre filled out.

13) I confirm that the nature of the PandoraStar lamp and the session named *<session name>* that I am about to experience has been explained to me

They will want to know this anyway as they should know what to expect and what the session they are doing is for. This is also a good record for you should there be any queries or problems later.

14) I confirm that I understand the PandoraStar lamp is NOT a medical or psychological therapy and is not intended as a treatment or remedy for any condition

Yes they will have goals for the session and many people do get amazing results. Be aware that no claims of medical benefit can be made or promised. Any benefit although encouraged to be talked about and explored is personal and not necessarily repeatable.

15) I confirm that whilst I have never suffered from epilepsy or seizures I understand that there is a statistical chance of 1 in 3000 that I could be sensitive to flickering light and that this in rare cases could lead to a seizure

Thankfully it is rare and becoming rarer as we learn but statistically the possibility will always be there. It's not a nice thing to either experience or witness, but with support before, during and after (if it happens) it can be minimised and recovered from quickly.

Note: if you have a client have a seizure please show you care by staying in contact in the days following. More can be learned from this and support and care need always be how we operate.

16) I confirm that I have been asked at this time whether I have any unanswered questions about the PandoraStar lamp and experience and I do not

Make them comfortable to ask ANY questions and put them at ease. The more you educate them and answer questions the more relaxed they will be and therefore the more likely they are to have a great experience.

17) I confirm that I am satisfied the person supervising my session has the knowledge and training to do so

If they ask, tell them you are trained and have first aid training etc.

18) I confirm that that I am a competent adult of at least 18 years of age and I sign this Informed Consent Form of my own free will. Please complete the details below in BLOCK CAPITALS.

Ensure that they DO print their name and contact number and sign the form.

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PandoraStar: Risk Assessment & Informed Consent Form

The PandoraStar lamp uses computer controlled LED technology to produce flickering white light that is observed through closed eye lids. This flickering white light guides our brainwaves through a natural process called the "frequency following response" to enable us to achieve and benefit from a variety of altered states of consciousness for both physical and mental benefit.

RISK ASSESSMENT: PANDORASTAR IS NOT SUITABLE FOR EVERYONE

To enable us to advise you on whether the PandoraStar lamp is suitable for you, please read the questions below carefully and circle your answer YES or NO. If you answer YES to any question then for your safety the PandoraStar lamp is not suitable for you.

1) Have you ever personally suffered from epilepsy or had a seizure?	YES	NO
2) Do you have any family history of epilepsy or seizures?	YES	NO
3) Are you taking any prescribed medication (*) including for anxiety or depression?	YES	NO
4) Do you have any psychological or psychiatric conditions?	YES	NO
5) Have you ever had any head or brain injuries, or had brain surgery?	YES	NO
6) Have you ever had a stroke?	YES	NO
7) Are you taking any photosensitive medication?	YES	NO
8) Are you pregnant?	YES	NO
9) Have you had laser treatment to your face within the last month?	YES	NO
10) Are you under the influence of recreational or psychoactive drugs?	YES	NO
11) Are you under the influence of alcohol?	YES	NO

INFORMED CONSENT: PLEASE READ ALL STATEMENTS CAREFULLY

12) I confirm that I have read the form carefully, understand the questions and have answered truthfully…

13) I confirm that the nature of the PandoraStar lamp and the session named: that I am about to experience has been explained to me… ☐

14) I confirm that I understand the PandoraStar lamp is NOT a medical or psychological therapy and is not intended as a treatment or remedy for any condition…

15) I confirm that whilst I have never suffered from epilepsy or seizures I understand that there is a statistical chance of 1 in 3000 that I could be sensitive to flickering light and that this in rare cases could lead to a seizure…

16) I confirm that I have been asked at this time whether I have any unanswered questions about the PandoraStar lamp and experience and I do not…

17) I confirm I am satisfied the person supervising my session has the knowledge and training to do so…

18) I confirm I am a competent adult of at least 18 years of age and I sign this Informed Consent Form of my own free will. **Please complete the details below in BLOCK CAPITALS.**

Client signature _____Print name_____

Date of Birth _____ Contact number _____

Emergency contact name and number _____

TO BE COMPLETED BY THE SESSION SUPERVISOR

Print name _____Signature_____Date_____/_____/____

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