Crystal Hearing Limited

MICRO-SUCTION

Ear-Wax Removal - Risk Assessment and Management

Devices used at Crystal Hearing

- DeVilbiss Vacu-Aide Quiet Suction Unit 7314P-U
- CA MI AS100
- DeVilbiss Suction Unit Rechargeable 7305P-U

All clinicians must confirm that they have read and fully understand the implications of this risk assessment and must have completed adequate approved micro-suction ear wax removal training AND observations by a qualified and experienced ear wax removal specialist representing Crystal Hearing BEFORE treating and patients / patients on behalf of Crystal Hearing Limited. Experience and training must never be assumed.

The 'risk level' assessed is based on proper practice being implemented following adequate training and a period of supervised observations.

Definition of micro-suction: Micro-suction is the process of removing wax from a patient's ear using gentle suction force from a suction pump unit attached to a thin probe by some flexible plastic tubing. The probe is placed inside the ear by the clinician using a plastic speculum placed at the entrance to the ear as a guide to get a good view into the ear canal. The ear wax is sucked out of the ear in small bits, or sometimes in one lump. The process can involve digging at the ear wax with the probe to break it down. The clinician needs to wear a form of headlamp / loupes to light up the inside of the ear.

Contra-indications to undertaking micro-suction include:

1. Having experienced previous problems having micro-suction
2. Having a history of severe dizziness
3. Having a condition that causes sudden movements – such as Parkinson's disease.
4. Increased sensitivity to loud noises – hyperacusis – that said, see weblink in section 6.

1. General patient safety and confidence in procedure	**Varying risk and damage level.** **Patients must be relaxed and comfortable in their surroundings, and also with the clinician undertaking the procedure to minimise risk of them moving, or jerking etc, from being nervous or wary.**	**1. Check clinician is adequately trained – confirm their qualifications are valid with the training provider;** **2. Carry out a series of micro-suction observations on new employees.** **3. Ensure clinicians fully understands the Company consent form, all contraindications to micro-suction, and all possible complications that may be observed (i.e. glue ear, false fundus – see checklist A).** **4. Check equipment is appropriate, certified where needed, and in good working condition and is correct for all purposes of operation i.e. loupes provide adequate light.** **5. Check clinician is competent using standard company equipment i.e. clinician has good eyesight when using loupes.** **6. Do not undertake micro-suction if under the influence of alcohol, or if feeling unwell and your ability to concentrate well has diminished.**	**Carry out reviews of performance –by** **1. Customer satisfaction surveys and** **2. Sporadic ongoing observations of clinician's performance.** **Ensure clinicians are following training guidelines and risk assessment protocol.** **Assess if further training or refresher studies are required.** **Clinicians to re-read sign risk assessments yearly and at each amendment.** **Clinician to report all incidents of damage, tinnitus or dizziness in client files.**
2. Insurance	**Essential.** **Patients must be protected against risk of damage.**	**Treatment liability insurance must be in place for every clinician.** **Recommended insurance broker – Barry Fenton's.**	**Barry Fenton's will send out reminders. Clinicians must renew.**
3. Legal issue due to use of	**Currently there are no CE marked**	**Perform risk assessment for all suction machines used.**	**Periodically reassess risk**

suction pumps that are not specifically CE-rated for aural micro-suction.	machines for aural micro-suction. Legally, if there is no effective alternative, a machine can be used 'off label', following the MHRA guidelines.	Patient must be informed that the suction machine has been adapted for aural micro-suction – include this information on patient consent form. Inform insurance provider.	assessment. Regularly review updates to government guidelines for the use of 'off label' medical devices. Review manufacturer developments for release of CE marked machine. Check insurance is renewed each year. See footnote *1.
4. Damage to the ear canal (external auditory meatus) – cuts, bleeding and haematomas.	Low to medium risk / low damage It is easy to cause minor bleeding or small haematomas by: 1. scraping or prodding the patients ear cancel with a probe, especially if digging at hard stubborn ear wax; or 2. by pushing the speculum in too hard. Risk is greater for patients on blood thinning medication as they bruise easily, and bleeding may not easily clot. Risk also arise from patient or clinician movement.	Take extra care when digging at stubborn wax. Advise patient to inform you of any discomfort (repeat for long and difficult procedures). Observe patient's reactions in peripheral vision for signs of discomfort. Observe consent form response – blood thinning medication or conditions causing sudden movements. Be aware of the Arnold Reflex – coughing caused by ear irritation. Have antibacterial wipes ready in case a patient needs to wipe bleeding from their ears. If any visible nicks, cuts or bruising invite patient to pop back in for a free check-up to ensure all has healed well after 2-3 days. Refer to GP if bleeding does not stop – especially if on blood thinning medication. Ensure seating is adequate to provide stability for both clinician and patient. Damage must be reported on client file.	As per section 1 Clinician to take photos of any cuts, bruising, damage, haematomas etc and inform their supervisor to assess each case and decide if any further training is required.
5. Discomfort, damage, or perforation of the ear drum / tympanic membrane (TM).	Low risk / high damage Damage to the TM could arise from: 1. Poor practice – i.e. going too close to the TM or touching it. 2. Pushing material forward into	Take extra care when digging at deep stubborn wax. Advise the patient to inform you of any discomfort (repeat for long and difficult procedures). Observe patient's reactions in peripheral vision for signs of discomfort. Observe consent form response for any conditions likely to cause sudden movements – i.e. Parkinsons.	As per section 1 Clinician to take photos of any cuts, bruising, damage, haematomas etc and inform their supervisor to assess each case and decide if further

	the TM. 3. Sudden patient or clinician movements. 4. Excessive suction flow.	Be aware of the Arnold Reflex – coughing caused by ear canal irritation. Do not go deeper than the 2nd bend with a probe unless completely confident. Do not push firmly against stubborn lumps of wax. Ensure lighting is good for deep extraction. If any discomfort or visible scratching etc invite patient to pop back for a free check-up after 2-3 days to ensure all has settled / healed well. Refer to GP if there is still visible damage, or if there is discomfort after 7 days. Ensure seating is adequate to provide stability for both clinician and patient. Damage must be reported on client file.	training is required.
6. Noise level of the suction and especially from immoveable flaps of skin rasping in the suction probe.	High risk / high damage Poor practice could lead to permanent tinnitus or hearing loss. Temporary tinnitus or shift of hearing threshold may happen occasionally. Patients may state the noise is ok when it could be loud enough to cause damage. Some patients may have hyper-sensitivity to loud sounds. Some clients may have tinnitus that is aggravated by loud noise.	Observe the consent form and take note if the patient has increased sensitivity to loud sounds. Instruct the patient to tell you stop if they feel the noise is too loud. Repeat this throughout the procedure. Ensure the terms of service state that the patient must advise / stop you if the noise is too loud; and ensure that the patient signs a consent form each visit. Observe patient reactions in your peripheral vision for signs of discomfort. Exercise good judgement to keep noise to a minimum – especially loud rasping noise for more than 1 second. For rasping skin, loud wax removal or deeper wax within 1cm of the ear drum, either: 1. use ear oil or warm water to soften it, 2. switch to dry tool or irrigation removal, or 3. use a fine-end probe. 4. or a combination of 1-3 to keep the noise levels to a minimum.	As per section 1 Undertake risk assessment of each suction pump to check the varying noise and suction levels. If possible, clinicians should undertake micro-suction on each other to be aware of the sound level of each pump and probe being used for increased awareness.

		Reports of onset of tinnitus (new or not) must be noted on the client file.	
7. Vertigo, dizziness or balance problems.	Low risk - unless the patient has a condition causing dizziness or a history of severe dizziness. A change of pressure in the ear can cause mild dizziness.	Ensure risk of dizziness is included in the terms of service. Ensure a history of dizziness is asked about on the consent form. If a patient reports that they have a history of severe dizziness do not undertake micro-suction. Pause the procedure if the patient reports dizziness and only proceed once dizziness subsides. Record notes of any dizziness on the client file for future reference. If a client suffers severe dizziness during micro-suction advise them not to drive home & suggest someone collects them and make a note of doing so. Request to send a message to their GP reporting the incident.	As per section 1
8. Transfer of infection from cross-contamination.	Low risk. Infection risk following micro-suction should be minimal if specula are single use and the suction probe does not touch the ear.	Use pre-sterilised single–use suction tubes and single use cannula. Wash hands with anti-bacterial soaps / gels. Appropriately wash / sanitise all other equipment. Take care not to nick the ear canal. Advise patient if any discomfort following procedure to call back for a free check-up.	Infection incidents must be reported to clinician's supervisor. Review equipment use and additional training requirements if incidents repeat.
9. Patient fainting	Low risk but can happen. Knowing what to do is important.	If someone suggest they feel faint or are about to faint, the easiest thing to do is to tell them to put their head	Feinting incidents must be reported to clinician's

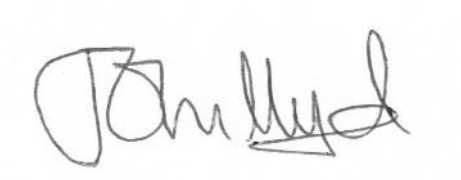
		between their knees if they are sat down. Do not let them get up. If patient does not regain consciousness within 1 – 2 minutes call 999. Place patient in the recovery position. https://www.nhs.uk/video/pages/recovery-position.aspx Report any fainting on client file.	supervisor. Clinicians to watch video link annually.
10. Clinician suffering from strain in shoulders and / or back from performing repeated micro-suction.	Low to medium risk. Clinician chair should be low to give good viewing – this can, however, cause strain on the lower back and the shoulder blades if maintaining the position for long difficult procedures.	Maintain good posture and take breaks in procedure if needed. Keep back straight and shoulders relaxed. Raise client if it aids clinician posture – i.e. hydraulic patient chair, or use of cushions. If wax removal is taking a long time, clinician can revert to using irrigation or use some oil in patient's ear to give clinician a short break.	Company to heed warnings of discomfort from clinician and to review and improve working conditions as required.
11. Trip hazard – long power cables attached to suction machine.	Low risk. Cables can create a potential trip hazard for both the patient and clinician.	Cables to run against the wall and away from the walking area wherever possible. Use cable ties as appropriate. Always use clearly visible and purposely designed cable covers to cover over any cables in the open floor space.	Regularly check cable ties & cable covers to ensure cables have not moved out of place and become a trip hazard.
12. Working on children / young adults (under 18)	Children may be more nervous and less understanding of what is expected or required, and what their pain and noise comfort thresholds may be. Ear canal will be shorter and narrower Ear drum will be smaller and more fragile.	Do not undertake micro-suction on patients under 12 years old. Ensure that the child is with a guardian if under 16 years old. Take extra care when explaining instructions and ensure that the guardian supports the child in case of anxiety. Repeat the instructions more often – 'stop me if it is too noisy or you feel discomfort or dizziness'.	As per section 1

	Note the BSA Guidance Notes state not to undertake MS on persons under 18 outside of a hospital environment – I was advised by the Rotherham Ear Care Centre no additional training is required. I have assessed that we can adequately facilitate children from age 12 upwards.	**Pause more often.** **Do not go past second bend with primary probe** **Use a fine end to reduce noise and attain / keep better view.**	

*1 - https://www.gov.uk/government/publications/medical-devices-off-label-use/off-label-use-of-a-medical-device#no-option-but-to-use-a-device-off-label

This risk assessment must be read in conjunction with the British Society of Audiologists Practice Guidance for Aural Care Ear Wax Removal - which can be found here: http://www.thebsa.org.uk/wp-content/uploads/2019/10/BSA-Practice-Guidance-Wax-Removal-For-Public-Consultation.pdf

By signing this risk assessment form you are signing that you have read and fully understand both the risks detailed herein and also the BSA Practice Guidance Notes, and that you will work in accordance with both of these documents when treating patients on behalf of Crystal Hearing.



John Lloyd RHAD – Managing Director of Crystal Hearing Limited